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ACUTE INPATIENT REHABILITATION

Policy # 443

Implementation Date: 6/28/10

Review Dates: 9/15/11, 7/18/13, 6/11/15, 6/16/16, 6/15/17, 6/21/18, 11/15/18, 12/16/19, 12/14/20, 10/26/21, 11/16/22, 12/15/23

Revision Dates: 11/25/13, 12/20/18

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Inpatient rehabilitation facilities (IRF) and units have many characteristics that differentiate them from other levels of care, such as acute hospitals, skilled nursing facilities (SNFs), long-term acute care (LTAC) facilities and home care programs. These facilities are licensed as hospitals or rehabilitation hospitals, depending on state law, and are subject to state health department rules and regulations. They provide medical, rehabilitation nursing, rehabilitation therapies and many other services on an intensive basis.

To qualify as rehabilitation hospitals and units the facilities must provide 24-hour, 7-day-a-week availability of physicians and nurses with specialized training or experience in medical rehabilitation. These include physiatrists, or other physicians with extensive experience in inpatient rehabilitation care, and nurses with training and certification in rehabilitation nursing (CRRN). Therapists include registered or licensed practitioners in physical therapy, occupational therapy, speech/language pathology, therapeutic recreation, and respiratory therapy. Psychologists, social workers, vocational counselors, prosthetists and orthotists, and dieticians or nutritional counselors must also be available. The number of staff members has to be sufficient to provide each patient with at least 3 hours of therapy usually 5 of 7 days a week and meet the rehabilitation medicine and rehabilitation nursing needs of the patients. Medical, surgical, and mental health specialists must be readily available to provide consultations and to obtain access to hospital services necessary for the diagnosis and treatment of the co-morbidities that frequently complicate the course of a patient's stay. Rehabilitation physicians, nurses, therapists and other professional staff members communicate and coordinate care as a group at least weekly to discuss the patient's progress and establish goals and time frames, conduct discharge planning, and function daily as an onsite interdisciplinary team of rehabilitation specialists.

Physicians are required to conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

SelectHealth covers acute inpatient rehabilitation for patients meeting specific criteria.

(Included Conditions are followed by Criteria for both Adult and Pediatric Populations)



Acute Inpatient Rehabilitation, continued

Conditions, such as the examples below, for which **ADULT (> 18 years)** patients may qualify for Acute Inpatient Rehabilitation:

1. Central nervous system (CNS) or traumatic brain injury (TBI):
 - a. Stroke:
 - o Rehabilitation therapy must begin within 60 days from the onset of the stroke.
 - b. Parkinson's disease
 - c. Multiple sclerosis
 - d. Post meningoencephalitis
 - e. Amyotrophic lateral sclerosis
 - f. Guillain-Barre syndrome
 - g. Brain surgery requiring post-surgery intensive inpatient physical rehabilitation therapy
 - h. TBI:
 - o Rancho level 3 and evolving response
 - o Rancho level 4–6 and behavior uncontrolled or unmanageable
2. Spinal Cord injury with:
 - a. Brown-Sequard syndrome
 - b. Post-spinal neurosurgery requiring post-surgery intensive inpatient physical rehabilitation therapy
 - c. Spinal cord injury or spinal cord stroke with quadriplegia or paraplegia
 - d. Spinal infectious disease (e.g., vertebral osteomyelitis, spinal abscess)
 - e. Transverse myelitis
3. Medical Conditions:
 - a. Cardiac surgery/disease or severe lung disease (e.g., COPD, interstitial fibrosis) and active comorbidity with functional limitation
 - b. Congenital deformity (e.g., spina bifida, cerebral palsy, spinal muscular dystrophy)
 - c. Failed acute setting vent weaning and tracheostomy with active comorbidity
 - d. Uncontrolled pain with neurologic or musculoskeletal etiology with ALL the following:
 - i. Failure of at least 2 trials of outpatient physical or occupational therapy
 - ii. Failure of at least 2 trials of pharmacologic or nonpharmacologic treatments
 - iii. Inability to perform ADLs
 - e. Complex medical issues:
 - i. Patients with frailty (Fried score ≥ 3)* and prolonged ICU stay (≥ 1 week) or post-transplant
Or
 - ii. Comorbid illnesses in combination with frailty, cognitive dysfunction, and inability to perform ADLs

*Fried score = Shrinking, Weakness, Exhaustion, Low Physical Activity, and Slowed Walking Speed

Shrinking	Weakness	Exhaustion	Low Physical Activity	Slowed Walking Speed
Unintentional weight loss ≥ 10 lbs in previous year or at least 5% of previous year's body weight	Grip strength of dominant hand ≤ 16 kg	Positive if at least 1 statement present for 3 or more days during previous week: (a) I felt that everything I did was an	Positive if physical activity per week: Male: < 383 kcal/week; Female: < 270 kcal/week	Cutoff time to walk 15 ft at usual pace: Male: height (cm): $\leq 173 = \geq 7$ (0.65 m/s), $> 173 = \geq 6$ (0.76 m/s); Females, height (cm): \geq

Acute Inpatient Rehabilitation, continued

		effort, (b) I could not get going		159 = ≥ 7 (0.65 m/s), > 159 = 6 (0.76 m/s)
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4. Musculoskeletal:
 - a. Amputation:
 - i. 1 limb including hand only with an active comorbidity and functional limitation. The complicating medical condition must be a separate disease process that requires the close attention and medical supervision of a physician.
 - ii. Loss of one or more extremities resulting in disability requiring an initial intensive physical rehabilitation program. Documentation for intensive physical therapy is required.
 - b. Fracture of the femur with a complicating medical condition.
 - o The complicating medical condition must be a separate disease process that requires the close attention and medical supervision of a physician.
 - c. Major joint replacement (hip, knee, or shoulder) with functional limitation
 - i. 1 joint with active comorbidity unrelated to joint replacement and requiring intense medical supervision
 - ii. > 1 joint
5. Burns, deep partial thickness or full thickness involvement with limitation of function in the extremities as a result of burns involving at least 15% of the body.

Conditions, such as the examples below, for which PEDIATRIC (≤ 18 years) patients may qualify for Acute Inpatient Rehabilitation:

1. CNS or TBI:
 - a. Acute disseminated encephalomyelitis or multiple sclerosis
 - b. Anoxic or traumatic brain injury
 - c. CVA
 - d. Guillain-Barre
 - e. Infectious disease (e.g., meningitis, encephalitis)
 - f. Neoplasm
 - g. Status post craniotomy
 - h. TBI:
 - i. Rancho level 3 and evolving response
 - ii. Rancho level 4–6 and behavior uncontrolled or unmanageable
2. Burns:
 - a. Deep partial-thickness or full-thickness involvement
 - b. Inhalation injury
 - c. Post tracheostomy; and
 - d. Requiring at least minimum assistance with functional activity limitations, and 2 of the following:
 - i. Mobility or motor impairment
 - ii. ADL impairment
 - iii. Respiratory impairment
3. Medically Complex:
 - a. Acute hospitalization extended by complication
 - b. Failed acute setting vent weaning and tracheostomy (ventilator patients)
 - c. Malignant or metastatic disease (excludes end-stage)
 - d. Respiratory compromise requiring ventilator management or weaning
4. Musculoskeletal:
 - a. Major joint replacement 1 joint and active comorbidity with functional limitation

Acute Inpatient Rehabilitation, continued

- b. Major joint replacement hip, knee, or shoulder) > 1 joint
 - c. Muscular dystrophy
 - d. Post-operative with congenital condition(s)
5. Trauma:
- a. Amputation \geq 1 limb
 - b. Multiple lower extremity fracture(s)
 - c. Pelvic or lower extremity fracture and upper extremity fracture
6. Spinal cord injury:
- a. Brown-Sequard syndrome
 - b. Post-spinal neurosurgery requiring post-surgery intensive inpatient physical rehabilitation therapy
 - c. Spinal cord injury or spinal cord stroke with quadriplegia or paraplegia
 - d. Spinal infectious disease (e.g., vertebral osteomyelitis, spinal abscess)
 - e. Transverse Myelitis
7. New impairment of mobility and functional activity limitation, requiring at least minimum assistance (ADL impairment), with:
- a. Motor learning
 - b. Cognitive, language, speech, swallowing, or feeding impairment
 - c. Respiratory impairment

Criteria for coverage: (ALL must be met)

1. The patient requires close medical supervision by a physiatrist or other physician qualified by specialized training and experience in inpatient rehabilitation to monitor their medical condition.
2. The patient's medical conditions are sufficiently stable to be reasonably managed in an inpatient rehabilitation facility allow routine participation in structured rehabilitative program.
3. The patient requires multidisciplinary care including, but not limited to, physical therapists, occupational therapists, speech language pathologists and psychosocial services to achieve optimal functional recovery with a minimum of three (3) hours active participation daily.
4. The patient is physically and cognitively capable and willing to participate in at least 3 hours of an intensive physical rehabilitation program.
5. Clearly written functional goals have been defined for the patient by a program manager assigned to the patient within 5 days of admission to the facility including documentation of appropriate discharge planning. Documentation must demonstrate the intent upon restoring the ability to perform activities of daily living (ADL) and ongoing documentation demonstrates progression toward meeting these goals.
6. A written statement is provided which certifies the patient has a high probability of achieving measurable functional improvement from the planned program of care within a maximum of seven to fourteen days (depending on the underlying diagnosis/medical condition) of admission to the inpatient rehabilitation program.
7. The patient has a community-based environment (e.g., house, apartment, shelter) and available care providers with a high likelihood of successful reintegration.
8. The patient has been evaluated by the admitting physician or his designee and accepted as meeting the above requirements.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Acute Inpatient Rehabilitation, continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Decisions to admit patients to or discharge them from rehabilitation hospitals are complex and require the consideration of many factors. This complexity precludes the development of rigid quantified criteria applicable to all cases. Because much of this complexity is the result of clinical variations unique to individual patients, the final decisions must be the responsibility of physicians.

The decision to admit a patient to a hospital is the responsibility of a physician and a primary function of the practice of medicine. In many cases, that decision is self-evident, for example when the patient has a life-threatening illness or injury. However, often the medical decision to admit a patient to an inpatient rehabilitation facility (IRF) is more complex and involves the consideration of medical, functional and other criteria that are almost always inter-related.

Many hospitals have formal admitting criteria. Many insurers, agencies, and regulatory bodies have attempted to create admitting decision tools or criteria. The lack of agreement between many of these criteria, and prevailing clinical practice is striking, and forms the basis of frequent disagreements that affect access to care by patients, and reimbursement for care provided by facilities and practitioners.

To address these disagreements, the American Academy of Physical Medicine and Rehabilitation (AAPM&R) convened an expert panel to develop a consensus position regarding the standards and elements that should be addressed by any decision tool or process intended to determine the correctness of the physician's judgment to admit a patient to a hospital for comprehensive inpatient rehabilitation care.

Facilities, referring physicians and hospitals, patients and payers all have somewhat different concerns regarding the criteria that are utilized to determine whether a patient should be admitted to an IRF. Facilities seek to accurately match the needs of the patient with the capability of the facility so that appropriate payment will follow. Psychiatrists seek to effectively utilize their skills and medical knowledge to help patients who are most in need of therapy and require hospital-based care. Referring physicians and hospitals want to transfer patients to the next setting for their continuing care with minimal confusion, delay, or effort. And patients seek to gain access to the best possible care and treatment for their health, well-being, and functional improvement. Payers are concerned that only patients who uniquely need care in the rehabilitation hospital are admitted, and seek to identify less expensive alternative settings, such as skilled nursing facilities (SNF), home health care agencies or outpatient services.

These standards are the best available consensus opinions of experts on the subject. In proposing these standards, the AAPM&R intended to stimulate the initiation of appropriate research to advance the state of the art and objectivity needed to assure proper clinical decisions are made while appropriately helping to conserve health care resources.

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

No specific codes identified

Acute Inpatient Rehabilitation, continued

Key References

1. AAPM&R Consensus Statement. Available at <https://www.aapmr.org/advocacy/position-statements>; https://www.aapmr.org/docs/default-source/protected-advocacy/Position-Statements/inpatient-rehabilitation-justification-for.pdf?sfvrsn=b1c5537c_2
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5. Hong, L., Goodwin, J.S., & Resteher, T.A., et al. Comparison Functional Status Improvements Among Patients with Stroke Receiving Post-Acute Care Inpatient Rehabilitation Versus Skilled Nursing Facilities. *JAMA Network* 2019 Dec 2. E1916646
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9. State of Utah Medicaid (October 2021) Utah Department of Administrative Services Division of Administrative Rules, Inpatient Hospital Intensive Physical Rehabilitation Services Rule R414-2B. Accessed November 16, 2022.

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BIOIMPEDANCE SPECTROSCOPY IN THE EVALUATION OF LYMPHEDEMA

Policy # 655

Implementation Date: 10/18/22

Review Dates: 10/19/23

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Bioimpedance analysis (BIA) measures the differential impedance (resistance) to low level electrical current to evaluate changes in body fluid composition that occur in conditions such as lymphedema (LE). BIA can be performed at a single frequency or multiple frequencies. Multiple frequency BIA (MFBIA) is often referred to as bioimpedance spectroscopy (BIS) to distinguish it from the single frequency BIA (SFBIA).

LE is the accumulation of protein-rich fluids in tissue that has inadequate lymphatic drainage. Treatments for breast cancer, such as axillary lymph node dissection (ALND), mastectomy, lumpectomy, and radiation therapy are common causes of LE of the upper extremity.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover bioimpedance spectroscopy for the diagnosis or management of lymphedema. There is a lack of any conclusive evidence which demonstrates clinical utility; therefore, this meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the **Select Health Commercial policy applies.** For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the **Select Health Commercial criteria will apply.** For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

The body of evidence concerning BIA for diagnosing, predicting development, and monitoring of LE, was large, but low in quality. The overall low-quality rating for the body of evidence reflects individual study

Bioimpedance Spectroscopy in the Evaluation of Lymphedema, continued

limitations and lack of comparison of BIA with all relevant technologies. Specifically, the studies of clinical utility compared BIA with manual circumference measurements using a tape measure rather than water displacement volumetry or automated scanning perometry that may both be more accurate for detection of small changes in volume that correspond to early onset of LE. Overall quality was determined based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of data to general practice.

The best available studies of BIA have found that the clinical performance and accuracy of MFBIA (i.e., BIS) is similar to or somewhat lower than the accuracy of other techniques for LE diagnosis, prediction of LE development, and guidance of LE treatment. With regards to clinical utility, although 7 of the reviewed studies investigated the capacity of MFBIA (BIS) to guide management of patients at risk for LE, these studies do not provide conclusive evidence of clinical utility. Additional studies are needed to determine the clinical role of BIS relative to established techniques such as manual CM, automated perometry, self-monitoring, and water displacement volumetry for LE diagnosis, prediction of LE development, and guidance of LE therapy.

Billing/Coding Information

Not covered: For the indications outlined above

CPT CODES

93702 Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

Key References

1. Hayes, Inc. Health Technology Assessment. Bioelectrical Impedance (Bioimpedance) Analysis for Assessment of Lymphedema. Last Reviewed: Aug. 18, 2022.
2. Shah, C., Whitworth, P., Valente, S., et al. Bioimpedance spectroscopy for breast cancer-related lymphedema assessment: clinical practice guidelines. *Breast Cancer Res Treat.* 2023 Feb;198(1):1-9. doi: 10.1007/s10549-022-06850-7.

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CHIROPRACTIC CARE (ADULT)

Policy # 643

Implementation Date: 9/17/20

Review Dates: 1/15/22, 2/15/23

Revision Dates: 9/8/21, 1/19/22

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Chiropractic care is a healthcare profession that focuses on disorders of the musculoskeletal system and the nervous system, and the effects of these disorders on general health. Chiropractic care is used most often to treat neuromusculoskeletal complaints, including but not limited to back pain, neck pain, pain in the joints of the arms or legs, and headaches. Doctors of chiropractic (DCs) practice a conservative approach to healthcare, which includes patient examination, diagnosis, and treatment. Chiropractors acquire broad diagnostic skills and are also trained to recommend and provide therapeutic and rehabilitative exercises.

The most common therapeutic procedure performed by chiropractic doctors is known as "spinal manipulation," also called "chiropractic adjustment." The purpose of manipulation is to restore joint mobility by manually applying a controlled force into joints that have become hypomobile—or restricted in their movement—as a result of a tissue injury. Tissue injury can be caused by a single traumatic event, such as the improper lifting of a heavy object, or through repetitive stresses, such as sitting in an awkward position with poor spinal posture for an extended period of time. In either case, injured tissues undergo physical and chemical changes that can cause inflammation, pain, and diminished function for the sufferer. Manipulation, or adjustment of the affected joint and tissues, restores mobility, thereby alleviating pain and muscle tightness and allowing tissues to heal.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers medically necessary chiropractic care when the plan determines that services can be expected to significantly improve the member's condition. This coverage is defined by a pre-specified benefit limit specific to the member's benefit plan.

1. The patient has a specific, neuromusculoskeletal diagnosis causing significant and persistent disability.
2. Conservative therapies (e.g., stretching, heat or ice, over-the-counter pain relievers) have been tried and have failed to relieve the symptoms.
3. Documentation supports patient is meeting objective measures of improvement, and chiropractic providers must follow the criteria set forth by the Council for Chiropractic Guidelines and Practice Parameters (CCGPP).

Chiropractic Care (Adult), continued

Select Health covers chiropractic care for habilitative services, except on plans that exclude habilitative services.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Evidence related to the support, efficacy, and safety of chiropractic care, specifically spinal manipulation, has seen considerable progress in the last two decades. What was once considered an unproven procedure in the care of low back pain, has demonstrated positive and safe outcomes for patients suffering from low back pain, neck pain, headaches, discogenic back pain, among many other neuromusculoskeletal ailments. Recently, chiropractic care and spinal manipulation have drawn support from the likes of many medical organizations, such as the American College of Physicians, as a first-line option in patients with musculoskeletal complaints part of a non-pharmacologic approach to conditions such as acute and chronic low back pain. In their 2017 low back pain clinical guidelines publication, they found moderate-quality evidence that, when compared with usual medical care, multidisciplinary care, including spinal manipulation, resulted in moderate pain improvement. Likewise, the Lancet report on low back pain, published in March 2018, noted a substantial gap between the evidence-informed clinical guidelines and the practical application of care and suggested that spinal manipulation and exercise be a first-line treatment option in acute and chronic low back pain.

Regarding safety, multiple articles have been published demonstrating the low risk of adverse effects of spinal manipulation. A 2018 article published in JMPT found that chiropractic care demonstrated similar clinical benefit to that of NSAIDs with no evidence of serious harm and a 51% lower adjusted likelihood of an adverse drug event. The most substantial risk believed to be associated with spinal manipulation is that of cervical artery dissection. In a 2016 article published by Church et al., the Stanford department of neurosurgery found no convincing evidence to support a causal link between chiropractic manipulation and CAD.

An additional concern in healthcare is cost. Chiropractic care, though performed more frequently than other procedures, has historically been more cost-effective than usual medical care for musculoskeletal complaints, such as neck pain and low back pain. Though the cost of care is important, it is reasonable to consider early access to conservative care. A study published by the Journal of General Internal Medicine in 2019 demonstrated the success of a conservative spine care pathway in reducing downstream costs associated with imaging and surgeries. They found a significant reduction in PMPM expenditure for spine care as well as decreased opioid usage.

Low back pain is most associated with chiropractic care and spinal manipulation. Spinal manipulation has demonstrated its efficacy in this population by providing significant improvement in disability scores when compared to treatment administered by a pain clinic where a study from 2008 found patients reported reductions in pain and disability. However, the most recent data support a multidisciplinary approach. A 2018 article published by Goertz et al. demonstrated moderate short-term treatment benefits in both low back pain intensity and disability, demonstrated a low risk of harm, high patient satisfaction, perceived

Chiropractic Care (Adult), continued

improvement, and found that six-week scores were statistically significant in favor of usual medical care plus chiropractic care when compared with usual medical care alone.

In support of conservative care for more complex cases, chiropractic care has demonstrated effectiveness in discogenic related care as well. In 2009, the Journal of Manipulative and Physiological Therapeutics studied a nonsurgical approach to the treatment of lumbar radiculopathy secondary to a herniated disc. They found that over 70% of patients made clinically meaning improvement in disability, while 74% of patients saw clinically meaningful improvement in their pain. In 2016, Annen et al. found that after two weeks of spinal manipulation, 53% of patients with MRI confirmed lumbar disc herniations with Modic changes, and 76% of patients without Modic changes reported improvement.

Other common conditions that patients present for chiropractic care are neck pain and headaches. While less data is available when compared to low back pain, current research appears to support a multidisciplinary approach to care that consists of spinal manipulation, exercise, and usual medical care. A 2010 Cochrane review found cervical manipulation to provide an immediate or short-term change in pain and function. Similar to low back pain studies, exercise, in addition to spinal manipulation, proves to be more effective than spinal manipulation alone with moderate-quality evidence for both acute and chronic neck pain. When spinal manipulation was compared to medication for acute and subacute neck pain in a 2012 Annals of Internal Medicine article, Bronfort et al. found spinal manipulation more effective in both the short- and long-term. Common in the treatment of neck pain is adjacent manipulation of the upper thoracic spine. With support from the previously referenced Cochrane review, Lau et al. found similar results, stating that thoracic manipulation was effective in reducing neck pain, improving dysfunction, and improving neck range of motion. Many headaches are believed to have a cervical spine component to cause. These cervicogenic headaches have also been shown to have a favorable response to spinal manipulation. One study published in 2017 reported 100% improvement in 33% of the participants as reported by the functional outcome measurement, Headache Index. A similar study from 2010 that attempted to measure dose-response found that the average spinal manipulative therapy patient could cut the number of headaches in half from 8 weeks of care.

While research and support are growing, especially with regards to spinal manipulation with exercise, both provided as usual chiropractic care; more studies are necessary to continue to build confidence in chiropractic care. At this time, we cannot definitively estimate the likely effect and the change it may bring. Organizations such as the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) frequently conduct reviews to provide the most current and best evidence, while also setting recommendations for the therapies provided, care length, frequency, and outcome expectations. These guidelines for low back and neck conditions should be in addition to the guidelines and recommendations as described by the local coverage determination (LCD).

Billing/Coding Information

CPT CODES

Covered for the indications listed above

97012	Application of a modality to 1 or more areas; traction, mechanical
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended), each 15 minutes
97024	Application of a modality to 1 or more areas; diathermy (eg, microwave)
97028	Application of a modality to 1 or more areas; ultraviolet
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes
97035	Application of a modality to 1 or more areas: ultrasound, each 15 minutes
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes

Chiropractic Care (Adult), continued

	stair climbing)
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes NOTE: 97140 should not be billed when a manipulation is performed on the same area.
97530	Therapeutic activities, direct (one-to-one) patient contact (use of dynamic activities to improve functional performance, each 15 minutes
98940	Chiropractic manipulative treatment (CMT); spinal one to two regions
98941	spinal, three to four regions
98942	spinal, five regions
98943	extraspinal, one or more regions
99202	Office or other outpatient visit for the E&M of a new patient, which requires these three key components: an expanded problem-focused history; an expanded problem focused examination; and straightforward medical decision-making. Usually, the presenting problem(s) are of low to moderate complexity. Physicians typically spend 20 minutes face-to-face with the patient and/or family.
99203	Office or other outpatient visit for the E&M of a new patient, which requires these three key components: a detailed history; a detailed examination; and medical decision making of low complexity. Usually, the presenting problem(s) are of moderate severity. Physicians typically spend 30 minutes face-to-face with the patient and/or family.
99204	Office or other outpatient visit for the E&M of a new patient, which requires these three key components: a comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 45 minutes face-to-face with the patient and/or family.
99205	Office or other outpatient visit for the E&M of a new patient, which requires these three key components: a comprehensive history; a comprehensive examination; and medical decision making of high complexity. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 60 minutes face-to-face with the patient and/or family.
99211	Office or other outpatient visit for the E&M of an established patient that may not require the presence of a physician. Usually, the presenting problems are minimal. Typically, 5 minutes are spent performing or supervising these services.
99212	Office or other outpatient visit for the E&M of an established patient, which requires at least two of these three key components: a problem-focused history; a problem-focused examination; and straightforward medical decision-making. Usually, the presenting problem(s) are self-limited or minor. Physicians typically spend 10 minutes face-to-face with the patient and/or family.
99213	Office or other outpatient visit for the E&M of an established patient, which requires at least two of these three key components: an expanded problem-focused history; an expanded problem focused examination; and medical decision-making of low complexity. Usually, the presenting problem(s) are of low to moderate complexity. Physicians typically spend 15 minutes face-to-face with the patient and/or family.
99214	Office or other outpatient visit for the E&M of an established patient, which requires at least two of these three key components: a detailed history; a detailed examination; and medical decision making of moderate complexity. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 25 minutes face-to-face with the patient and/or family.
99215	Office or other outpatient visit for the E&M of an established patient, which requires at least two of these three key components: a comprehensive history; a comprehensive examination; and medical decision making of high complexity. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 40 minutes face-to-face with the patient and/or family.

Chiropractic Care (Adult), continued

Manipulation (CMT) Codes: *

- 98940** Chiropractic manipulative treatment (CMT); spinal, one or two regions
98941 ; spinal, three to four regions
98942 ; spinal, five regions
98943 ; extraspinal, one or more regions

* Medicare limits chiropractic billing to the above chiropractic CPT codes only

Not Covered for the indications listed above

- 22505** Manipulation of spine requiring anesthesia, any region

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**COMPUTERIZED MICROPROCESSOR-CONTROLLED
KNEE PROSTHESES
(OTTOBOCK-C LEG, ENDOLITE ADAPTIVE PROSTHESIS,
OSSUR PROSTHESIS)**

Policy # 233

Implementation Date: 7/30/04

Review Dates: 8/18/05, 8/17/06, 8/23/07, 8/21/08, 8/13/09, 8/19/10, 9/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/20/19, 6/18/20, 6/17/21, 5/3/22, 2/15/24

Revision Dates: 7/11/06, 8/21/17, 5/13/22

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Lower limb amputation may be required due to trauma or various medical conditions. Amputations may be above the knee (AK), also known as transfemoral (TF), or below the knee (BK), also known as transtibial (TT). To allow patients with amputations to maintain productive and active lives, multiple prosthetic devices have been developed for their use. Devices available for BK amputees are much less complex due to the involvement of only 1 articulating joint (the ankle). AK amputees experience much greater difficulties due to the involvement of 2 articulating joints (the knee and ankle) necessary for ambulation. In an effort to maximize the functionality of AK amputees and create a more natural gait, prosthetics of greater complexity and sophistication are being developed. These newer prostheses incorporate computer-programmed microsensors to make frequent adjustments of the prostheses to the speed of the gait, impact intensity, and contact surface.

There are two categories into which the available computerized knee prostheses fall: "swing control" and "swing and stance control." The latter reflects the additional capability of this category of prostheses (e.g., "stance" control).

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, U.K.), the Adaptive (Endolite, England), the Rheo (Ossur, Iceland), the C-Leg, Genium Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN), and Seattle Power Knees (3 models include Single Axis, 4-bar, and Fusion, from Seattle Systems). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. In addition, these devices (with the exception of the IP) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) By improving stance control, they may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and stiffen the knee, thus, avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain and reduction in energy expenditure and concentration required for ambulation. The C-Leg was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA; K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses utilize additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement.

Computerized Microprocessor-Controlled Knee Prostheses (OttoBock C-Leg, Endolite Adaptive, Prosthesis, Ossur Prosthesis), continued

One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used, for example, in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers microprocessor-controlled knee when specific criteria are met.

Criteria for Coverage of Microprocessor Knee Prosthetics:

1. Patient is a K-Level 3* or K-Level 4*, **or**
2. Patient is a K-Level 2* with a trial of a standard prosthetic and the potential for K-Level 3*.

***Lower Limb Rehabilitation Classification Levels:** A clinical assessment of member's rehabilitation potential must be based on the following classification levels.

K-Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.

K-Level 1: Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

K-Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

K-Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

K-Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Computerized Microprocessor-Controlled Knee Prostheses (OttoBock C-Leg, Endolite Adaptive, Prosthesis, Ossur Prosthesis), continued

Summary of Medical Information

The literature primarily consists of small within-subject comparisons of microprocessor-controlled versus pneumatic prostheses, along with systematic reviews of these studies. Following is a summary of key studies to date.

In 2000, the Veterans Administration Technology Assessment Program issued a “short report” on computerized lower-limb prosthesis. This report offered the following observations and conclusions:

- Energy requirements of ambulation (compared to requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee’s customary speed but are not significantly different at customary speeds.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficits in the reintegration of amputees to normal living, particularly those related to decreased recreational opportunities.
- Users’ perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of study participants choose not to return to their conventional prosthesis or to keep these only as back-up to acute problems with the computerized one.
- Users’ perceptions may be particularly important for evaluating a lower-limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient, the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the pre-amputation level.

C-Leg. A 2010 systematic review evaluated safety and energy efficiency of the C-leg microprocessor-controlled prosthetic knee in transfemoral amputees. Eighteen comparative studies were included that used objective/quantifiable outcome measures with the C-leg in 1 arm of the trial. Due to heterogeneity, meta-analyses were not performed. The 7 papers on safety had low methodologic quality and a moderate risk of bias, showing an improvement in some safety or surrogate safety measure. Effect sizes ranged from 0.2 (small) to 1.4 (large). Of the 8 papers identified on energy efficiency, 1 was considered to be of high methodologic quality, and 5 were considered to be of low quality. Two of the trials reported a statistical improvement in energy efficiency, and 4 reported some improvement in efficiency or speed that failed to reach statistical significance. There were no adverse events, safety concerns, or detriments to energy efficiency reported in association with use of the C-leg.

A number of lower-limb amputees returning from Operation Iraqi Freedom and Operation Enduring Freedom have received a microprocessor-controlled prosthesis from the Department of Veterans Affairs (VA); for example, in 2005, 155 veterans were provided with a C-Leg. A series of papers from the VA report results from a within-subject comparison of the C-Leg to a hydraulic Mauch SNS knee. Eight (44%) of the 18 functional level 2 to 3 subjects recruited completed the study; most withdrew due to the time commitment of the study or other medical conditions. Of the 8 remaining subjects, half showed a substantial decrease in oxygen cost when using the C-Leg, resulting in a marginal improvement in gait efficiency for the group. The improvement in gait efficiency was hypothesized to result in greater ambulation, but a 7-day activity monitoring period in the home/community showed no difference in the number of steps taken per day or the duration of activity. Cognitive performance, assessed by standardized neuropsychological tests while walking a wide hallway in 5 of the subjects, was not different for semantic or phonemic verbal fluency and not significantly different for working memory when wearing the microprocessor-controlled prosthesis. Although the study lacked sufficient power, results showed a 50% decrease in errors on the working memory task (1.63 vs 0.88, respectively). Due to the lack of power, the effect of this device on objective measures of cognitive performance cannot be determined from this study. Subjective assessment revealed a perceived reduction in attention to walking while performing the cognitive test (effect size, 0.79) and a reduction in cognitive burden with the microprocessor-controlled prosthesis (effect size, 0.90). Seven of the 8 subjects preferred to keep the microprocessor-controlled prosthesis at the end of the study. The authors noted that without any prompting, all the subjects had mentioned that stumble recovery was their favorite feature of the C-Leg.

Computerized Microprocessor-Controlled Knee Prostheses (OttoBock C-Leg, Endolite Adaptive, Prosthesis, Ossur Prosthesis), continued

Kaufman et al. published 2 reports (2007, 2008) describing a within-subject objective comparison of mechanical- and microprocessor-controlled knees in 15 transfemoral amputees (12 men, 3 women; mean age, 42 years) with a Medicare Classification Level 3 or 4. Following testing with the subject's usual mechanical prosthesis, the amputees were given an acclimation period of 10 to 39 weeks (average, 18 weeks) with a microprocessor knee before repeat testing. Patients rated the microprocessor knee as better than the mechanical prosthesis in 8 of 9 categories of the prosthesis evaluation questionnaire. Objective gait measurement included knee flexion and the peak extensor moment during stance measured by a computerized video motion analysis system. Both the extensor moment and knee flexion were significantly different for the 2 prostheses, indicating a reduction in active contraction of the hip extensors to "pull back" and force the prosthetic knee into extension and resulting in a more natural gait with the microprocessor knee. Balance was improved by approximately 10%, as objectively determined with a computerized dynamic post-urography platform. Total daily energy expenditure was assessed over 10 days in free-living conditions. Both daily energy expenditure and the proportion of energy expenditure attributed to physical activity increased. Although the subjects perceived that it was easier to walk with the microprocessor-controlled knee than the mechanical prosthesis, energy efficiency while walking on a treadmill was not significantly different (2.3% change). Taken together, the results indicated that amputees in this study spontaneously increased their daily physical activity outside of the laboratory setting when using a microprocessor knee.

Johansson et al. assessed energy efficiency in 8 amputees while using the C-Leg, Össur Rheo, and hydraulic Mauch SNS knee. The participants could ambulate at least at a functional classification K3 level and had approximately 10 hours of acclimatization with each prosthesis that was not his or her usual prosthesis (4 C-Leg, 1 Rheo, 1 Endolite, 1 Teh Lin, 1 Mauch). The order in which the knee systems were evaluated was randomized. Oxygen uptake was measured on a quarter-mile indoor track, and kinematic and kinetic data were collected in a motion analysis laboratory with subjects walking at self-selected speeds. Compared with the Mauch knee, oxygen consumption was significantly reduced for the Rheo (-5% reduction), but not for the C-leg (-2%). The Rheo and C-Leg were found to result in enhanced smoothness of gait, a decrease in hip work production, a lower peak hip flexion moment at terminal stance, and a reduction in peak hip power generation at toe-off.

In a manufacturer-sponsored study from 2007, Hafner et al. evaluated function, performance, and preference for the C-Leg in 21 unilateral transfemoral amputees using an A-B-A-B design. Subjects were fully accustomed to a mechanical knee system (various types) and were required to show proficiency in ambulating on level ground, inclines, stairs, and uneven terrain prior to enrollment. Of the 17 subjects (81%) who completed the study, patient satisfaction was significantly better with the microprocessor-controlled prosthesis, as measured by the Prosthesis Evaluation Questionnaire (PEQ). Fourteen preferred the microprocessor-controlled prosthesis, 2 preferred the mechanical system, and one had no preference. Subjects reported fewer falls, lower frustration with falls, and an improvement in concentration. Objective measurements on the various terrains were less robust, showing improvements only for descent of stairs and hills. Unaffected were stair ascent, step frequency, step length, and walking speed. The subjective improvement in concentration was reflected by a small (nonsignificant) increase in walking speed while performing a complex cognitive task (reversing a series of numbers provided by cell phone while walking on a city sidewalk). A 2013 study by Highsmith et al. used a within-subjects pre- and post-design, first evaluating outcomes with a non-microprocessor-controlled prosthesis followed by the same evaluation after receiving a microprocessor-controlled prosthesis. These researchers reported significantly improved descent times by 23% (6.0 vs 7.7 seconds) and Hill Assessment Index scores (8.9 vs 7.8) with a C-Leg compared with the subjects' own non-microprocessor prosthetic knees.

Hafner and Smith evaluated the impact of the microprocessor-controlled prosthesis on function and safety in level K2 and K3 amputees. The K2 ambulators tended to be older (57 years old vs. 42 years old), but this did not achieve statistical significance in this sample ($p=0.05$). In this per-protocol analysis, 8 level K2 and 9 level K3 amputees completed testing with their usual mechanical prosthesis, then, with the microprocessor-controlled prosthesis, a second time with their passive prosthesis, and then at 4, 8, and 12 months with the prosthesis that they preferred/used most often. Only subjects who completed testing at least twice with each prosthesis were included in the analysis (4 additional subjects did not complete the study due to technical, medical, or personal reasons). Similar to the group's 2007 report, performance was assessed by questionnaires and functional tasks, including hill and stair descent, an attentional demand task, and an obstacle course. Self-reported measures included concentration, multitasking

Computerized Microprocessor-Controlled Knee Prostheses (OttoBock C-Leg, Endolite Adaptive, Prosthesis, Ossur Prosthesis), continued

ability, and numbers of stumbles and falls in the previous 4 weeks. Both level K2 and K3 amputees showed significant improvements in mobility and speed (range, 7%–40%) but little difference in attention with the functional assessments. The self-reported numbers of stumbles and falls in the prior 4 weeks was found to be lower with the microprocessor-controlled prosthesis. For example, in the level K2 amputees, stumbles decreased from an average of 4.0 to 2.7 per month, semi-controlled falls from 1.6 to 0.6, and uncontrolled (i.e., complete) falls from 0.5 to 0 when using the microprocessor-controlled knee. Reevaluation of each participant's classification level at the conclusion of the study showed that 50% of the participants originally considered to be K2 ambulators were now functioning at level K3 (about as many K3 ambulators increased as decreased functional level). These results are consistent with the Veterans Health Administration Prosthetic Clinical Management Program clinical practice recommendations for microprocessor knees, which state that use of microprocessor knees may be indicated for Medicare Level K2, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device and if the patient has cardiovascular reserve, strength, and balance to use the prosthesis.

C-Leg Compact. Two crossover studies evaluated the effect of the C-Leg Compact (stance phase only) on functional performance in Medicare functional level K2 ambulators.

Functional performance with 17 simulated activities of daily living was assessed with the C-Leg Compact in 28 level K2 ambulators. Participants first used their own mechanically-controlled knee and then with 2 types of microprocessor-controlled knee joints (C-Leg and C-Leg Compact) in a randomized order with 1 week of acclimation. Performance times were significantly improved for the subset of activities that required balance while standing but not for other activities. Stratifying participants into low, intermediate, and high functional mobility level showed that the 2 higher functioning subgroups performed significantly faster using microprocessor-controlled knee joints. Perceived performance was improved with the C-Leg for some subscales of the PEQ, but this did not translate to an increase in activity level. With the C-Leg Compact, 2 of 8 subscales on the PEQ were improved, and only in the subgroup with high functional mobility. There was no change in activity level with the C-Leg or C-Leg Compact when compared with the mechanically-controlled knee.

Level walking and ramp walking were assessed in 10 level K2 ambulators with the C-Leg Compact and with the participant's usual mechanical prosthetic knee joint. Seven of the 10 subjects used upper extremity assistive devices (e.g., a cane or walker) while ambulating. Participants were tested first with their own prosthesis, and then with the C-Leg Compact after a 3-month acclimation period. Use of the C-Leg Compact led to a significant increase in velocity (20%), cadence (9%–10%), stride length (12%–14%), single-limb support (1%), and heel-rise timing (18%) with level walking. Ramp ascent and descent were 28% and 36% faster, respectively, with the C-Leg Compact, due to increases in stride length (17%) and cadence (16%) on the ramp. Participants also had significantly faster Timed Up and Go test (17.7 vs 24.5 seconds) scores and higher functional scores on the PEQ. At the end of the study, the participants chose which prosthesis to keep; all 9 who were offered the opportunity selected the C-Leg Compact.

Genium. The Genium prosthesis was compared with the subject's own C-Leg in a crossover study with 11 transfemoral amputees. This was a manufacturer-sponsored biomechanical study (e.g., comparison of ground reaction forces, flexion angles, load distribution) that did not evaluate clinical outcomes.

Rheo Knee. A small industry-sponsored study compared the Rheo Knee II with the subject's own non-microprocessor-controlled knee in 10 patients with a functional level of K2 (n=2), K3 (n=5) or K4 (n=3). There was little difference in performance between the 2 prostheses as assessed with the PEQ, Activities-Specific Balance Confidence Scale, TUG, Timed Up and Down Stairs, Hill Assessment Index, Stairs Assessment Index, Standardized Walking Obstacle Course, and One Leg Balance Test. One limitation of this study is that although participants had an 8-week acclimation period, they did not receive step-over-step training on stairs and ramps before being tested with the microprocessor knee.

Intelligent Prosthesis. Early literature focused on the Intelligent Prosthesis (IP), which is similar to the C-Leg, but is not distributed in this country. Kirker et al. reported on the gait symmetry, energy expenditure, and subjective impression of the IP in 16 patients who had been using a pneumatic prosthesis and were offered a trial of an IP. At the beginning of the study, the patients had been using the IP for between 1 and 9 months. Using a visual analog scale, subjects reported that significantly less effort was required when using the IP prosthesis walking outdoors or at work at normal or high speeds, but there was no difference for a slow gait. Subjects reported a strong preference for the IP versus the standard pneumatic

Computerized Microprocessor-Controlled Knee Prostheses (OttoBock C-Leg, Endolite Adaptive, Prosthesis, Ossur Prosthesis), continued

leg. Datta and Howitt reported on the results of a questionnaire survey of 22 amputees who were switched from pneumatic swing-phase control prostheses to an IP device. All patients, who were otherwise fit and fairly active, reported that the IP was an improvement over the conventional prosthesis. The main subjective benefits were the ability to walk at various speeds, reduction of effort of walking, and patients' perception of improvement of walking pattern. Datta et al. also reported oxygen consumption at different walking speeds in 10 patients using an IP and a pneumatic swing gait prosthesis. The IP was associated with less oxygen consumption at lower walking speeds only.

The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees versus hydraulic knee joints. Studies on the C-Leg in Medicare level K3 and K4 amputees show objective improvements in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. Evidence on the C-Leg Compact in Medicare level K2 ambulators is more limited but suggests a possible benefit. Only 1 biomechanical study of the next-generation Genium prosthesis was identified. One small study found little difference in performance between the Rheo Knee II and the user's own non-microprocessor-controlled knee.

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

- L5856** Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
- L5857** ; swing phase only, includes electronic sensor(s), any type
- L5858** ; stance phase only, includes electronic sensor(s), any type
- K1014** Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
- K1022** Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type
- L2006** Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
- L5859** Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)

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Computerized Microprocessor-Controlled Knee Prostheses (OttoBock C-Leg, Endolite Adaptive, Prosthesis, Ossur Prosthesis), continued

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CONSTRAINT-INDUCED MOVEMENT THERAPY (CIMT)

Policy # 660

Implementation Date: 3/29/23

Review Dates:

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Stroke, also called cerebrovascular accident (CVA), is injury or death of brain tissue caused by a lack of blood flow and the resulting lack of oxygen to a portion of the brain. Blood supply to part of the brain is cut off most commonly by a blockage in any arterial pathways to the brain (e.g., atherosclerotic plaque, clot, embolus, infection, or vascular constriction), by bleeding of a blood vessel in the brain (i.e., hemorrhagic stroke), or in the brain itself (i.e., ischemic stroke). As a leading cause of death, stroke has occurred in approximately 6.6 million people in the United States, and 800,000 Americans suffer a stroke annually. Of those, approximately 66% survive their stroke and require rehabilitation, with most individuals experiencing some upper extremity weakness or dysfunction. Severity can range from weakness or limitation in performing voluntary movements (i.e., paresis) to a complete inability to perform voluntary movements (i.e., paralysis), leading to impaired quality of life (QOL) and ability to work.

Following a stroke, the standard care for upper extremity paresis, paralysis, and/or other motor problems is conventional rehabilitation, including physical and occupational therapy. Physical therapy (PT) may include employing exercises to improve muscle strength, coordination, and range of motion. Occupational therapy (OT) is focused on improving activities of daily living (ADLs), including eating, drinking, dressing, and bathing, among other activities. As a part of PT or OT, there is increased interest in the use of constraint-induced movement therapy (CIMT) to improve limb function. However, investigation into its benefits is still underway.

Constraint-Induced Movement Therapy (CIMT) is a form of neurological rehabilitation therapy for treating upper extremity impairments in post-stroke patients. Broadly, CIMT aims to improve limb function through forced/induced use of the patient's impaired limb due to constraining or blocking the use of the patient's unimpaired limb (e.g., a mitt, splint, or sling). Traditionally, this constraint is generally kept in place during 90% of the patients' waking hours for 2 weeks, thus, inducing intensive task-specific use of the affected limb. Alternatively, modified versions of CIMT (mCIMT) have been tested that vary the CIMT type, duration/frequency of therapy, and timing of therapy post-stroke to improve therapy adherence.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health considers constraint-induced movement therapy (CIMT) medically necessary for the treatment of upper limb hemiparesis for post-stroke patients who have at least 10 degrees of active wrist and finger extension, and who have no sensory and cognitive deficits.

Constraint-Induced Movement Therapy (CIMT), continued

Select Health considers CIMT experimental/investigational for all other indications, including but not limited to, the treatment of traumatic brain injury and cerebral palsy.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

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Billing/Coding Information

CPT CODES

- 97799** Unlisted physical medicine/rehabilitation service or procedure
- 92507** Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual [constraint-induced aphasia/language therapy alone or in combination with transcranial magnetic stimulation]
- 92508** group, 2 or more individuals [constraint-induced aphasia/language therapy alone or in combination with transcranial magnetic stimulation]
- 97110** Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
- 97112** neuromuscular reeducation of movement, balance coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
- 97140** Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes
- 97530** Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes

HCPCS CODES

- G0151** Services performed by a qualified physical therapist in the home health or hospice setting, each 15 minutes
- S9131** Physical therapy; in home, per diem

Key References

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Constraint-Induced Movement Therapy (CIMT), continued

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DIAGNOSTIC AND THERAPEUTIC INTERVENTIONS FOR SPINAL PAIN

Policy # 626

Implementation Date: 5/15/19

Review Dates: 6/17/21, 6/26/22, 6/8/23

Revision Dates: 6/24/19, 7/12/19, 2/21/20, 6/19/20, 4/28/21, 7/21/21, 9/30/21, 10/19/21, 1/12/22, 8/26/22, 12/2/22, 2/2/23, 7/7/23

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Facet joints are paired diarthrodial articulations of the superior and inferior articular processes of adjacent vertebrae. The medial branch of the dorsal rami of the segmental nerves innervate facet joints and the medial branch nerves from the two adjacent dorsal rami innervate each joint.

Facet joint injections/medial branch blocks are the injections of local anesthetic agent and/or corticosteroid in the facet capsule or along the nerves supplying the facet joints. Facet joint injections/medial branch blocks are used in diagnosis and/or treatment of chronic neck and back pain. A diagnostic facet joint injection/medial branch block (MBB) may be performed to determine whether spinal pain originates in the facet joint or nerves surrounding the facet joint.

Radiofrequency nerve ablation (RFA) procedures (also referred to as neurotomy, neurectomy, rhizotomy, and denervation) are offered for a variety of pain syndromes: categorized as being cervical, thoracic, lumbar, or sacroiliac (SI) in origin. These are conditions such as cervicogenic headache, mechanical low back pain, or whiplash (flexion-extension injury), which may cause significant and persistent pain yet have no identifiable etiology on x-ray or exam. Frequently, it is felt that the pain originates in the facet joints of the involved section of the spine and is more common with advanced facet arthritis, inflammation of the facet joint on MRI or with abnormal bone scan. If other etiologies, such as herniated intervertebral discs, fractures, or symptomatic nerve root impingement have been excluded, a trial of a diagnostic nerve block of the facet joint is attempted.

This is often done at several levels as the innervation of the facet joints can arise from the levels above and below the affected joint. This diagnostic injection can be either an MBB or a diagnostic facet block. It is temporary and is designed to see if the patient may respond to a more definitive radiofrequency procedure or therapeutic steroid injection. If there is at least an 80% reduction in pain, then the patient may undergo a therapeutic procedure, either RFA, or a therapeutic steroid facet injection. Unlike cervical and lumbar pain, the anatomy of the medial branch is less clearly defined in the thoracic region. As a result, the nerve location may be difficult to assess, and radiofrequency ablation may be more difficult.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Diagnostic and Therapeutic Interventions for Spinal Pain, continued

Select Health covers Facet Joint Interventions (MBB, RFA, facet cyst rupture/aspiration) when ALL the following are met:

1. Patient has experienced moderate-to-severe lower back (lumbosacral) OR neck (cervical) pain limiting activities of daily living for ≥ 3 months in the current episode, unrelieved by all conservative medical management strategies as listed below:
 - a) NSAIDs/Analgesic > 3 weeks or contraindicated
 - b) Activity modification > 6 weeks
 - c) 4 PT or chiropractic visits within a 3-month period; must have been performed within the previous 2 years. If there have been significant clinical changes or surgery has been performed in the previous 2 years, then repeat PT or chiropractic therapy may be necessary.
2. Potential non-facet sources of pain found on diagnostic imaging have been addressed in the documentation.
3. The clinical exam is consistent with facet joint as the source of pain.
4. There is no evidence of infection, malignancy, or other serious contraindication
5. MBBs must be performed without analgesics being administered prior to the procedure

DIAGNOSTIC FACET JOINT INJECTION CRITERIA

Select Health may cover two MBBs or two diagnostic anesthetic facet blocks* when all the above criteria (1–5) are met:

Select Health covers the second MBB or the second diagnostic facet block when the previous diagnostic MBB or the previous diagnostic facet block achieved $\geq 80\%$ reduction of pain, in addition to criteria 1–5 being met.

*Intraarticular facet block will not be reimbursed as a diagnostic test unless MBBs cannot be performed due to specific documented anatomic restrictions.

Medial branch blocks and facet injections that include corticosteroids are considered therapeutic, not diagnostic.

THERAPEUTIC FACET JOINT CRITERIA (CHRONIC PAIN)

Select Health covers therapeutic steroid facet joint injections if the patient has had two diagnostic facet joint injections that achieved $\geq 80\%$ reduction of pain. A diagnostic facet injection is required prior to this to confirm correct level and requires all the above criteria (1–5) be met.

Continuation of therapeutic steroid facet injections requires documentation showing $\geq 50\%$ reduction of facet-related pain for at least 3 months OR $\geq 50\%$ improvement in ability to perform previously painful movements or ADLs after the initial diagnostic facet injection.

A maximum of 4 therapeutic steroid facet joint injections is allowed per rolling 12 months per joint.

THERAPEUTIC FACET JOINT CRITERIA (ACUTE PAIN)

Single-level therapeutic facet intervention for treatment of severe, acute facet-mediated pain, provoked by facet maneuvers, is covered. Two injections will be allowed within 3 months. **Two diagnostic blocks are not required for this acute therapy.**

Diagnostic and Therapeutic Interventions for Spinal Pain, continued

RADIOFREQUENCY ABLATION (RHIZOTOMY) CRITERIA

Select Health covers non-pulsed thermal radiofrequency ablation (RFA) of the cervical and lumbar facet joints in *limited circumstances*, when criteria (1–5) and ALL the following conditions are met:

The diagnosis of facet joint pain has been confirmed by a controlled, two-step diagnostic nerve block (MBB) or two-step facet diagnostic block, performed under local anesthetic fluoroscopic guidance without the use of analgesics the patient has experienced $\geq 80\%$ reduction of pain.

Repeat (e.g., second) RFA procedures are covered when the following criteria are met:

1. The patient experienced $\geq 50\%$ reduction in facet-related pain from the previous RFA; **OR**
2. The patient experienced $\geq 50\%$ improvement in ability to perform previously painful movements or ADLs after previous RFA; **AND**
3. **It has been at least 6 months** since the previous RFA.

FACET CYST ASPIRATION/RUPTURE

Intra-articular facet joint injection performed with synovial cyst aspiration is considered medically necessary when above criteria (1–5) **AND** the following criteria are met:

- a) Advanced diagnostic imaging study (e.g., MRI/CT/myelogram) confirm compression or displacement of the corresponding nerve root by a facet joint synovial cyst; **AND**
- b) Clinical and physical symptoms related to synovial facet cyst are documented

Cyst aspiration/rupture may be repeated once if patient has $\geq 50\%$ reduction in the pain from previous procedure for at least 3 months.

EXCLUSIONS

Select Health does NOT cover radiofrequency ablation of the thoracic facet joints (except for select self-funded groups who have opted to provide this coverage). Current evidence has failed to demonstrate adequate efficacy of this procedure. This meets the plan definition of investigational/experimental.

Select Health does NOT cover diagnostic MBBs or diagnostic facet blocks when performed as a precursor to thoracic RFA procedures as thoracic RFA procedures are not covered (except for select self-funded groups who have opted to provide this coverage).

All other techniques of facet joint denervation except for radiofrequency ablation for the treatment of chronic cervical/lumbar back pain are considered investigational, including, but not limited to:

- Pulsed radiofrequency denervation
- Laser
- Cryodenervation
- Chemical denervation (e.g., alcohol, phenol, or high-concentration local anesthetics)

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Diagnostic and Therapeutic Interventions for Spinal Pain, continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

The magnitude and duration of benefit from radiofrequency ablation of medial nerves for facet joint pain (RFN-FJP) remains unclear.

Additionally, there are several fundamental questions that remain unanswered, including:

- The validity of the facet joint pain syndrome,
- The sensitivity and specificity (i.e., value) of diagnostic blocks in determining patients likely to benefit from RFN-FJP,
- Benefit and durability of RFN-FJP,
- Benefit and durability of the alternative treatments, and
- Cost-effectiveness of RFN-FJP versus its alternatives.

Maas et al (2015) in a Cochrane Review concluded that there is no high-quality evidence for RFA in low back pain. Legget et al (2014) reported in a systematic review that RFA is effective for lumbar facet and sacroiliac joint pain with 5/6 RCTs showing benefit. Manchikanti et al (2015) looked at therapeutic injection and RFA in 21 RCTs and 5 observational studies and reported level II evidence for RFA in lumbar and cervical spine. Engel et al (2016) concluded using a systematic analysis that cervical RFA was effective. The 2020 ASIPP consensus Guidelines found it to be effective in the lumbar spine. The NASS Guidelines state: "Therapeutic medial branch RFA is a validated treatment for facet mediated pain, and repeat procedures are equally successful if the response to the initial RFA lasted at least three months. These guidelines advocate dual diagnostic MBB with $\geq 80\%$ relief of the primary (index pain), and the onset, and minimum duration of relief is consistent with the agent employed. Also, RFA should be performed at the same level no more than twice annually, and only if the initial radiofrequency lesion results in significant pain relief ($>50\%$) for at least six months."

Fundamental questions also remain unresolved about RFA's alternatives. That being said, the preponderance of evidence seems to support the value of RF ablation of the nerves innervating painful facet joint(s). However, outcomes seem to be highly dependent on the skills of the operator/surgeon, patient selection (especially the type of diagnostic block used) the techniques used, including equipment (e.g., size of RFA "needle", RF generator), and characteristics of the patients, including indications and contraindications. These details have yet to be worked out, as evidenced by the wide variability in outcomes.

Recommendations for MBBs vary. It is difficult to optimally select patients for this procedure due to lack of reliable history, physical and imaging. This means that success of the MBB in relieving pain is the criteria to assess it is facet pain. 2020 ASIPP Guidelines reported on ten studies in the lumbar spine and found prevalence rates ranged from 27% to 40% with false-positive rates of 27% to 47%, with = 80% pain relief. They conclude level 1-2 evidence with moderate to strong strength of recommendation of lumbar, diagnostic facet nerve blocks. Cutoff values for designating positivity are also controversial. 2020 ASIPP Guidelines reported on ten studies in the lumbar spine and found prevalence rates ranged from 27% to 40% with false-positive rates of 27% to 47%, with = 80% pain relief. They conclude level 1-2 evidence with moderate to strong strength of recommendation of lumbar, diagnostic facet nerve block. The literature and societal guidance report that diagnostic injections should be medial branch blocks, not intraarticular injections (Cohen et al, 2020 ASIPP Guidelines, and NASS Guidelines).

Many societal recommendations do not support the use of therapeutic facet joint injections (Cohen et al, NICE, AANS 2014). Some do support therapeutic facet injections (2020 ASIPP Guidelines, American Society of Anesthesiologists). Ultimately, more high-quality studies are necessary in this area to define if these injections are effective and should be recommended long-term.

Diagnostic and Therapeutic Interventions for Spinal Pain, continued

Billing/Coding Information

CPT CODES

Covered: ONLY for the conditions outlined above

- 64490** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
- 64491** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)
- 64492** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
- 64493** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
- 64494** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)
- 64495** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)
- 64633** Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
- 64634** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
- 64635** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
- 64636** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
- 0213T** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
- 0214T** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure)
- 0215T** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
- 0216T** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level
- 0217T** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary procedure)
- 0218T** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)

Diagnostic and Therapeutic Interventions for Spinal Pain, continued

HCPCS CODES

No specific codes identified

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Diagnostic and Therapeutic Interventions for Spinal Pain, continued

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EPIDURAL ADHESIOLYSIS (PERCUTANEOUS OR ENDOSCOPIC) FOR THE TREATMENT OF CHRONIC BACK PAIN

Policy # 249

Implementation Date: 10/26/04

Review Dates: 10/15/05, 10/19/06, 12/20/07, 4/23/09, 8/19/10, 9/15/11, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/15/20, 11/28/21, 9/15/22, 10/13/23

Revision Dates: 7/13/09, 11/29/12

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Low back pain ranks first among musculoskeletal disorders and is the most common ailment in the modern era, burdening approximately 15%–39% of the population, ranging from children to the elderly, and with serious financial and social consequences. It is estimated that 10%–20% of lumbar surgeries result in failed back surgery syndrome. Epidural fibrosis with or without adhesive arachnoiditis most commonly occurs as a complication of spinal surgery and may be included under the diagnosis of "failed back syndrome." Both result from manipulation of the supporting structures of the spine. Epidural fibrosis can occur in isolation, but adhesive arachnoiditis is rarely present without associated epidural fibrosis. Arachnoiditis is most frequently seen in patients who have undergone multiple surgical procedures.

Lysis of epidural adhesions with epidural injections of hypertonic saline in conjunction with steroids and analgesics has been investigated as a treatment option for epidural fibrosis/adhesions. There are 2 primary methods used to achieve the dual goals of disrupting the adhesions and delivering medication to the (presumed) inflamed epidural space: percutaneous and endoscopic. Various protocols for lysis have been described; in some situations, the catheter may remain in place for several days for serial treatment sessions.

Percutaneous lysis of epidural adhesions is also known as epidural adhesiolysis, epidural neurolysis, epidural decompressive neuroplasty, and Racz neurolysis. With this procedure, a 16-gauge RK needle followed by the advancement of a Racz catheter enters the epidural space either caudally, using an interlaminar approach, or by a transforaminal approach. Under radiographic control utilizing nonionic contrast medium, local anesthetic and steroids are injected into the epidural space through the catheter. Lysis of adhesions is then carried out by slow and intermittent injections of hypertonic saline. Catheter manipulation and hypertonic saline both aid in adhesion disruption.

Spinal endoscopy is also known as myelotomy, spinal canal endoscopy, spinal epiduroscopy, spinal or lumbar epiduroscopy, and endoscopic adhesiolysis. With this technique a spinal endoscope is placed in the caudal canal via a Seldinger guidewire technique using fluoroscopy. In conjunction with gentle irrigation using normal saline, the catheter and fiberoptic myeloscope are manipulated and rotated in multiple directions, with visualization of the nerve roots at various levels. Gentle irrigation may be carried out by slow, controlled infusion. Adhesiolysis and decompression are carried out by distension of the epidural space with normal saline, and by mechanical means using the fiberoptic endoscope.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover lysis of epidural adhesions, whether performed percutaneously (e.g., Racz procedure) or endoscopically, for any indication, as this technology

Epidural Adhesiolysis (Percutaneous or Endoscopic) for the Treatment of Chronic Back Pain, continued

meets the plan's definition of experimental/investigational. The quality of evidence is weak, related to the efficacy and safety of this procedure, and medical consensus concerning these procedures remains absent.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

When initially reviewed in 2004, no evidence from adequate well-designed randomized controlled clinical trials in the peer-reviewed medical literature supporting the safety and effectiveness of manipulation of an indwelling epidural Racz catheter or epidural injections of hypertonic saline or hyaluronidase to relieve back pain in patients with epidural adhesions, adhesive arachnoiditis, or failed back syndrome from multiple previous surgeries for herniated lumbar disc were identified.

Most of the reported studies of the Racz catheter are retrospective (Racz & Holubec, 1989; Manchikanti, et al., 2001; Manchikanti, et al., 1999) or lacking a control group (Racz, et al., 1999). Manchikanti, founder and president of the American Society of Interventional Pain Physicians (ASIPP), is a leading advocate of the use of the Racz catheter (Manchikanti, et al., 1999; Manchikanti & Bakhit,

2000; Manchikanti & Singh, 2002). He is lead author of ASIPP guidelines that incorporate the Racz catheter into the management of chronic spinal pain (Manchikanti, et al., 2003).

Manchikanti, et al. (2001, 2004) has reported the results of two controlled clinical studies of the Racz catheter in the ASIPP's official journal, *Pain Physician*; this journal is not indexed in the National Library of Medicine's MEDLINE database of quality assessed biomedical journals. One of these studies involved 45 patients with chronic low back pain, 30 of whom received Racz catheter treatment, and a control group of 15 patients who did not receive Racz catheter treatment. The study was unblinded and utilized a biased control group, as control group subjects were patients who refused Racz catheter treatment, either because coverage was denied by their insurer or for other reasons (Manchikanti, et al., 2001). In another study, subjects with chronic low back pain were randomized to a sham control group or two treatment groups (n = 25 in each group). Nineteen of 25 subjects in the control group were unblinded or lost to follow-up before completion of the 12-month study (Manchikanti, et al., 2004). Both controlled clinical studies involved small groups of patients and are from the same group of investigators from a single private practice, raising questions about the generalizability of the findings (Manchikanti, et al., 2001; Manchikanti, et al., 2004).

The small sample sizes of these studies did not allow adequate evaluation of potential adverse outcomes that may occur with the procedure (Fibuch, 1999). A Joint Health Technology Assessment of the German Medical Association and the German National Association of Statutory Health Insurance Physicians (KBV, 2003) concluded that: "Due to insufficient evaluation and lack of empirical data, at present there is no convincing evidence for the efficacy or effectiveness of the Racz treatment procedure."

An updated review completed June 2009 review found 7 systematic reviews on the role, outcomes, and complications of adhesiolysis have been published. The reviews tended to support the efficacy and safety of epidurolysis. These conclusions, however, are significantly limited in the bias that may exist as the

Epidural Adhesiolysis (Percutaneous or Endoscopic) for the Treatment of Chronic Back Pain, continued

systematic reviews identified for inclusion in the review derived their conclusions from a single author group publishing studies at a single institution. Additional multi-site studies are needed to replicate their findings. Moreover, trials comparing the procedure against other surgical procedures are lacking; long-term outcomes are also limited.

Overall, the extant literature supports epidural or endoscopic adhesiolysis as alternative treatments for treating chronic back pain. Multiple systematic reviews also conclude that the procedure is effective.

Billing/Coding Information

Not covered: Experimental/Investigational/Unproven for this indication

CPT CODES

62263 Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days

62264 ; 1 day

HCPCS CODES

J7131 Hypertonic saline solution, 1 ml

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Epidural Adhesiolysis (Percutaneous or Endoscopic) for the Treatment of Chronic Back Pain, continued

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FUNCTIONAL ANAESTHETIC DISCOGRAPHY

Policy # 422

Implementation Date: 8/13/09

Review Dates: 8/19/10, 9/15/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 11/28/18, 12/18/19, 12/16/20, 11/28/21, 11/17/22, 12/20/23

Revision Dates:

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Description

For most patients with back pain in whom episodes of back pain are self-limited and resolve without specific therapy, an etiologic diagnosis is not established.

Patients with chronic or disabling back pain, or those who are surgical candidates for persistent nerve-impingement symptoms, may warrant additional diagnostic studies. Most patients will undergo MRI or CT scans to identify the etiology of the problem and determine appropriate therapeutic interventions.

Provocative discography is a test in which contrast is injected under fluoroscopy into the nucleus of a disc thought to be the cause of a patient's low back pain. The test is considered positive if it demonstrates an annular disruption (contrast extravasation through tears in disc or tears to the outer disc annulus) and reproduces the patient's usual back pain. The premise behind the test assumes that if a particular disc is painful, then pressurizing it should reproduce the patient's pain. If the disc is not the source of a patient's pain, then pressurizing it should neither be painful nor reproduce the usual back pain. The standard interpretation of the test is that if a discogram is positive according to several commonly used criteria, then the tested disc is the primary source of the patient's pain. However, there is no universally accepted definition of the criteria for a positive discogram, and no gold standard to compare competing diagnostic strategies. As a result, the interpretation of discography has been a longstanding controversy. Not only does the test rely on subjective feedback, but results themselves, have been shown to have false positives and false negatives, with up to 30%–40% of patients with back pain having discography. Similarly, some patients have reported feeling a replication of their usual pain during discography, even though it is later found that another, non-discogenic cause was the actual origin of the pain. These observations suggest that the test is not highly specific.

Functional anesthetic discography involves first a standard provocative discogram using a 2-needle technique (outer needle 18g, inner needle 22g or 25g). Once the candidate's painful discs are noted on provocative discography, the next step involves the placement of a catheter into the relevant lumbar discs that were either painful on injection or radiographically highly suggestive of being a possible pain generator. A dedicated FAD catheter (Kyphon Inc., Sunnyvale, California) has been approved by the FDA and is commercially available; it is inserted over a guidewire and has a balloon anchor at its tip, which prevents migration of the catheter out of the disc during functional testing.

The patient is then allowed to recover from sedation and assume a position or begin an activity that would ordinarily be painful for the patient. It is critical that the patient be able to reliably elicit the pain with a particular position or activity. If this is not the case, the findings of the procedure will be difficult to interpret. The seated position and bending are the most common provocative positions used. An injection of a small volume (0.6 cc) of short-acting local anesthetic (4% lidocaine) or placebo control (normal saline) is then delivered into the disc, and the response of the patient to the anesthetic or placebo is recorded. A volume of 0.6 cc for the injection as this volume is typically below the volume of disc injection

Functional Anaesthetic Discography, continued

at which extravasation into the epidural space is noted on fluoroscopy during discography (1–1.5 cc in degenerated discs), and as such minimizes the likelihood of the anesthetic effect being due to an epidural effect.

The initial injection of anesthetic into the disc typically causes an exacerbation of the patient's typical low back pain, followed by, in positive cases, pain relief from the 4% lidocaine in approximately 2–5 minutes. The effect of the 4% lidocaine typically lasts 25–30 minutes, and then the injection can be repeated as necessary to confirm the diagnosis. A positive result is one in which the patient reports that the intradiscal delivery of the local anesthetic causes a decrease in the visual analog scale (VAS) score of 2 points or greater during the provocative position or activity, and reports that the pain is significantly less than is typical for them. The choice of a VAS score decrease of 2 points as a threshold was somewhat arbitrary. This level cannot be validated as an appropriate one until it can be correlated with successful clinical results after treatment.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover functional anesthetic discography. This meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

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Select Health Community Care (Medicaid)

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Summary of Medical Information

A single empirical article was identified for this review. Ohtori et al. randomly assigned 42 patients with low back pain to either conventional discography or functional analgesic discography (referred to as discoblock in this study). Patients who experienced either pain exacerbation (discography) or pain relief (discoblock) went on to undergo anterior discectomy and interbody fusion. At the 3-year follow-up, the discoblock group (n = 15) reported a mean visual analogue scale (VAS) pain rating, Japanese Orthopedic Association Score (JOAS), and Oswestry Disability Index (ODI) score that were significantly improved relative to the discogram group (n = 15). The rate of improvement in the VAS score was 69% (discography) vs. 83% (discoblock) (p < 0.05); that of the JOAS was 75% (discography) vs. 93% (discoblock) (p < 0.05); and that of the ODI was 62% (discography) vs. 83% (discoblock) 3 years after surgery. The authors concluded that functional analgesic discography improved surgical outcomes and, compared with discography, was a useful tool for the diagnosis of discogenic low back pain.

In a recent review, Derby et al. discuss the results of 2 conference abstracts and their own unpublished data on functional analgesic discography. Noting a lack of data on the sensitivity and specificity of conventional discography, the article concluded that neither test is adequate for diagnosis of discogenic pain of the lower back and suggested that functional analgesic discography could be used as a standalone test or confirmatory to discography. They noted that more research was needed for more definitive diagnostic tests for the various sources of low back pain.

Functional Anaesthetic Discography, continued

In a 2008 article presenting a series of case studies in which functional analgesic discography was utilized, the developer of the test noted that questions remain about the validity of this technique in diagnosing discogenic pain, the clinical utility of test results, and the mechanism of test action. Noting the need for more research into the process of diagnosing chronic low back pain, Alamin observed that further study of the technique will allow more definitive recommendations with regards to its validity and utility.

In summary, a lack of literature on this technology limits conclusions about its clinical utility in diagnosing discogenic low back pain. While Ohtori et al. suggests a potentially important clinical benefit from this type of testing, the results from this small sample study need replication. Thus, the literature does not support use of this technology as an alternative to conventional discography.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

62290	Injection procedure for discography, each level; lumbar
62291	Injection procedure for discography, each level; cervical or thoracic
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation

HCPCS CODES

No specific codes identified

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FUNCTIONAL ELECTRICAL STIMULATION (FES) NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)

Policy # 413

Implementation Date: 1/12/09

Review Dates: 2/18/10, 2/17/11, 2/16/12, 7/18/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/15/22, 9/1/23

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Description

A variety of conditions may affect motor control and muscle strength in the extremities. Two of the most common conditions to do this are stroke and spinal cord injury (SCI). To prevent muscular atrophy in some clinical situations, various devices have been developed that stimulate and exercise muscles electrically. Muscles can be exercised by applying electrical pulses through electrodes attached to the skin surface, a technique known as neuromuscular electrical stimulation (NMES). NMES can usually be administered on an outpatient basis by a physical therapist or, in some cases, by patients or family members at home. Low-intensity and threshold NMES are typically applied six nights per week, for 6 to 12 hours per night, and for 6 months to 1 year.

Electrical stimulation can also be used to activate muscles of the upper or lower extremity rehabilitation and foot drop problems to produce coordinated movement patterns, such as standing and walking, in patients with paraplegia. This application of electrical stimulation is called functional electrical stimulation (FES). A variety of devices have been employed to provide functional electrical stimulation. One system is used to allow paraplegics and quadriplegics to pedal a stationary exercise cycle. For this device, electrical stimulation is provided in an ordered sequence through 6 electrodes attached to the skin surface. The electrical current applied ranges up to 140 milliamps, making cycling speeds of 35–50 rpm readily attainable.

Available functional electrical stimulation (FES) systems include the Bioness H200 Hand Rehabilitation System and the L300 Foot Drop System FES. These devices are examples of non-invasive, advanced neuroprostheses custom-fit orthosis that uses FES to sequentially activate muscle groups in the forearm or lower extremity to produce functional movement patterns.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover functional electrical stimulation/neuromuscular electrical stimulation (FES/NMES). This meets the plan's definition of experimental/investigational.

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Functional Electrical Stimulation (FES); Neuromuscular Electrical Stimulation (NMES), continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Neuromuscular Electrical Stimulation (NMES): One systematic review examined NMES. A January 2008 Hayes Directory included 27 studies, which comprised small, randomized controlled or comparative studies to evaluate NMES to in stroke-related paralysis or orthopedic surgery, or cerebral palsy. The report found conflicting results in terms of long-term benefits of the therapy. The report concluded that sample sizes were too small and follow-up times insufficient to support definitive conclusions regarding NMES for any indication. The review gave NMES a 'C' rating for rehabilitation of wrist and finger function after stroke-related partial paralysis, prevention or correction of shoulder subluxation after partial paralysis due to stroke, and treatment of swallowing disorders after stroke and a 'D' rating for all other indications.

Eight studies met criteria for inclusion and 7 of these were randomized controlled studies. Bakhiatry et al. randomly assigned 40 stroke patients with ankle plantarflexor spasticity conventional rehabilitation or combination rehabilitation combined with electrical stimulation. The treatment group experienced statically significant improvements in passive ankle joint dorsiflexion, plantarflexor muscle tonicity, and dorsiflexor muscle strength. However, no difference was observed in amplitude of H-reflex. In a study of post-surgical proximal femoral fracture patients, Braid et al. randomly assigned 15 patients to supplementary electrical stimulation of the quadriceps, while 11 patients received standard physiotherapy. They found no difference in leg extensor power, functional mobility, disability, and health status. Moreover, only 3 of the treatment patients tolerated stimulation of sufficient intensity to produce knee extension. Khalili et al. assigned 1 knee of 11 children with cerebral palsy with bilateral knee flexor spasticity to a regimen of electrical stimulation of the quadriceps and passive stretching while the other leg received passive stretching alone. At the end of the 4-week trial, the experimental leg had 4 degrees more passive knee extension than the control knees, leading the investigators to conclude that electrical stimulation was marginally effective for limb spasticity in this population. Reza Nourbakhsh randomly assigned 18 patients with chronic lateral epicondylitis to either 6 sessions of electrical stimulation over tender points or to a placebo group with the intensity of electrical stimulation was set at 0. The treatment group experienced clinically and statistically significant improvements in grip strength, functional activity, pain intensity, and activity limitation due to pain relative to the control group. At 6 months, 100% of subjects maintained the improved function, and 83% remained pain-free for at least 6 months post-treatment.

Bily et al. randomly assigned 36 patients with patellofemoral pain syndrome to supervised physical therapy (PT) or PT combined with NMES. After 12 weeks and one year, there was no statistically significant difference in knee pain or isometric knee extensor strength between groups. Harris et al. randomly enrolled 46 patients with stable NYHA Class II/III heart failure to either a 6-week training program using a bicycle ergometer or to FES of the quadriceps and gastrocnemius muscles. Both treatments produced improvements in a 6-minute walk time, treadmill exercise time, and maximum leg strength, and the authors concluded that FES produced benefits similar to those observed with exercise, though, no statistical comparisons were reported. Karavidas enrolled 30 patients with stable CHF to either a training program involving FES or placebo. After 6 weeks, patients in the FES group experienced a significant improvement in quality of life, depression, and a 6-minute walk time and a trend toward lower plasma B-type natriuretic peptide, relative to controls.

Finally, in a pilot study, Sillen et al. examined the metabolic response during resistance training and during NMES of the quadriceps femoris muscles in 13 patients with COPD entering pulmonary rehabilitation. Patients each received a session of NMES and a session of resistance training. The authors found the metabolic response to be lower during NMES, compared to resistance training, but concluded that the metabolic response was acceptable in both modalities, resulting in acceptable levels of dyspnea and leg fatigue.

Functional Electrical Stimulation (FES); Neuromuscular Electrical Stimulation (NMES), continued

Overall, the literature on NMES offers mixed support for its use in reducing muscle atrophy. The 5 studies examined 5 different indications, treatment regimens, and outcomes in very small sample sizes, which eliminates any comparisons across studies and limits generalizing findings to other populations. In short, there is insufficient evidence to support use of NMES for treatment of muscle atrophy in any patient population.

Functional Electrical Stimulation (FES): Two systematic reviews have been published on the topic of FES. The 2003 Hayes Directory review examined FES for lower limb rehabilitation. Noting a limited number of small, prospective controlled and uncontrolled clinical trials (11 studies), the review concluded that FES offered potential to slow or reverse muscular atrophy in patients with tetraplegia and paraplegia. However, the literature provided no evidence that ambulation achieved during FES translates into reduced use of a wheelchair, improved mobility, or physiological benefits superior to those achieved with electrically stimulated stationary exercise. Hayes gave FES a 'D' rating for all indications.

A 2007 Cochrane review included 8 studies and concluded that patients who received FES after stroke were more likely to achieve independent ambulation than patients who received gait training through other methods. The review noted a need for studies examining long-term follow up to determine the durability of treatment effects.

Twenty studies published since the Hayes review from 2003 met criteria for inclusion. Of these, 12 were randomized clinical trials. Alon et al. used FES in ischemic stroke survivors to improve upper-extremity volitional motor control. Thirteen were assigned to an FES + exercise group and 13 to an exercise alone group. After 12 weeks of training, volitional motor control was significantly better for the FES group, but hand function overall was no different between groups. In practical terms, 8 FES patients vs. 3 controls regained the ability to transfer 5 or more blocks and 6 vs. 2 completed the Jebsen-Taylor light object lift task in 30 seconds or less; marginal, but not statistically significant differences. The authors concluded that the addition of FES minimized motor loss did not enhance the ability to use upper extremities after ischemic stroke.

Ferrante et al. randomly assigned 20 post-acute stroke patients to standard rehabilitation or FES cycling in addition to standard rehabilitation. After 4 weeks of training, the FES group experienced a significantly higher increase of muscular force produced by the quadriceps while 70% of FES patients learned to perform a sit-to-stand movement at three different rising speeds compared with none from the control group. However, this difference was not statistically significant.

Hara et al. enrolled 20 stroke patients with spastic upper-extremity impairments who were randomly assigned to a FES or control condition for five months. The FES group experienced significantly greater improvements in RMS, active range of motion of wrist and finger extension and shoulder flexion, modified Ashworth scale and functional hand tests, and was able to smoothly perform activities of daily life using the hemiplegic upper extremities. Hesse et al. randomly assigned 54 German patients 4–8 weeks post-stroke to standard treatment plus 20–30 minutes on an arm trainer or electrical stimulation every workday for 6 weeks. Fugl-Meyer scores improved for both groups over time but did not differ between groups. After treatment, 5 arm trainer patients were able to transport at least 3 blocks vs. 3 FES patients, which was statistically significant. No significant differences were observed between the groups on the secondary Box and Block outcome. In Ho et al., 15 children with spastic cerebral palsy and 6 children developing normally were randomly assigned to FES or a no treatment control. At 15 weeks, participants switched groups. There was no significant difference between the normal controls and the children with CP in the no-FES condition on speed-normalized dimensionless impulse. In the FES condition, children with CP had a significantly higher median value than normal controls. FES significantly increased speed-normalized dimensionless impulse while walking but did not result in any significant change in stiffness, stride length, and stride frequency while walking.

Janssen et al. assigned 12 stroke patients with lower-extremity hemiparesis 5 months post-stroke to a cycling group with either a FES component or no FES. After 6 weeks, while both groups improved in aerobic capacity, maximal power output, functional performance, and 6-minute walk time, the 2 training groups did not differ on any outcome measure. Kowalczewski randomly assigned 19 stroke patients with upper-extremity hemiplegia to either a FES-assisted exercise group or a group with low-intensity electrical stimulation in conjunction with exercise. After 4 weeks, the FES group experienced significant improvements in some tests of motor function over low-intensity controls. However, the 2 groups did not

Functional Electrical Stimulation (FES); Neuromuscular Electrical Stimulation (NMES), continued

differ in a self-assessment of motor activity or in Fugl-Meyer Assessments, leading the authors to conclude that the improvements were of questionable clinical significance.

Ng et al. evaluated gait training in 54 stroke patients who were assigned to either conventional over ground gait training treatment (CT, n = 21), electromechanical gait trainer (GT, n = 17) and, electromechanical gait trainer with functional electrical stimulation (GT-FES, n= 16). After 4 weeks of training, and at the 6-month follow-up, the GT-FES and GT groups showed significantly better improvement in Elderly Mobility Scale (EMS), Functional Ambulatory Category (FAC), and gait speed, but no difference was observed in the Berg Balance test, the FIM, the Barthel Index, or the Motricity Index leg subscale. Ring et al. enrolled 22 subacute stroke patients into 2 groups. The first used a neuroprosthetic device designed to deliver electrical stimulation to the finger vs. a control group. All patients underwent physical and occupational therapy on an outpatient basis and the treatment group used the neuroprosthetic device at home. At the end of 6 weeks, the neuroprosthesis group had significantly greater improvements in spasticity, active range of motion, and scores on the functional hand tests.

Thrasher et al. used FES in 21 stroke patients to improve reaching and grasping function. Randomized into either standard occupational or physical therapy vs. standard therapy plus FES, the FES group, relative to controls, experienced significant improvements in object manipulation, palmar grip torque, pinch grip pulling force, Barthel Index, Upper Extremity Fugl-Meyer scores, and Upper Extremity Chedoke-McMaster Stages of Motor Recovery. Finally, van der Linden et al. randomized 14 children with cerebral palsy to either 2 weeks of outpatient FES followed by 8 weeks of in-home FES or to a control group consisting of standard physiotherapy. Treatment in both groups was directed at dorsiflexors and quadriceps muscle groups. After 2 weeks, FES had significant ($p < 0.01$) effect on gait kinematics but no long-term treatment effect of using FES for 8 weeks was found.

Overall, the literature on FES suggests that the procedure does produce some improvements in laboratory assessments of mobility, strength, and function. However, there is a dearth of studies examining outcomes beyond a few weeks and very few "real world" assessments of functioning. Thus, it is unclear whether the initial gains observed in laboratory testing translate into improved daily functioning outside of a treatment center. One self-assessment suggested patients did not feel they had improved despite clinicians' assessments of improvement. These "real world" outcomes are important for validating the addition of FES to standard rehabilitation for stroke and other disorders that affect physical mobility.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

No specific codes identified

HCPCS CODES

E0764 Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program

E0770 Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

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Functional Electrical Stimulation (FES); Neuromuscular Electrical Stimulation (NMES), continued

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Functional Electrical Stimulation (FES); Neuromuscular Electrical Stimulation (NMES), continued

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INFUSION PUMPS (EXTERNAL OR IMPLANTABLE)

Policy # 609

Implementation Date: 7/31/17

Review Dates: 7/16/18, 6/20/19, 6/17/20, 7/2/21, 5/13/22, 5/31/23

Revision Dates: 5/25/22, 11/30/23, 2/13/24

Related Medical Policies:

[#133 Insulin Pumps](#)

[#137 Intrathecal Baclofen Therapy](#)

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

An external infusion pump is a computerized device that includes a loaded syringe and infusion set for needle insertion for a continual basal rate and bolus delivery of a drug; either subcutaneous or intravenously.

An implantable infusion pump is remotely controlled (either closed loop or open loop system) and delivers medication at a controlled rate. The pump is usually implanted in the peritoneal cavity. These devices are not used for insulin therapy.

Pain is another reason for an implantable pump. The pump delivers pain medicines, via a catheter, either into the epidural space surrounding the spinal cord or directly into the spinal fluid (intrathecally). The primary drug dispensed from the pump is morphine, but other drugs are frequently added as adjuncts (experimentation with different drugs and drug regimens is currently a very active area of research).

Since the receptors for opioids (e.g., morphine) reside within the spinal cord, oral dosing often requires large dose regimens to elicit and maintain a therapeutic effect. Unfortunately, large systemic loads of opioids have several significant negative side effects; including nausea, pruritus (itching), urinary retention, and (potentially fatal) respiratory depression.

Implantation of infusion pumps permits delivery of drug directly to the target tissue, the spinal cord, thus facilitating dramatic reductions in drug-related side effects. Compared to oral dosing, intrathecally-delivered pain medications may require only 1/300 the medicine for an equivalent analgesia effect, resulting in substantial savings in drug costs over time.

The drugs can be delivered continuously or intermittently, and the new models of programmable pumps can provide steady state delivery, bolus delivery, or a combination of continuous and bolus delivery. Patients considered for these devices must first undergo rigorous screening to determine possible appropriateness for implantation, followed by a trial infusion. A trial involves a bolus infusion of morphine (typically) and assessment of response to determine appropriateness of implantation.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers external infusion pumps in the following circumstances:



Infusion Pumps (External or Implantable), continued

1. *Iron poisoning*: when used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overloads. Only **external pumps** are a covered benefit.
2. *Thromboembolic disease*: administration of heparin for thromboembolic disease and/or pulmonary embolism. Only external pumps used in an **institutional setting** are covered.
3. *Diabetes mellitus*: See Insulin Pump Criteria (medical policy #133)
4. Other uses of external infusion pumps are covered if the appropriateness and medical necessity of the overall therapy plan that includes the prescribed pump for the individual patient is verified (e.g., chemotherapy or morphine for intractable pain).

Select Health covers **implantable*** infusion pumps in the following circumstances:

1. The implantable infusion pump is considered appropriate for individuals requiring the continuous administration of chemotherapy drugs (usually for hepatic or colorectal cancer).
2. For the management of chronic pain, or intractable cancer pain, when the following criteria are met:
 - a. Treatment decisions are managed by a certified, physician pain specialist.
 - b. More conservative methods have failed:
 - 1) Over-the-counter drugs (e.g., NSAIDs);
 - 2) Physical therapy, TENS/PENS;
 - 3) Nerve blocks;
 - 4) Psychological/behavioral therapies;
 - 5) Long-acting opioids.
 - c. Further surgical intervention is not indicated, or the implantable infusion pump therapy has a better likelihood of success (50%–75% or better).
 - d. The pain is not completely or specifically neuropathic in origin.
 - e. No contraindications to a surgical procedure are present (e.g., sepsis, coagulopathy).
 - f. Psychological clearance has been obtained (not necessary for malignant pain patients) and is managed by a licensed clinical psychologist or board-certified psychiatrist. This 'clearance' is to include evaluation of any serious, untreated drug habituation problem. However, clearance is not necessary for malignant pain and baclofen pumps for spasticity.
 - g. A documented, long-term follow-up plan, specific for the patient and procedure, has been established and is managed by a certified, physician pain specialist, with coordination of multiple disciplines if needed due to the failure of a multidisciplinary pain management team to exist within the Intermountain system.
 - h. Test (e.g., trial) dosing has been successful; this requirement does not apply to cancer patients.
3. Other uses: The drug to be administered must be reasonable and necessary for the treatment of the specific patient; it must be medically necessary to administer the drug by an implanted infusion pump. The FDA approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.
4. Intrahepatic Chemotherapy Infusion for Liver Metastases from Colorectal Cancer
 - a. Implantable infusion pumps are considered medically necessary for administration of intrahepatic chemotherapy (e.g., floxuridine) to members with primary hepatocellular

Infusion Pumps (External or Implantable), continued

carcinoma and for metastatic colorectal cancer where metastases are limited to the liver.

Note: For intrathecal baclofen therapy, please see medical policy #137.

Select Health considers implanted infusion pumps experimental and investigational for all other indications.

*Implantable pumps are contraindicated when patients have an infection, are allergic or intolerant of the drug to be administered, body size cannot accommodate the device, or patients have other necessary programmable devices that may cause a 'crosstalk' problem resulting in malfunction.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

A 1999 Hayes review concluded the following about implantable infusion pumps for chronic pain: "There is evidence from case series reports and small, uncontrolled prospective studies that intrathecal opioid therapy via implantable infusion pump can provide effective pain relief for selected patients with chronic nonmalignant pain who do not respond to or cannot tolerate other less invasive pain control measures, who have a life expectancy of at least 3 months, and who have had a positive response to a trial dose of intrathecal analgesic. However, the complication rate is relatively high, and information about long-term outcomes is lacking. Moreover, there are little data regarding the effect of intrathecal opioid therapy on other health outcomes, such as degree of disability, ability to work, or overall health status. Therefore, a Hayes Rating of C has been assigned for intrathecal opioid therapy delivered via implantable pump in patients with chronic nonmalignant pain who have failed other less invasive forms of pain management."

A 2004 technology assessment from the National Health Service in the UK concluded the following about implantable infusion pumps for diabetes:

"Control of diabetes consists of more than just control of blood glucose as reflected in glycated haemoglobin. Compared with optimised multiple injection insulin therapy, [continuous subcutaneous insulin infusion] results in a modest but worthwhile improvement in glycated haemoglobin, but its main value may be in reducing other problems such as hypoglycaemia and the dawn phenomenon, and in improving quality of life by allowing greater flexibility of lifestyle. Pumps appear to be a useful advance for patients having particular problems, rather than a dramatic breakthrough in therapy, and would probably be used by only a small percentage of patients."

In 2005, the Ontario Ministry of Health and Long-Term Care (OHTAC) concluded the following about intrathecal baclofen for spasticity:

- There is Level 2 evidence of the effectiveness of intrathecal baclofen infusion for the short-term reduction of severe spasticity in patients who are unresponsive or cannot tolerate oral baclofen

Infusion Pumps (External or Implantable), continued

- There is Level 3 evidence of the effectiveness of intrathecal baclofen for the long-term reduction of severe spasticity in patients who are unresponsive or cannot tolerate oral baclofen
- There is Level 4 qualitative evidence of functional improvement for patients who are unresponsive or cannot tolerate oral baclofen
- Intrathecal baclofen is cost effective with costs which may or may not be avoided in the Ontario health system
- The true functional use of intrathecal baclofen remains to be determined

Billing/Coding Information

CPT CODES

36260	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
36261	; non-programmable pump
36262	; programmable pump, including preparation of pump, with or without programming
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62325	; with imaging guidance (ie, fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	; with imaging guidance (ie, fluoroscopy or CT)
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy
62351	; with laminectomy
62355	Removal of previously implanted intrathecal or epidural catheter
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; non-programmable pump
62362	; programmable pump, including preparation of pump, with or without programming
62365	Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill
62368	; with reprogramming
62369	; with reprogramming and refill
62370	; with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

Infusion Pumps (External or Implantable), continued

77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)
95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed;
95991	; requiring skill of a physician or other qualified health care professional
96521	Refilling and maintenance of portable pump
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (eg, intravenous, intra-arterial)
96523	Irrigation of implanted venous access device for drug delivery systems

HCPGS CODES

A4220	Refill kit for implantable infusion pump
C1772	Infusion pump, programmable (implantable)
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement.
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

Key References

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7. Source: Modified, in part, from Health Net: Medical Policy Manual, 1994, Woodland Hills, CA with permission.
8. St. Anthony's Medicare Coverage Manual, St. Anthony's Publishing, Reston, VA, Annually with updates.

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Infusion Pumps (External or Implantable), continued

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INTRACEPT

Policy # 648

Implementation Date: 4/9/21

Review Dates: 3/16/22, 5/23/22, 4/20/23, 4/18/24

Revision Dates: 5/2/23, 4/24/24

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

There are approximately thirty million adults in the United States with chronic lower back pain (CLBP), which represents approximately 10–13% of the US adult-aged population. Of these patients with CLBP, one in six (approximately 5 million people), have vertebrogenic CLBP with Type 1 and/or 2 Modic changes (MC). Patients with Modic Type 1 or 2 endplate changes are known to have high levels of disability, poor outcomes with standard treatments, and to incur high rates of healthcare utilization and high costs. The resulting economic burden for these patients with MC, who are currently being treated inconsistently, and ineffectively, is excessive.

Patients with vertebrogenic pain present with low back pain, with or without referral into the buttocks or thighs (somatic referred pain). The pain is often disabling, with over 70% being classified as at least moderately disabled on the Oswestry Disability Index (ODI). In fact, patients with Modic type 1 or 2 changes are known to have the highest levels of disability, the poorest outcomes with standard treatments, and incur the highest rates of healthcare utilization and costs. Enrollment in the two Level I randomized controlled trials of BVN ablation for CLBP would suggest that the mean age of patients is 47 to 50 years old.

Patients with vertebrogenic pain are often treated as having non-specific LBP, and their treatment usually does not follow validated care pathways. This results in over- or under-treatment, suboptimal outcomes, and high costs. Furthermore, clinical guidelines and payer policies governing nonoperative and surgical treatments for CLBP are inconsistent and have a high degree of heterogeneity. Common therapies aimed at chronic non-specific LBP are limited by small effect size, leaving many patients dissatisfied. When compared to a standard care control, treatment of patients with CLBP failed to demonstrate a statistically significant difference or failed to exceed established thresholds of clinical relevance using acupuncture, cognitive behavioral therapy massage, multidisciplinary rehabilitation, and yoga. Some patients ultimately go on to fusion surgery. While fusion surgery for instability, scoliosis, and other well-defined conditions yields very positive outcomes, a recent meta-analysis of 7 studies comparing segmental fusion to different types of structured and unstructured care for CLBP revealed a weighted mean difference in ODI of 5.13 points (95% CI 0.19-10.07) in favor of fusion surgery.

The Intracept Procedure is a minimally invasive outpatient procedure that targets the basivertebral nerve (BVN) for relief of chronic low back pain caused by vertebrogenic pain between L3 and S1. The procedure is performed under at least moderate conscious sedation. Fluoroscopic imaging is utilized to guide transpedicular positioning of the intervertebral instruments. After reaching the location of the BVN trunk a flexible bipolar radiofrequency (RF) probe is inserted and then connected to a RF generator to heat the tip to 85 C for 15 minutes. This energy creates a 1 cm diameter spherical ablation zone. The procedure is repeated at each additional vertebral body identified pre-operatively.

Intrasept, continued

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers intraosseous ablation of the basivertebral nerve (Intrasept), for members who meet all the following criteria:

1. Has failed an adequate course of conservative treatment (at least 6 months), as defined by:
 - a) NSAIDs/Analgesics > 3 weeks or contraindicated
 - b) Activity modification > 6 weeks
 - c) Physical therapy (minimum of 4 visits within a 3-month period), or chiropractic therapy (minimum of 4 visits within a 3-month period); and
2. Type 1 and/or Type 2 Modic changes are present, and confirmed on radiologic report; and
3. Other sources of lower back pain have been ruled out, specifically radiofrequency of the facet joints is either not indicated, contraindicated, or have failed to relieve the lower back pain; and
4. Patient does not have significant radicular pain.

*Four vertebral bodies may be performed per procedure; levels should include only L3-S1.

**The procedure may not be repeated for five years after the initial procedure.

Select Health considers all other indications for intraosseous ablation of the basivertebral nerve (Intrasept) to be experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

SMART Trial

The SMART trial was a prospective randomized, sham-controlled, double-blinded, FDA-IDE trial conducted to evaluate the safety and efficacy of RF ablation of the BVN for the treatment of CLBP. A total of 225 CLBP patients with Type I or Type II Modic changes noted in vertebral bodies L3 to S1 were randomized to either a sham-control (78 patients) or BVN ablation treatment (147 patients). All study participants were treated with the same operating protocol and pedicle access. The sham-control arm

Intracept, continued

received simulated RF ablation therapy. Treatment success was adjudicated in a blinded review of the 6-week MRI. Study participants were followed at 2 weeks, 6 weeks, and 3, 6, 9, and 12 months post-randomized intervention. The primary efficacy endpoint was change in ODI from baseline to 3 months post-procedure. The primary safety endpoint was a comparison of musculoskeletal and neurologic adverse events at 12 months.

Participants in this study were of working age (mean of 47 years), reported severe disability impact from their low back pain (mean ODI of 42), and more than 68% had been experiencing CLBP for greater than 5 years. At 3 months, the mean ODI in the treatment arm decreased 20.5 points, as compared to a 15.2-point decrease in the sham arm ($p = 0.019$, per-protocol population). The reduction in ODI experienced by the treatment arm was twice the minimally clinically important difference of ≥ 10 points and responder rates were 75.6% in the treatment arm compared to 55.3% in the sham control arm. There were no serious device or procedure-related adverse events reported in patients randomized to the RF ablation treatment arm through 12 months.

This level 1 trial demonstrated significant functional improvement in patients treated with RF ablation of the BVN for CLBP compared to patients treated with a sham procedure. Safety of the procedure was also demonstrated. The results supported BVN ablation as a minimally invasive treatment for the relief of chronic low back pain.

SMART 24-Month Outcomes

This prospective, single-arm study is an extension of follow-up for the RF ablation treatment arm of the SMART trial. Per the original SMART RCT protocol, at completion of the 12-month primary safety endpoint, patients in the sham-control arm could cross to BVN ablation treatment; 73% elected to cross. Due to this high rate of cross-over, the 147 RF ablation treatment arm participants acted as their own control in comparing 24-month outcomes to baseline.

Clinical improvements in the ODI, VAS, and the Medical Outcomes Trust Short-Form Health Survey Physical Component Summary (SF-36 PCS) were statistically significant compared to baseline at all follow-up time points through 2 years (3, 6, 9, 12, 18 and 24 months). The mean percent improvements at 2 years in ODI and VAS compared to baseline were 53.7% and 52.9%, respectively. Responder rates for ODI and VAS were also maintained through 2 years for both a 10-point ODI MCID threshold (76.4% of patients) and an ODI 20-point improvement threshold (57.5% of patients). The MCID threshold for VAS of 1.5 cm improvement was reported in 70.2% of patients at 24 months. In summary, patients treated with RF ablation of the BVN for CLBP exhibited sustained clinical benefits in ODI and VAS and maintained high responder rates through 2 years following treatment.

Table 1 – SMART Treatment Arm Data

Visit	Baseline	Week 2	Week 6	Month 3	Month 6	Month 12	Month 24
Oswestry Disability Index							
N	128	128	128	128	128	128	106
Total Score a	42.4 ± 10.92	23.5 ± 15.41	23.1 ± 15.19	22.1 ± 15.39	21.6 ± 14.92	22.6 ± 15.71	18.8 ± 15.89
Mean Δ ± SD a		-18.9 ± 15.92	-19.3 ± 15.27	-20.3 ± 15.56	-20.8 ± 15.92	-19.8 ± 16.18	-23.4 ± 18.35
P		<.001	<.001	<.001	<.001	<.001	<.001
%		44.2%	45.2%	47.6%	48.2%	46.2%	53.7%
Visual Analog Scale							
N	128	127	127	127	126	125	104
Total Score b	6.73 ± 1.383	3.74 ± 2.280	3.75 ± 2.532	3.80 ± 2.625	3.74 ± 2.684	3.96 ± 2.830	3.13 ± 2.636
Mean Δ ± SD b		-2.97 ± 2.407	-2.95 ± 2.558	-2.90 ± 2.642	-2.98 ± 2.639	-2.76 ± 2.887	-3.59 ± 2.739
P		<.001	<.001	<.001	<.001	<.001	<.001
%		43.5%	43.7%	42.8%	44.2%	40.1%	52.9%
SF-36 Physical Component Summary							
N	128			126	127	125	106
Total Score b	33.50 ± 7.366			43.32 ± 9.481	43.89 ± 8.686	42.83 ± 9.199	45.83 ± 9.216
Mean Δ ± SD b				9.83 ± 9.479	10.29 ± 8.915	9.21 ± 9.425	11.84 ± 9.882

Intracapt, continued

p				<.001	<.001	<.001	<.001
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a Last observation carried forward used to impute missing values through Month 12. Missing values at Month 24 were not imputed.

b Observed data only. Missing values were not imputed. P-value from paired t-test.

INTRACEPT Trial

This prospective, parallel, open-label, randomized control trial conducted at 20 US sites compared the effectiveness of intraosseous RF ablation of the basivertebral nerve (BVN) to standard care for the treatment of chronic low back pain (CLBP) in patients suspected to have vertebrogenic-related pain symptomatology. A total of 140 patients with CLBP of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 to S1, were randomized 1:1 to undergo either RF ablation of the BVN or continue standard care. The primary endpoint was a between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment. Secondary outcome measures included LBP pain scores via Visual Analog Scale (VAS), ODI, and VAS responder rates, SF-36, and EQ-5D-5L at 3, 6, 9, and 12-months post-procedure. An interim analysis to assess for superiority was prespecified and overseen by an independent data management committee (DMC) when a minimum of 60% of patients had completed their 3-month primary endpoint visit.

The interim analysis showed clear statistical superiority ($p < 0.001$) for all primary and secondary patient-reported outcome measures in the RF ablation arm compared to the standard care arm. This resulted in a DMC recommendation to halt enrollment in the study and offer early cross-over to the control arm. As a result, the study reported the outcomes of the 104 patients included in the intent-to-treat (ITT) analysis of the 3-month primary endpoint, which included 51 patients in the RF ablation arm and 53 patients in the standard care arm. At baseline, the mean age was 50 years, mean ODI was 46.1 (severe pain disability) and mean VAS was 6.67 cm (on a 0 to 10 cm scale). More than 67% of patients reported experiencing LBP for greater than 5 years and more than 70% had received prior injections at baseline.

Comparing the RF ablation arm to the standard care arm, the mean changes in ODI at three months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points ($p < 0.001$); and mean changes in VAS were -3.46 versus -1.02, respectively, an adjusted difference of 2.44 cm ($p < 0.001$). In the RF ablation arm, 74.5% of patients achieved the minimal clinically important difference (MCID) of ≥ 10 -point improvement in ODI, compared with 32.7% in the standard care arm ($p < 0.001$). With a MCID of 2.0 cm improvement in VAS, 72.5% of patients in the RF ablation arm reached clinical success compared to 34.0% of patients in the standard care arm. No RF ablation patients received a spinal injection prior to the 3-month endpoint, while in the standard care arm, 6 standard of care patients (11%) received injections across 5 study sites. The study concluded that minimally invasive RF ablation of the BVN leads to significant improvement of pain and function at 3-months in patients with chronic vertebrogenic related LBP.

Billing/Coding Information

CPT CODES

22899 Unlisted procedure, spine

[Updated CPT codes, effective January 1, 2022]

64628 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral

64629 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

HCPCS CODES

C9752 Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum or just "Intraosseous destruct add!" for short, used in surgery

Intracapt, continued

C9753 Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure) or just "Intraosseous destruct add'l" for short, used in surgery

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2. The Intracapt Procedure: Basivertebral Nerve Ablation for the Relief of Chronic Vertebrogenic Low Back Pain. Version 18; March 23, 2020.

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LYPHHEDEMA THERAPY

Policy # 147

Implementation Date: 7/98

Review Dates: 1/4/00, 2/22/01, 8/15/02, 10/23/03, 11/18/04, 11/7/05, 10/19/06, 12/20/07, 4/12/12, 4/5/23, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 7/20/18, 4/12/19, 4/14/20, 4/13/21, 2/22/22, 4/5/23

Revision Dates: 8/19/02, 9/14/06, 11/10/08, 4/21/11, 1/14/22, 4/13/23

Related Medical Policies:

[#424 Sclerotherapy for the Management of Lymphangiomata](#)

[#525 Pneumatic Compression Therapy for DVT Prophylaxis](#)

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Lymphedema refers to swelling that generally occurs in an extremity because of obstruction or accumulation of lymphatic fluid. Although lymphedema tends to affect just one arm or leg, depending upon the location of the blockage or disruption to lymphatic fluid flow, both limbs may be affected. It can also extend into the trunk.

Causes for lymphedema include mechanical insufficiency (e.g., obstruction) or low-volume insufficiency of the lymphatic system (e.g., low oncotic pressure). The major causes of lymphedema are generally classified as primary (hereditary) or secondary (acquired), which are much more common. Specific common causes include:

The keystones of lymphedema treatment are elevation, compression, and exercise. The ultimate goal in the treatment of lymphedema is to control/reduce limb swelling to reduce the complications of the swelling since the underlying disease cannot usually be corrected. Modalities used to control lymphedema may consist of nonsurgical therapies such as exercise, gradient pressure garments, bandages, massage therapy or manual decompressive lymphedema drainage (MLD), and pneumatic compression. Antibiotics are appropriate for the treatment of associated cellulitis or lymphangitis, or with the presence of bacteremia.

An intensive form of MLD, complete/complex decongestive physiotherapy (CDT), uses manual therapy as well as compressive bandaging and elastic garments in a 2-phase physical therapy program. The program typically involves attending physical therapy sessions 2–5 times per week for 2 weeks. During this time, patients will be educated on a self-management program after an initial in-office program of 1 to 2 weeks.

For information about the coverage and treatment of lymphatic malformation (LM) refer to Policy #424: "Sclerotherapy for the Management of Lymphangiomata."

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.



Lymphedema Therapy, continued

Select Health covers compression garments for the treatment of chronic lymphedema of the arm or leg in *limited circumstances* as outlined below.

Conditions which must be met to for coverage of compression garments are:

Coverage will be for the initial garments (2-pair) and replacements at a minimum interval of every 6 months.

Compression Garments

Select Health covers non-elastic compression garments, (e.g., LegAssist or ArmAssist), for the treatment of chronic lymphedema of the arm or leg in *limited circumstances* as outlined below.

Conditions which must be met for coverage of compression garments are:

Coverage will be for the initial orthotic and replacement every 5 or more years.

Complete Decongestive Therapy

Select Health covers complex/complete decongestive therapy (CDT) as medically necessary.

Pneumatic Devices

Select Health covers segmental and non-segmental pneumatic devices without calibrated gradient pressure.

Select Health only covers segmental pneumatic pumps with calibrated gradient pressure (e.g., Flexitouch) when either of the following criteria are met:

- 1) Member has a diagnosis of lymphedema, with the lymphedema affecting either the chest, trunk, genital, head, or neck regions, or
- 2) Lymphedema has been refractory to at least a 4-week trial with documentation demonstrating compliance of a segmental pneumatic pump without calibrated gradient pressure

Select Health will only allow purchase of segmental pneumatic pumps with calibrated gradient pressure (e.g., Flexitouch) after 3 months of rental.

Non-Pneumatic Compression Systems

Select Health does not cover the use of non-pneumatic compression systems (e.g., Koya Dayspring system) in the treatment of lymphedema due to lack of established efficacy.

Select Health does NOT cover the following, as the use thereof is considered investigational:

- Microwave or thermal therapy used for the specific treatment of lymphedema

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp> or [the manual website](#)

Lymphedema Therapy, continued

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Lymphedema Therapy

A 2004 Cochrane review noted the following about lymphedema therapy:

“Any edema of the surface tissues that involves a fluid component is likely to be influenced by the application of external pressure, as clinical experience world-wide has demonstrated over many years. From a physiological point of view, difficulties are likely to arise if fluid is trapped in fatty tissues (since fat absorbs pressure) or in fibrotic tissues where it becomes difficult for fluid to be displaced. Both of these scenarios are common in lymphedema but despite these problems few therapists specializing in the management of lymphedema doubt that improvements can be obtained through treatment. The question is not so much 'Can lymphedema be treated?' but rather 'What treatments reduce swelling, and the morbidity associated with swelling, most effectively?' In addition to this question, we need to ask 'What treatments produce lasting improvements?' since short-term improvements satisfy no one.

It appears that at present there is no drug or surgery that will reduce chronic edema and allow the reduction to be maintained. Physical therapies remain the most commonly used treatments for lymphedema and are usually combined in a treatment program, since the general view is that no one treatment is likely to be successful on its own. The difficulty lies in establishing which of these physical treatments plays the most critical part in reducing and controlling swelling and which, if any, can be safely left out of the treatment program.”

Most of the studies conducted so far in this field are either designed poorly or are poorly reported. Most are too small and provide too little follow-up to be of any use. There is a tendency to concentrate on one section of the lymphedema population (i.e., breast cancer patients) when the growing body of evidence on prevalence and incidence suggests that lower limb edema, either of primary origin or secondary to cancer and other conditions, is also a significant problem.

An updated review of the literature completed as part of an October 2008 SelectHealth Medical Technology review found limited additional evidence. In this body of literature, 10 studies met criteria for inclusion in the review. Three of these were randomized controlled trials. In the first study from 1998, Dini et al. randomly assigned 80 patients with postmastectomy lymphedema of the arm to receive 2 cycles of pneumatic compression therapy (5 2-hour sessions/week for 2 weeks) or to no treatment at all. No statistically significant differences in response rates between the 2 groups were observed.

Another set of randomized studies by Szuba et al. in 2002 involved patients with breast carcinoma-associated lymphedema of the arm. In the first study, 23 previously untreated patients were randomized to receive either decongestive lymphatic therapy (DLT) alone or DLT with daily adjunctive intermittent pneumatic compression (IPC). The second study involved 27 in the maintenance phase of therapy who were similarly randomized. In study 1, after 2 weeks of treatment, the mean percent reduction in volume of the edematous arm was 45.3% for the experimental group and 26% for controls ($p < 0.05$). After the completion of intensive therapy at day 40, the mean percent volume reduction was 30.3% (range, -13%-83%) for the experimental group and 27.1% (range, -23%-59.5%) for controls. These results were not significantly different compared with the outcomes noted at day 10. In study 1, following a month of self-administered maintenance therapy with DLT alone, there was a mean \pm standard deviation increase in volume of the treated limb of 32.7 ± 115.2 mL. There was no apparent effect of treatment order. Conversely, during the month of therapy that included self-administered, adjunctive IPC, there was a mean volume reduction of 89.5 ± 195.5 mL ($p < 0.05$).

Lymphedema Therapy, continued

The randomized trial from 2006 by Wilburn et al. studied 10 patients with unilateral breast cancer-associated lymphedema of the arm. Subjects were allocated randomly, in equal numbers, to begin treatment with either the experimental approach (daily use of the Flexitouch) or with use of standard treatment measures (compression garment plus daily self-administered massage). Crossover to the alternate arm of therapy occurred in each enrolled patient after the designated observations and interval treatment washout had been completed. Arm volume reduced significantly from pre-treatment after the Flexitouch (mean change, -208 ± 157 ml, $p = 0.002$) but not after self-administered massage ($+52 \pm 106$ ml, NS). When the absolute volume differences following Flexitouch treatment were compared to those following self-administered massage, the reduction in volume attained with the device was statistically significant. The effect of treatment on the percent excess volume, when compared to the contralateral arm, was significant for Flexitouch (pretreatment, $15 \pm 7\%$ vs. post-treatment, $12 \pm 6\%$, $p = 0.0005$) but not for self-administered massage (pre- and post-treatment, $14 \pm 7\%$, NS). As a corollary effect of partial edema resolution, the patients' mean weight decreased significantly after Flexitouch (-2.3 ± 1.3 kg, $p = 0.0002$) but not after self-administered massage.

Of the nonrandomized studies published since the previous review, the only notable study was the quasi-experimental trial completed by Ridner et al. in 2008 involving 155 patients. This trial was notable as it is specific to the Flexitouch System and was the largest study published on this topic to date. This "real world" trial focused primarily on patient satisfaction with the therapy and did not measure specific objective outcomes though it noted a reduction in use of professional manual lymphatic drainage (MLD) therapy, self-MLD, and bandaging declined after they initiated use of the Flexitouch system. It concluded patients were satisfied with the system, perceived it to be effective and reported improvement in physical and emotional status.

In summary, 2 of these randomized studies concluded that pneumatic compression therapy is an effective supplement to standard therapies for lymphedema. These studies are weakened however, by very small sample sizes, which raise concerns about generalizability. Additionally, the largest RCT by Dini et al. found no difference between pneumatic compression therapy and no treatment at all. Remaining studies were small retrospective or uncontrolled prospective studies that did not involve a comparison group or investigations of non-clinical aspects of the procedure. Finally, there are no published head-to-head studies specifically comparing the Flexitouch system (segmental pneumatic compression with calibrated gradient pressure) [E0652] to standard pneumatic therapy without calibrated gradient compression or non-segmental compression [E0650/E0651]. While these studies concluded pneumatic compression is an effective means of treating lymphedema, the literature in support of pneumatic compression therapy remains sparse. There is a dearth of quality comparative studies involving adequate sample sizes. Additional randomized controlled trials are needed before conclusions about the utility of segmental pneumatic compression therapy with calibrated gradient can be made.

An April 2011 literature review found no significant changes in available data; however, 8 additional references were added.

Complex/Complete Decongestive Therapy

A Medical Technology Assessment performed in October 2011 focused on complex/complete decongestive therapy for the treatment of lymphedema. One systematic review was identified, and 11 peer-reviewed papers met criteria for inclusion. All but one evaluated the effectiveness of complex decongestive therapy (CDT) in secondary lymphedema specifically.

The systematic review by the Agency for Healthcare Research and Quality (AHRQ) from 2010 lists several nonpharmacological and nonsurgical treatments for the treatment of lymphedema and goes on to state: "Although a great deal of research into the diagnosis and treatment of secondary lymphedema has already been undertaken, there is no evidence to suggest an optimal diagnostic testing protocol, an optimal frequency or duration of treatment, the most efficacious treatment combinations (including the use of maintenance therapy), the length of time for which persons should be tested or treated for lymphedema, and whether certain tests or treatments may benefit some types of patients more than others." This is apparent throughout all the literature as treatment protocols and methods vary from study to study.

Of the 11 primary literature articles, only 2 studies were published subsequent to the AHRQ review. These studies do not clarify the unanswered questions noted by AHRQ.

Lymphedema Therapy, continued

Eight of the studies (73%) specifically assessed the treatment of lymphedema secondary to breast cancer. Despite a lack of a uniform standard for performing CDT, the studies generally demonstrate effectiveness of CDT in treating secondary lymphedema. A typical example of this is the 2008 study by Karadibak, in which 62 women with lymphedema after breast cancer treatments underwent CDT treatment. Mean initial lymphedema volume was 925 ml and decreased to 510 ml after 12 weeks of treatments. Similar decreases in lymphedema volume were found by Ko et al. (1998), Liao et al. (2004), and Yamamoto et al. (2007 and 2008).

Issues not addressed in the studies include patient selection, duration of efficacy, protocol, who will administer the treatment (physical therapists, occupational therapists, massage therapists, nurses, or physicians), and lack of standard for diagnosing severity of the disease or how frequently patients should be monitored after therapy.

Much of the scientific and nonscientific literature approaches CDT as some type of standard of care. This tends to make any conclusions from the studies difficult to determine. However, the data from the reviewed studies suggests CDT is effective in reducing the limb volume of patients with chronic lymphedema, but many questions remain unanswered.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

- 97016** Application of modality to one or more areas; vasopneumatic devices
- 97140** Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes

HCPCS CODES

Covered: For the conditions outlined above

- A6530 - A6549** Gradient compression stockings
- E0650** Pneumatic compressor; non-segmental home model
- E0651** Segmented home model without calibrated gradient pressure
- E0655** Non-segmental pneumatic appliance for use with pneumatic compressor; half arm
- E0656** Segmental pneumatic appliance for use with pneumatic compressor, trunk
- E0657** Segmental pneumatic appliance for use with pneumatic compressor, chest
- E0660** ; full leg
- E0665** ; full arm
- E0666** ; half leg
- E0667** Segmental pneumatic appliance for use with pneumatic compressor; full leg
- E0668** ; full arm
- E0669** ; half leg
- E0671** Segmental gradient pressure pneumatic appliance, full leg
- E0672** ; full arm
- E0673** ; half leg
- E0675** Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
- E0652** Segmented home model with calibrated gradient pressure
- E0677** Non-pneumatic sequential compression garment, trunk

Lymphedema Therapy, continued

S8950 Complex lymphedema therapy, each 15 minutes

Not covered for the indications listed above:

A7049 Expiratory positive airway pressure intranasal resistance valve

K1031 Nonpneumatic compression controller without calibrated gradient pressure

K1032 Nonpneumatic sequential compression garment, full leg

K1033 Nonpneumatic sequential compression garment, half leg

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Lymphedema Therapy, continued

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MANIPULATION UNDER ANESTHESIA (MUA) FOR MANAGEMENT OF BACK AND PELVIC PAIN

Policy # 425

Implementation Date: 10/12/09

Review Dates: 4/21/11, 4/12/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 9/18/18, 4/12/19, 4/6/20, 4/14/21, 3/16/22, 4/20/23

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Low back pain is a major health problem, with approximately 90% of American adults developing this symptom at some time in their lives. The highest prevalence of low back pain occurs in patients 45–64 years of age; however, younger individuals are also at risk. Low back pain may be symptomatic of a wide range of clinical disorders; however, over 90% of cases have a mechanical origin, with the remaining cases are due to systemic or visceral disease.

Most patients with low back pain, in the absence of serious conditions, respond to conservative measures such as medication, rest, and physical therapy. Various physical therapy modalities have also been applied, including the use of superficial heat, ultrasound deep heat, and diathermy, all of which have some element of controversy. The application of cold packs is a more accepted treatment modality when used in conjunction with stretching and toning exercises. Other therapies used for patients with low back pain include chiropractic spinal manipulation, transcutaneous electrical nerve stimulation (TENS), and other electrotherapeutic modalities.

Manipulation under anesthesia (MUA) is a non-invasive procedure offered for acute and chronic conditions, including neck pain, back pain, muscle spasm, shortened muscles, fibrous adhesions, and long-term pain syndromes arising from the cervical, thoracic, and lumbar spine, as well as the sacroiliac and pelvic regions. MUA uses a combination of specific short lever manipulations, passive stretches, and specific articular and postural kinesthetic maneuvers to break up fibrous adhesions and scar tissue around the spine and surrounding tissue. The rationale behind the procedure is that fibrous tissue restricts movement and that patients anesthetized to reduce muscle tone and protective reflexes to manipulate the joint more effectively. The manipulation procedures can be offered under general anesthesia, during mild sedation, following the injection of anesthetic solutions into specific tissues of the spine. Within the realm of chiropractic, MUA is generally performed over multiple sessions depending on the diagnosis and site of pain. The procedure can be used by chiropractors, osteopathic physicians, or medical physicians with an anesthesiologist in attendance.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover manipulation under anesthesia for the management of back and pelvic pain. Evidence is limited; therefore, this meets the plan's definition of experimental/investigational.

Manipulation Under Anesthesia (MUA) for Management of Back and Pelvic Pain, continued

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

A systematic review by Kohlbeck included studies about MUA with general anesthesia. The review noted despite a 70-year history of treatment with this type of spinal manipulation that the evidence for the effectiveness of these protocols remains largely anecdotal.

Seven studies met criteria for inclusion in this report. Most of these were small case series involving patients with chronic back pain who had failed previous therapies who underwent MUA. Most of these were case series reporting outcomes in a small number of patients. Two studies reported comparative outcomes. Kohlbeck et al. conducted a prospective cohort study of 68 patients who underwent MUA. All study patients received a 4–6-week course of spinal manipulation therapy (SMT). Patients were then reevaluated after the initial treatment period. Based on the patient's clinical progress, treating clinicians made recommendations regarding additional care that included continued spinal manipulation or supplemental care with MAM. Ultimate decisions regarding choice of treatment group resided with the patient. Patients who remained in the SMT group received the therapy at a schedule similar to that provided during the first 4–6 weeks. MUA patients underwent 1–3 sessions of the procedure. At baseline, patients completed a pain/disability scale consisting of 11 items, 2 of which questioned the patient about frequency and magnitude of back pain symptoms. The remaining 9 items pertained to the impact of these symptoms on activities of daily living (ADLs). Responses to these 11 items were averaged and rescaled to a 100-point scale with a score of 0 representing the most possible pain and disability and a score of 100 representing least possible pain and disability. They also completed the SF-36 Health Survey, Version 2 (SF-36v2), which measures general health-related quality of life. Five of 8 subscales measuring domains of health were used: (1) physical functioning, (2) role limitations caused by physical health, (3) role limitations caused by emotional problems, (4) general health perceptions, and (5) mental health. All five measures are scored on a 0–100-point scale.

Improvement in adjusted mean pain/disability scores during the initial 4–6-week trial of therapy was 8.0 points for SMT patients and 14.5 points for MUA patients. During the subsequent three months, the SMT group experienced a further improvement of 1.2 points, whereas the MUA group experienced a 9.1-point improvement in pain and disability scores. At 3 months, the adjusted mean pain and disability score for the MUA group increased to 84.8, whereas the SMT group score remained virtually unchanged at 80.4. About 66% of all patients experienced improvement in pain and disability by 10 points or more during the first 3 months, and approximately 64% of study participants reported improvement of at least 10 points at 1 year. Eighty-one percent of the MUA group had a 10-point or more improvement in pain and disability scores between baseline and 3 months, compared with 42% of SMT-only patients. At 1 year, 74% of the MUA group reported an improvement of at least 10 points over baseline scores compared with 48% of the patients continuing with SMT alone. The authors concluded by noting the promising implications of their findings and recommended further investigation in a randomized clinical trial.

In another comparative study, Palmieri and Smoyak provided MUA to 38 patients and chiropractic therapy to 38 patients with chronic low back pain. The MUA group received from 1–4 MUA procedures consecutively over the same number of days. This was followed by specific MUA rehabilitation therapy

Manipulation Under Anesthesia (MUA) for Management of Back and Pelvic Pain, continued

lasting 4–6 weeks. The patients in the nonintervention group received traditional chiropractic treatment, consisting of spinal manipulative therapy and passive therapeutic modalities, and were also asked to complete home exercises. Participants completed the Roland-Morris Questionnaire (RMQ) on low back pain disability and a Numerical Pain Scale (NPS) at baseline, after their final MUA or SMT procedure, and again four weeks later. The Numeric Pain Scale is numbered from 0–10. The patient selects the appropriate number to rate their pain, with 10 representing excruciating pain and 0 representing no pain. This scale has been compared with the Visual Analogue Scale in terms of reliability and validity. The RMQ is considered a valid and reliable instrument to measure low back pain-related disability. It contains 24 questions regarding a patient's ability to perform daily activities related to quality of life. The total "yes" answers are added to determine total disability (from 0–24). Some authors suggest that a change of at least four points is required for clinically applicable change to be measured accurately. A score of 14 or greater represents significant disability.

In the intervention group, the mean response on the NPS was 7.31 at baseline, 4.36 after the final procedure, and 3.66 at follow-up evaluation, a mean improvement of nearly 50%. In the nonintervention group, the NPS score was 6.78 at baseline and 4.98 at follow-up evaluation, a mean improvement of approximately 26%. In the intervention group, the average RMQ score was 10.9 before the procedure, 7.8 after the final procedure, and 5.3 at follow-up evaluation, a mean improvement of approximately 51%. In the nonintervention group, RMQ scores were 6.9 at baseline and 4.3 at follow-up evaluation, a mean improvement of 38%. Similar to Kohlbeck et al., the authors noted the need for large-scale studies on MUA as part of their conclusions.

Though the studies by Kohlbeck et al. and Palmieri et al. suggest a beneficial effect of MUA, both authors, in their studies, noted the need for large-scale studies on MUA. Overall, the literature on MUA is sparse, with only two trials comparing treatment outcomes with standard therapies. Comparative trials are particularly important in pain studies as the potential for placebo effects is high in this population. The literature suggests that MUA may be effective for treating chronic back pain, but as Kohlbeck and Palmieri note, additional studies are needed to replicate these findings in larger patient samples.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

- 27198** Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; with manipulation, requiring more than local anesthesia (ie, general anesthesia, moderate sedation, spinal/epidural)
- 22505** Manipulation of spine requiring anesthesia, any region

HCPCS CODES

No specific codes identified

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Manipulation Under Anesthesia (MUA) for Management of Back and Pelvic Pain, continued

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NEGATIVE PRESSURE WOUND THERAPY (VACUUM ASSISTED WOUND CLOSURE)

Policy # 185

Implementation Date: 2/8/02

Review Dates: 3/4/02, 6/25/03, 6/24/04, 5/19/05, 5/4/06, 5/17/07, 8/13/09, 8/19/10, 11/29/12, 10/24/13, 10/15/15, 10/20/16, 10/19/17, 10/25/18, 10/7/19, 10/14/20, 1/17/22, 2/16/23, 10/10/23

Revision Dates: 6/30/03, 11/30/05, 2/22/08, 3/11/08, 8/18/08, 9/30/11, 1/20/15, 2/4/15, 7/16/15, 3/1/18, 5/27/21, 1/21/22, 8/10/22, 3/22/23, 7/14/23, 11/2/23, 1/26/24

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Chronic superficial and deep soft tissue injuries occasionally develop into difficult to heal wounds. These ulcers typically form in areas of excessive pressure or dependency. Such ulcers are called stasis or decubitus ulcers (bed sores). Dehiscence of surgical wounds can promote the same environment. This may be due to underlying vascular insufficiency of the affected tissue related to age, chronic circulatory impairment, immunocompromise, or co-morbidities such as diabetes mellitus. These wounds can be difficult to heal using the standard wound care methods of frequent dressing changes, saline irrigation, treatments, and/or surgical debridement.

Negative pressure wound therapy (NPWT) (also known as Vacuum Assisted Closure or Negative Pressure Vacuum Wound Therapy) is a procedure for evacuating wound fluid to expedite the healing of complex wound failures, including those in previously irradiated tissue. Negative pressure wound therapy consists of a nonadherent, porous wound dressing, a drainage tube placed adjacent to or inserted in the dressing, an occlusive transparent film sealing the wound and the drainage tube, and a connection to a vacuum source, which supplies the negative pressure. The hypothesis underlying its development is that negative pressure removes extracellular fluid and exudate, promotes moist healing, reduces bacterial colonization, reduces edema, and improves blood flow thereby providing oxygenation and nutrition to a wound site, and promoting accelerated healing. The application of controlled sub-atmospheric pressure causes mechanical stress to the affected tissue which stimulates mitosis specific to development of new blood vessels, in addition to stabilizing mechanical forces that draw the wound closed. The degree of pressure to the wounded tissue is small.

This technique is usually considered for chronic wounds (those that fail to progress through the normal phases of healing-inflammation, proliferation, maturation-and thus do not heal), acute wounds (wounds that are expected to heal and demonstrate evidence of progression through the phases of healing), and difficult wounds (wounds with such associated factors as diabetes, arterial insufficiency, and venous insufficiency).

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.



Negative Pressure Wound Therapy, continued

Select Health covers negative pressure wound therapy (NPWT) in limited circumstances for acute and chronic wounds as the medical literature has demonstrated improved outcomes of this therapy over conventional treatment.

Select Health covers NPWT using the nonmechanical Smart Negative Pressure (SNaP) Wound Care System in limited circumstances for acute and chronic wounds as the medical literature has demonstrated improved outcomes of this therapy over conventional treatment and equivalent outcomes to standard NPWT devices.

Select Health does NOT cover NPWT using the V.A.C. Via or PICO devices as current evidence is inadequate to reach conclusions regarding the safety and efficacy of this therapy compared to standard NPWT devices.

Select Health does NOT cover incision management systems using the Prevena System or any other device. Current evidence related to the clinical effectiveness and appropriate patient selection remains unanswered and thus this technology meets the plan definition of investigational.

All requests for coverage should be referred to case management for individual evaluation and consideration as an exception to benefit.

Consideration for coverage as an exception to benefit will be based on the following guidelines:

A. Wounds Related to Recent Surgery:

Indications for initial approval:

1. The member has complications of a surgically created wound (e.g., dehiscence or open wound) or a traumatic wound (e.g., pre-operative flap or graft), where there is documentation of the medical necessity for accelerated formation of granulation tissue, which cannot be achieved by other available topical wound treatments (e.g., other conditions the member may have that will not allow for healing times achievable with other topical wound treatments).

B. Outpatient Setting:

Indications for initial approval:

An initial 30-day trial of therapy will be authorized if both of the following conditions are met:

1. Chronic wounds that have not improved by more than 25% in volume in 4 weeks.
2. Recommended by a wound care specialist or surgical care specialist.

C. Continued Approval for either the Inpatient or Outpatient Setting:

After initial approval, continued re-certification is mandatory for continued reimbursement. Each subsequent approval period is of a maximum of 2 weeks.

To receive continued approval for reimbursement the patient/patient's wound must demonstrate the following:

1. Must have met initial criteria.
2. Stability with ongoing infection, or improvement has been documented in either surface area or wound depth.
3. Reimbursement will only be provided for days when wound vac is being actively used by member.

D. Contraindications:

1. Non-enteric or unexplored fistulas to organs or body cavities
2. Necrotic tissue with eschar

Negative Pressure Wound Therapy, continued

3. Osteomyelitis (untreated)
4. Malignancy in the wound
5. Direct placement of system over-exposed arteries or veins

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

A 2007 Hayes Medical Technology Directory evaluated the literature on NPWT and noted that most published research on the technology involved the KCI V.A.C. The review offered the following conclusion: there is moderate evidence from randomized controlled trials that NPWT improves wound healing in carefully selected patients who have acute, subacute, or chronic wounds that are refractory to or have failed standard therapies, which are not suitable candidates for surgical wound closure or are at high risk for delayed or nonhealing wounds. However, although the feasibility and relative safety of NPWT has been demonstrated, the heterogeneous nature of the patient populations makes it difficult to determine 1) which specific types of wounds best respond to NPWT and 2) when NPWT should be instituted. Due to the lack of clinical trials that focus on specific types of wounds, the patient selection criteria for NPWT have not been well defined. The results of additional studies are needed to further refine the patient selection criteria for this therapy and to determine the most appropriate role for NPWT in the continuum of care.

Unlike the KCI V.A.C., the NPWT devices offered by BlueSky have been subjected to far fewer empirical studies. As of December 2007, 2 studies describing observations from a total of 4 patients have been published. The first report from Campbell describes three cases of patients with chronic wounds who had previously undergone surgical debridement. In each case, the authors reported decreased wound surface area and wound depth. The period of treatment lasted between 30 and 74 days during which the wound areas decreased from 40.0%–79.9% and wound depth diminished 47.6%–85.7%. Patients experienced little or no pain during the application of vacuum during changes. This study was supported by a product grant by BlueSky Medical.

The second study from Miller et al. reported a single case of NPWT being used in the treatment of a bite from a brown recluse spider. The author used the BlueSky Versatile 1 pump in conjunction with the Miller DermiVex drain to apply NPWT at 6–8-hour intervals over 2.5 months. Interestingly, though the authors suggest the wound healed, they do not provide any information about change in wound depth or area over time. Again, this research was supported by a grant from BlueSky Medical.

It is apparent that the extant literature suffers from multiple major weaknesses that limit any conclusions regarding the effectiveness and safety of the BlueSky device. Larger sample sizes in controlled study designs, preferably with comparison between alternative procedures including KCI's NPWT device, are sorely needed. BlueSky suggests several design differences between their NPWT systems and the V.A.C. from KCI that suggest the Versatile 1 to be a superior NPWT device. Based on this literature review, these assumptions are primarily speculative as there is no evidence in the literature that the BlueSky Versatile 1 EZCARE and V1STA Wound Vacuum Systems are equivalent in terms of safety and efficacy to the KCI V.A.C. Selected reports of 4 patients offer little in the way of evidence that the BlueSky

Negative Pressure Wound Therapy, continued

device works as stated. Given the high prevalence of chronic dermal wounds, larger, more controlled studies could surely be done.

Similarly, the literature related to both the Innovative Therapies Inc. and Boehringer Wound Systems devices is scant. Of the few citations available, 6 articles related to the SVEDMAN NPWT were proof of concept papers, three of which were animal studies. The most recent study was published in 1990. None involved the SVEDMAN system presently approved for use by the FDA.

Boehringer provided several citations that used the KCI NPWT system. In a presentation to the 20th Annual Symposium on Advanced Wound Care & Wound Healing Society Meeting, Griolami et al. reported 6 case histories that employed the Engenex device. Wound volume had reduced by 70%–100% within 3–9 weeks of initiating treatment. The authors highlighted a “raised budding appearance” as visual evidence that the device was working. At the same conference, Hill et al. reported on 3 patients with full thickness wounds. The reduction in wound volume at first visit post-Engenex ranged from 16%–38%. Patients reported low pain with use of the device.

No studies, conference presentations, or other available evidence demonstrated any safety concerns.

Even though current available evidence related to efficacy is limited, available literature suggests probable equivalence of both the SVEDMAN and Engenex Negative Pressure Wound Therapy Systems to the KCI Wound V.A.C. System. Both devices have received FDA 510(k) approval with the predicated device being the KCI wound care system. Given the 510(k)-approval process is designed to assure equivalent safety of the approved device and design features of the devices are quite similar to the KCI wound V.A.C. system, the safety of the devices is not questioned. Additionally, no specific safety issues have been identified with the devices and they appear more cost effective.

A Medical Technology Assessment on the Prevena Incision Management System by KCI did not identify any systematic reviews but did identify 8 peer-reviewed journal articles. Most of the papers studied medium to large patient populations (average = 96) over typically seven days. There are statistically significant differences between standard surgical dressings and topical negative pressure (TNP) with results favoring TNP in reduction of seroma, reduction of infection rate and reduction of exudate secretion.

Articles supporting wound vacuum therapy infection rates and healing are listed below in the key references.

Limitations to the published literature include a lack of utilization on several different incisions as most literature focused on use in traumatic acetabular, tibial and calcaneal fractures requiring open surgical correction. Only small studies looked at the use of the technology post total hip arthroplasty or sternotomy. Thus, it is hard to reach conclusions as to whether the benefit would be similar in other types of procedure such as abdominal incisions or breast reconstruction procedure, both which have a fairly high incidence of wound complications. Also, there remains a lack of any sort of criteria to be applied to prospectively determine which candidates are “high risk” for problems and thus should have this technology applied.

Though the evidence is promising, and the therapy may have clinical benefit, due to the lack of systematic reviews, evidence of reduction of bacterial load (Braakenburg et al., 2006), cost effectiveness studies vis-à-vis standard dressings and with only a narrow scope of incisions in which this technology has been assessed. Important unanswered questions remain which lead to the conclusion that these questions need to be resolved prior to general utilization of this technology on a broad population.

Mechanical/Non-powered NPWT Devices: A review completed in January 2015 identified two systematic reviews and seven peer-reviewed primary studies met inclusion criteria for review. Most studies (five of the seven (71%)) primary studies were focused on the SNaP device. The seven peer-reviewed studies demonstrated substantial heterogeneity in study protocols and patient selection groups. These studies were also smaller in size, with only 260 patients in the seven studies of which 206 were involved in the use of SNaP 33 from the V.A.C Via and 21 using the PICO device. These studies identified the SNaP device to be safe and effective in multiple circumstances and often in a comparative study format to standard NPWT devices. When compared to standard NPWT, SNaP demonstrated no difference in the number of complete wound closures, patients healed, percent of wound size reduction, or adverse events or infections. Additionally, some studies suggest healing using the SNaP device was twice as fast as using wound dressings alone.

Negative Pressure Wound Therapy, continued

Given the limited number of studies and small study size, conclusions could not be reached regarding V.A.C., VIA, and PICO.

Billing/Coding Information

CPT CODES

- 97605** Negative pressure wound therapy (e.g. vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
- 97606** ; total wound(s) surface area greater than 50 square centimeters
- 97607** Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.
- 97608** ; total wound(s) surface area greater than 50 square centimeters.

HCPCS CODES

Covered: For the conditions outlined above

- E2402** Negative pressure wound therapy electrical pump, stationary or portable
- A6550** Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
- A7000** Canister, disposable, used with suction pump, each
- A9272** Wound suction, disposable, includes dressing, all accessories and components, any type, each

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Negative Pressure Wound Therapy, continued

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NONSURGICAL SPINAL DECOMPRESSION FOR THE TREATMENT OF CHRONIC LOW BACK PAIN

Policy # 323

Implementation Date: 10/31/06

Review Dates: 10/18/07, 10/23/08, 10/22/09, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 7/16/18, 4/11/19, 4/6/20, 4/14/21, 3/15/22, 4/20/23

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Low back pain is a major health problem, with approximately 90% of American adults developing this symptom at some time in their lives. Low back pain may be symptomatic of a wide range of clinical disorders; however, over 90% of cases have a mechanical origin, with the remaining cases due to systemic or visceral disease. Common mechanical etiology of acute low back pain includes ligament sprain; muscle strain; injury to, or aggravation of underlying facet or disc degeneration; and disc herniations.

Most patients with low back pain, in the absence of serious conditions, respond to conservative measures such as medication, rest, and physical therapy. Various physical therapy modalities have been applied, including the use of superficial heat, ultrasound deep heat, and diathermy, all of which have some questionable benefit. The application of cold packs is a more accepted treatment modality when used in conjunction with stretching and toning exercises. Other therapies used for patients with low back pain include chiropractic spinal manipulation, transcutaneous electrical nerve stimulation (TENS), and other electrotherapeutic modalities.

Mechanical traction is another technique used to treat chronic back pain. This technique involves applying a distracting force to produce either a realignment of a structural abnormality or to relieve abnormal pressure on nociceptive receptor systems. Lumbar traction has been used for many years as a treatment to reduce vertebral compression and alleviate many of the conditions that cause low back pain and associated radiculopathy. Studies of clinical efficacy (including an AHRQ report) have yielded equivocal results regarding the efficacy of lumbar traction therapy, and it has not gained wide acceptance as a treatment for low back pain. The successful application of lumbar traction has been limited by patient tolerance and the design of mechanical devices. Patients had difficulty tolerating the forces needed to relieve pain if delivered continuously. Furthermore, the thoracic corsets worn by patients to prevent movement on the table were uncomfortable, restricted respiration, and can compromise venous return to the heart.

To overcome some of the issues associated with traction therapy, axial spinal distraction (vertebral axial decompression) therapy has been investigated as a nonsurgical treatment for low back pain. The theory underlying the use of spinal distraction is that decreased load bearing at the affected site will reduce associated pain and promote healing of injured tissues. A number of devices are being marketed for spinal distraction; the devices with the greatest market share are the DX9000 True Non-Surgical Spinal Decompression System (Axiom Worldwide, Inc., Tampa, FL), the VAX-D Therapeutic Table (Vat-Tech, Inc., Palm Harbor, FL), the Decompression Reduction Stabilization (DRS) System (Universal Pain Technology Canada Inc., Prince George, British Columbia, Canada), and the Accu-SPINA Intervertebral Differential Dynamics Therapy System (North American Medical Corporation, Marietta, Georgia). These are all computerized devices that apply controlled distractive tension along the spinal axis; the mechanism of action behind axial spinal distraction therapy is unknown.

Nonsurgical Spinal Decompression for the Treatment of Chronic Low Back Pain, continued

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover non-surgical spinal decompression therapy. This therapy meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Of the 7 articles located for this review, 1 was a randomized controlled trial. The first by Sherry et al. randomly assigned patients with chronic low back pain for at least 3 months duration (mean duration = 7.8 years) to spinal decompression with the VAX-D or to TENS therapy. After 8 weeks of treatment, 68.4% (13 of 19) of the VAX-D patients were successfully treated ($\geq 50\%$ improvement in pain and any improvement in reported disability), whereas 0% (0 of 21) of TENS-treated patients experienced similar results ($p < 0.001$). Thirteen of 21 TENS patients reported an increase in their pain during treatment. Of the successfully treated VAX-D patients available at the 6-month follow-up ($n = 10$), 7 reported persistent pain control. However, the study lacked blinding and a large enough sample size, which limits confidence that these results would be observed in an unselected group of patients. Moreover, 1 of the authors was the medical director for the manufacturer's Australia headquarters.

Shealy et al. involved patients with ruptured discs and sciatica ($n = 19$), ruptured discs without sciatica ($n = 4$), facet arthroses with mild-to-moderate sciatica and significant mobility limitations ($n = 6$), or facet arthroses with ruptured discs (number not reported). All participants had pain lasting less than 1 year. Participants were randomly assigned to receive spinal decompression with the DRS system or conventional lumbar traction. Five to 8 weeks after the study of those with disc ruptures, 86% achieved "good" (50%–89% improvement) to "excellent" (90%–100% improvement) results with decompression. Only 55% of the traction patients achieved "good" improvement and none reported "excellent" improvement. Again, interpretation of these results is limited; however, this is because of small sample size and an inadequate follow-up period. Thus, the long-term outcome and generalizability of their results are not known. One of the authors is the director of the DRS treatment center, who conducted the study.

A study from Ramos et al. also employed a randomized design, but 1 regimen of spinal decompression was examined, and a non-decompression control group was not included. In that study, 76% of patients who underwent 18 sessions of decompression achieved remission of low back pain compared to 43% of patients who underwent 9 sessions. One of the authors of this study is the vice president of VAX-D Medical Technologies.

The remaining studies were non-randomized case series reporting clinical outcomes of patients who underwent decompression during routine clinical care. The largest of these was from Gose et al. who reported results from 778 patients with herniated disc, degenerative disc, or facet syndrome, who were treated with at least 10 VAX-D sessions at 1 of 22 medical centers. Immediately following treatment, 71% reported a reduction in pain to 0 or 1 (0–5 scale) and 92% reported some improvement in pain. Success varied, by pain etiology: extruded herniation (53%), multiple herniations (72%), single herniation (73%),

Nonsurgical Spinal Compression for the Treatment of Chronic Low Back Pain, continued

degenerative disc disease (72%), and facet syndrome (68%). Moreover, 77% of all patients reported improvement in mobility, and 78% reported improvement in activity limitation.

In the only study examining the DRX-9000, Gionis and Groteke reported on 229 people, randomly selected from 500 patients with symptoms associated with herniated and degenerative disc disease present for at least 4 weeks. Each patient's diagnosis was confirmed by MRI. All patients underwent 18 sessions of decompression with the DRX system. Upon completion of therapy, 86% of patients reported treatment as "successful" (a reduction in pain to 0 or 1 on the Oswestry Pain Scale) with no further need for medication or treatment. Likewise, 92% of patients with abnormal physical findings improved post-treatment. After 90 days, 5 patients (2%) had relapsed to pre-treatment pain levels and 3% had abnormal findings.

Naguszewski, et al. reported on 7 patients with low back pain and unilateral or bilateral L5 or S1 radiculopathy who underwent decompression with the VAX-D. Within 2 weeks of completion of therapy, all patients reported $\geq 50\%$ reduction in pain with an average pain reduction of 77%. Pain was completely eliminated in 3 patients.

Only 1 study reported any adverse outcomes associated with decompression. Deen et al. reported on one patient with S1 radiculopathy who experienced a sudden and severe exacerbation of his pain during therapy with VAX-D. An MRI revealed the disc protrusion had enlarged and a microdiscectomy was required to correct the problem.

Overall, these studies suggest that spinal decompression may produce relief for low back pain from a variety of etiologies. However, this conclusion is tempered by many weaknesses in the literature and an overall paucity of research in this area. Weaknesses include small sample size, lack of randomization, inadequate follow-up, lack of blinding, and non-standardized treatment regimens. None of the studies provided radiographic or other evidence that decompression had, in fact, occurred. Studies that measured secondary outcomes (functioning and activity levels) relied on fairly unsophisticated self-report measures. Randomized, blinded studies are the only means to control for the placebo effect, which is especially problematic with research on pain treatments. Moreover, many of the studies published were by authors with financial conflicts of interest that may affect the objectivity of the study data. Therefore, conclusions about long-term effectiveness and safety and the relative benefit of this therapy over other treatment options remain unproven.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproven for this indication.

CPT CODES

- 97012** Application of a modality to one or more area; traction, mechanical
97799 Unlisted physical medicine/rehabilitation procedure or service

HCPCS CODES

- E0830** Ambulatory traction device, all types, each
E0941 Gravity assisted traction device, any type
S9090 Vertebral axial decompression, per session

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Nonsurgical Spinal Compression for the Treatment of Chronic Low Back Pain, continued

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PERCUTANEOUS ELECTRICAL NERVE STIMULATION (PENS)

Policy # 162

Implementation Date: 7/98

Review Dates: 1/4/00, 2/27/01, 10/1/01, 9/1/02, 10/23/03, 11/18/04, 11/18/05, 10/18/07, 10/23/08, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 9/18/18, 4/12/19, 4/6/20, 4/14/21, 3/15/22, 4/20/23

Revision Dates: 9/20/06, 12/19/09

Related Medical Policies:

[#420 Peripheral Nerve Stimulation for Occipital Neuralgia and Chronic Headaches](#)

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Percutaneous electrical nerve stimulation (PENS) uses acupuncture-like needle probes positioned in the soft tissues and/or muscles to stimulate peripheral sensory nerves at appropriate dermatomal levels to produce pain relief. The needles of the PENS device are placed under the skin above, below, and into the central area of pain. The treatment is offered in an ambulatory care setting and must be performed by a physician or incidental to other physician services. Percutaneous electrical nerve stimulation may be effective for pain relief when transcutaneous electrical nerve stimulation (TENS) does not provide a satisfactory response.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers implantation of percutaneous electrical nerve stimulation (PENS) electrodes *in limited circumstances* that have shown to improve the health outcomes of members.

Coverage criteria:

1. Patient has a chronic pain syndrome that has been present and ongoing for ≥ 6 months; and
2. Patient has failed routine medical therapy for the pain or is intolerant to that therapy; and
3. Patient has undergone a 1-month trial of PENS, and it has been effective in eliminating or significantly reducing the patient's pain $\geq 50\%$; and
4. Device is implanted by a board-certified physician.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the **Select Health Commercial policy applies**. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)



Percutaneous Electrical Nerve Stimulation (PENS), continued

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

A 2004 study by Yokoyama et al. evaluated the long-term effect of PENS on chronic low back pain. Three patient groups underwent treatment on a twice-weekly schedule. Group A (n = 18) received PENS for 8 weeks, group B (n = 17) received PENS for the first 4 weeks and TENS for the second 4 weeks, and group C (n = 18) received TENS for 8 weeks. Pain level, degree of physical impairment, and the daily intake of nonsteroidal anti-inflammatory drugs (NSAIDs) were assessed before the first treatment, 3 days after week 2, week 4, and week 8 treatments, and at 1 month and 2 months after the sessions. The 8-week PENS therapy produced more lasting effects than did the 4-week trial or TENS. However, pain relief did not persist beyond 2 months. The authors concluded that PENS provides immediate pain relief, but treatments must be continued to sustain analgesia.

Ghonomie et al. conducted a randomized cross-over sham trial comparing PENS with transcutaneous electrical nerve stimulation (TENS) or flexion-extension exercise therapies. In this population of 60 patients with chronic low back pain, PENS was significantly more effective in decreasing patient pain ratings after each treatment than sham-PENS, TENS, and exercise therapies. The average daily use of 2.6 ± 1.4 oral nonopioid analgesics at baseline was decreased to 1.3 ± 1.0 pills per day with PENS ($p < .008$) compared with 2.5 ± 1.1 , 2.2 ± 1.0 , and 2.6 ± 1.2 pills per day with sham-PENS, TENS, and exercise, respectively. In all, 91% of the patients reported that PENS was the most effective in decreasing their LBP. PENS were also significantly more effective in improving physical activity, quality of sleep, and sense of well-being ($p < .05$ for each).

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

64565	Percutaneous implantation of neurostimulator electrode array; neuromuscular
64580	Incision for implantation of neurostimulator electrode array; neuromuscular
64585	Revision or removal of peripheral neurostimulator electrode array

HCPCS CODES

No specific codes identified

Key References

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Percutaneous Electrical Nerve Stimulation (PENS), continued

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PERCUTANEOUS SACROPLASTY

Policy # 433

Implementation Date: 12/26/09

Review Dates: 4/21/11, 4/12/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 7/16/18, 4/12/19, 4/15/20, 4/15/21, 3/15/22, 4/20/23

Revision Dates:

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Description

Sacral insufficiency fractures (SIFs) are one of many causes of back pain. Bone insufficiency is often the result of osteoporosis or other metabolic bone disease, though osseous metastatic disease and marrow replacement processes can also cause insufficiency fractures. Fractures may be unilateral or bilateral. The fractures typically are vertical but may also have a horizontal component to the fracture through the sacral bodies. Patients with SIFs most commonly present with diffuse low back pain, which may radiate to the buttock, hip, or groin. Patients may have some tenderness to palpation in the lower back and sacral region, though this is not a consistent finding. Neurologic symptoms related to SIFs are unusual, though may be seen in 5%–6% of patients, most commonly manifesting as a sacral radiculopathy.

The standard of care for the treatment of SIFs has been conservative management, with variable courses of bed rest, rehabilitation, and analgesics prescribed. Some clinicians recommend strict bed rest and pain control, whereas others suggest moderation of activity supplemented with crutches or a walker, in addition to analgesics. There have also been reports promoting early physical rehabilitation. Although most patients improve symptomatically following conservative therapy, the time course can be prolonged and quite variable.

Sacroplasty has emerged as a minimally invasive alternative to conservative therapy for SIFs. Similar to vertebroplasty in the thoracolumbar spine, it involves injection of PMMA cement into the fractured sacrum under imaging guidance, typically using a posterior approach. The goal of sacroplasty is to provide early symptomatic relief, allowing more rapid mobilization. This would limit the need for significant narcotic analgesics, and lessen the risks associated with prolonged bed rest.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover percutaneous sacroplasty as it meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp> or [the manual website](#)

Percutaneous Sacroplasty, continued

Select Health Community Care (Medicaid)

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Summary of Medical Information

A 2009 Medical Technology Assessment identified 7 studies regarding percutaneous sacroplasty. This limited body of literature consists primarily of small retrospective case series. For instance, Strub et al.'s report was on 13 female patients with osteoporotic sacral insufficiency fractures. Five of 6 patients available at the 15-month follow-up reported no pain symptoms whatsoever. The sixth patient reported continued pain on one side. In Whitlow et al., 12 patients underwent sacroplasty, and 21 underwent vertebroplasty. Patients rated pain intensity and functioning before and after either procedure. At an average of 1.5 years, patients reported statistically significant improvements in pain, ability to ambulate, and ability to perform ADLs regardless of the procedure performed. The largest of the studies was a 2008 prospective observational cohort study by Frey et al. This multicenter study was sponsored by Stryker, Inc. (an orthopedic device manufacturer), and involved 52 osteoporotic patients with sacral insufficiency fractures. Within 30 minutes of the procedure, mean visual analog scale (VAS) pain ratings had declined from 8.1 to 3.4. Patients reported continued improvement in pain with the mean VAS dropping to 0.8 at 1 year following the procedure. Reduction in the VAS paralleled the reduction in the use of narcotic medication. An earlier study by Frey et al. of 37 patients reported similar findings out to 1 year.

The literature emerging on sacroplasty suggests the procedure holds promise as a treatment for sacral fractures. These studies suggest pain is improved both immediately after the procedure and that these improvements persist, at least in the short-term. However, the literature has multiple methodological weaknesses such as small study samples, few prospective, blinded trials, lack of comparative design, and no long-term data on outcomes. These factors limit confidence in these reported outcomes and larger, more methodologically rigorous studies are needed before the procedure can be viewed as a legitimate alternative to accepted treatments for sacral fractures.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

- 0200T** Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
- 0201T** Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

HCPCS CODES

No specific codes identified

Key References

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2. Frey ME, DePalma MJ, Cifu DX, Bhagia SM, Daitch JS. Efficacy and safety of percutaneous sacroplasty for painful osteoporotic sacral insufficiency fractures: a prospective, multicenter trial. *Spine (Phila Pa 1976)*, 32.15 (2007): 1635-40.
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Percutaneous Sacroplasty, continued

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PERCUTANEOUS VERTEBROPLASTY/KYPHOPLASTY

Policy # 310

Implementation Date: 7/15/03

Review Dates: 8/26/04, 12/15/05, 8/17/06, 8/23/07, 6/11/09, 6/17/10, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 11/28/18, 12/11/19, 12/17/20, 11/28/21, 11/17/22, 12/20/23

Revision Dates: 5/30/06, 8/13/08, 10/11/11, 8/22/19, 2/18/22, 4/29/22

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Description

Percutaneous vertebroplasty is a technique in which acrylic cement is injected through a needle into a collapsed or weakened vertebra in an effort to relieve pain and provide stability. Since the mid-1980s in France and the mid-1990s in the United States, radiologists have been successfully treating osteoporotic compression fractures, and pathologic vertebral fractures secondary to malignancy.

This procedure is effective for treating certain types of painful vertebral compression fractures and some painful or unstable benign and malignant vertebral lesions that fail to respond to the traditional conservative therapies. Most experts believe that pain relief is achieved through mechanical support and stability provided by the bone cement. The semisolid mixture of polymethylmethacrylate (PMMA), acrylic cement used in orthopedic procedures, has been shown to restore strength and stiffness in vertebral bodies in postmortem studies.

Vertebroplasty is most performed in the angiography/interventional radiology suite under high-quality fluoroscopy. Midazolam, fentanyl, or other medications may be administered to provide moderate sedation. Patients who are in severe pain may require general anesthesia to tolerate the prone positioning required for this procedure. Using sterile technique and fluoroscopic guidance, an 11-gauge needle is advanced into the vertebral body via a transpedicular or parapedicular approach.

Kyphoplasty was developed in 1997 as a modification to vertebroplasty. It has the additional preliminary step of carefully inserting and inflating a bone tamp (a small balloon-like device) inside the vertebra to create a cavity which can then be filled with polymethylmethacrylate (PMMA). This technique purports to have several advantages over vertebroplasty alone, including helping to realign and restore the lost height of the fractured vertebra, as well as creating a cavity that can allow safer injection of PMMA at lower pressures.

The procedure is performed at a hospital or outpatient facility under fluoroscopic guidance using either local or general anesthesia. The physician makes a small incision in the patient's back and creates a pathway into the fractured bone. A special balloon catheter is placed through the pathway and inflated. The balloon is then deflated and removed, leaving a space within the vertebra. The space is injected with PMMA to support the bone and prevent further collapse, stabilizing the fracture and providing immediate pain relief in many cases. The inflation of the balloon prior to the injection may partially restore vertebral body height and configuration. The procedure generally takes about one hour per vertebrae involved and must be followed by routine post-operative recovery.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.



Percutaneous Vertebroplasty/Kyphoplasty, continued

Select Health covers percutaneous vertebroplasty and percutaneous kyphoplasty in limited circumstances.

Criteria for coverage:

1. Acute/subacute compression fracture(s) by x-ray or MRI, associated with any one of the following:
 - a) Multiple myeloma; or
 - b) Painful and/or aggressive hemangiomas; or
 - c) Painful vertebral eosinophilic granuloma; or
 - d) Painful, debilitating osteoporotic collapse/compression fractures*; or
 - e) Primary malignant neoplasm of bone or bone marrow; or
 - f) Secondary osteolytic metastasis, excluding sacrum and coccyx; or
 - g) Steroid-induced fracture; **and**
2. The patient has debilitating pain and the compression fracture is less than 4 months old; **and**
3. Requested treatment levels are between level T5 – L5; **and**
4. No more than 3 vertebral levels can be treated on any one date of service.

*Osteoporosis is defined by T-score \leq -2.5 standard deviations at any site based upon bone mineral density (BMD) measurement by dual-energy x-ray absorptiometry, or fragility fracture (defined as fracture in the absence of major trauma; particularly at the spine, hip, wrist, humerus, rib, and pelvis).

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Vertebroplasty (VP) is a direct injection of bone cement to fill vertebral fracture lines, stabilizing the fracture and reducing pain. Percutaneous vertebroplasty is usually performed under local anesthesia, combined with neuroleptanalgesia, and may be performed as an outpatient procedure or may require a short hospital stay. For this procedure, the patient lies in the prone position and a large-bore (10–15 gauge) needle is placed into the vertebral body lesion under radiological guidance from computed tomography (CT) scanning or fluoroscopy. Acrylic bone cement, usually polymethylmethacrylate (PMMA), is then injected into the affected vertebra until resistance is met or the cement reaches the posterior wall of the vertebral body. This preparation is viscous to reduce leakage of the bone cement into adjacent structures or into the vasculature. The procedure generally takes 1–2 hours. CT may be used several hours after injection to assess vertebral body filling and to detect any leakage of the bone cement. Nonsteroidal or steroidal anti-inflammatory drugs can be used for 2–4 days after vertebroplasty to minimize the inflammatory reaction to the heat of polymerization of the acrylic compound.

Hayes observed that uncontrolled trials demonstrated the procedure to be effective in reducing pain and in improving mobility and quality of life in > 70% of patients with medically refractory, painful osteolytic

Percutaneous Vertebroplasty/Kyphoplasty, continued

lesions and osteoporotic compression fractures. The review assigned a 'B' rating for medically refractory pain due to osteolytic or osteoporotic lesions of the vertebrae that have no specific contraindications to injection of bone cement. A 'D' rating, reflecting no proven benefit and/or not safe was assigned for patients with specific contraindications.

In Barbero et al., for example, 101 patients (173 vertebrae) were treated with the procedure. At 270 days post-surgery, the authors reported pain relief in 88% of osteoporotic patients and 84% of neoplastic patients. Pulmonary cement emboli were identified in 4 patients, all of whom were asymptomatic. Caudana treated 106 (182 vertebrae), reporting 98% patients with partial or complete pain relief within 24 hours of treatment. One case of pneumothorax and two cases of symptomatic cement leakage. Mild complications included two cases of cement pulmonary embolism. During the follow-up, 8 osteoporotic patients presented a new vertebral fracture, and new vertebral metastases appeared in two oncological patients. He et al. reported on 242 patients (334 procedures). Fifteen patients did not experience pain relief and underwent a second procedure. After 1 month, mean pain VAS rating was reduced from 8.6 to 1.67. At 15 months, complete and partial pain relief were reached in 11 (75%) and 4 (27%) patients. In 98 patients retrospectively evaluated by Lin et al., 62 re-fractures occurred within the 26.9-month follow-up period.

The literature supporting kyphoplasty has demonstrated similar safety and efficacy in treating pain related to vertebral compression fractures. Saliou et al. reported on a case series of 5 patients (7 vertebrae). No complications occurred with balloon inflation with one cement leak occurring afterward. Mean reduction in local kyphosis was 4.4 degrees; at one month, all patients were pain-free. Korovessis et al. prospectively evaluated 23 patients with thoracolumbar A3-type burst fracture with or without neurologic deficit. After surgery, no patient experienced a decline in ASIA grade while 5 patients with incomplete neurologic lesions improved by one or more ASIA grades. Overall sagittal alignment and vertebral body height improved after surgery; 4 cases of cement leakage were reported. A second study of 18 patients with lumbar (L1–L4) burst and severe compression fractures were followed for 22 months. Segmental kyphosis and vertebral body height improved after surgery. Spinal canal encroachment was also reduced. Bone cement leakage was observed in 4 patients without clinical sequelae. In none of these studies were clinical outcomes compared to vertebroplasty.

A literature review performed in October 2011 identified a June 2011 BCBS TEC on vertebroplasty and kyphoplasty. Their review on vertebroplasty identified 2 placebo-controlled, randomized trials, 3 open-label, randomized trials, 1 comparative study, and 6 case series studies. Results of the 2 placebo-controlled randomized trials were similar, with both concluding that vertebroplasty conferred no additional benefit over a sham procedure (injection of local anesthetic into the facet capsule and/or periosteum). These studies were designed to determine short-term efficacy and safety of vertebroplasty for alleviating pain and improving physical functioning in persons with painful osteoporotic vertebral fractures. Results of the 3 open-label randomized trials showed significant differences in immediate pain relief among those receiving vertebroplasty versus those undergoing medical management; 1 concluding that among patients with acute fractures vertebroplasty conferred a benefit over conservative management through 12 months, the other 2 reported immediate drops in pain 1 day after the procedure; however, significant between-group differences in pain were not observed at later time points.

The first placebo-controlled randomized trial recruited 38 participants into the treatment group and 40 into the control arm; 91% completed the 6 months of follow-up. Participants had back pain of less than 12 months' duration, and at least 1, but no more than 2, vertebral fractures. For the primary outcome of overall pain, the authors reported no significant difference in VAS pain score at 3 months, 2.6 vs. 1.9, respectively, mean difference 0.6 (95% CI: -0.7, 1.8).

The second placebo-controlled trial was also a multicenter, randomized, double-blind, sham-controlled trial in which participants with 1–3 painful osteoporotic vertebral fractures of duration less than one year were assigned to undergo vertebroplasty or sham procedure (i.e., injection of local anesthetic into the facet capsule and/or periosteum). Sixty-eight participants had vertebroplasty while 63 received sham; 97% completed 1 month of follow-up and 95% completed 3 months. For the primary endpoints at 1 month, there were no significant between-group differences. Both randomized, controlled trials showed a greater frequency of clinically meaningful improvements in pain.

The largest of the open-label randomized trials was a multicenter, prospective, nonblinded trial where participants with at least 1 painful osteoporotic vertebral fracture of duration of 6 weeks or less were

Percutaneous Vertebroplasty/Kyphoplasty, continued

assigned to undergo vertebroplasty or conservative management (i.e., bed rest, analgesia, and cast and physical support). One-hundred and one participants were randomized to each group. Ninety-three participants received vertebroplasty while 95 received conservative management; 81% of participants completed 1-year of follow-up. For the primary endpoints of pain relief at 1 month and 1 year, there were significant between-group differences in mean VAS scores 2.6 (95% CI: 1.74 to 3.37, $p < 0.0001$) at 1 month and 2.0 (95% CI: 1.13 to 2.80, $p < 0.0001$) at 1 year. Significant pain relief (i.e., 30% change) was quicker (29.7 vs. 115.6 days) and was achieved in more patients after vertebroplasty than after conservative management.

Results of the 2 other randomized trials and one comparative study come from trials of fewer rigors than the previously mentioned randomized trials. These appeared to show an effect favorable to vertebroplasty immediately following the procedure. However, differences between groups quickly diminished. One trial reported no difference at 2 weeks' follow-up; another showed diminished differences at 6 weeks post-procedure, with the third study reporting no differences at 3- and 12-months' follow-up.

The BCBS TEC review on kyphoplasty identified 1 randomized trial and 2 nonrandomized studies comparing kyphoplasty to medical management, 1 study comparing kyphoplasty to vertebroplasty, and 4 case series studies. The randomized trial showed a greater improvement in mean SF-36 physical component score for the kyphoplasty group over medical management. The comparative studies showed greater improvement in pain scores and other outcomes compared to medical management.

In the study that compared kyphoplasty to vertebroplasty, improvements in pain were reported in both study groups, and there were no differences between the 2 procedures. The case series studies showed a consistent 4- to 5-point improvement in VAS pain ratings (0–10 scale) after kyphoplasty. The improvement appeared to be durable out past 1 year, but all studies suffered from losses to follow-up.

Analysis and interpretation are difficult in a nonrandomized setting, as it is difficult to separate out effects of the intervention from differences between the treatment and control groups. These studies enrolled different patients with respect to age of fracture; one study enrolled patients with fractures older than 1 year, while another enrolled patients with acute fractures meeting specific radiologic criteria for instability. The brief format of the acute fracture study does not allow an assessment of the similarity of the kyphoplasty and control groups. Contrary to a nonrandomized 2003 study of vertebroplasty, the control groups in this study did not improve appreciably over a period of weeks to months.

To date, there are currently 3 trials underway comparing vertebroplasty and kyphoplasty. The KAVIAR study is a randomized, open label trial. The primary outcome of this study is the proportion of patients with subsequent fractures at 12 and 24 months. The trial is currently recruiting participants. OSTEO+6 and OSTEO-6 are 2 randomized, open-label, uncontrolled trials based in France, comparing vertebroplasty to kyphoplasty (and conventional treatment in OSTEO-6) with the primary aim being change in the kyphotic angle of the vertebra measured at 1 year. OSTEO+6 and OSTEO-6 are currently enrolling participants with fractures more than and less than 6 weeks old, respectively.

Unfortunately, the limitation of these trials is that they aim not to show the efficacy of kyphoplasty but to set kyphoplasty apart from vertebroplasty by showing additional benefits of one procedure over the other in terms of restoration of vertebral height, or by offering a lower number of subsequent fractures. These trials presuppose the efficacy of these procedures. There are no randomized trials comparing kyphoplasty to sham or medical management.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

CPT CODES

Vertebroplasty

22510 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic

22511 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; lumbar

Percutaneous Vertebroplasty/Kyphoplasty, continued

- 22512** Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

Kyphoplasty

- 22513** Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic
- 22514** Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); lumbar
- 22515** Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

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Percutaneous Vertebroplasty/Kyphoplasty, continued

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PERIPHERAL NERVE TREATMENT

Policy # 654

Implementation Date: 3/29/23

Review Dates:

Revision Dates: 4/13/23, 8/4/23, 12/27/23

Related Medical Policies:

[#557 Radiofrequency Ablation of the Genicular Nerve](#)

[#420 Peripheral Nerve Stimulation for Occipital Neuralgia and Chronic Headaches](#)

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Peripheral nerve stimulation, frequently referred to as PNS, is a commonly used approach to treat chronic pain. It involves placement of a small electrical device (a wire-like electrode) next to one of the peripheral nerves. The electrode delivers rapid electrical pulses, which feel like mild tingles (so-called paresthesia). During the trial period, the electrode is connected to an external device, and if the trial is successful, a small generator is then implanted into the patient's body. Like heart pacemakers, electricity is delivered from the generator to the nerve, or nerves, using one or several electrodes. The patient can control stimulation by turning the device on and off and adjusting stimulation parameters as needed.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers peripheral nerve stimulation (PNS) for the treatment of shoulder pain, knee pain, or other peripheral nerve pain when the following criteria are met:

A. Shoulder:

1. Patient has experienced chronic shoulder pain limiting activities of daily living for ≥ 6 months, unrelieved by all conservative medical management strategies as listed below:
 - a) NSAIDs/Analgesics > 3 weeks or contraindicated
 - b) Activity modification > 6 weeks
 - c) Physical therapy (minimum of 4 visits within a 3-month period)
 - d) Steroid injections or nerve block to affected nerve resulting in 80% pain reduction

B. Knee:

1. Patient has experienced chronic knee pain limiting activities of daily living for ≥ 6 months, unrelieved by all conservative medical management strategies as listed below:
 - a) NSAIDs/Analgesic > 3 weeks or contraindicated
 - b) Activity modification > 6 weeks
 - c) Physical therapy (minimum of 4 visits within a 3-month period)
 - d) Steroid injections; **AND**
2. Patient has failed a genicular nerve radiofrequency procedure (see MP #557)



Peripheral Nerve Treatment, continued

C. Other Peripheral Nerve

1. Other peripheral nerves would be considered if patient has experienced pain of the affected nerve limiting activities of daily living for ≥ 6 months, unrelieved by all conservative medical management strategies as listed below:
 - a) NSAIDs/Analgesic > 3 weeks or contraindicated
 - b) Activity modification > 6 weeks
 - c) Physical therapy (minimum of 4 visits within a 3-month period)
 - d) Steroid injections; **AND**
2. Nerve conduction studies have been done on the affected nerve and demonstrate continued injury; **OR**
3. Patient has had a positive 80% improvement in pain relief following nerve block.

Select Health does NOT cover peripheral nerve stimulation for the occipital nerve/occipital neuralgia or chronic headaches; this meets the plan's definition of experimental/investigational (see medical policy #420).

Select Health does NOT cover the Reactiv8 Implantable Neurostimulation System; this therapy meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Billing/Coding Information

Covered for the indications listed above

CPT CODES

- 64555** Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
- 64575** Peripheral nerve (excludes sacral nerve)
- 64585** Revision or removal of peripheral neurostimulator electrodes
- 64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- 64595** Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

Peripheral Nerve Treatment, continued

- 95970** Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detectopm algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
- 95971** Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detectopm algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
- 95972** Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detectopm algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS CODES

- A4438** Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
- C1767** Generator neurostimulator (implantable) non-rechargeable
- C1778** Lead, neurostimulator
- C1787** Patient programmer, neurostimulator
- C1816** Receiver and/or transmitter neurostimulator (implantable)
- C1820** Generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
- C1822** Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
- C1897** Lead neurostimulator test kit (implantable)
- L8678** Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
- L8679** Implantable neurostimulator, pulse generator any type
- L8680** Implantable neurostimulator electrode, each
- L8681** Patient programmer (external) for generator, replacement only use with implantable programmable neurostimulator pulse
- L8682** Implantable neurostimulator radiofrequency receiver

- L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
- L8685 Implantable neurostimulator pulse generator, single array, rechargeable includes extension
- L8686 Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
- L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
- L8688 Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
- L8689 External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

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PHONOPHORESIS

Policy # 306

Implementation Date: 5/20/06

Review Dates: 5/17/07, 4/24/08, 4/23/09, 2/18/10, 4/21/11, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/5/19, 2/3/20, 2/3/21, 1/3/22, 2/1/23, 1/29/24

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Phonophoresis, also known as sonophoresis, generally is the use of ultrasound to enhance the delivery of topically applied drugs. Phonophoresis has been used to enhance the absorption of topically applied analgesics and anti-inflammatory agents through the therapeutic application of ultrasound. The procedure utilizes an ultrasound apparatus that generates frequencies of 0.7 MHz-1.1 MHz. The ultrasound intensities employed usually range from 0.0 Watts-3.0 Watts per cm². Both continuous-mode, as well as pulse-mode applications, have been utilized with most treatments lasting from 5-8 minutes. Larger treatment areas (greater than 36 cm²) often require more than 8 minutes. The exact mechanism, enabling drugs to be propelled into the subcutaneous structures, is still unclear.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover phonophoresis. There is inadequate published clinical evidence which demonstrates the effectiveness of this therapy in improving health outcomes; this meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Phonophoresis has been suggested by early studies to enhance the absorption of analgesics and anti-inflammatory agents. More recent, better-controlled studies have consistently failed to demonstrate that phonophoresis increases the rate of absorption or the extent of absorption over placebo. Several reviews stated that more research is needed to ascertain optimal techniques and conditions for safe and

Phonophoresis, continued

efficacious utilization of physical modalities including phonophoresis; and there is a need for additional research to establish clinical effectiveness and determine optimal treatment parameters for the physical agents (e.g., phonophoresis) used most frequently to alleviate pain in hand therapy.

In a randomized study (n = 60) comparing the effectiveness of ibuprofen phonophoresis with conventional ultrasound therapy in patients with knee osteoarthritis, Kozanoglu et al. found that ibuprofen phonophoresis was not superior to conventional ultrasound.

A recent review of literature revealed multiple studies and papers regarding the clinical efficacy of phonophoresis using a variety of topical anti-inflammatory agents both steroidal and non-steroidal; most concluded that further research needs to be done. One study published in the Journal of Athletic Training in 2007 (Jul-Sep), titled, "Phonophoresis and the Absorption of Dexamethasone in the Presence of an Occlusive Dressing," concluded that a 2-way repeated-measures analysis of variance (condition x time) revealed a significant main effect for ultrasound treatment ($P = .047$). The rate of appearance and the total concentration of dexamethasone in the serum were greater in subjects after phonophoresis than after sham ultrasound. The sham group had only trace amounts of dexamethasone in the serum, indicating that drug absorption was negligible without the ultrasound energy. The effect size of the phonophoresis condition fell within a 95% confidence interval after the baseline measurement.

The study involved 10 subjects including a sham group and used high performance liquid chromatography to measure the presence of dexamethasone in the blood stream at various intervals. This study differed from other studies in that they used an occlusive dressing to deliver the medication which is rather atypical. Studies examining the clinical effectiveness of phonophoresis as opposed to whether the topical medication is absorbed into the bloodstream are inconclusive.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproved for this indication

CPT CODES

97035 Application of a modality to 1 or more areas; ultrasound, each 15 minutes

HCPCS CODES

No specific codes identified

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Phonophoresis, continued

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PHYSICAL THERAPY (PT)/OCCUPATIONAL THERAPY (OT)

Policy # 518

Implementation Date: 1/7/13

Review Dates: 2/20/14, 2/16/17, 2/15/18, 2/7/19, 2/17/20, 2/28/21, 1/3/22, 2/1/23, 1/29/24

Revision Dates: 4/4/14, 4/16/14, 6/10/15, 1/1/16, 10/11/18, 9/9/22

Related Medical Policies:
[#178 Speech Therapy Guidelines](#)

Disclaimer:

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

As a result of injury, accident, or illness, some patients develop functional limitations from which they require assistance to achieve maximal recovery or functional improvement. In these instances, providers may prescribe various modalities of physical therapy, occupational therapy, or other related therapies to assist in the recovery.

Physical therapy (PT) consists of a prescribed program to relieve symptoms, improve function, and prevent further disability for individuals disabled by chronic or acute disease or injury. Treatment may consist of various active and passive modalities, including various forms of heat and cold, electrical stimulation, therapeutic exercises, ambulation training, phonophoresis, iontophoresis, and training in functional activities.

Occupational therapy (OT) is similar to physical therapy in that it involves training and strengthening muscles. It involves the use of purposeful activities to help people regain performance skills lost through injury or illness. Individual programs are designed to improve quality of life by recovering competence, maximizing independence, and preventing injury or disability as much as possible so that a person can cope with work, home, and social life.

Aquatic therapy, or pool therapy, consists of an exercise program that is performed in the water. It is a beneficial form of therapy that is useful for a variety of medical conditions. Aquatic therapy uses the physical properties of water to assist in patient healing and exercise performance.

Manual therapy, also known as manipulative therapy, is a physical treatment that is typically used in conjunction with traditional physical therapy techniques. A physical therapist will use their hands to apply pressure on muscle tissue and/or manipulate joints of the body—as opposed to using a machine or device. Manual therapy can be quite effective for treating both acute and chronic pain. Optimal benefit is seen when manual therapy is used in conjunction with other therapies such as ice, heat, ultrasound, interferential therapy (ICF), transcutaneous electrical nerve stimulation (TENS), and/or exercise prescription.

Neuromuscular reeducation consists of manual techniques (i.e., PNF-proprioceptive neuromuscular facilitation), activities for balance and core-control (i.e., BOSU ball exercises/therapeutic ball exercises), and other therapeutic exercises that are designed to redevelop normal, controlled movement patterns. The goal of neuromuscular reeducation activities in the outpatient orthopedic setting is the same as in any other setting: to retrain a body part to perform a task which it was previously capable of performing.

Physical Therapy (PT); Occupational Therapy (OT), continued

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers medically necessary physical therapy (PT) and occupational therapy (OT), when the plan determines that services can be expected to significantly improve the member's condition as defined by the following. *(This coverage may be limited by a pre-specified benefit limit specific to the member's benefit plan.)*

- 1) Documentation of a written plan of care that is sufficient to determine the medical necessity of treatment. The written plan of care should include all the following:
 - a. The diagnosis along with the date of onset or exacerbation of the disorder/diagnosis; and
 - b. A reasonable estimate of when the goals will be reached; and
 - c. Long-term and short-term goals that are specific, quantitative, and objective; and
 - d. PT or OT evaluation; and
 - e. The frequency and duration of treatment; and
 - f. The specific treatment techniques and/or exercises to be used in treatment; and
 - g. If the treatment is in a home setting, explanation of why it cannot be done in the office setting needs to be included.

Continuation of Therapy:

- 2) Select Health covers continuation of PT or OT with objective documentation showing improvement and progress towards pre-established PT or OT goals; improvement is evidenced by successive objective measurements.

Select Health covers physical therapy and occupational therapy for all covered diagnoses, based on specific plan guidelines.

Select Health covers physical therapy and occupational therapy for habilitative services, on plans that cover habilitative services.

Not Covered:

Physical therapy or occupational therapy for members whose condition is not improving is considered not medically necessary.

Physical therapy or occupational therapy for goals beyond ADLs.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Physical Therapy (PT); Occupational Therapy (OT), continued

Physical therapy is employed in several clinical circumstances for which effectiveness has been demonstrated. This therapy has been shown to be equal or superior to medication or surgery in treating some medical conditions. Chou et al., in their study published in *Annals of Internal Medicine* in 2007 identified: "... good evidence of moderate efficacy for chronic or subacute low back pain are cognitive-behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation." George et al. in their updated clinical practice guidelines published in the *Journal of Orthopedic and Sports Physical Therapy* in 2021 found level A evidence for the use of manual therapy and level B evidence for exercise in the treatment of acute low back pain. These findings have led to incorporation of physical therapy into the American College of Physicians/American Pain Society Low Back Pain Guidelines.

Similarly, clinical practice guidelines have been published showing the effective use of physical therapy in achilles tendinopathy by Martin et al. in 2018, in neck pain by Blanpied et al. in 2017, in osteoarthritis of the hip by Cibulka et al. in 2017 and in many other conditions. Short-term improved functionality and quality of life improvement for patients undergoing primary total knee replacement was also identified by Lowe et al. in their systematic review published in 2007. Other systematic reviews have also identified efficacy of physical therapy in the management of temporomandibular joint disorder, chronic tension headache, stroke, post-bypass surgery, and many other conditions.

Additionally, multiple studies have demonstrated the value of occupational therapy. This is highlighted by a large-scale review by Hand et al. reviewed the effectiveness of community occupational therapy interventions, delivered alone or within a multidisciplinary team, in improving occupational outcomes for adults. They reviewed 16 studies including patients with heart disease, depression, rheumatoid arthritis, osteoarthritis, chronic obstructive pulmonary disorder, and diabetes. Ten studies found significant differences between intervention and control groups for at least one outcome of function in activities of daily living, functional self-efficacy, social or work function, psychological health, general health, or quality of life. Conflicting evidence exists regarding the impact of intervention on physical function and health. They concluded that occupational therapy could improve occupational outcomes in adults with chronic diseases.

Billing/Coding Information

CPT CODES

Physical Therapy

- 97161** Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
- 97162** Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
- 97163** Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable

Physical Therapy (PT); Occupational Therapy (OT), continued

assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.

- 97164** Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.

Occupational Therapy

- 97165** Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
- 97166** Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
- 97167** Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
- 97168** Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
- 97750** Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes

Physical Therapy (PT); Occupational Therapy (OT), continued

97755 Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact by provider, with written report, each 15 minutes

Physical and Occupational Therapy

97010 Application of a modality to one or more areas; hot or cold packs

97012 ; traction, mechanical

97014 ; electrical stimulation (unattended)

97016 ; vasopneumatic devices

97018 ; paraffin bath

97022 ; whirlpool

97024 ; diathermy (e.g., microwave)

97026 ; infrared

97028 ; ultraviolet

97032 ; electrical stimulation (manual), each 15 minutes

97033 ; iontophoresis, each 15 minutes

97034 ; contrast baths, each 15 minutes

97035 ; ultrasound, each 15 minutes

97036 ; Hubbard tank, each 15 minutes

97110 Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

97112 ; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities

97113 ; aquatic therapy with therapeutic exercises

97116 Therapeutic procedure, one or more areas, each 15 minutes; gait training (includes stair climbing)

97124 ; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

97140 Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes

97530 Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes

97535 Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact by provider, each 15 minutes

97542 Wheelchair management (e.g., assessment, fitting, training), each 15 minutes

HCPCS CODES

Physical Therapy

G0151 Services performed by a qualified physical therapist in the home health or hospice setting, each 15 minutes

S9131 Physical therapy; in the home, per diem

Physical Therapy (PT); Occupational Therapy (OT), continued

Occupational Therapy

- G0129** Occupational therapy services requiring the skills of a qualified occupational therapist, furnished as a component of a partial hospitalization treatment program, per session (45 minutes or more)
- G0152** Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
- G0159** Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
- G0160** Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
- S9129** Occupational therapy, in the home, per diem
- S9131** Physical therapy; in the home, per diem

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PLATELET RICH PLASMA (PRP)/PLATELET GRAFTING FOR BONE AND SOFT TISSUE HEALING/AUTOLOGOUS PLATELET-DERIVED PREPARATIONS

Policy # 315

Implementation Date: 9/19/06

Review Dates: 10/18/07, 10/21/10, 10/13/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/16/23

Revision Dates: 11/10/08, 12/17/09

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Injury to soft or osseous tissues activates a cascade of physiological events to promote healing of the wound and platelets play a central role in wound healing. Platelets contain several growth factors, which are important to the healing process. Activated platelets initiate soft tissue repair by releasing potent locally acting growth factors that stimulate a connective tissue response, causing division and migration of fibroblasts and formation of new capillaries. Wound macrophages derived from circulating monocytes take over the regulatory role from platelets 24 hours after wounding and continue to produce similar locally acting growth factors that stimulate fibroblast migration, division, and enhanced structural macromolecule synthesis. This complex interaction produces closure of the wound space with a neovascularized collagen mesh, a process called granulation. Following the formation of granulation tissue, epithelialization occurs, which involves epidermal division and migration, covering the collagen-vascular mesh with new skin.

Several recent technologies attempt to accelerate or enhance this natural healing process by applying additional platelet growth factors to the wound site. These products include Procuren, a solution of autologous growth factors that includes platelet-derived growth factor (PDGF) and TGF- β , and Regranex, a recombinant form of PDGF.

A newer strategy for enhancing natural wound healing is to apply whole platelets or megakaryocytes from bone marrow derived concentrate (rather than individually derived growth factors) to the wound or injury site. Several different applications are proposed for purpose. These include platelet-rich plasma (PRP) containing concentrated platelets to enrich the natural blood clot or bone marrow aspirate concentrate. These are applied to the site with the intent of initiating a more rapid and complete healing process. Currently, there is no accepted standard for the preparation of PRP. Ideally, blood is drawn immediately prior to surgery to avoid premature platelet activation that would interfere with processing. Bone marrow may also be used to prepare PRP, though, the available literature suggests that this processing method is not conventional.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover blood-derived platelet therapies, platelet grafting for bone and soft tissue healing, or autologous platelet-derived preparations for use in acceleration of bone or soft tissue healing, as these treatments are considered experimental/investigational.

POLICY # 315 – PLATELET RICH PLASMA (PRP)/PLATELET GRAFTING FOR BONE AND SOFT TISSUE HEALING/AUTOLOGOUS PLATELET-DERIVED PREPARATIONS
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Page 1



Platelet Rich Plasma (PRP) Grafting for Bone and Soft Tissue Healing/Autologous Platelet-Derived Preparations, continued

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Most of the literature examining applications of platelet growth factors for healing has been conducted using animal models. Another extensive body of literature has focused on use of PRP for dental applications. However, the clinical studies on use of platelet-rich plasma for other musculoskeletal indications are a heterogeneous body of literature. The 10 studies identified focused on seven different applications of PRP. Sample sizes ranged from 18–76 with a median of 20 patients. This literature offers equivocal support for the efficacy of PRP for injury healing.

Platelet growth factors were most frequently examined as an adjunct to spinal fusion. In a feasibility study by Lowery et al. of 19 patients who underwent posterior (n = 15) or anterior (n= 4) lumbar fusions using autologous iliac crest bone for the graft, the authors noted that PRP offers "... theoretical advantages that need to be examined in controlled studies." A 2003 study by Hee et al. examined use of autologous growth factors as an adjunct to spinal fusion. Twenty-three patients were injected with platelet growth factors in conjunction with instrumented transforaminal lumbar interbody spinal fusion followed for 2 years. In comparison with an historical cohort, there was no significant difference in overall fusion rates, but bony healing was faster in treated patients. A 2005 retrospective cohort study by Carreon et al. evaluated 76 patients who underwent lumbar fusion with autologous iliac crest bone graft mixed with platelet gel and compared these with a control group of randomly selected patients who had undergone fusion without platelet gel. The 2 groups were matched on age, sex, smoking history, and number of levels fused. The fusion nonunion rate was 25% in the platelet gel group and 17% in the control group.

Other applications of PRP were also studied. Bibbo et al. examined union rates in 62 patients undergoing elective foot and ankle surgery; all were high-risk for non-union. PRP was applied intraoperatively after preparation of bony surfaces and final operative site irrigation. Of the 123 procedures performed, 116 achieved union (mean time to union = 41 days). Barrow et al., utilized PRP to enhance healing in 20 total ankle arthroplasties and reported a 100% union rate at 6 months, compared with a 62% union rate for historical controls. However, without randomized controlled trials, it is difficult to determine whether these union rates would also be achieved without use of PRP.

In an abstract presented at the 2005 Meetings of the American Academy of Orthopedic Surgeons, Mishra et al. described a randomized controlled trial of patients with elbow epicondyle tendinosis. Twenty patients were randomly assigned to a percutaneous injection of PRP or bupivacaine (control group). At 4 weeks, the patients who underwent PRP injection reported a 46% and 60% improvement in pain ratings vs. a 17% improvement in controls. At 8 weeks, 60% of control subjects had withdrawn from the study and were no longer evaluable. At 6 months, PRP patients noted an 81% improvement in their pain scores. These data suggest a potential novel application for PRP but data from a larger sample published in a peer-reviewed journal are needed before these findings can be generalized.

A few studies examined maxillofacial applications of PRP. Camargo used a split-mouth design on 18 patients to examine the effect of PRP on promoting periodontal regeneration in intrabony defects. In

Platelet Rich Plasma (PRP) Grafting for Bone and Soft Tissue Healing/Autologous Platelet-Derived Preparations, continued

addition to the grafting material PRP was also combined with guided tissue regeneration (GTR) and evaluated against GTR alone. Use of the combined therapy produced significant improvement over GTR alone on all regeneration outcomes. Franchini et al. used PRP in 19 patients undergoing 22 reconstructive procedures. After nearly 13 months, patients had improved osteoblastic activity and reconstruction of bone. Raghoebar et al. evaluated PRP enhancing healing in augmentation of the maxillary sinus floor. In a split-mouth design, PRP was added to the bone graft in 1 sinus but not the other. After 3 months, bone biopsies revealed no statistically significant difference in healing between the treated and untreated sinus floors.

An October 2008 technology review found 8 studies were identified which met criteria for inclusion in the review. The same problems with the literature noted in the previous M-Tech report persist with the present group of studies; namely, the research on autologous blood-derived preparations consists primarily of small-sample, uncontrolled studies of a heterogeneous group of diagnoses.

Only 3 studies were randomized controlled trials. The first, by Feiz-Erfan et al., involved 50 patients who underwent anterior cervical fusion with allograft bone and internal fixation. Twenty-nine patients had degenerative (hard) cervical disc disease with osteophytes (degenerative disc disease), and 21 had a (soft) herniated cervical disc (herniated cervical disc). Patients were randomized on a blinded 1:1 basis to receive either VG2 (DePuy, Johnson & Johnson) cervical allograft with platelet concentrate or VG2 without concentrate. Of the 50 patients, 45 (90%) completed the radiological and clinical testing at 1 year, and 42 (84%) continued to participate in follow-up review for 2 years. When all 81 treated levels were analyzed, regardless of surgical indication (i.e., degenerative disc disease or herniated disc), there was no significant difference in the fusion rates between patients receiving the platelet gel and the controls. In patients with degenerative disc disease treated with the platelet concentrate, 18 (60%) of the 30 levels had fused compared with 12 of the 25 levels in the control group at 12 weeks ($p = 0.04$). By 1 year this difference was no longer statistically significant ($p = 0.82$). In patients with a herniated disc, fewer patients receiving the gel had achieved fusion at each follow-up interval compared with the control group (6 weeks; $p = 0.017$; 12 weeks; $p = 0.044$). There was no significant difference in fusion rates at 1 year ($p = 0.97$). The authors concluded that the platelet concentrate had no consistent effect in promoting early fusion in cervical disc disease in patients who required relatively extensive bone removal.

The second randomized controlled study, from Hanna et al., involved 13 patients who underwent bone grafting in treatment of periodontal intrabony defects. Eligible patients had defects with loss of attachment of ≥ 6 mm, a radiographically detectable defect of ≥ 4 mm, 2+ remaining osseous walls, and defects not primarily related to furcation involvement. Patients were enrolled in a randomized, split mouth, double-masked fashion to receive derived xenograft (BDX) alone or BDX in combination with platelet-rich plasma (PRP). At 6 months, both groups had significant benefits in probing depth (PD), clinical attachment level (CAL), and recession (REC). Paired t-tests yielded significant differences between treatments for PD reduction (3.54 and 2.53 mm) and CAL gain (3.15 and 2.31 mm), ($p < \text{or} = 0.05$).

In the final randomized trial, Yassibag-Berkman et al. reported on 30 interproximal intrabony defects that were randomly assigned to one of three treatment options: graft alone beta-tricalcium phosphate (beta-TCP), graft + PRP, and graft + PRP + collagen barrier membrane. Radiographic analyses at 12 months revealed no statistically significant differences in radiographic measurements, suggesting that the use of PRP conferred no additional benefit over conventional treatments.

The only study found specific to chronic elbow tendinosis was also inadequate to draw any conclusions regarding the effectiveness of this therapy in this clinical setting despite its positive findings. This study published in 2006 by Mishra et al. was a cohort study, was not randomized and had a small number of patients. Though the study identified a benefit to platelet therapy compared with placebo (bupivacaine injection), the authors concluded in what they identified as a pilot study that: "Further evaluation of this novel treatment is warranted."

Finally, Gardner et al. reported a retrospective analysis of 98 unilateral knee arthroplasties, 61 of which involved intraoperative use of platelet gel. Patients receiving platelet gel during surgery had less postoperative blood loss, used fewer IV and oral narcotics, achieved a higher range of motion prior to discharge, and were discharged an average of 1 day earlier than controls. The remaining studies were small, uncontrolled studies that did not involve a comparison treatment group.

Platelet Rich Plasma (PRP) Grafting for Bone and Soft Tissue Healing/Autologous Platelet-Derived Preparations, continued

In summary, weaknesses persist in the most recent literature related to blood-derived platelet related therapies. The literature consists of a heterogeneous group of primarily small-sample, uncontrolled studies. Moreover, 2 randomized controlled studies concluded that PRP conferred no additional benefit over standard therapies. There were no published reports on BMAC at all. Though PRP may offer some healing benefit for orthopedic injuries, additional randomized controlled trials are needed to better understand the effect of autologous blood-derived preparations on healing.

A December 2009 literature review identified a review by Hall et al., which concluded that even though the use of PRP in sports medicine will mostly increase, the available evidence supporting the efficacy is minimal.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

0232T Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

HCPCS CODES

G0460 Autologous platelet rich plasma (PRP) or other blood-derived product for nondiabetic chronic wounds/ulcers (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)

G0465 Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)

P9020 Platelet-rich plasma, each unit

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PRESSURE SPECIFIED SENSORY DEVICE (PSSD) FOR ASSESSMENT OF PERIPHERAL NEUROPATHY

Policy # 217

Implementation Date: 1/26/04

Review Dates: 2/11/05, 1/23/06, 1/26/07, 2/21/08, 2/26/09, 2/17/11, 2/16/12, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/12/18, 8/7/19, 8/20/20, 8/19/21, 7/19/22, 8/22/23

Revision Dates: 2/18/10

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Pressure specified sensory device (PSSD) testing is proposed for the assessment of nerve damage in a variety of neuropathies; in lower extremity compressive neuropathies by podiatrists (and others) and by orthopedists, plastic surgeons, neurologists, and neurosurgeons in upper extremity neuropathies. It is proposed as a complement to standard neurological assessment and as a replacement, principally, for nerve conduction studies, but may also replace magnetic resonance imaging (which is appearing in the literature as a useful tool for the assessment of neuropathies). The secondary issue is whether the use of PSSD testing leads to improved decision making, which subsequently leads to clinical decisions leading to improved patient outcomes.

The PSSD procedure involves a measuring device that collects sensory data which is downloaded and analyzed by the integrated computer (laptop + software), a computer-based sensory testing system, available in desktop or portable configurations. Package includes computer, monitor, printer, device electronics, and PSSD. Modules available: PSSD, Skin Compliance, Grip Strength, Pinch Strength, Range of Motion, Dexterity Board, Micrometer, Caliper, and Volumeter. The PSSD system also provides protocols and guidelines that help guide providers in choice of treatment, including shoe modification, corrective shoe inserts, or surgical decompression.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover pressure specified sensory device (PSSD) testing as available evidence fails to prove the validity of this testing in comparison to standard testing such as EMG/NCS. This meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health

Pressure Specified Sensory Device (PSSD) for Assessment of Peripheral Neuropathy, continued

Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

No systematic reviews were identified for this report. Scores of traditional reviews, editorials, and small case series were identified; many of which were (co-) authored by the inventor of the device (A. Lee Dellon).

Pressure specified sensory device testing can be used as a substitute for the relatively expensive (and somewhat painful) nerve conduction/EMG studies and/or to augment simple monofilament sensory testing. PSSD testing also seems to represent a paradigm shift in thinking about the cause of a variety of peripheral neuropathies, which is associated with different treatment strategies. Thus, evaluation of PSSD testing requires examination of both the performance characteristics of the test, compared to its alternatives, but also requires examination of the treatment outcomes associated with the neuropathies for which it is being used or proposed. Currently, the literature base is limited to small case series and a handful of small, poorly conducted, randomized trials. The literature clearly suggests controversy about both the role and value of PSSD testing and patient outcomes associated with treatment decisions that rely on PSSD testing. However, without better designed studies (e.g., randomized, controlled, and blinded), the validity of this testing, and thus, the applicability of the testing on specific medical conditions remains in doubt.

In addition to the bias inherent in studies when authored or supported by vested interests (e.g., Dellon as inventor and executive officer of the company that sells the PSSD testing device and related products), in this circumstance, there is the additional element of patient management guidelines built into the software that comes with the PSSD "system." Through this system, Dellon appears to be distributing not only the device, but also his view of patient evaluation and management, which is clearly not the accepted standard, on either account.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

- 0106T** Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation
- 0107T** ; using vibration stimuli to assess large diameter fiber sensation
- 0108T** ; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia
- 0109T** ; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia
- 0110T** ; using other stimuli to assess sensation

HCPCS CODES

- G0255** Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve

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Pressure Specified Sensory Device (PSSD) for Assessment of Peripheral Neuropathy, continued

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PULSED ELECTRICAL STIMULATION WITH AN INTEGRATED UNLOADING BRACE (E.G., BIONICARE STIMULATOR)

Policy # 251

Implementation Date: 12/14/04

Review Dates: 2/16/06, 5/17/07, 4/24/08, 4/23/09, 6/17/10, 4/12/12, 6/20/13, 4/17/14, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/14/20, 11/28/21, 9/15/22, 10/17/23

Revision Dates: 12/13/10, 2/24/11, 10/19/17

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Description

Osteoarthritis is a common, chronic, degenerative condition, which may affect a variety of joints. The principal symptom associated with OA is pain, which is typically exacerbated by activity and relieved by rest.

Non-steroidal anti-inflammatory drugs (NSAIDs) are the usual first-line therapy for osteoarthritis patients. As the disease progresses, some patients may undergo physical therapy to work to strengthen leg muscles or correct for gait disturbances related to the osteoarthritis and associated developing deformities and pain and may also attempt bracing. Some patients will also choose to undergo injection therapy with either corticosteroids or viscosupplementation in an attempt to treat their knee pain and maintain functionality. Various arthroscopic or open surgical procedures are also performed in an attempt to maintain or regenerate articular cartilage in OA knees. These include arthroscopic debridement, osteochondral autografts, mosaicplasty, the OATS procedure, and as a last resort, total knee arthroplasty.

Since 2004, the BioniCare Stimulator System, Model Bio-1000 (BioniCare Medical Technologies, Inc., Sparks, MD) has been available as an additional modality to treat the pain associated with osteoarthritis of the knee. The device is an unloading brace designed with an integrated pulsed electrical stimulator. The device is usually worn 6–10 hours a day, most often while the patient is sleeping. The BioniCare device has 3 major components: a signal generator (a 9-volt, battery-powered unit that provides the therapeutic electrical signal); a signal applicator, designed to fit the treatment site and the individual, that wraps the joint and holds the contact elements; and snap-in, replaceable contact elements. These are placed over the affected area and held in place with the applicator. Small electrical currents are then delivered that are imperceptible to the patient.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover pulsed electrical stimulation with an integrated offloading brace, such as the BioniCare device for the treatment of osteoarthritis. There is inadequate evidence supporting improvement in long-term outcomes with use of this therapy; this meets the plan's definition of experimental/investigational.



Pulsed Electrical Stimulation with an Integrated Unloading Brace (e.g., Bionicare® Stimulator), continued

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

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Summary of Medical Information

The initial review of the medical literature in 2004 identified only a single study published in 1995. In this study, 78 patients with osteoarthritis of the knee were randomized to receive either pulsed electrical stimulation with the Bionicare or a sham treatment with the device. Treatment occurred for 4 hours at night and continued for 4 weeks. Treatment effects were evaluated by a subjective global assessment of the physician, and the patient's subjective evaluation of pain and function. The study was not controlled for other concomitant treatment of the arthritis. The study demonstrated safety, and a small positive treatment effect, and concluded that additional long-term confirmatory investigation was needed. However, the demonstration of a placebo effect, the small size and short duration of the study and absence of subsequent trials to support its findings render this single study inadequate to permit scientific conclusions regarding the efficacy of this device.

A follow-up Medical Technology Assessment performed in November 2010 identified only 1 systematic review and 3 primary literature articles related to pulsed electrical stimulation for osteoarthritis and the Bionicare device. The systematic review was performed by the Cochran Collaborative and was published in 2009. It reviewed the use of transcutaneous electrostimulation for OA of the knee, performing a meta-regression study. A high degree of study heterogeneity coupled with poor reporting and methodological protocols were identified. The review concluded that based upon the available evidence it could not be determined whether transcutaneous electrostimulation is effective for pain relief.

The 3 primary studies identified a total of 424 patients observed over a course of several months while being treated with the Bionicare knee brace. Primary outcome measurements were physician global observation, patient pain assessment or Western Ontario and McMaster Universities (WOMAC) questionnaires. Patients reported a decrease in morning stiffness (the brace is to be worn during sleep) and other subjective outcomes. Of note, 2 of the 3 primary literature papers were researched and published from the labs of the CEO and Medical Consultant for Bionicare. This raises concerns with regards to the objectivity of the groups' data analysis, findings, and conclusions.

These studies did not identify objective measurements of increased knee health by means of MRI, ultrasound, CT, etc., reported despite claims by the manufacturer that this therapy may "heal" cartilage. Additionally, though 1 of the manufacturers supported trial had outcomes out to 600 days; the other 2 trials were of short duration so there is a lack of evidence of long-term, improved health outcomes with continued use of the device. Also, no data is given to suggest residual improved health outcomes after discontinuation of regular use of the device. Most importantly, none of the studies provided evidence to differentiate the impact of the offloading brace component versus the electrical stimulation in improving pain and function for the patient.

Most recently, a study published in 2011 enrolled 34 participants randomized to PES and 36 to control. Intention to treat analysis showed a statistically significant improvement in pain VAS over 26 weeks ($p \leq 0.001$) in both groups, but no difference between groups (mean change difference 0.9 mm; 95%CI -11.7 mm to 12.5 mm). Similarly, no differences existed between groups for changes in WOMAC pain, function and stiffness scores SF-36 physical and mental component scores, patient global assessment or activity

Pulsed Electrical Stimulation with an Integrated Unloading Brace (e.g., Bionicare® Stimulator), continued

measures ($p > 0.16$). Fifty-six percent of the PES group achieved a clinically relevant 20 mm improvement in pain VAS at 26 weeks compared with 44% of controls (95%CI -11% to 33%). Fary concluded 26 weeks of PES was no more effective than placebo.

In summary, though there are limited studies subjectively suggesting clinical efficacy, the lack of adequate studies to answer key outcomes questions related to magnitude of response, durability of effect, and actual improvement in outcomes over currently available standard methods treatment, conclusions cannot be reached at this time with regards to the efficacy of this treatment approach in managing knee osteoarthritis.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproved for this indication

CPT CODES

No specific codes identified

HCPCS CODES

E0762 Transcutaneous electrical joint stimulation device system, includes all accessories

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Pulsed Electrical Stimulation with an Integrated Unloading Brace (e.g., BionCare® Stimulator), continued

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RADIOFREQUENCY ABLATION (RFA) OF THE DORSAL ROOT GANGLION (DRG) OF THE SPINE

Policy # 226

Implementation Date: 5/1/04

Review Dates: 3/11/06, 5/17/07, 4/24/08, 4/23/09, 2/18/10, 4/21/11, 4/12/12, 4/25/13, 2/20/14, 10/20/16, 10/19/17, 11/14/18, 10/15/19, 10/15/20, 11/28/21, 9/15/22, 10/17/23

Revision Dates: 3/18/05, 5/15/15

Related Medical Policies:

[#389 Radiofrequency Ablation \(RFA\) of the Sacroiliac \(SI\) Joint](#)
[#626 Diagnostic and Therapeutic Interventions for Spinal Pain](#)

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Radiofrequency nerve ablation procedures (also referred to as neurotomy, neurectomy, rhizotomy, and denervation) are offered for a variety of pain syndromes; categorized as being cervical, thoracic, lumbar, or sacroiliac (SI) in origin. These are conditions such as cervicogenic headache, mechanical low back pain, or whiplash (flexion-extension injury), which all may cause significant and persistent pain, yet have no identifiable etiology on an X-ray or exam. Frequently, the pain generator is located in the facet joints of the involved section of the spine. If other etiologies, such as herniated intervertebral discs, fractures, spondylosis, spondylolisthesis, or nerve root impingement have been excluded, a trial of a diagnostic nerve block of the facet joint is attempted. This is often done at several levels as the innervation of the facet joints can arise from the levels above or below the affected joint. This diagnostic injection is called a medial nerve block or a sympathetic medial nerve block. It is temporary and is designed to see if the patient may respond to a more definitive RF procedure. If the patient has a response, the patient may then undergo the definitive procedure. Unlike cervical and lumbar pain, the anatomy of the medial branch is less clearly defined in the thoracic region. As a result, the nerve location may be difficult to assess, and radiofrequency ablation may be more difficult.

The procedure is commonly performed with fluoroscopy, although the use of CT scans has been described. A common target point is the midpoint of the zygapophyseal joint, although inferior or superior recesses can also be entered. The skin and tissue overlying the target point is anesthetized and a 22G needle is advanced into the capsular joint under radiographic guidance. A lateral view is obtained to ensure that the needle has not been advanced into the intervertebral foramen. Sometimes clinicians will also try and localize the nerve with EMG recordings. This has not been shown to significantly alter the outcomes. Once the nerve is isolated, the radiofrequency catheter is positioned, and a pre-determined amount of radiofrequency generated energy is applied. This causes heating of the tissues and destruction of the nerve fibers. If successful, the patient may have a small area of numbness in the skin overlying the area. In appropriately identified and treated patients, up to 80% reduction in pain may result for periods as long as one year. Due to regeneration of nerve fibers, repeat procedures 6 to 12 months after an initial successful procedure, may be indicated.

Dorsal root ganglions (DRG) are collections of cell bodies of peripheral sensory nerves that are located in the intervertebral foramen of the spine at every level. Radiofrequency nerve ablation (RFA) procedures are offered for a variety of pain syndromes of spinal origin. Varying amounts of evidence exist for RFA efficacy, but evidence is strongest in the cervical and lumbar spine, and weaker for the thoracic spine and DRG. When RFA of the DRG is performed to treat radicular arm or leg pain (sciatica), an RF electrode is placed under fluoroscopic guidance into the intervertebral foramen and energy (from 42–80° Celsius) is

Radiofrequency Ablation (RFA) of the Dorsal Root Ganglion (DRG) of the Spine, continued

applied to the DRG. Low temperatures are usually applied with pulsed RF at 42–45 °C which is thought to stun the nerve, cause mild demyelination, and cause neuromodulation (electromagnetic scrambling). At higher temperatures, 60–80°C, the nerve has axonal damage and stops functioning until it can heal in 3–24 months, at which point the RFA of the DRG is traditionally performed. DRG RFA is mostly performed with pulsed RF at lower temperatures because the DRG neurons carry more information than just pain.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does **NOT** cover radiofrequency ablation of the dorsal root ganglion of the spine. This procedure meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

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Summary of Medical Information

The evidence relating to the application of radiofrequency energy to the dorsal root ganglion (of the spine) is complex, despite its relatively small volume, for an assortment of reasons. First, is the source of energy itself, radiofrequency. Originally described in 1974, the RF was applied continuously, at temperatures as high as 90° C, but with experience, more commonly around 67° C (temperatures above 45° C results in permanent neuroablation). In recent years, because of further developments, the RF energy used has been reduced (by some) to yield temperatures less than 45° C. These lower temperatures allow nerve function to be selectively influenced either as a function of selective demyelination and/or “modulation” of neural function through mechanisms that may include regulation of gene expression. The latter mechanism is believed to occur by virtue of the electromagnetic field created by the RF energy, which is independent of the heat effect.

Manipulation of the RF energy characteristics also permits “pulsing” of the energy source (as opposed to continuous energy), which further reduces the potential damaging effects of the RF probe/energy. In fact, an RF probe that is pulsed at temperatures less than 45° C is believed NOT to ablate or even damage (substantially) neurons but to modulate through either or both mechanisms mentioned above.

Additionally, the tip of the RF electrode can be placed either in contact with the target tissue (e.g., ganglion) or in close proximity; the former with the consequence of ablating the tissue (which varies according to temperature) or “neuromodulating” by virtue of the RF field. Given the difficulty in anatomic placing of the RF probe without direct vision (i.e., fluoroscopic guidance is used to place the probe), the intended effect (i.e., ablation vs. neuromodulation) is neither assured nor necessarily known.

Thus, clinical effects are markedly different depending on the temperature generated by the RF energy, whether pulsed or not, and whether the RF electrode is placed in contact with or into the DRG or “in close proximity.”

Subsequent to these developments, there are currently two almost diametrically opposed views on the mode of action of RF, and thus, no consensus in the literature about which protocols are best for given

Radiofrequency Ablation (RFA) of the Dorsal Root Ganglion (DRG) of the Spine, continued

targets (i.e., “heat” vs. “fields”). Clearly, there is not consensus about the value of RF to the DRG for spine-related pain.

Pauza et al. (including Bogduk), in an RCT using IDET, identified an additional issue which adds to the controversy surrounding the effectiveness of this therapy. That is the impact of sham treatments of the placebo effect in patients with (discogenic) back pain. In his study related to IDET, some 38% reported an improvement in pain of greater than 20 points, and 33% reported greater than 50% improvement, with one patient reporting complete relief of pain. The sham treatment was performed in a rigorous and disciplined manner. Perceptually, the sham treatment had all the hallmarks of a formal, surgical treatment. It was conducted in a procedure suite, with fluoroscopy operating, and treatment devices operating. Physically, however, it consisted of no more than the insertion of a needle into the patient’s back. Yet, substantial numbers of patients benefited. Though Pauza’s study was specific to IDET, his findings suggest that many procedures designed to treat mechanical low back pain may be associated with a substantial placebo effect, generated by nonspecific features of the procedure. It is important to note that no other surgical procedure for discogenic low back pain has been subjected to a placebo-controlled trial. The results of the Pauza study indicated that nonspecific therapeutic effects may be a major component of the observed outcomes of other treatments. In particular, the results of the present study warn consumers to be wary of results claimed for new intradiscal therapies, when those therapies have not been subjected to placebo-controlled trials. What appear to be reasonable or promising outcomes may be the result of no more than the circumstances of “having a procedure.” It is noted, however, that van Kleef et al. suggest that the placebo/sham effect of RF lesions of the DRG is low; about 18% in 1 study.

Winifred S. Hayes Inc. reported on Radiofrequency Ablation for Chronic Spinal Pain in a systematic review in February 2004. The Hayes report noted: “While there is some evidence that RFA may provide short-term pain relief in selected patients with chronic spinal pain, the majority of patients do not experience complete pain relief, and the durability of the effects remains unclear due to a lack of prospective long-term follow-up data from randomized controlled trials. Documented reoperation rates, necessitated by pain recurrence, varied widely among trials. A lack of standard procedure techniques, patient selection criteria, and outcome measurements makes definitive conclusions regarding the safety and efficacy of RFA for facet joint pain problematic. Additional well-designed, long-term randomized controlled trials are required to compare the safety, efficacy, and cost-effectiveness of RFA with other medical or surgical therapies for chronic back pain.”

Furthermore, a 2003 Cochrane review states that there is limited evidence that radiofrequency denervation offers short-term relief for chronic cervicobrachial pain. Lord and Bogduk, in a practice guideline, state that for patients with “cervicobrachialgia,” there is limited evidence of marginal short-term benefit from cervical DRG procedures (this was published prior to the Geurts 2003 “negative” RCT), that procedure-associated morbidity is poorly quantified and serious complications have been reported, and that “the risk/benefit ratio of this application appears unfavorable.” Likewise, Geurts et al. acknowledge the mixed results and limitations of current evidence. Zundert et al., in a “state-of-the-art review” by “key opinion leaders,” stated that for cervicobrachial there is limited evidence of effectiveness, for thoracic indications evidence is “sparse,” and for lumbosacral, the evidence is mixed with the only reported RCT demonstrating no benefit compared to sham therapy. Geurts et al., in a systematic review, states that there seems to be insufficient evidence supporting the effectiveness of most RF treatments for spinal pain; specifically, “There is limited evidence that RF heating of the dorsal root ganglion is more effective than placebo in chronic cervicobrachialgia.”

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

- | | |
|--------------|---|
| 64635 | Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint |
| 64636 | Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure) |
| 64640 | Destruction by neurolytic agent; other peripheral nerve or branch |

Radiofrequency Ablation (RFA) of the Dorsal Root Ganglion (DRG) of the Spine, continued

HCPCS CODES

No specific codes identified

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RADIOFREQUENCY ABLATION OF THE GENICULAR NERVE

Policy # 557

Implementation Date: 9/1/14

Review Dates: 10/15/15, 10/20/16, 10/19/17, 11/14/18, 10/15/19, 10/13/20, 11/28/21, 9/15/22, 10/17/23

Revision Dates: 7/29/15, 11/4/20, 11/17/21

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Geniculate nerve radiofrequency ablation (RFA) can be used in patients with failure or contraindications to NSAID use, such as diabetes, renal disease, cardiovascular risk, and gastrointestinal risks. In a meta-analysis from Chen et al. (2020) (see reference below), thermal RFA is superior to intra-articular (IA) corticosteroid injections with much longer duration of effectiveness (12 to 24 months versus 4 to 6 weeks) and does not have the risks of cartilage loss and periprosthetic infection associated with IA corticosteroids. Geniculate nerve thermal RFA can also be used in obese/morbidly obese patients or other patients requiring weight loss, smoking cessation, or other optimization before surgery. Thermal RFA of geniculate nerves is more effective at treating knee OA pain and function than current treatments, including NSAIDs or IA corticosteroids, and the pain relief is clinically notable to 24 months.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers radiofrequency ablation of the genicular nerve in the treatment of osteoarthritis or failed total knee replacement when the following criteria are met.

1. Patient has experienced moderate-to-severe knee pain limiting activities of daily living for ≥ 3 months in the current episode, unrelieved by all conservative medical management strategies as listed below:
 - NSAIDs/Analgesic > 3 weeks or contraindicated
 - Activity modification > 6 weeks
 - Physical therapy (minimum of 4 visits over a 6-week period)
2. Radiographic evidence, which demonstrates articular injury or mild-to-severe osteoarthritis, or prior knee replacement
3. Patient has had an 80% response to a genicular nerve block
4. Patient is not medically capable or willing to undergo total knee replacement, or further surgery is not recommended

Select Health will cover genicular RFA once every rolling 12 months. For coverage of a second RFA procedure to be considered, the member must have experienced $\geq 60\%$ reduction in



Radiofrequency Ablation (RFA) of the Genicular Nerve, continued

knee pain resulting from the previous procedure, and it has been ≥ 12 months since the previous procedure.

Select Health does not cover cryoablation of the genicular nerve due to the lack of clinical trials supporting continued clinical response; this meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

A comprehensive search of PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials was conducted based on the key terms and concepts to identify all studies evaluating the relative effectiveness of geniculate nerve thermal (heated or cooled) RFA compared with other nonsurgical treatments of knee OA.

Bibliographies of relevant systematic reviews were manually searched for additional references. All databases were last searched on November 13, 2019, with the limits for publication dates from 1966 to present and English language. Full search strategy can be found in the Supplementa IData File (Supplemental Digital Content 1, <http://links.lww.com/JAAOS/A517>). Two independent abstractors (F.C. and V.V.) reviewed and analyzed the literature for geniculate nerve thermal RFA including comparators such as: IA corticosteroids, IA HA, oral analgesics, and control/sham procedures. Geniculate nerve thermal RFA is often performed by a preprocedural anesthetic block with monitoring of pain relief, followed by nerve ablation using probes inserted under fluoroscopy or ultrasonography guidance using anatomic landmarks.

Inclusion was based on the following criteria: English language, human subjects, symptomatic knee OA, comparative design, and quantitative patient-reported outcome data. As shown in Figure 1, of the 267 unique abstracts returned from the systematic search, 46 full-text articles were reviewed, and seven randomized trials met the inclusion criteria for analysis. The quality of included articles was appraised based on the GRADE methodology assessing possible risk of bias in the following domains: randomization, allocation concealment, blinding, incomplete data, selective reporting, and other bias (relevant author conflict, industry funding, baseline differences, or unaccounted confounding factors). Unusual methodology and quality appraisal disagreements between abstractors were individually assessed and consensus was reached. Clinical effectiveness of pain relief was determined as pain relief greater than or equal to the minimum clinically important difference (MCID) or minimal clinically important improvement.

The MCID for pain relief was 1.9925 and was the same MCID used in the AAOS Treatment of Osteoarthritis of the Knee, Second Edition evidence-based CPG. Included study group means and standard deviations were extracted for all pain, function, and composite patient-reported outcomes, including visual analog scale, numeric rating scale, Western Ontario, and McMaster Universities Arthritis Index (WOMAC), Short Form-36, Lysholm knee score, Oxford Knee Score, and Global Perceived Effect

Radiofrequency Ablation (RFA) of the Genicular Nerve, continued

(GPE). These values were then used to calculate the mean difference, and statistical significance was evaluated using a 95% confidence interval. Meta-analysis was assessed using STATA 12.1 software, but the level of heterogeneity was too high for reliable comparison because of varying treatment and outcome comparisons. Five high-quality and two moderate-quality RCTs met the inclusion criteria for this systematic review. Regarding the primary outcomes, all included studies reported pain and six of seven studies reported functional outcomes. Composite scores built from pain, function, stiffness, and other patient reported outcomes were also collected and reported (Table 1). The most common follow-up time was three months. However, three studies assessed outcomes at six months and one study measured outcomes up to one year.

Patient Outcomes

Overall, the results showed agreement across studies in favor of geniculate nerve thermal RFA use for conservative treatment of knee OA for nearly all measured outcomes and treatment comparisons. One high-quality and one moderate-quality RCT compared geniculate nerve RFA with sham/control procedures and found geniculate nerve RFA to be markedly superior for pain and functional outcomes (Figures 2 and 3). Geniculate nerve RFA also displayed superiority over a variety of active treatment comparisons within the included studies. When compared with IA corticosteroids, one high-quality RCT31 found that geniculate nerve heated RFA was markedly favored for WOMAC function ($P = 0.003$ at 1 month) and stiffness ($P = 0.007$ at 3 months) and visual analog scale pain ($P = 0.001$ at 1 month), although no significant difference was noted on the WOMAC pain subscale ($P = 0.639$). Another high-quality RCT26 evaluated geniculate nerve cooled RFA to IA corticosteroids and found RFA to be markedly favored for reducing pain and improving function measured up to 6 months after intervention. When geniculate nerve RFA was compared with acetaminophen and diclofenac, one high-quality RCT27 showed geniculate nerve RFA to provide notable benefit for overall WOMAC, function, and pain for up to 6 months.

However, for the subset outcome of stiffness, the acetaminophen/diclofenac combination appeared to provide a notable improvement over geniculate nerve RFA at 3 ($P = 0.004$) and 6 months ($P, 0.001$). One high-quality and one moderate-quality RCT compared geniculate nerve RFA with IA HA. Both studies found geniculate nerve RFA to be markedly superior to IA HA for pain, function, and composite outcomes (Figures 2–4); the moderate-quality RCT measured pain and function as far as 1 year. The composite outcome scores of WOMAC, Short Form-36, and GPE were used for geniculate nerve RFA treatment comparisons. Four high quality RCTs 27,29,31,32 showed that geniculate nerve RFA had favorable outcomes for overall WOMAC and GPE scores when compared with IA HA, IA corticosteroids, conventional oral nonopioid analgesics, and sham procedures. One high quality RCT29 found geniculate nerve RFA to be markedly favored over IA corticosteroids at 1 month for WOMAC total but did not find a notable difference at 3 months. All three RCTs reported greater than a 4-point improvement in pain relief (.2 MCIDs) at all time points. Clinically effective pain relief was noted at 6 months in two RCTs and at 12 months in one RCT.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

- | | |
|--------------|--|
| 64454 | Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed |
| 64624 | Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed |

Not Covered for the conditions listed above

- | | |
|--------------|--|
| 0441T | Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve |
| 64640 | Other peripheral nerve or branch |

Radiofrequency Ablation (RFA) of the Genicular Nerve, continued

HCPCS CODES

No specific codes identified

Key References

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RADIOFREQUENCY ABLATION (RFA) OF THE SACROILIAC (SI) JOINT

Policy # 389

Implementation Date: 1/21/08

Review Dates: 2/26/09, 2/17/11, 4/25/13, 2/20/14, 10/20/16, 10/19/17, 11/14/18, 10/15/19, 10/14/20, 11/29/21, 9/15/22, 10/17/23

Revision Dates: 2/18/10, 2/16/12, 5/15/15, 8/7/18, 1/1/20, 4/12/22, 8/25/22, 9/6/22, 11/2/22, 12/8/22, 2/2/23, 4/19/24

Related Medical Policies:

[#226 Radiofrequency Ablation \(RFA\) of the Dorsal Root Ganglion \(DRG\) of the Spine](#)
[#626 Diagnostic and Therapeutic Interventions for Spinal Pain](#)

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Radiofrequency ablation (RFA) is the application of electrical currents to promote thermocoagulation and nerve destruction. It is commonly used to ablate various nerve pathways involved in the transmission of pain. One site chosen to treat chronic somatic/mechanical back pain includes the sacroiliac (SI) joint. Because it somewhat modulates the nerve, resulting in decreased nerve function, this technique is most often utilized when other measures have failed.

The SI joint is the primary source of back pain in 10%–26.6% of cases in patients with symptoms of suspected sacroiliac joint pain. Sacroiliac joint pain is more commonly unilateral. It is thought to arise from chronic inflammation within the joint and the deep interosseous ligament, which forms the posterior capsule and is the largest syndesmosis in the body.

Conservative treatment for SI joint pain includes cold application, anti-inflammatory medication, and rest in the acute stages. Once pain has subsided, further efforts should be employed to restore normal mechanics, including manual medicine techniques, pelvic stabilization exercises to allow dynamic postural control, and muscle balancing of the trunk and lower extremities.

Intra-articular injections using steroids are considered for those patients who have not responded to conservative treatment, or who have reached an unsatisfactory plateau. In these cases, SI joint injection may avoid unnecessary surgery, reduce pain, and facilitate rehabilitation.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. **Select Health covers radiofrequency ablation (RFA) of the sacroiliac joint (SIJ) when all the following criteria are met:**

1. Patients with confirmed diagnosis of SIJ mediated pain based on history and physical exam;
2. Physical examination documentation reflects SIJ pain confirmed with:



Radiofrequency Ablation (RFA) of the Sacroiliac (SI) Joint, continued

- a) At least 3 of the 5 provocative maneuvers that stress the SI joint (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver), causing the patient's typical pain.
3. History documentation includes:
 - a) Onset, location, character, duration, and modifiers of pain;
 - b) Prior treatments and results;
 - c) Medication use; and
 - d) Prior surgical and non-surgical procedures and results.
4. Advanced imaging studies of the joint such as CT, MRI, or alternating standing films to exclude other diagnoses (e.g., L5/S1 compression, hip osteoarthritis, etc.);
5. Persistent SIJ pain of moderate-to-severe despite conservative therapy (baseline score of 30 or greater on the Oswestry Disability Index (ODI) and/or numeric pain score of 5 or higher on a 10-point VAS scale);
6. Failure to adequately respond* to at least 6 months of non-surgical treatment (if not contraindicated), including ALL the following:
 - a) Non-steroidal anti-inflammatory drugs and/or opioids;
 - b) Course of physical therapy (minimum of 4 visits within a 3-month period); must have been performed within the previous 2 years. If there have been significant clinical changes or surgery has been performed in the previous 2 years, then a repeat course of physical therapy may be necessary.
 - c) Activity modification; and
 - d) CT or fluoroscopic-guided SIJ steroid injection.
7. Two diagnostic blocks (Injection(s), anesthetic agent(s); nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography) are required, without steroids, separated by two weeks, which both blocks achieved $\geq 80\%$ reduction in pain. These blocks include the following: L5 dorsal ramus and the lateral branches of S1–S3.

*Failure to adequately respond is defined as continued pain interfering in activities of daily living or resulting in functional disability.

B. REPEAT RFA PROCEDURES

Repeat (e.g., second) RFA procedures are covered when the following criteria are met:

1. The patient experienced $\geq 50\%$ reduction in facet-related pain from the previous RFA;
OR
2. The patient experienced $\geq 50\%$ improvement in ability to perform previously painful movements or ADLs after previous RFA; **AND**
3. **It has been at least 6 months** since the previous RFA.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Radiofrequency Ablation (RFA) of the Sacroiliac (SI) Joint, continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Two recent systematic reviews have examined the safety and efficacy of RFA for SI joint pain. The Hayes Directory from 2007 evaluated RFA treatments for low back pain, including SI joint pain. Most of the Hayes review focused on the RFA for facet disease. From their analysis, a single study published since 1990 met criteria for inclusion. That prospective study from Vallejo et al. included 22 patients with presumptive SI joint pain who failed conservative therapy (arthrographically confirmed steroid/local anesthetic SIJ injection). Six months after pulsed RFA of the medial branch of L4, posterior (lateral) primary rami of L5, and lateral branches S1 and S2, 16 patients (72.7%) experienced good (> 50% reduction in VAS), or excellent (80% reduction in VAS) pain relief. Based on these limited data, Hayes gave RFA for SI joint pain a 'D' rating, indicating that an appraisal of safety and efficacy cannot be made due to limited research regarding the procedure.

A 2007 review by Hansen et al. included studies with follow-up periods over 3 months. Of the 52 reports identified in the literature, only 5 prospective trials tracked pain outcomes beyond 3 months. The abstract from Burnham et al. is discussed below. The second prospective study was the Vallejo et al. report described above. Three retrospective studies measured outcomes beyond 3 months. Ferrante et al. reported outcomes of 50 SI joint radiofrequency denervations performed in 33 patients with SI joint syndrome. Only 12 of 33 patients (36%) of the patients experienced treatment success at 6 months. The average duration of pain relief was 12.0 ± 1.2 months in responders versus 0.9 ± 0.2 months in non-responders. Yin et al. reported results in 14 patients with persistent SI joint pain. After 6 months, 64% of the patients experienced a successful outcome with 36% experiencing complete relief. Cohen et al. tested 9 patients who experienced greater than 50% pain relief following nerve blocks of the L4-5 primary dorsal rami and S1-3 lateral branches innervating the affected joint. Eight of 9 patients (89%) obtained 50% or greater pain relief from this procedure that persisted at their 9-month follow-up. Based on these data, Hansen et al. concluded that: "... evidence supporting the use of therapeutic RFA for SI joint pain is limited.

Burnham et al.'s 2007 study involved nine patients with confirmed SI joint pain treated with RF strip lesions performed adjacent to the lateral dorsal foraminal aperture plus conventional monopolar lesioning at the L5 dorsal ramus. After the procedure, significant reductions of back and leg pain frequency and severity, analgesic intake, and dissatisfaction with their current level of pain occurred; complications were minimal. Overall, 8 of the 9 subjects were satisfied with the procedure. The median decrease in pain intensity was 4.1 points (1–10 rating scale) and the reduction of disability was 17.8 (Oswestry Disability Scale). Overall satisfaction was 67% at the 12-month follow-up.

The most comprehensive systematic review by Cohen was also the basis for the systematic review by Hansen et al. He defined the clinical syndrome and critically reviewed the limited number of well performed studies. Cohen felt there was limited data to support the RFA procedure. He did believe that some results from steroid injections into the SI joint could last for up to 6–12 months, if performed with radiological guidance.

Finally, the guidelines from the American Society of Interventional Pain physicians have evaluated the use of RFA in SI joint treatment and concluded that there was limited data to endorse this form of therapy.

Given the lack of quality research regarding use of RFA for treatment of SI joint pain, any conclusions about the safety and efficacy of this procedure are limited. The lack of large sample studies on long-term pain relief and disability following treatment contribute to this limitation. None of the published studies appears to have been blinded, which introduces potential bias to the study. While the available data suggests that RFA relieves SI joint pain with few complications in selected patient samples, additional prospective, randomized, blinded clinical trials are needed before the procedure can be considered as safe and effective.

Radiofrequency Ablation (RFA) of the Sacroiliac (SI) Joint, continued

Billing/Coding Information

CPT CODES

- 64451** Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
- 64493** Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral
- 64625** Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
- 77002** Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)
- 77003** Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)
- 77012** Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation

HCPCS CODES

No specific codes identified

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SANEXAS THERAPY

Policy # 679

Implementation Date: 7/13/21

Review Dates: 7/19/22, 8/22/23

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

The neoGEN-Series (Sanexas) system is a medical device that produces electric cell signaling energy waves. The system is used to treat circulatory issues and acute and chronic pain. The neoGEN-Series also offers specific-parameter signaling for neuromuscular reeducation, muscle strengthening, and relaxation of muscle spasm activity.

Electric cell signaling treatment (EST) is the use of electronic signal energy waves produced by an ultra-high digital frequency generator (UHdfq). These therapeutic pulsed energy waves are noninvasively delivered directly into the desired anatomical region of the body.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover Sanexas Therapy for any indication as there is insufficient published evidence to assess either safety or impact on health outcomes; this meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)



Sanexas Therapy, continued

Billing/Coding Information

Not covered for the indications listed above

CPT CODES

- 20552** Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
- 20553** Injection(s); single or multiple trigger point(s), 3 or more muscles
- 64999** Unlisted procedure, nervous system [when specified as percutaneous neuromodulation therapy]
- 96732** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or Intramuscular
- 97112** Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
- 97032** Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

HCPCS CODES

- J1885** Injection, ketorolac tromethamine, per 15 mg
- J3490** Unclassified drugs
- J7999** Compounded drug, not otherwise classified
- S8130** Interferential current stimulator, 2 channel
- S8131** Interferential current stimulator, 4 channel

Key References

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SPINAL CORD/DORSAL ROOT GANGLION STIMULATION FOR THE TREATMENT OF CHRONIC PAIN

Policy # 179

Implementation Date: 1/97

Review Dates: 7/25/02, 10/23/03, 11/18/04, 11/7/05, 10/19/06, 12/20/07, 12/18/08, 5/19/11, 6/20/13, 4/17/14, 4/14/16, 12/13/18, 12/18/19, 12/16/20, 11/28/21, 11/17/22, 12/20/23

Revision Dates: 11/18/04, 4/25/06, 12/17/09, 3/24/17, 1/3/19, 2/19/21

Related Medical Policies:

[#47 Spinal Cord Stimulation-Test Trial Portion](#)

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

A variety of chronic pain disorders are difficult to treat successfully, particularly those that are neurological, vascular, or musculoskeletal in origin. Examples of neurological or neurogenic disorders are spinal cord injuries, brachial plexus injuries, multiple sclerosis, and phantom limb pain. Vascular cases are often related to diabetes and arteriosclerotic disease. Many patients develop musculoskeletal pain after failed back surgery. Stimulators for spinal cord stimulation may be either totally or partially implanted. Totally implanted stimulators, referred to as implantable pulse generators (IPGs), currently account for approximately 80% of all stimulators used. Implantable pulse generators must be replaced when their internal batteries are depleted, on average every 3–5 years. Partially implanted stimulators are powered externally and are referred to as radiofrequency (RF) systems. An RF system consists of an implanted receiver, an external RF transmitter, and an antenna. The transmitter, which is usually worn on the belt, transmits RF energy to the implanted receiver via the antenna taped to the skin.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers spinal cord stimulation (SCS), except burst frequency or position-adaptive stimulation SCS, when ALL the following criteria are satisfied AND any one of the diagnoses listed has been established:

1. Criteria for placement of trial of dorsal column spinal cord stimulator:

- a. For patients with severe, chronic intractable pain; and
- b. When appropriate, more conservative treatment modalities (e.g., pharmacologic, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory or were contraindicated for the patient; and
- c. Patient has undergone careful screening and diagnosis by coordinated multiple disciplines before implantation and has been determined to be capable and willing to comply with the treatment plan; and
- d. The patient has obtained psychological clearance by a psychologist or psychiatrist with training and experience in chronic pain problems; and



Spinal Cord/Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain, continued

- e. Patient has a defined pathological condition of the nervous, musculoskeletal, or vascular system; and
- f. Patient does not have any untreated, existing drug habituation problems; and
- g. Patient should have a life expectancy of more than 1 year, except if done for ischemic or palliative purposes and then life expectancy should be more than 6 months.

B. Dorsal Root Ganglion (DRG) Stimulation

1. Select Health considers DRG stimulators (e.g., Axiom Neurostimulator System) medically necessary for moderate-to-severe chronic intractable pain of the lower limbs in persons with complex regional pain syndrome (CRPS) types I and II, when criteria for placement of trial spinal cord stimulators are met (see above).

2. Select Health considers DRG stimulators experimental and investigational for all other indications (e.g., treatment of chronic pelvic pain (meralgia paresthetica), failed back surgery syndrome, and peripheral neuropathy).

C. Criteria for placement of either a SCS or a DRG permanent stimulator:

- a. Patient experienced a 50% reduction in pain with a minimum 4-day trial of percutaneous spinal stimulation.

D. Eligible Disorders for Spinal Cord Stimulator (Diagnoses):

1. Adult patients seeking treatment for neuropathic pain with diagnoses, such as failed neck or back surgery syndrome (FBSS) with radicular symptoms, complex regional pain syndrome (CRPS) type I of the upper or lower extremity, diabetic peripheral neuropathy (DPN) of the lower extremities, and chronic intractable pain of the trunk and/or limbs.
2. Incomplete spinal cord injury with segmental pain confined to the level of the spinal cord injury.
3. End-stage peripheral vascular disease which is inoperable leading to severe refractory pain.
4. Member has angiographically documented severe coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting or percutaneous transluminal coronary angioplasty and is resistant to medical therapy.

E. Exclusion criteria for the use of SCS in treating intractable angina pectoris include ANY of the following:

1. Myocardial infarction in the previous 3 months, or
2. Significant valve abnormalities as demonstrated by echocardiography, or
3. Vasospastic angina, or
4. Other cardiac diseases, or
5. Somatic disorders of the spine leading to insurmountable technical problems in treatment with SCS.

F. Spinal cord stimulation is considered investigational for any other diagnosis or condition not listed above including, but not limited to, the following:

1. Cauda equina syndrome/injury
2. Occipital neuralgia
3. Post-herpetic neuralgia
4. Pain due to cervical or lumbosacral root avulsion and/or syringomyelia
5. Primary bone and joint disease
6. Brachial or Lumbosacral Plexopathy

Spinal Cord/Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain, continued

G. Contraindications to the use of spinal cord stimulation include the following:

1. Gangrene
2. Axial pain exceeding radicular pain in the upper or lower extremity
3. Axial, somatic nociceptive pain
4. Patient fails screening
5. Patient adverse to electrical stimulation
6. Patient adverse to an implant as a modality of treating pain
7. Uncontrolled coagulopathy at time of procedure
8. Coagulopathy which cannot be reversed due to a medical condition
9. Localized or disseminated infection at time of planned implantation
10. Physicians lack experience or training in implanting stimulator devices
11. Patient has "demand" cardiac pacemaker or other
12. Pregnancy
13. Patient needs magnetic resonance imaging in the foreseeable future
14. Untreated and unresolved alcohol and drug habituation
15. Absence of an objectively documented cause for the pain

H. Removal/Revision of Implanted Spinal Cord Stimulator

Neurostimulator electrodes sometimes migrate or move from the area that needs stimulation. This may result in the need for a revision. The electrodes may need to be removed if the patient is unable to tolerate them, the modality becomes ineffective, or the leads and/or pulse generator become infected (HCFA).

1. Indications:

- a. Failure of equipment
- b. Loss of effectiveness
- c. Intolerance by patient
- d. Infection

2. Limitations:

To be eligible for this service, the leads must have been implanted in accordance with the plan's coverage indications for insertion of the device (above). Any exception to this requirement would be made through individual consideration with a special report explaining why there is no documentation of pre-operative work-up.

Select Health does NOT cover burst frequency or position-adaptive SCS as these are considered experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Spinal Cord/Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain, continued

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Although SCS has been in clinical use for 30 years, there remains a distinct void of high quality randomized, controlled, and blinded studies on SCS. Consequently, it is difficult to determine magnitude or likelihood of benefits or risks for all or any of the many pain indications for which it is used. Thus, it is difficult to state with confidence which patient populations are most likely to benefit, for how long, and equally difficult to state how SCS compares to treatment alternatives. It has been demonstrated by two authors that SCS is cost-effective.

Hayes rated SCS as a 'B' for 3 different indications; other systematic reviews have been less generous.

While much controversy remains about the specifics of the effectiveness of SCS, and its alternatives, there seems to be near consensus in the medical community that SCS provides substantial benefit to an assortment of patients with chronic pain involving the spinal cord:

"It is well to remember that with the exception of one or two neurosurgical procedures, almost none of the operations that we neurosurgeons perform daily have been subjected to the type of scrutiny suggested by Turner et al. for the SCS procedure. Although virtually all of the reported data thus far consist of both retrospective and prospective case series, I think that the data on SCS currently in the neurosurgical literature far exceed the vast majority of follow-up information available for most other neurosurgical operations."

Studies that provide support for specific trial duration typically cite Kemler's 2000 study of SCS in chronic reflex sympathetic dystrophy patients or Burchiel's trial in patients with back and extremity pain. Most studies do not provide any literature support for the trial duration, however, and their rationale behind these trial periods is unknown. Kemler and Burchiel's trial durations do not appear to be based on any empirical data. In Burchiel et al.'s 1996 multi-site study, trial periods were from 2–5 or 5–7 days, depending on the site. Because the duration of test stimulation was not controlled, they could not assess the impact of duration on outcomes. The authors noted diverging opinions about the benefits of extended trial periods before permanent implantation with extended, home-based screening vs. shorter inpatient monitoring of pain being advocated by various individuals. They did not provide any citations for these opinions. In Kemler et al.'s study of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy, patients were permanently implanted if they experienced at least a 50% reduction in pain during a 7-day trial period. Again, no rationale was offered for this 7-day duration.

Forouzanfar et al. used a 7-day trial period in complex regional pain syndrome patients and Kumar used a 3–7-day trial for patients of varying pain etiologies. In a 1996 study by Rainov et al., 32 patients with failed back syndrome underwent test stimulation lasting between 24 and 72 hours. Twenty-nine patients underwent permanent implantation and 25 of these patients reported continued analgesia 2–3.5 years later. Four patients reported decreased analgesia over the follow-up period. The authors concluded that if patients are carefully selected according to well-defined criteria, test stimulation periods can be kept relatively short, thus, reducing therapeutic failures, risk of infection, and costs of therapy. Thus, this literature supports use of an initial period of test stimulation in selecting patients for permanent implantation and to improve pain outcomes.

In a 1990 review of SCS, Meyerson stated that a trial period lasting at least 1 week before permanent implantation is extremely important. He noted that after the technique of percutaneous trial stimulation came into use, the short-term success rate generally increased to 80%, and the long-term rate to about 50% or more. However, he did not provide any rationale for duration. He further stated that patients are only encouraged to use the device during the trial period when pain is severe and that 20–30 minutes of stimulation are generally sufficient to produce 2–4 hours of pain relief.

Spinal Cord/Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain, continued

Linderoth et al. discussed trial stimulation in Wall and Melzack's Textbook of Pain. The authors note that test stimulation of the spinal cord, either via temporary electrodes or via a temporary, percutaneous connection with potentially permanent electrodes, has considerable intuitive appeal. It has become widely adopted, is strongly advocated by many practitioners and is a prerequisite for reimbursement in some countries. However, data on the predictive value of trial stimulation for long-term outcome are conflicting, and it is to date not possible to give any general recommendation as to whether to deploy this strategy for selecting patients for permanent implantation of the device.

While it is true that there is no empirical research supporting any trial stimulation duration, the need for test stimulation seems evident by consistent evidence in the literature that some patients do not experience analgesia during the test period. Note that some studies allowed a few days to elapse before beginning to measure analgesia during test stimulation, presumably, to allow patients time to recover from the procedure and to resume a more routine activity level. In one study, Urban reported that over 50% of patients with intractable pain did not respond to trial stimulation. Of the patients in Burchiel et al.'s study on chronic back pain, 17% did not experience pain relief during test stimulation nor did 33% of the patients in Kemler's study on reflex sympathetic dystrophy. Twenty percent of diabetic neuropathy patients in Tesfaye et al.'s study did not respond during a 2-day test stimulation period. In Rainov et al., 10% of patients did not experience analgesia during test stimulation. Kim et al. reported a 39% non-response rate in their study of limb and neuropathic pain. Eighteen percent did not experience pain relief during a 7-day trial in De La Porte's study of failed back syndrome. In Kumar et al., 20% of patients did not experience satisfactory initial pain relief. Turner et al.'s review of 4 studies found a mean nonresponse rate of 28% after a period of test stimulation. By providing test stimulation in these patients, the cost and risk of permanent implantation were avoided in some patients and the probability of long-term success may be increased.

A 2009 literature review identified a review by Jeon and Hun supporting spinal cord stimulation as a common indication for use. They concluded that this technique has proven to be cost-effective in the long-term despite its high initial cost.

A May 2011 literature review did not identify any new information.

High Frequency Neurostimulation

The evidence for high-frequency SCS in individuals who have treatment-refractory chronic pain of the trunk or limbs includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency to standard stimulation found a large and statistically significant benefit associated with high-frequency SCS. In contrast, a smaller study found no benefit for those receiving high-frequency stimulation compared with sham control. Given the uncertainty in these findings, additional trials are needed to corroborate the benefit of high-frequency stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

63650	Percutaneous implantation of neurostimulator electrode; epidural
63655	Laminectomy for implantation of neurostimulator electrode plate/ paddle, epidural
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e. cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

Spinal Cord/Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain, continued

95971	; simple spinal cord, or peripheral (i.e. peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	; complex spinal cord, or peripheral ((ie peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS CODES

C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

Spinal Cord/Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain, continued

- L8688** Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
- L8689** External recharging system for implanted neurostimulator, replacement only

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TOPICAL OR PARTIAL (LOW PRESSURE) OXYGEN THERAPY

Policy # 202

Implementation Date: 11/18/03

Review Dates: 11/18/04, 11/9/05, 10/19/06, 12/20/07, 12/18/08, 12/19/09, 10/13/11, 2/16/12, 4/25/12, 10/23/14, 10/15/15, 10/20/16, 12/21/17, 10/15/18, 10/7/19, 10/14/20, 1/17/22, 2/16/23

Revision Dates: 10/21/10

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Low pressure oxygen therapy refers to the use of oxygen at one atmosphere or less pressure. The oxygen is applied topically to wounds beneath a canopy. When applied topically, the technique may be referred to as topical oxygen therapy. Low pressure oxygen therapy or topical oxygen therapy is separate and distinct from systemic hyperbaric oxygen therapy in which the individual is entirely enclosed in a pressure chamber and breathing oxygen at a pressure of at least 1.4 atmospheres absolute (atm abs). Topical oxygen therapy can be delivered by the patient in the home.

For topical oxygen therapy, a disposable appliance is positioned around the wound area. Conventional oxygen tanks, typically gas, are used to supply the oxygen. Topical oxygen may be performed in the office, clinic, or self-administered by the patient in the home. Typically, the therapy is offered for 90 minutes per day for 4 consecutive days. After a 3-day break, the cycle is repeated. The regimen may last for 8–10 weeks.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover topical or low-pressure oxygen therapy. This therapy meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

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Topical or Partial (Low Pressure) Oxygen Therapy, continued

Summary of Medical Information

There is insufficient scientific evidence to isolate and validate the contribution of low-pressure oxygen therapy or topical oxygen therapy to an overall program of wound care. Due to their different methods of delivery, topical and systemic hyperbaric oxygen are distinct technologies. The outcomes associated with systemic hyperbaric oxygen therapy cannot be extrapolated to topical therapy. However, there is minimal published literature regarding topical hyperbaric oxygen therapy.

In 1984, Heng et al. published a controlled study of topical hyperbaric oxygen therapy in 6 patients with 27 ulcers compared to no treatment in 5 patients with 10 ulcers. Although a greater improvement was noted in the treated group, the results were calculated according to the number of ulcers rather than based on individual patients. A follow-up of this same study was published in 2000. Thirteen patients were randomized to the topical hyperbaric oxygen group and 27 were randomized to the control group. Results were again calculated according to number of ulcers rather than based on individual patients. This method of reporting, plus the increase in number of patients assigned to the control group, makes it difficult to interpret and to draw conclusions concerning effectiveness. Leslie et al. reported on a trial that randomized 18 patients with diabetic foot ulcers to receive either topical hyperbaric oxygen therapy plus standard wound care, or standard wound care alone. Changes in ulcer size and depth did not differ between the two groups.

An updated search of the literature conducted in 2003 on topical hyperbaric oxygen therapy revealed additional articles consisting of anecdotal reports and uncontrolled case series. No articles in the published medical literature were identified that addressed the limitations noted above for topical hyperbaric oxygen. Specifically, no controlled studies were identified.

Topical hyperbaric oxygen therapy administered to the open wound in small limb-encasing devices does not meet the definition of systemic HBO₂ therapy and its efficacy has not been established due to the lack of controlled clinical trials. In addition, *in vitro* evidence suggests that topical hyperbaric oxygen does not increase tissue oxygen tension beyond the superficial dermis. Examples of topical hyperbaric oxygen therapy devices are TOPOX portable hyperbaric oxygen extremity and sacral chambers (Jersey City, NJ), Oxyboot and Oxyhealer from GWR Medical, L.L.P. (Chadds Ford, PA).

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

Not covered when billed with topical therapy

99183 Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

HCPCS CODES

E0446 Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

Key References

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Topical or Partial (Low Pressure) Oxygen Therapy, continued

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**TRANSCUTANEOUS ELECTRICAL MODULATION
PAIN REPROCESSING (TEMPR)
[CALMARE/CALMAR
OR “SCRAMBLER THERAPY”]**

Policy # 503

Implementation Date: 4/11/12

Review Dates: 6/20/13, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/2/19, 2/17/20, 2/16/21, 1/18/22, 2/16/23, 2/15/24

Revision Dates: 4/15/20

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the “Policy” section for more information.

Description

Chronic pain is among the most common reasons for seeking medical attention and is reported by 20%– 50% of patients seen in primary care. It is traditional to distinguish between malignant (related to cancer and its treatment) and nonmalignant (e.g., neuropathic, musculoskeletal, inflammatory) chronic pain. Nonmalignant chronic pain is frequently further classified into inflammatory (e.g., arthritic), musculoskeletal (e.g., low back pain), headaches, and neuropathic pain (e.g., postherpetic neuralgia, phantom pain, complex regional pain syndrome [CRPS], diabetic neuropathy, human immunodeficiency virus–associated neuropathy). The chief symptoms of neuropathic pain include spontaneous lancinating, shooting or burning pain, hyperalgesia, and allodynia, or any combination of such pain.

Treatment options for chronic pain generally fall into 6 major categories: pharmacologic, physical medicine, behavioral medicine, neuromodulation, interventional, and surgical approaches. A neuromodulation device, transcutaneous electrical modulation pain reprocessing (TEMPR), also called “scrambler therapy,” is intended to interrupt transmission of pain signals by delivering electrical stimulation that is interpreted by the nervous system as “no pain.” Cutaneous nerves are stimulated using 5 surface electrode pairs (i.e., channels) that are placed in the dermatomes (an area of skin that is mainly supplied by a single spinal nerve) above and below the pain area. Unlike conventional TENS, scrambler therapy is administered in the office setting under physician supervision. The manufacturer of this device, Competitive Technologies, Inc., received FDA approval of the Calmare Pain Therapy device under the name Scrambler Therapy MC-5A TENS Device in 2009.

The Calmare treatment protocol for mixed or neuropathic pain consists of 10–12 consecutive treatments, lasting 30–60 minutes each, once a day for 5 days a week. The treatment protocol for oncologic pain consists of an initial treatment program consisting of 10–12 consecutive treatments of 45 minutes, once a day, and every time the pain reappears. The maximum benefit is achieved through follow-up treatments. The patient may be able to go for extended periods of time between subsequent treatments while experiencing significant pain control and relief. The period between treatments depends on the underlying cause and severity of the pain in addition to other factors.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN’S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover transcutaneous electrical modulation pain reprocessing (TEMPR), or “scrambler therapy,” including, but not limited to the Calmare or Calmar devices, for



Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) [Calmare®/Calmar™ or “Scrambler Therapy”], continued

any indication. Current evidence is inadequate to determine the efficacy, safety, durability, or appropriate therapeutic protocols for transcutaneous electrical modulation pain reprocessing.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

A Medical Technology Review performed in March 2012 did not identify any systematic reviews related to transcutaneous electrical modulation pain reprocessing (TEMPR), or “scrambler therapy.” The review only identified 5 peer-reviewed primary literature articles. It is important to note that 3 of the 5 papers were authored by Giuseppe Marineo, the inventor of the Calmare device.

In addition to the limitations in the number of studies on this technology, several other issues are present in the literature which makes it difficult to reach strong conclusions regarding the efficacy and safety of TEMPR in clinical practice. In Marineo et al.’s 2003 study, participants were not randomized, no comparative outcomes were reported with respect to other pain-alleviating therapies, and the administrators were not blinded. No data is given to substantiate the author’s claim that the remainder of the patients still taking analgesics at the end of the scrambler therapy, “... considerably reduced the dosage taken.” Though the study design in a second study by Marineo et al., published in 2012, was much better, Calmare therapy was compared to drug management rather than the more likely alternative therapy of TENS or interferential therapy. Even with this comparison of Calmare to guideline-based drug management, the continual reduction in pain was only observed in the first 2 months. After 2 months of treatment with the Calmare therapy, pain scores began to rise. As there is no data beyond 3 months, no conclusions can be made as to the durability of treatment.

In conclusion, no studies were identified that compared Calmare to TENS or interferential treatment for the alleviation of pain. There are no studies comparing Calmare to sham treatment. Most of the research involves small patient populations for short duration (e.g., Smith et al. only followed patients for 10 days.). There is very little scientifically rigorous evidence demonstrating the safety and efficacy of Calmare therapy for the relief of pain.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

(Not covered if associated with Scrambler/Calmare)

- | | |
|--------------|--|
| 97014 | Application of a modality to 1 or more areas; electrical stimulation (unattended) |
| 97032 | Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes |

HCPCS CODES

- | | |
|--------------|---|
| 0278T | Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy), each treatment session (includes placement of electrodes) |
|--------------|---|

Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) [Calmare®/Calmar™ or “Scrambler Therapy”], continued

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Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) [Calmare®/Calmar™ or “Scrambler Therapy”], continued

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