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MEDICAL POLICY

CHIROPRACTIC SERVICES FOR CHILDREN

Policy # 584

Implementation Date: 5/9/16 Review Dates: 7/25/18, 7/8/19, 8/17/20, 8/16/21, 7/12/22, 8/24/23 Revision Dates: 6/15/17, 3/6/20, 9/8/21, 11/19/21, 6/16/22, 7/21/22, 10/4/23

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.

The most common therapeutic procedure performed by chiropractic doctors is known as "spinal manipulation," also called "chiropractic adjustment." The purpose of spinal 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 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. 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.

A. Criteria for Utah/Idaho/Nevada Large Employer plans and Utah Small Employer plans

Select Health covers chiropractic care for children ages 13 to 18.

For children ages 9 to 12, chiropractic care is allowed when the following criteria are met:

- 1. The child has a neuromusculoskeletal disorder causing significant and persistent disability; <u>and</u>
- 2. Other conservative therapies (e.g., stretching, heat or ice, over-the-counter pain relievers) have been tried and have failed to relieve the symptoms.
- B. Exclusions

Select Health does not provide chiropractic benefits in the following circumstances:

a. Chiropractic appliances;

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- b. Services for treatment of non-neuromusculoskeletal disorders;
- c. Professional radiology services (reading of an X-ray); and
- d. **Services for children ages 8 and under***; there is a lack of evidence affirming efficacy or safety for this age group as established in medical literature; this meet's the plan's definition of experimental/investigational.

*This age restriction does not apply to Idaho/Nevada Small Employer and Idaho/Nevada Individual ACA plans [this also applies to corresponding Colorado plans, effective Jan. 1, 2024], which do not have age restrictions for chiropractic care. <u>All other coverage criteria apply to these plans.</u>

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 <u>http://health.utah.gov/medicaid/manuals/directory.php</u> or the <u>Utah Medicaid code Look-Up</u> tool

Summary of Medical Information

Current evidence related to the safety and efficacy of chiropractic care in children and adolescents is limited and weak. This fact was acknowledged in the consensus guidelines published and funded by the Foundation for Chiropractic Education and Research, and authored by Hawk et al., in 2009. In this article which relates "best care," based on a Delphi approach of consensus, it is stated: "A 2008 systematic review on chiropractic manipulation for children's health problems concluded that "the evidence rests primarily with clinical experience, descriptive case studies, and very few observational and experimental studies." This guideline acknowledges the weakness of clinical evidence, in noting one of the limitations to their conclusions relates to the consensus process itself, which represents chiefly expert opinion, which is a less convincing level of evidence than that provided by large-scale experimental studies, and it goes on to state: "It is essential that rigorous observational and experimental studies be implemented to provide a more substantial body of evidence to inform future clinical guidelines."

A 1998 study by Balon et al., is an example of the lack of good evidence to support chiropractic care in a pediatric population. This study compared active to simulated chiropractic manipulation in children with asthma who were also receiving concomitant pharmacologic intervention. The primary outcome variable was improvement in morning peak flow after 2 and 4 months of chiropractic treatment. Multiple secondary variables included FEV1, methacholine sensitivity (PC20), symptom diary scores, rescue medication use, and quality of life questionnaires; patients were randomized to receive sham versus active manipulation. The patients and data managers were blinded but the chiropractors were not. Children 7 to 16 years of age with physician-diagnosed asthma were recruited, and inclusion required vertebral subluxation as determined by chiropractic screening. Of 199 subjects screened, 91 were eligible completed the 4-month study period: 38 received active chiropractic treatments and 42 received simulated chiropractic treatments. Both groups experienced minimal increases in peak flow and decreases in symptom scores and rescue beta-agonist use. There was no difference between groups in peak flow, FEV1, PC20, symptoms, rescue beta agonist use, oral steroid use, or quality of life measures. The authors postulated that the observed improvements were due to increased compliance and frequent professional attention during the study. No adverse side effects were noted. This study failed to identify a benefit of chiropractic manipulation for childhood asthma.

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Finally, a systematic review published in 2009 by Gotlib and Rupert substantiated the lack of high-quality evidence to support pediatric chiropractic care. The authors noted the health claims made by chiropractors with respect to the application of manipulation as a healthcare intervention for pediatric health conditions continue to be supported by only low levels of scientific evidence. Chiropractors continue to treat a wide variety of pediatric health conditions. The evidence rests primarily with clinical experience, descriptive case studies, and very few observational and experimental studies. The health interests of pediatric patients would be advanced if more rigorous scientific inquiry was undertaken to examine the value of manipulative therapy in the treatment of pediatric conditions.

Billing/Coding Information

CPT 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

- **97140** Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
- **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 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.
- 97010 Application of a modality to 1 or more areas; hot or cold packs

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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)	
97016	Application of a modality to 1 or more areas; vasopneumatic devices	
97018	Application of a modality to 1 or more areas; paraffin bath	
97022	Application of a modality to 1 or more areas; whirlpool	
97024	Application of a modality to 1 or more areas; diathermy (eg, microwave)	
97026	Application of a modality to 1 or more areas; infrared	
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	
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes	
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes	
97036	Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes	
97039	Unlisted modality (specify type and time if constant attendance)	
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	
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	
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises	
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)	
97139	Unlisted therapeutic procedure (specify)	
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes	
97150	Therapeutic procedure(s), group (2 or more individuals)	
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	

- S3900 Surface electromyography (EMG)
- S9131 Physical therapy; in the home, per diem

setting, each 15 minutes

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HYPOTHERMIA FOR TREATMENT OF NEONATAL HYPOXIC-ISCHEMIC ENCEPHALOPATHY

Policy #536

Implementation Date: 8/12/13 Review Dates: 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/25/18, 6/19/19, 6/18/20, 6/17/21, 5/19/22, 6/15/23 Revision Dates:

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Description

Neonatal encephalopathy is a heterogeneous syndrome characterized by symptoms of central nervous system dysfunction in newborns born at term or late preterm (\geq 36 weeks gestation). An infant with neonatal encephalopathy may exhibit abnormal levels of consciousness, seizures, tone and reflex abnormalities, apnea, and feeding difficulties. Birth asphyxia and hypoxic-ischemic (anoxic) encephalopathy (HIE) are responsible for some, but not all cases of neonatal encephalopathy.

Supportive therapy with use of intravenous fluids, close monitoring in the neonatal ICU, oxygen therapy, and treatment of complicating conditions such as seizures have been the standard of care in managing patients with HIE.

Hypothermia has been proposed as a method for reducing the combined outcome of death or long-term neurodevelopmental disability at 18 months in term infants. Clinical trials have found similar effects, using either selective head cooling with mild systemic hypothermia or total body cooling, on death and disability; however, there are no randomized trials comparing head and body cooling. Selective head cooling with mild systemic hypothermia or total body cooling. Selective head cooling with mild systemic hypothermia can be achieved with cooling caps fitted around the infant's head, with the aim of maintaining fontanelle temperature below 30°C. The speed of rewarming is controversial and varies between increasing rectal temperatures by 0.5°C every hour to every four hours. The consensus is that rewarming should be slow. Most centers rewarm infants by 0.5°C every two hours. A rectal temperature of 34±0.5°C is maintained with a servo-controlled radiant heater. Hypothermia should be applied within six hours of birth, and continued hypothermia for 72 hours.

Besides cooling blankets, one specific device has been FDA approved for use in the treatment of HIE. The **Olympic Cool-Cap system** (manufactured by Olympic Medical Corporation, a subsidiary of Natus Medical Incorporated of San Carlos, CA.) is a helmet designed to provide hypothermia therapy. The device works by a steady flow of water at a selected temperature through a cap covering the infant's head to cool the brain.

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

Select Health covers hypothermia for treatment of neonatal hypoxic-ischemic encephalopathy as a proven therapy.

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,

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Hypothermia for Treatment of Neonatal Hypoxicischemic Encephalopathy, continued

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-guicksearch.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

Six systematic reviews and 15 peer-reviewed primary studies were reviewed in determining this policy. Excluding the patients from Jacobs et al., given that the article was commentary on the Shankaran et al. studies, outcomes of 1,958 patients were reported; most of the studies were prospective and randomized.

Overall, the systematic reviews favored the use of hypothermia in neonates who were under six hours old, and who have moderate-to-severe encephalopathy-with the World Health Organization (WHO) particularly noting the number needed to treat (NNT) to see benefit was seven. The single systematic review which did not demonstrate a mortality and/or neurodevelopment benefit was the paper by Pauliah et al., which focused on the benefit of this therapy to patients in low-/middle-income countries.

The primary literature also supports the benefit of this hypothermia therapy on improvement in survival and neurodevelopmental outcomes at 18. It is also shown to improve primary patient outcomes in all the rest of the literature cited in the primary literature section of this report; if not for every endpoint, at least in improved survival, neurological disability, and normal brain MRIs.

Weaknesses identified in the literature include a lack of direct comparisons between selective head cooling and whole-body cooling, though separate studies suggest similar safety and effectiveness, longer duration data beyond 18 to 24 months, and the lack of evidence in infants born before 36 weeks gestational age.

Overall, the current published literature has demonstrated efficacy and safety for hypothermia therapy in the treatment of full-term neonates with hypoxic-ischemic encephalopathy (Grade 1A).

Billing/Coding Information

CPT CODES

99184 Initiation of selective head or total body hypothermia in the critically ill neonate, includes appropriate patient selection by review of clinical, imaging and laboratory data, confirmation of esophageal temperature probe location, evaluation of amplitude EEG, supervision of controlled hypothermia, and assessment of patient tolerance of cooling

HCPCS CODES

No specific codes identified

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Hypothermia for Treatment of Neonatal Hypoxicischemic Encephalopathy, continued

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Hypothermia for Treatment of Neonatal Hypoxicischemic Encephalopathy, continued

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MEDICAL POLICY

INHALED NITRIC OXIDE (INO) THERAPY

Policy#663

Implementation Date: 6/8/23 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

Nitric oxide (NO) is a lipophilic gas that is readily absorbed across pulmonary membranes in the ventilated lung after inhalation. iNO therapy increases the partial pressure of arterial oxygen by dilating pulmonary vessels in better ventilated areas of the lung, redistributing pulmonary blood flow away from lung regions with low ventilation/perfusion ratios toward regions with normal ratios.

Respiratory distress syndrome (RDS) is one of the most common causes of preterm infant respiratory failure and mortality. RDS results from developmental immaturity of the lungs, which leads to insufficient surfactant production and function. Bronchopulmonary dysplasia (BPD) is a long-term pulmonary complication of RDS in preterm newborns and is associated with prolonged hospitalization and lasting pulmonary and neurodevelopmental problems.

A high-quality, consistent body of evidence indicates that early rescue use iNO within the first 3 days of life does not increase survival, decrease pulmonary morbidity, or improve neurodevelopmental outcomes in preterm infants < 35 weeks gestation who require respiratory support. Similarly, 2 moderate-quality, consistent bodies of evidence assessing later treatment (after 3 days of life) in preterm infants at increased risk of BPD and routine treatment in preterm infants requiring respiratory support suggest no benefit of iNO regimens for survival, pulmonary morbidity, or improved neurodevelopmental outcomes.

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 considers inhaled nitric oxide (iNO) proven and medically necessary for the following:

A. Treating newborns with persistent pulmonary hypertension of the newborn (PPHN), with hypoxic respiratory failure or echocardiographic evidence, with the following:

1. Failure of conventional treatments (e.g., mechanical ventilation) with severe hypoxic respiratory failure refractory to conventional therapies with clinical or echocardiographic evidence of pulmonary hypertension; or

B. In the postoperative management of pulmonary hypertension associated with heart or lung surgery in infants, iNO is a clinically accepted option and will be covered as bridge therapy during the acute recovery phase; or

C. The diagnostic use of INO is considered medically necessary as a method of assessing pulmonary vaso-reactivity in persons with pulmonary hypertension.



Inhaled Nitric Oxide (INO) Therapy, continued

<u>Note:</u> INO therapy is considered medically necessary for no longer than 14 days if the oxygen desaturation has been resolved. Medical director review required for use beyond 14 days.

Select Health considers INO therapy experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

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 <u>http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&</u> 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 <a href="http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http://health.utah.gov/medicaid-http

Billing/Coding Information

CPT CODES

- 94002 Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day
- 94003 Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day
- 94004 Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day
- **94005** Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (eg, assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more
- **93463** Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (List separately in addition to code for primary procedure)
- **99503** Home visit for respiratory therapy care (e.g., bronchodilator, oxygen therapy, respiratory assessment, apnea evaluation)

Key References

- Boly, T. J., et al. Response categorization and outcomes in extremely premature infants born at 22-26 weeks gestation that received inhaled nitric oxide for hypoxic respiratory failure. *J Perinatol.* 2023 March; 43(3): 324–331. doi:10.1038/s41372-022-01582-4
- 2. Hayes, Inc. Health Technology Assessment. Inhaled Nitric Oxide for the Treatment of Respiratory Failure in Preterm Newborns. Dec. 14, 2021.
- 3. Lakshminrusimha, S. Just Say No to iNO in Preterms--Really? The Journal of Pediatrics. 2020 March; 218: 243–252.

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Inhaled Nitric Oxide (INO) Therapy, continued

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MEDICAL POLICY

PROGRESSIVE ADOLESCENT IDIOPATHIC SCOLIOSIS

Policy#662

Implementation Date: 6/8/23 Review Dates: Revision Dates:

Disclaimer:

- . 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

Scoliosis is a musculoskeletal disorder characterized by abnormal lateral curvature of the spine measuring more than 10 degrees in the coronal plane. The spinal curve may develop as a single curve (shaped like the letter C) or as 2 curves (shaped like the letter S). Adolescent Idiopathic Scoliosis (AIS) is by far the most common type of scoliosis, affecting children between ages 10 to 18; it is found in as many as 4 in 100 adolescents. In general, AIS curves progress during the rapid growth period of the patient. While most curves slow their progression significantly at the time of skeletal maturity, some, especially curves greater than 60°, continue to progress during adulthood. Many theories exist with regards to the cause of AIS, including hormonal imbalance, asymmetric growth, and muscle imbalance.

AIS is usually confirmed through a physical examination, an x-ray, spinal radiograph, computed tomography (CT) scan, or magnetic resonance imaging (MRI). Imaging tests take a closer look at the spine to determine whether there are any problems with the bones and to measure the curvature of the spine. The curve is measured in degrees commonly referred to as the Cobb angle. A positive diagnosis of scoliosis is made based on a coronal curvature measured on a posterior-anterior radiograph of > 10°. In general, a curve is considered significant if it is greater than 25° to 30°. Curves exceeding 45° to 50° are considered severe and often require more aggressive treatment.

The goal of treatment in AIS is to correct the spinal deformity while allowing for thoracic growth for optimal cardiopulmonary function. Treatment options include observation, bracing or casting, or surgery. The type of treatment chosen depends on several factors, including etiology, severity of the spinal curve, curve pattern, and remaining growth of the patient. Spinal fusion surgery is often recommended for individuals with severe scoliosis. However, if performed too early, fusion surgery can lead to arrested development, thoracic insufficiency syndrome (TIS), and loss of mobility over the fused section.

The ApiFix System is indicated for AIS patients with deformity classified as Lenke type 1 and 5 and a Cobb angle up to 60 degrees. Both major and secondary curves must be flexible, confirmed using Lateral Bending X-rays, to allow gradual correction over time. For patients with these indications, the surgical procedure is less invasive, compared to the traditional standard of care. The unilateral implant system is attached to the spine on the concave side of the major curve using only two to three screws. There is an insufficient quantity of published, peer-reviewed, human clinical data to evaluate the Minimally Invasive Deformity Correction (MID-C)/ApiFix System for adolescent idiopathic scoliosis in a health technology assessment.

Vertebral body tethering (VBT) is a fusionless surgical technique to modulate spine growth, provide spinal curve correction, and preserve spine mobility in skeletally immature patients with severe, progressive, idiopathic scoliosis who have failed or are intolerant to bracing. Placement of The Tether VBT system can

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Pediatric Adolescent Idiopathic Scoliosis, continued

be performed thoracoscopically, which is less invasive than the open surgical technique used for posterior spinal fusion (PSF) and prompts faster recovery.

The Tether (Zimmer Biomet Spine Inc.) is one of several spinal tethering systems currently available or in clinical trials and is the only anterior VBT system allowed for in use in the United State outside a clinical trial setting (H190005). The Tether is indicated for treatment of idiopathic scoliosis* in skeletally immature patients who have failed or are intolerant to bracing, have a major Cobb angle of 30° to 65°, and have adequate vertebral bone structure to support necessary screws.

VBT, a nonfusion technique first published in 2010 by Crawford and Lenke (in human patients; animal model studies published earlier), modulates spinal growth by using an internal mechanical restraint in the form of a flexible cord that is anchored by screws placed into several adjacent vertebrae. The cord applies a compressive force to the convex side of the anterior aspect of the spine, which slows growth of the concave side of the spine, allowing it to grow relatively more than the convex side, thus creating conditions for a straighter spine to develop over time. Procedures are performed under general anesthesia using a thoracoscopic or mini-open approach. There is a known learning curve for surgeons new to this surgical technique that may affect operative time (including time patient spends intubated and under anesthesia), estimated blood loss for the patient, and hospital length of stay. VBT may also be referred to as dynamic spinal stabilization, soft stabilization, dynamic growth modulation, fusionless anterior scoliosis correction, or spine ligamentoplasty. VBT is not the same procedure as vertebral body stapling.

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

Select Health does not cover posterior dynamic deformity correction devices (e.g., MID-C/ApiFix System) for the treatment of progressive adolescent idiopathic scoliosis. There is insufficient clinical data available to support improved outcomes or long-term safety; therefore, this meet's the plan's definition of experimental/investigational.

Select Health does not cover anterior vertebral body tethering (e.g., Zimmer Biomet/The Tether) for the treatment of progressive adolescent idiopathic scoliosis. There is insufficient clinical data available to support improved outcomes or long-term safety; therefore, this meet's 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 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-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 http://health.utah.gov/medicaid/manuals/directory.php or the http://health.utah.gov/medicaid/manuals/directory.php or the http://health.utah.gov/medicaid/manuals/directory.php or the http://health.utah.gov/medicaid/

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Pediatric Adolescent Idiopathic Scoliosis, continued

Billing/Coding Information

Not covered for the indications listed above

CPT CODES

- 0656T Vertebral body tethering, anterior; up to 7 vertebral segments
- 0657T Vertebral body tethering, anterior; 8 or more vertebral segments
- 20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only
- 20931 Allograft, structural, for spine surgery only
- 20936 Autograft for spine surgery only; local
- 20937 Autograft for spine surgery only; morselized (through separate skin or fascial incision)
- 20938 Autograft for spine surgery only; structural bicortical or tricortical (through separate skin or fascial incision)
- **22612** Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
- **22800** Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments (levels)
- +22840 Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)
- +22842 Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments
- +22843 Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments
- 22899 Unlisted procedure, spine [when specified as vertebral body stapling or implantation of a posterior (dynamic) distraction device]

Key References

- 1. Hayes, Inc. Minimally Invasive Deformity Correction System (ApiFix) for Adolescent Idiopathic Scoliosis. Evidence Analysis Research Brief. Nov. 20, 2020.
- 2. Hayes, Inc. The Tether (Zimmer Biomet) for Skeletally Immature Patients With Progressive Idiopathic Scoliosis. Evolving Evidence Review. Apr. 7, 2022.
- Hayes, Inc. Evidence Analysis Research Brief. ApiFix (ApiFix Ltd.) for Treatment of Adolescent Idiopathic Scoliosis. Dec. 11, 2023.

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