Select Health Medical Policies

General Surgery Policies

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MEDICAL POLICY

ATHLETIC PUBALGIA (SPORT'S HERNIA) REPAIR

Policy # 674
Implementation Date: 9/30/11
Review Dates: 11/29/12, 12/19/13, 12/18/14, 12/10/15, 5/22/16, 6/15/17, 6/21/18, 6/20/19, 6/18/20, 6/17/21, 5/4/22, 6/8/23
Revision Dates:

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Description

A sports hernia, also known as athletic pubalgia, Gilmore's groin, and slap shot gut is an uncommon but often missed cause of groin pain in high level athletes. It is poorly understood and poorly defined in the medical community. It is also very difficult to identify based on history and physical exam of an athlete with groin pain. The name sports hernia is a misnomer as well because there is no discernable hernia (or protrusion of abdominal cavity contents) present in this condition. Sports hernias may result from chronic, repetitive trauma or stress to the musculotendinous portions of the groin. They typically develop in an insidious fashion without sudden or dramatic pain. Symptoms typically come from overuse of the lower abdominal musculature and the muscles of the upper thigh.

Sports hernias are more common in men than in women and are more common with sports such as hockey, soccer, rugby, and football, in which the athlete bends or leans forward. However, virtually all sports can produce sports hernia because leaning or bending forward into the typical "athletic stance" is a common pose in any athletic endeavor. Additionally, high-speed twisting and turning and torquing the groin, likely contribute to the development of the condition.

Diagnosis of athletic pubalgia can be elusive but is established by history and physical examination. In a 2004 study by Susmallian et al., 35 professional soccer players underwent laparoscopic inguinal exploration and repair of sports hernias. This article suggests that with close enough examination, surgeons could typically find athletic pubalgia in most patients (97%). There is still neither consensus as to what exactly athletic pubalgia is nor how to treat it.

Treatment is initially conservative with rest, ice, nonsteroidal anti-inflammatory drugs, physical therapy, and fluoroscopically-guided injections. Once an adequate trial of conservative treatment fails, surgery is often considered.

Two surgeries are most performed in the treatment of a sports hernia. The first is a pelvic floor repair. In this procedure the inferolateral edge of the rectus abdominus muscle is reattached to the pubis and adjacent anterior ligaments. In the other, the patient undergoes an adductor release. In this procedure the anterior epimysial fibers of the adductor longus muscle are divided about 2 to 3 cm from pubic insertion; the muscle belly is left intact. This can be performed independently, or concomitantly, with pelvic floor repair—it is rarely successful independently.

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

Select Health does NOT cover athletic pubalgia (sport's hernia) repair due to ill-defined nature of the condition and lack of consensus as to the approach to treatment. 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

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Summary of Medical Information

A Medical Technology Assessment performed in September 2011 identified a systematic review from Hayes on surgery for treatment of athletic pubalgia in December of 2006. The technology brief concluded that although there appear to be benefits to performing surgery for the treatment of athletic pubalgia, the scarcity of randomized controlled trials is concerning. Hayes notes that the procedure appears to be safe and reasonably effective.

Since the Hayes review, nine peer-reviewed journal articles were identified concerning surgical treatment for athletic pubalgia. Of these, only one article (Paajanen et al.) was prospective and comparative. Given that the standard treatment for sport's hernia is conservative physiotherapy, it is concerning that no other article compared surgery to this standard of care. All the articles identified in this review reiterate that there is no one definition for what athletic pubalgia is. Likewise, there is no consensus for patient selection, postoperative rehabilitation duration, preoperative screening, or if preoperative therapy should be considered before being a candidate for surgery—none of the papers discussed revision surgery rates. With that said, it is evident that after conventional therapies have failed, surgery may be the only viable option for many patients.

A Hayes review completed in April 2016, noted that based on a low-quality body of evidence there is insufficient evidence to determine whether a laparoscopic or open surgical technique is superior to another. More rigorous studies are needed to establish the relative benefits and harms of different laparoscopic and open surgical procedures for this patient population; comparative evidence was limited to 5 observational studies and 2 RCTs.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

49659	Unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy
49999	Unlisted procedure, abdomen, peritoneum and omentum
49650	Laparoscopy, surgical, repair initial inguinal hernia

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

AUTOLOGOUS FAT TRANSFER (AFT) IN BREAST RECONSTRUCTION

Policy # 507

Implementation Date: 9/3/12
Review Dates: 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/25/18, 10/15/19, 10/15/20, 11/27/21, 9/15/22, 10/22/23
Revision Dates: 12/6/21, 11/7/23

Related Medical Policies:
#508 EVE Breast Systems

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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

After a patient has experienced a mastectomy, trauma, burn, or has been diagnosed with a disorder such as Poland Syndrome or amastia, they may seek reconstruction of the breast(s).

Various methods may be chosen to perform the breast reconstruction. There are 2 general types of reconstructive options: prosthetic devices (i.e., saline implants, silicone implants, tissue expanders) or autologous tissue reconstructions with tissue flaps that are transferred from adjoining or distant donor sites to the anterior chest wall.

An alternative method more recently being employed in select women is the use of autologous fat transfer (AFT) to create a reconstructed breast from a person's own fat transferred from another location in the body. In most cases, AFT is accomplished by lipoinjection of autologous adipose tissue directly into breast tissue. Lipoinjection is performed in 1−3 stages, as needed. The amount of fat injected per operation per breast ranges from 1.5−2.5 cc for nipple reconstruction and 30−460 cc for augmentation and correction of defects. The fat is typically harvested from the abdomen, hip, and inner thigh.

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 autologous fat transfer (AFT) in conjunction with covered breast reconstructions for the indications listed below. Current evidence demonstrates autologous fat transfer to be a safe, effective, and durable therapy used in breast reconstructions.

Covered indications:

- Surgical correction due to a medically necessary mastectomy or a medically necessary lumpectomy that results in a significant deformity;
- Repair of breast significant/obvious asymmetry directly related to trauma (deformity/asymmetry must be apparent after the trauma/injury).
- AFT is also indicated in breast augmentation for patients who have been treated for contralateral breast cancer and are seeking a symmetry procedure. AFT offers the ability to perform smaller volume breast augmentation with a broader distribution of volume than breast implants can

Select Health does NOT cover autologous fat transfer (AFT) for any other indication for the breast. These procedures are considered cosmetic, and therefore, are not covered.

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

A Medical Technology Assessment performed in August 2012 identified 5 systematic reviews and 8 peer-reviewed journal articles regarding autologous fat transfer (AFT). Within the peer-reviewed articles alone, 1,194 patients received AFT and were followed for an average of 15.5 months post-surgery. The average reported complication rate was 9.6% where the most common complications were fat necrosis/oily cysts, cellulitis, ecchymosis, striae, and infection.

Of the 5 systematic reviews, Hayes and The National Institute for Clinical Excellence (NICE, UK) reported the most favorable data as it pertained to patient and physician satisfaction with AFT, breast size and shape postoperatively, long-term breast symmetry, low rates of oily cysts and fat necrosis, and lack of interference as a result of the procedure with imaging of the breast for future cancer surveillance. The older Australian and New Zealand Horizon Scanning Network (ANZHSN) from 2008 reported more issues than did Hayes and NICE regarding the technique for fat transfer and durability of improvement in the long-term. Regarding fat grafting to the breast, there are no reports suggesting an increased risk of malignancy associated with fat grafting. It could be that harvesting techniques and the approach to the procedure have changed enough that outcomes have also changed.

A couple of the primary studies showed results pertinent to the durability and safety questions related to ATF. In the first by de Blacam et al., from 2011, 49 patients (68 breasts) received AFT after breast reconstruction. After a 2−4-year follow-up, the group concluded that fat transfer was safe and that it significantly improved aesthetics. The Illouz et al. study, though retrospective, analyzed patients who received AFT to the breast over a 25-year period (1983−2007). This study noted that the results of the procedure have been predictable and satisfying.

In conclusion, autologous fat transfer after mastectomy, partial mastectomy, or breast reconstruction surgery appears to be safe and efficacious in most cases. Patient and physician satisfaction scores with AFT are high. The complication rate ranged from 2%−20%, as noted by Hayes, though the mean complication rate is 7.3%. As there have been no cost-effective studies performed, it is difficult to ascertain, by the literature alone, if AFT is more economically efficient.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

19499	Unlisted procedure, breast

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Autologous Fat Transfer (AFT) In Breast Reconstruction, continued

HCPCS CODES

No specific codes identified

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Autologous Fat Transfer (AFT) In Breast Reconstruction, continued

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MEDICAL POLICY

BARIATRIC SURGERY GUIDELINES

Policy # 295

Implementation Date: 1/1/06

Review Dates: 10/18/07, 10/23/08, 10/21/10, 6/21/12, 6/18/14, 6/11/15, 6/16/16, 9/18/18, 8/8/19, 8/20/20, 9/23/21, 8/2/22, 8/17/23

Revision Dates: 10/30/06, 6/24/08, 2/9/09, 2/26/09, 11/2/09, 5/9/11, 2/11/13, 10/21/13, 9/21/16, 8/8/17, 5/28/19, 1/1/20, 3/3/20, 4/9/20, 7/1/20, 12/28/20, 6/9/21, 10/7/21, 10/20/22, 11/2/22, 3/9/23, 4/3/23, 11/29/23, 1/16/24

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Description

Morbid obesity is defined as a body mass index > 40 kg/m^2, which results in significant health complications and a shortened life span. Conditions shown to have a higher morbidity in association with overweight and obese conditions include hypertension, diabetes mellitus, coronary heart disease, stroke, gallbladder disease, osteoarthritis, respiratory problems, and some types of cancer (endometrial, breast, prostate, and colon). Conditions in which subsequent weight loss from a previously obese state show an improvement in health outcomes include diabetes, hypertension, obesity-hypoventilation syndrome, and osteoarthritis.

Many patients have tried unsuccessfully to lose weight through exercise, dietary, and lifestyle modifications, and pharmacotherapy, with limited success. However, only 5%–10% of these patients can achieve and sustain significant weight loss. Thus, surgical remedies are being considered with greater interest as the population of obese and super-obese individuals (defined as patients with BMI > 50kg/m^2) increases. Surgical options that have been found to be most successful with the least amount of surgical complications and greatest success are sleeve gastrectomy, gastric bypass, and biliopancreatic diversion with duodenal switch.

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 will provide *limited coverage* for *some* bariatric surgical procedures, when all the following criteria are met:

1. Age of at least 18 years; and
2. BMI > 40, within 1 year prior to surgery; or
3. BMI > 35, within 1 year prior to surgery, with any of the following severe comorbidities:
    a. Clinically significant obstructive sleep apnea; or
    b. Coronary heart disease, with objective documentation (by exercise stress test, radionuclide stress test, pharmacologic stress test, stress echocardiography, CT

angiography, CT angiography, coronary angiography, heart failure, or prior myocardial infarction); or

c. Hypertension on medical therapy; or

d. Type 2 diabetes mellitus on medical therapy; or

e. Dyslipidemias on medical therapy; or

f. Compensated NASH or cryptogenic cirrhosis; or

g. Severe DJD of hip, back, or knee; or

h. Reflux which is medically treated

AND

4. a) Surgery will be performed at a facility accredited or pending accreditation with the Metabolic & Bariatric Surgery Accreditation & Quality Improvement Program (MBSAQIP); or

   b) Bariatric surgery will be allowed at facilities that are undergoing pre-credentialing for MBSAQIP within one year of application for accreditation and supervised by either an accredited MBSAQIP center or by Intermountain Surgical Specialty Services; a qualified surgeon must have 3 cases proctored and verified by Intermountain Surgical Specialty Services; and

5. 1-month of tobacco abstinence, which includes refraining from cigarette usage, e-cigarette usage, or vaping; and vaping of any other substances, for the month prior to surgery; and

6. Evidence that all other alternatives have been discussed with and offered to patient, and that all reasonable non-surgical options have been attempted; and

7. Within one year of the surgery date, there is documentation of a preoperative nutritional assessment, which includes the following:

   a. Weight history

   b. Assesses eating habits

8. Preoperative psychological clearance has been obtained for any member with:

   a. A history of severe psychiatric conditions, including but not limited to, schizophrenia, borderline personality disorder, suicidal ideation, severe depression; and

   b. Any member under the care of a psychologist/psychiatrist proximate to surgery.

   Note: The presence of mild-to-moderate depression is not normally considered a contraindication to obesity surgery.

Select Health covers the following bariatric surgeries:

- Laparoscopic/open gastric bypass (Roux-en-Y) with short limb (< 150 cm)
- Laparoscopic/open sleeve gastrectomy
- Biliopancreatic bypass with or without duodenal switch
- Loop duodenal switch (also referred to as single-anastomosis duodenal switch (SADS) or stomach intestinal pylorus-sparing surgery (SIPS))

Select Health does NOT cover the following bariatric surgeries:

- Laparoscopic gastric banding
- “Mini-gastric bypass”

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- Garren gastric bubble
- Gastric bypass with long-limb (> 150 cm) (also called distal gastric bypass)
- Gastric wrapping
- Gastroplasty (stomach stapling)
- Intragastric balloons (IGBs)
- Jejunoileal bypass (Scorpinaro procedure)
- Loop gastric bypass
- Vagal nerve blocking (VBLOC) or vagal nerve stimulation (VNS)

Select Health will only cover revisional bariatric surgery for complications of prior bariatric surgery.

Select Health will only cover bariatric surgery once per lifetime, except for those individuals with initial BMI > 60 where biliopancreatic bypass with duodenal switch is allowed after a prior sleeve gastrectomy, or for individuals who have had a prior laparoscopic gastric banding. *These additional procedures would not be considered a revision of the initial procedure.*

Select Health does not cover any bariatric procedure for any other indication such as the treatment of diabetes mellitus or gastroparesis. Members should not have any other severe comorbidity which would increase morbidity and mortality associated with bariatric surgery.

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

Assessment of the outcomes of bariatric surgery is complicated by the variability in how the data is reported. Data is typically reported in terms of weight loss, although it may be reported in terms of absolute weight loss, percentage of excess weight loss, percentage of patients losing > 50% of excess body weight, percentage of subjects achieving ideal body weight or decrease in body mass index (BMI). In terms of determining medical necessity of a surgical procedure, weight loss itself may be considered an intermediate outcome, because the medical necessity of a surgical procedure is based on the treatment of the comorbidities of obesity, including but not limited to diabetes, hypertension, or obstructive sleep apnea. There is sufficient evidence to conclude that surgery improves health outcomes for patients with morbid obesity compared to nonsurgical treatment. The most compelling evidence for an improvement in comorbid conditions comes from the Swedish Obese Subjects (SOS) intervention trial that reported a large reduction in diabetes over a 5.5-year mean follow-up for the surgery group. However, it is not possible to draw conclusions as to the relation of increment of weight loss to increment

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of improvement in health outcome measures. It is also not possible to identify a weight loss threshold for success of a surgical procedure.

Adjustable gastric banding devices do not remove portions of the stomach. There are 2 FDA approved devices used for gastric banding: the LAP-BAND and the REALIZE Adjustable Gastric Band. Based on the data presented to the FDA as part of the FDA approval process, the degree of weight loss appears to be less with the LAP-BAND than that associated with either vertical sleeve gastrectomy or gastric bypass. For example, the percent of excess weight loss after 3 years with the LAP-BAND device is reported as 36.2%, compared to a mean percent of excess weight loss of 48%–74% for gastric bypass, and 50%–60% for vertical sleeve gastrectomy. One randomized study published by Morino et al. reported on the results of 100 morbidly obese patients who were randomized to undergo either a LAP-BAND procedure or a vertical sleeve gastrectomy; follow-up continued for a minimum of 2 years. The LAP-BAND procedure was associated with a shorter operative time, hospital stay, and early morbidity (6.1% vs. 9.8%). However, the LAP-BAND was associated with a higher late complication rate (32.7% vs. 14%), with slippage of the band the most frequent complication. While there were no late re-operations among those undergoing vertical sleeve gastrectomy, 24.5% of the LAP-BAND group required re-operation. The percentage of excess weight loss was also greater in those undergoing vertical sleeve gastrectomy. Heill and colleagues reported on a non-randomized trial comparing consecutive patients, matched on sex, age, and BMI, undergoing 1 of 3 types of bariatric surgery (i.e., gastric bypass, vertical sleeve gastrectomy, or laparoscopic gastric banding). Weight loss outcomes were reported as the percent of patients with at least 50% excess weight loss and were superior for gastric bypass as compared to laparoscopic banding. However, the bulk of the published data regarding the LAP-BAND device comes almost entirely from clinical series, which suggest that substantial weight loss occurs following laparoscopic gastric banding, but that the percentage of excess weight loss at one year may be less than that seen with gastric bypass. Short-term adverse event rates are low with gastric banding, and probably less than seen with gastric bypass. Longer term adverse events, however, occur more frequently and may include serious complications such as erosion of the band through the gastric wall. The incidence and patterns of these longer-term adverse events cannot be well characterized from the available data, nor can they be readily compared with expected long-term adverse rates for gastric bypass.

Seven systematic reviews reported evaluated clinical outcomes and complications from laparoscopic gastric banding, concluding that the procedure is both a safe and effective means of inducing rapid weight loss in obese patients. However, most reviews did not offer comparative assessments of outcomes from REALIZE Band versus LAP-BAND. Cunneen conducted the only comparative review in a meta-analysis of 129 studies involving either LAP-BAND or Swedish Band, predecessor to REALIZE Band. The author concluded that both procedures produce equivalent weight loss, improvements in health, and risk of adverse events.

Twenty-four empirical studies met criteria for inclusion in a 2009 Medical Technology Assessment. None of these specifically evaluated the REALIZE Band and instead reported outcomes on the Swedish Band. Again, these studies conclude that the Swedish band is a safe and effective method of weight loss. Four of these studies were comparative trials between Swedish Band and LAP-BAND. Though LAP-BAND may result in more rapid weight loss initially, each of these studies concluded that both procedures ultimately led to equivalent weight loss. Ponson et al. for example, reported nearly identical weight loss at six months (28 kg vs. 30 kg), 1 year (36 kg vs. 38 kg), and 2 years (46 kg vs. 42 kg) for Swedish Band and LAP-BAND, respectively. Suter et al. reported improvements in self-reported quality of life after both procedures up to 3 years after surgery, but ratings did not differ between groups. Furthermore, complication types and rates did not differ significantly between the procedures.

In short, the extant literature suggests the outcomes from REALIZE Band are essentially the same as those seen with LAP-BAND. The few published comparative studies substantiate this conclusion in that the 2 procedures produce virtually identical outcomes with fairly few complications, at least in the short-term. Long-term comparative data are not available, so it is unknown whether these results would hold over time. Furthermore, economic studies have not been published so it is unknown which procedure is the more cost-effective alternative.

Short-limb gastric bypass, also known as the Roux-en-Y, is considered the standard surgical treatment for morbid obesity, and thus, outcomes of malabsorptive procedures will be compared with this gold

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standard. While there have been no randomized, controlled studies directly comparing the outcomes of gastric restrictive procedures with malabsorptive procedures, case series have suggested that biliopancreatic bypass is associated with a greater percentage of excess weight loss, but also associated with an increased risk of metabolic abnormalities, including liver failure resulting in death or liver transplant. The duodenal switch, a variant of the biliopancreatic bypass, is designed to limit these metabolic complications. A study by Anthone et al. analyzed the results of 701 patients who underwent the duodenal switch procedure at one academic medical center over a 10-year period. The perioperative mortality rate (1.4%), morbidity (2.9% including leaks, wound dehiscence, splenectomy, and postoperative hemorrhage), and weight loss (66%–73% of excess body weight loss at 3 years) were comparable to the published results for the Roux-en-Y gastric bypass procedure. Anthone also reported that from a metabolic standpoint, the patients in the study fared well, with 98% having a normal serum albumin at 3 years. Additionally, hemoglobin and calcium levels at 3 years appeared in line with results seen in gastric bypass procedures and there was no incidence of dumping in those who underwent the duodenal switch procedure.

In another case report by Deveney et al., comparing Roux-en-Y gastric bypass with duodenal switch, the results showed that while the average length of stay was longer for those individuals undergoing duodenal switch, there were no statistical differences in morbidity or mortality. Weight loss was similar in the 2 groups at 1- and 2-years post-procedure. Finally, advocates of the duodenal switch procedure propose that it offers an improved quality of life in comparison to gastric restrictive procedures. For example, gastric restrictive procedures may be associated with nausea and vomiting if the ingested food exceeds the limited stomach capacity. This complication may be reduced with malabsorptive procedures; however, there have not been any significant comparative studies that have focused on quality-of-life outcomes.

Some bariatric surgeons may advocate some type of malabsorptive procedure specifically for those with super-obesity on the basis that these patients may require a greater absolute amount of weight loss to reduce the comorbidities. Several studies have compared the outcomes of gastric bypass surgery to malabsorptive procedures in the super obese. For example, Brolin et al. reported a retrospective comparison of case series done at one institution at different points in time by comparing standard gastric bypass with 2 variations of long-limb gastric bypass. Another comparative study by Mason and colleagues reported data from a bariatric surgery registry with prospective data collection, comparing gastric bypass with distal gastric bypass. This voluntary registry, maintained by the American Society Bariatric Surgery, maintains data on weight loss outcomes, and on overall morbidity and mortality rates. Although these studies are of poor quality due to non-comparability of groups, they reported that the percentage of excess weight loss at 1 year to be in the 55%–75% range, similar to that seen for standard gastric bypass. The overall rate of early complications was higher with gastric bypass as compared to long-limb gastric bypass (2.3% vs. 1.2%) in the registry data, but this data was not broken down into individual complications and statistical testing was not reported. In the Brolin study, there were some differences in the complication rates between procedures, but the small numbers in each group precludes meaningful comparisons of these rates. Therefore, there is inadequate scientific data to permit conclusions regarding the superiority of a long-limb gastric bypass procedure vs. a standard gastric bypass procedure in the super obese.

The **biliopancreatic diversion (BPD)** was introduced by Nicola Scopinaro in 1979 as a solution to the high rates of liver failure resulting from bowel exclusion in the jejunoileal bypass.

The procedure consists of a partial gastrectomy and gastroileostomy with a long segment of Roux limb and a short common channel (the part of the small bowel that receives both food and biliopancreatic secretions) resulting in fat and starch malabsorption. Up to 72% excess weight loss at 18 years after surgery has been reported. Laparoscopic BPD has also been performed with acceptable outcomes. Its use has been limited by the high rates of protein malnutrition, anemia, diarrhea, and stomal ulceration. In the United States, the role of BPD has generally been limited to revisional bariatric surgery.

Biliopancreatic diversion with duodenal switch (BPD/DS): BPD/DS is a variant of the BPD and is primarily a malabsorptive operation. The BPD/DS procedure involves a partial sleeve gastrectomy with preservation of the pylorus, and creation of a Roux limb with a short common channel. The BPD/DS procedure differs from the BPD in the portion of the stomach that is removed, as well as preservation of

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the pylorus. It is associated with a lower incidence of stomal ulceration and diarrhea than with BPD alone. Although complex, BPD/DS has been performed laparoscopically by several groups. This procedure is performed at only a few centers in the US. This procedure has been advocated for patients with very severe obesity (BMI > 50 kg/m^2), a group in which it has been associated with improved weight loss. BPD/DS is not widely accepted as a first-line surgical treatment for less severe obesity because of concerns regarding the risks of long-term malabsorption.

In a 2017 Medical Technology review, a large body of published literature was identified which included 3 systematic reviews and 32 primary studies that met criteria for review. This evidence evaluated the efficacy and safety of 12,959 patients with many studies comparing biliopancreatic duodenal switch (DS) with gastric sleeve and Roux-en-Y gastric bypass (RYGB). Only one study by Marceau in 2010 focused on adolescent patients and involved only 13 patients limiting any conclusions regarding safety and efficacy of this therapy in this population.

Overall, the studies supported continued benefit and durability of effect from the surgery, though notably, the Aasprang et al. study in 2016, which looked at 10-year healthcare related quality of life, noted only 60% of patients maintained their HRQL improvements.

With regards to efficacy as defined by weight loss, resolution of diabetes, HTN, sleep apnea, or other metabolic disturbances, overall, the body of evidence showed superior excessive weight loss and equal if not more rapid resolution of the various metabolic disturbances particularly with type 2 diabetes mellitus. Methods compared to duodenal switch included vertical gastric banding (VGB) (Cottam 2016), sleeve gastrectomy (Cottam et al., 2016, Polega et al., 2017), and multiple studies comparing to RYGB (Duarte et al. 2014, Hedberg et al., 2012, Pranchard et al., 2006, Roslin et al., 2014, and Topart et al., 2013).

The literature also is notable in that most studies occur in patients with a BMI > 50kg/m2. Some studies such as Biertho et al. from 2010 assessed the effectiveness and safety in patients with a BMI < 50 kg/m2. This study showed similar efficacy in excess weight loss to that achieved in the super-obese (> 50 kg/m2 BMI) category, though, this population perhaps experienced greater post-operative complications and adverse effects. The safety and effectiveness of duodenal switch surgery was also confirmed in the study by Buchwald et al. in 2008, which compared in a prospective fashion, the 30-day post-operative morbidity and mortality of performing duodenal switch in patients with BMIs above or below 50 kg/m2.

The comparative studies also tended to support a higher complication rate or adverse event occurrence, though, the study by Cottam in 2016 which compared DS to RYGB demonstrated more gastric specific complications such as ulcers with RYGB than DS. More common side effects identified with duodenal switch included long-term micronutrient deficiencies (Nett et al., 2016).

In summary, the duodenal switch in adults demonstrated similar or greater efficacy for the morbidly obese or super obese population, with evidence suggesting even greater benefit in overcoming metabolic issues in the super obese (> 50kg/m2 BMI) population. Though long-term nutrient and protein malnutrition issues appear to be greater with this procedure than with other bariatric procedures, it appears relatively easy to manage with supplementation and close monitoring.

Jejunoileal Bypass: The jejunoileal bypass was one of the first bariatric operations, performed initially in 1969. It has since been abandoned due to the high complication rate and frequent need for revisional surgery. Its importance lies in the care of surviving patients who have undergone this procedure. The procedure was performed by dividing the jejunum close to the ligament of Treitz and connecting it a short distance proximal to the ileocecal valve, thereby, diverting a long segment of small bowel, resulting in malabsorption. Although excess weight loss was excellent, jejunoileal bypass was associated with multiple complications, such as liver failure (up to 30%), death, diarrhea, electrolyte imbalances, oxalate renal stones, vitamin deficiencies, malnutrition, and arthritis. Patients who have undergone this procedure should be monitored closely for complications (particularly liver disease) and undergo reversal if such complications arise.

Gastric wrapping which envelops the stomach in a customized Teflon (polytetrafluoroethylene) mesh and the **Garren gastric bubble** represent obsolete techniques. The jejunoileal bypass has also been abandoned due to severe metabolic complications, and largely has been replaced by the biliopancreatic bypass. Other Garren gastric bubbles are available but not covered.

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Long-Limb Roux-en-Y Gastric Bypass: In the gastric bypass with long-limb (> 150 cm), also called the distal gastric bypass, surgeons are working to capitalize on the weight loss experience of the BPD operations above without creating malnutrition. They use the tiny stomach pouch that has established success in the standard Gastric Bypass (GBP) and make the small bowel connection much further downstream (the Roux limb of small bowel is longer), so that food and digestive juices mix for a shorter distance in the gut. In our opinion, any GBP with a Roux limb less than 150 cm is not a long-limb GBP, and it is not always a long-limb at 150 cm. To do a true long-limb GBP, it is necessary for the surgeon to measure backward from the ileocecal valve (where the small intestine connects with the colon). The long-limb GBP procedure is reported to result in more weight loss than the "standard" GBP, but (similar to the BPD-DS) there is a somewhat higher rate of electrolyte (blood salt) disturbances and other nutritional complications. The Y-connection is formed much closer to the lower (distal) end of the small bowel, usually 100 to 150 cm (39 to 59 in) from the lower end of the bowel, causing reduced absorption (mal-absorption) of food, primarily of fats and starches, but also of various minerals, and the fat-soluble vitamins. The unabsorbed fats and starches pass into the large intestine, where bacterial actions may act on them to produce irritants and malodorous gases. These increasing nutritional effects are traded for a relatively modest increase in total weight loss.

Gastroplasty was designed in the early 1970s to be a safer alternative to the RYGBP and the JIB. The operation itself was made possible by the introduction of mechanical staplers. The gastroplasty was the first purely restrictive operation performed for the treatment of obesity. The original (horizontal) gastroplasty involved stapling the stomach into a small partition—and only leaving a small opening for food to pass from the upper stomach pouch to the lower one. Thus, the lay term: stomach stapling. This form of gastroplasty resulted in very poor long-term weight loss, and after several attempted modifications, was abandoned eventually**.**

Vertical banded gastroplasty (VBG) is an updated version of gastroplasty and is a purely restrictive procedure in which the upper part of the stomach is partitioned by a vertical staple line with a tight outlet wrapped by a prosthetic mesh or band.

The small upper stomach pouch gets filled quickly by solid food and prevents consumption of a large meal. Weight loss occurs because of decreased caloric intake of solid food. Patients who have undergone VBG can be expected to have excess weight loss (EWL) of 58%. The effectiveness of such a restrictive mechanism depends upon the durability of pouch and stoma (outlet) size.

Ingestion of high-calorie liquid meals and gradually increased pouch capacity due to overeating have been some of the major causes of its failure. Sweets-eaters who rely on soft meals (i.e., ice cream, milk shakes) do not benefit significantly from this procedure.

VBG has been replaced largely by other procedures and is rarely performed due to lack of sustained/desired weight loss, as well as the high incidence of complications requiring revision (20%–56%). Most revisions are required for staple line disruption, stomal stenosis, band erosion, band disruption, pouch dilatation, vomiting, and gastroesophageal reflux disease.

The **loop gastric bypass, "mini-gastric bypass," or Billroth II anastomosis,** has limited data in the published medical literature. The first use of the gastric bypass, in 1967, used a loop of small bowel for re-construction, rather than a Y-construction as is prevalent today. Although simpler to create, this approach allowed bile and pancreatic enzymes from the small bowel to enter the esophagus, sometimes causing severe inflammation and ulceration to either the stomach or the lower esophagus. If a leak into the abdomen occurs, this corrosive fluid can cause severe consequences. Numerous studies show the loop reconstruction (Billroth II gastrojejunostomy) works more safely when placed low on the stomach but can be a disaster when placed adjacent to the esophagus. Thus, even today, thousands of "loops" are used for general surgical procedures such as ulcer surgery, stomach cancer, and injury to the stomach, but bariatric surgeons abandoned use of the construction in the 1970s, when it was recognized that its risk is not justified for weight management.

The Mini-Gastric Bypass, which uses the loop reconstruction, has been suggested as an alternative to the Roux en-Y procedure, due to the simplicity of its construction, which reduced the challenge of laparoscopic surgery. While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis, one of the reasons that this anastomosis has been

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abandoned in general, in favor of a Roux-en-Y anastomosis that diverts the biliary juices away from the stomach.

Sleeve gastrectomy was reviewed in a May 2011 Medical Technology Assessment and identified 6 systematic reviews and 22 primary literature sources were identified concerning laparoscopic sleeve gastrectomy (LSG) as a treatment for weight loss. Most of the literature follows patients through 12 months.

Some papers only had a 3-month follow-up period and 1 article (Himpens et al., 2010) reported outcomes through 6 years post LSG procedure. It is primarily for the lack of long-term studies that Hayes, The Canadian Agency for Drugs and Technologies in Health (CADTH), and the California Technology Assessment Forum (CTAF), have not fully endorsed this procedure. Though short-term results look promising, there is very little long-term safety and efficacy data.

Specific to the systematic reviews, a Hayes Brief from 2010 noted: "... the preliminary evidence from these studies suggests that the safety and efficacy of laparoscopic sleeve gastrectomy for super obesity is similar to the safety and efficacy of other common weight loss surgeries such as laparoscopic adjustable gastric banding and laparoscopic Roux-en-Y gastric bypass, and that it might be a viable treatment option for selected patients such as those who are not acceptable candidates for conventional bariatric surgery. Laparoscopic sleeve gastrectomy has been cautiously endorsed by professional organizations particularly when used as a one-stage procedure for high-risk patients including the super obese, who are poor candidates for other extensive bariatric procedures."

In 2010, the CADTH reviewed laparoscopic sleeve gastrectomy's clinical benefits and harms and reported that as the procedure compares to laparoscopic roux-en-Y gastric bypass (LRYGB), there were no statistically significant differences in BMI or weight loss between the 2 procedures at 12 months but there was a larger percent excess weight loss at 12 months with LSG (69.7% vs. 60.5%, $p = 0.05$). These findings are somewhat discrepant from the findings in many other studies and reviews. Of note, the CADTH, also reported on vitamin deficits that result following LRYGB and LSG. The incidence of Vitamin B12 deficiency 2 years after the procedure was significantly higher in LRYBG patients than in LSG patients (58% vs. 18%, $p < 0.001$). Vitamin D deficiencies were also significantly higher in LRYGB patients than in LSG patients (52% vs. 32%, $p = 0.02$). Secondary hyperthyroidism also occurred more frequently in LRYGB patients (33% vs. 14%, $p = 0.02$). The committee's final statement concerning LSG as a treatment for weight loss was that LSG appears to be equally or more effective as other bariatric surgeries.

One other point of note, many of the published studies focused on its use in the treatment of patients with diabetes mellitus (DM). As this is an important reason often cited by providers and patients in seeking bariatric surgery, the ability to impact diabetes mellitus would seem to be important to how this procedure measures up to other procedures. An example of this is the systematic review published by Gill et al. (2010), which noted the mean percentage of excess weight loss was 47.3% (range 6.3%–74.6%), with a mean follow-up of 13.1 months (range 3–36). DM had resolved in 66.2% of the patients, improved in 26.9% and remained stable in 13.1%. The mean decrease in blood glucose and hemoglobin A1C after sleeve gastrectomy was -88.2 mg/dL and -1.7%, respectively. The group reported that most patients with Type 2 diabetes experienced resolution or improvement in diabetic markers after LSG. Laparoscopic sleeve gastrectomy might play an important role as a metabolic therapy for patients with Type 2 diabetes.

In summary, most of the literature is favorable regarding laparoscopic sleeve gastrectomy as a weight loss treatment. The most concerning shortfall is the lack of long-term safety and efficacy trials.

Vagal nerve stimulation: The VBLOC procedure or vagal nerve stimulation (VNS**)** attempts to control weight loss through an effect on satiety and the digestive process related to stimulation of the vagal nerves. The vagal nerves begin in the brain and extend to multiple organs and regions of the digestive system. Each vagus nerve provides direct two-way communication between the brain and the digestive system without the additional spinal cord processing of impulses that is typical for most other human nerves. No published empirical studies or literature reviews could be located on VBLOC. The manufacturer, EnteroMedics has completed a study, the EMPOWER Study, to assess this technology. The EMPOWER Study is a randomized, double-blind, placebo-controlled pivotal study designed to evaluate the safety and effectiveness of the Maestro® System for the treatment of obesity. The study data

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demonstrated it did not meet its primary and secondary efficacy endpoints. There were no therapy-related serious adverse events reported in the study.

It should be noted that most published studies of bariatric surgery have included only adult patients. There is minimal data regarding bariatric surgery in adolescents. While studies have shown that the techniques are technically feasible, there is inadequate data regarding additional outcomes such as impact on growth and development, and compliance issues.

Billing/Coding Information

CPT CODES

Covered: For the indications outlined above when criteria are met

43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy

Not covered: Investigational/Experimental/Unproven for this indication

43659	Unlisted laparoscopy procedure, stomach
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty

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43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
43999	Unlisted procedure, stomach

HCPCS CODES

S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

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MEDICAL POLICY

CRYOABLATION FOR DESMOID TUMORS

Policy # 565
Implementation Date: 6/2/15
Review Dates: 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 9/23/21, 8/2/22, 1/2/24
Revision Dates: 7/13/21

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Description

Desmoid tumors are rare, they account for about 0.03% of all neoplasms and < 3% of all soft tissue tumors. The estimated incidence in the general population is 1 to 4 per million population per year. Individuals between the ages of 15 and 60 are most affected; desmoids are rare in the young and in the elderly. They are slightly more common in women than in men and there is no significant racial or ethnic predilection. Desmoid tumors (also called aggressive fibromatosis, deep musculoaponeurotic fibromatosis, and formerly termed fibrosarcoma grade I of the desmoid type) are locally aggressive tumors with no known potential for metastasis or dedifferentiation. The term "desmoid" originates from the Greek word "desmos," meaning band or tendon-like, and was first applied in the 1800s to describe tumors with a tendon-like consistency. Although they lack the capacity to establish metastases, desmoids are locally aggressive and have a high rate of recurrence even after complete resection. Tumor-related destruction of vital structures and/or organs can be fatal, particularly when these tumors arise in patients with familial adenomatous polyposis (FAP, Gardner's syndrome).

Treatment of an extra abdominal or abdominal wall desmoid is indicated for symptomatic patients, and for those with progressively enlarging tumors irrespective of symptoms, if there is imminent risk to adjacent structures or if the tumor creates cosmetic concerns.

Radiation therapy is an effective primary therapeutic option for desmoid tumors in patients who are not good surgical candidates, those who decline surgery, and those for whom surgical morbidity would be excessive. The time to regression after RT alone is often quite long and several years may elapse before regression is complete.

In a number of reports, RT alone (50 to 60 Gy), or combined with surgery in patients with incomplete resection, achieves long-term local control in approximately 70 to 80% of desmoids. The volume of disease does not appear to influence the probability of local control.

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

Select Health covers cryoablation for desmoid tumors as this procedure is considered medically necessary.

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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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

Literature on this technology identified no systematic reviews and only 2 primary studies related to the use of cryoablation in the management of desmoid tumors. One additional paper, which would normally not meet inclusion criteria due to it's being a single case study, was included in an effort to include as much information as possible on the topic. These studies have multiple methodological flaws including small sample size (19 total patients studied), lack of comparative design, lack of randomization, etc., which limit the ability to draw conclusions regarding the safety and efficacy of this therapy.

Billing/Coding Information

CPT CODES

20999 Unlisted procedure, musculoskeletal system, general

HCPCS CODES

C2618 Probe/needle, cryoablation

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MEDICAL POLICY

GASTRIC DIVERSION

Policy # 659

Implementation Date: 1/20/23
Review Dates:
Revision Dates:

Related Medical Policies:

#295 Bariatric Surgery

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

Gastroesophageal reflux disease (GERD) is a common comorbid condition in bariatric patients. It pertains to the exposure of the esophagus to stomach content, leading to esophageal mucosal damage. The etiology is not completely understood but may include a mixture of hereditary and functional factors with a role of abnormal relaxation of the lower esophageal sphincter (LES), increased frequency of transient sphincter relaxation, or from increased pressure from the stomach secondary to a hiatus hernia or increased intra-abdominal pressure. This can lead to symptoms including heartburn, regurgitation, dysphagia, odynophagia, increased salivation, and chest pain.

Although weight loss and lifestyle modifications are important in reducing the symptoms of GERD, gastric diversion procedures have provided effective symptom alleviation. Comparing the Roux-en-Y gastric bypass (RYGB) with lifestyle modification, it appears that patients who underwent RYGB had a better alleviation of GERD symptoms. RYGB involves creation of a gastric pouch with the pouch drained by a roux limb from the proximal jejunum alleviation.

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 gastric diversion for members who meet ALL the following criteria:

1. BMI > 35 or BMI < 35 with prior sleeve gastrectomy; and
2. Daily reflux symptoms despite maximum PPI; and
3. Objective evidence of reflux with 24−48-hour ambulatory pH probe (DeMeester score* > 14.7 as a positive pH study); or
   EGD documenting esophagitis of at least grade C/D reflux or Barrett's; and
4. Documentation of failed medically managed weight loss

*DeMeester score (DMS)

DMS: This composite score measures the overall esophageal acid exposure level and includes six parameters: (1) total number of reflux episodes, (2) % total time esophageal pH < 4 (AET), (3) % upright time esophageal pH < 4, (4) supine time esophageal pH < 4, (5) number of reflux episodes > 5 minutes, and (6) longest reflux episode (minutes). The DMS is the sum of the 6 parameter scores, and the simplified formula for scoring each component is as follows: component score = (Pt value – mean + 1) / standard deviation

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(SD). In this study, the DMS was automatically calculated by software, and reflux exceeding the threshold value (14.7) was considered abnormal reflux. DMS calculator: https://www.mdapp.co/demeester-score-calculator-365/

Select Health Advantage (Medicare/CMS)

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Billing/Coding Information

CPT CODES

43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (Roux Limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption

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MEDICAL POLICY

GENDER AFFIRMING MEDICAL AND SURGICAL TREATMENT

Policy # 386

Implementation Date: 1/11/08
Review Dates: 2/26/09, 2/18/10, 8/15/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 9/19/18, 8/8/19, 8/20/20, 8/19/21, 7/15/22, 8/17/23
Revision Dates: 7/17/14, 6/17/15, 12/5/16, 10/10/17, 12/20/18, 11/1/19, 8/27/20, 2/12/21, 3/17/22, 7/20/22, 10/7/22, 5/3/23, 7/3/23, 7/21/23, 9/7/23

Related Medical Policies:

#677 Gender Affirming Medical and Surgical Treatment for Colorado Based Plans

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

Gender affirming medical and surgical treatment (GAMST) is part of the spectrum of care considered for individuals with gender dysphoria (which also includes individuals who identify as non-binary), a condition in which a person feels a strong and persistent identification with the opposite gender, accompanied with a severe sense of discomfort in their own gender. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5-Text Revision [TR]) provides for one overarching diagnosis of gender dysphoria, with separate specific criteria for children, and for adolescents and adults.

In adolescents and adults, a gender dysphoria diagnosis involves a difference between one's experienced/expressed gender and assigned gender, and significant distress or problems functioning. It lasts at least six months and is manifest by at least two of the following:

- A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics
- A strong desire to be rid of one's primary and/or secondary sex characteristics
- A strong desire for the primary and/or secondary sex characteristics of the other gender*
- A strong desire to be of the other gender*
- A strong desire to be treated as the other gender*

According to the World Professional Association for Transgender Health (WPATH), gender dysphoria is broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics). For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered, including gender affirmation surgery.

Gender affirming medical and surgical treatment is not a single intervention or procedure, but part of a complex process that may involve multiple medical, psychiatric, and surgical modalities working in conjunction with each other and the patient to achieve successful outcomes.

*Per the DSM-5: Other gender = Some alternative gender different from one's assigned gender.

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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 considers gender affirmation surgery medically necessary when all the following criteria are met for all surgical interventions:

1) Member must be age 18 or older; and

2) Healthcare professionals (HCPs) assessing transgender and gender diverse (TGD) individuals meet the minimum necessary requirements outlined by WPATH Standards of Care 8 (SOC8) (see Appendix B); and

3) HCPs assessing TGD individuals consult with other professionals from different disciplines; and

4) Gender dysphoria is diagnosed and considered marked and sustained (according to DSM5-TR [see Appendix A]); and

5) Exclude other possible explanations for gender incongruence prior to treatment; and

6) Discuss impacts of surgical treatments on any other mental health condition; and

7) Discuss impacts of surgical treatment on any other physical health condition; and

8) Ensure the capacity to consent to the requested medical treatment; and

9) Social transitioning has occurred prior to Gender Affirming Medical and Surgical Treatment (GAMST); and has been considered with risks and benefits discussed.

B. Requirements for breast removal:

1) Member must be age 18 or older; and

2) Single letter of referral from a qualified healthcare professional (see Appendix B); and

3) Surgeon has assessed risk factors associated with breast cancer.

C. Requirements for breast augmentation (implants/lipofilling):

1) Member must be age 18 or older; and

2) Single letter of referral from a qualified healthcare professional (see Appendix B); and

3) Surgeon has assessed risk factors associated with breast cancer.

Notes:

- More than one breast augmentation (excluding fat grafting) is considered cosmetic and not medically necessary. This does not include a medically necessary replacement of breast implants.
- Current guidelines do not recommend a specific timeline for hormone treatment prior to breast augmentation for adults; however, to obtain the desired surgical results, a period of hormone treatment may be a surgical recommendation.

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D. Non-coverage for gender affirming facial surgery ("feminizing" and "masculinizing")

1) There are no facial features that identify to a specific gender. Thus, facial procedures intended to feminize or masculinize are considered cosmetic.

E. Requirements for gonadectomy (hysterectomy and oophorectomy or orchiectomy):

1) Member must be age 18 or older; and

2) One referral letter from a qualified healthcare professional (see appendix B); and

3) Six months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise not desired); and

4) Reproductive effects, including loss of fertility and preservation options have been discussed and pursued, if desired, prior to irreversible surgical intervention.

F. Requirements for genital reconstructive surgery (i.e., vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, placement of a testicular prosthesis and erectile prosthesis, penectomy, vaginoplasty, labiaplasty, and clitoroplasty):

1) Member must be age 18 or older; and

2) One referral letter from qualified healthcare professional (see Appendix B); and

3) Six months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise not desired); and

4) Reproductive effects, including loss of fertility and preservation options have been discussed and pursued, if desired, prior to irreversible surgical intervention.

G. Other gender-specific medical care is medically necessary for transgender and gender diverse (TGD) individuals include:

1) Hair removal from the body and genital areas, excluding the face, by laser or electrolysis, in preparation for body and genital surgery;

2) Breast cancer screening may be medically necessary for TGD individuals regardless of medical or surgical history;

3) Prostate cancer screening may be medically necessary for TGD individuals who have retained their prostate;

4) Cervical, ovarian, or endometrial cancer screening may be medically necessary for TGD who have the same risk as cisgender women.

H. Select Health considers the following procedures that may be performed as a component of a gender transition as cosmetic and not medically necessary:

- Abdominoplasty
- Blepharoplasty
- Body contouring (liposuction of waist)
- Brow lift
- Calf implants
- Cheek/malar implants

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- Collagen injections
- Construction of a clitoral hood
- Face lifting
- Feminization of torso
- Forehead lift
- Jaw reduction (jaw contouring)
- Hair transplantation
- Lip enhancement
- Lip reduction
- Liposuction
- Masculinization of torso
- Mastopexy, when completed without breast augmentation
- Neck tightening (platysmaplasty = neck lift)
- Nose implants
- Pectoral implants
- Pitch-raising surgery
- Removal of redundant skin
- Skin resurfacing (dermabrasion/chemical peel)
- Tracheal shave (reduction thyroid chondroplasty)
- Voice modification surgery (laryngoplasty, cricothyroid approximation, or shortening of the vocal cords)
- Voice therapy/voice lessons

I. Appendix A

DSM 5 Criteria for Gender Dysphoria in Adults and Adolescents:

I. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by two or more of the following:

a) A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or, in young adolescents, the anticipated secondary sex characteristics)

b) A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or, in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)

c) A strong desire for the primary and/or secondary sex characteristics of the other gender

d) A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)

e) A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)

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f) A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

II. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Note: WPATH SOC8 indicates gender incongruence must be "marked and sustained" (statement 5.3.a) in order to recommend gender affirming surgical treatment. The gender dysphoria diagnosis and clinical criteria originate from the DSM-5-TR, requiring at least 6 months duration. Therefore, "marked and sustained" is interpreted through the DSM criteria requiring a minimum of 6 months duration.

J. Appendix B

Characteristics of Qualified Healthcare Professionals assessing for gender-affirming treatments:

1) Master's degree or equivalent in a clinical field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; and
2) Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; and
3) Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria, incongruence, and diversity; and
4) Ability to assess capacity to consent for treatment; and
5) Knowledgeable and experience about gender diverse identities and expressions, and the assessment and treatment of gender dysphoria; and
6) Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a health care professional and/or mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

g) Engagement with other health care professionals from different disciplines within the field of transgender health for consultation and referral, as needed.

K. Additional requirements for healthcare professionals working with gender diverse children and adolescents:

1) Receive theoretical and evidence-based training and expertise in general child, adolescent, and family mental health across the developmental spectrum.
2) Receive training and have expertise in gender identity development and gender diversity in children and adolescents, and across the lifespan.
3) Possess the ability to assess capacity to assent and consent.
4) Receive training and have expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with an expert in these areas.
5) Engage in continuing education related to gender diverse children, adolescents and with families.

L. Appendix C

Format for Referral Letters from Qualified Health Professionals:

1) Client's general identifying characteristics; and
2) Results of the client's assessment, including any diagnoses; and

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3) Description of the healthcare professional's licensure and experience (see Appendix B)
4) An explanation that the WPATH criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery; and
5) A statement about the fact that informed consent has been obtained from the patient; and

Note: There is no minimum duration of relationship required with a mental health professional. It is the professional's judgment as to the appropriate length of time before a referral letter can appropriately be written.

Note: Evaluation of candidacy for gender affirmation surgery by a healthcare professional is covered under the member's medical benefit, unless the services of a mental health professional are necessary to evaluate and treat a mental health problem, in which case the mental health professional's services are covered under the member's behavioral health benefit. Please check benefit plan descriptions.

Note: All formats of referral documentation, including narrative and assessment templates, are acceptable, if items a through e are included.

Note: Original and electronic signatures are acceptable.

Select Health Advantage (Medicare/CMS)

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Summary of Medical Information

Guideline-Directed Therapy

The Standards of Care (SOC-8) [also referred to as WPATH] guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender-affirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve.

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The SOC-8 supports the role of informed decision-making and the value of harm reduction approaches. In addition, this version of the SOC recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Health care professionals can use the SOC to help patients consider the full range of health services open to them in accordance with their clinical needs for gender expression …

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Healthcare Services

The goal of gender-affirming care is to partner with TGD people to holistically address their social, mental, and medical health needs and well-being while respectfully affirming their gender identity. Gender-affirming care supports TGD people across the lifespan—from the very first signs of gender incongruence in childhood through adulthood and into older age—as well as people with concerns and uncertainty about their gender identity, either prior to or after transition. Transgender health care is greater than the sum of its parts, involving holistic inter- and multidisciplinary care between endocrinology, surgery, voice and communication, primary care, reproductive health, sexual health and mental health disciplines to support gender-affirming interventions as well as preventive care and chronic disease management. Gender-affirming interventions include puberty suppression, hormone therapy, and gender-affirming surgeries among others. It should be emphasized there is no 'one-size-fits-all' approach and TGD people may need to undergo all, some, or none of these interventions to support their gender affirmation. These guidelines encourage the use of a patient-centered care model for initiation of gender-affirming interventions and update many previous requirements to reduce barriers to care. Ideally, communication and coordination of care should occur between providers to optimize outcomes and the timing of gender-affirming interventions centered on the patient's needs and desires and to minimize harm …

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Billing/Coding Information

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Claims for gender affirming breast reduction and/or removal for transgender male and non-binary members ***should not be coded*** with 19303 for complete mastectomy +19350 for nipple/areola reconstruction.

Covered: For the conditions outlined above for plans with gender reassignment supplemental coverage.

CPT CODES

00402	Anesthesia for procedures on the integumentary system on the extremities, anterior trunk and perineum; reconstructive procedures on breast (eg, reduction or augmentation mammoplasty, muscle flaps)
00926	Anesthesia for procedures on male genitalia (including open urethral procedures); radical orchiectomy, inguinal
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
15100-15101	Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children + each additional 1%
15120	Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less. of wound surface area.
15272	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity

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15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with mocrovascular anastomosis
15860	Intravenous injection of agent (eg, fluorescein) to test vascular flow in flap or graft
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19318	Reduction mammaplasty
19325	Breast augmentation with implant
35236	Repair blood vessel with vein graft; upper extremity
35256	(Repair blood vessel with vein graft; lower extremity)
51102	Aspiration of bladder; with insertion of suprapubic catheter
53405	Urethroplasty; second stage (formation of urethra), including urinary diversion
53410	Urethroplasty, 1-hyphenstage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
53450	Urethromeatoplasty with mucosal advancement
54120	Partial amputation of the penis
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis
54690	Laparoscopy, surgical; orchiectomy
55150	Resection of scrotum
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy, simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57210	Colpoperineorrhaphy, suture of injury of vagina and/or perineum (nonobstetrical)

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57282	Colpopexy, vaginal; extra-hyphenperitoneal approach (sacrospinous, iliococcygeus)
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s);
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and /or ovary(s);
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
58999	Unlisted procedure, female genital system (nonobstetrical) [metoidioplasty]
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64859	Suture of each additional major peripheral nerve
64874	Suture of nerve; requiring extensive mobilization, or transposition of nerve

HCPCS CODES

C1789	Prosthesis, breast (implantable)
C1813	Prosthesis, penile, inflatable
L8600	Implantable breast prosthesis, silicone or equal
S0189	Testosterone pellet, 75 mg

Not Covered for the indications listed above

19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19350	Nipple/areola reconstruction

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MEDICAL POLICY

GENDER AFFIRMING MEDICAL AND SURGICAL TREATMENT FOR COLORADO BASED PLANS

Policy # 677

Implementation Date: 1/1/24
Review Dates:
Revision Dates:

Related Medical Policies:

#386 Gender Affirming Medical and Surgical Treatment

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

Gender affirming medical and surgical treatment (GAMST) is part of the spectrum of care considered for individuals with gender dysphoria (which also includes individuals who identify as non-binary), a condition in which a person feels a strong and persistent identification with the opposite gender, accompanied with a severe sense of discomfort in their own gender. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5-Text Revision [TR]) provides for one overarching diagnosis of gender dysphoria, with separate specific criteria for children, and for adolescents and adults.

In adolescents and adults, a gender dysphoria diagnosis involves a difference between one's experienced/expressed gender and assigned gender, and significant distress or problems functioning. It lasts at least six months and is manifest by at least two of the following:

- A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics
- A strong desire to be rid of one's primary and/or secondary sex characteristics
- A strong desire for the primary and/or secondary sex characteristics of the other gender*
- A strong desire to be of the other gender*
- A strong desire to be treated as the other gender*

According to the World Professional Association for Transgender Health (WPATH), gender dysphoria is broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics). For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered, including gender affirmation surgery.

Gender affirming medical and surgical treatment is not a single intervention or procedure, but part of a complex process that may involve multiple medical, psychiatric, and surgical modalities working in conjunction with each other and the patient to achieve successful outcomes.

*Per the DSM-5: Other gender = Some alternative gender different from one's assigned gender.

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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.

In conjunction with the Affordable Care Act Essential Health Benefits provision, the following Gender Affirming Medical and Surgical Treatment procedures are covered for plans based in Colorado:

1) Hormone therapy
2) Genital and non-genital surgical procedures
3) Blepharoplasty (eye and lid modification)
4) Face/forehead and/or neck tightening
5) Facial bone remodeling for facial feminization
6) Genioplasty (chin width reduction)
7) Rhytidectomy (cheek, chin, and neck)
8) Cheek, chin, nose implants
9) Lip lift/augmentation
10) Mandibular angle augmentation/creation/reduction (jaw)
11) Orbital recontouring
12) Rhinoplasty (nose reshaping)
13) Laser or electrolysis hair removal
14) Breast/chest augmentation, reduction, construction

For all other Gender Affirming Medical and Surgical Treatment procedures, the member must be at least 18 years of age and meet criteria outlined in Select Health medical policy #386.

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

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Summary of Medical Information

Guideline-Directed Therapy

The Standards of Care (SOC-8) [also referred to as WPATH] guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender-affirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve.

The SOC-8 supports the role of informed decision-making and the value of harm reduction approaches. In addition, this version of the SOC recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Health care professionals can use the SOC to help patients consider the full range of health services open to them in accordance with their clinical needs for gender expression …

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Claims for gender affirming breast reduction and/or removal for transgender male and non-binary members ***should not be coded*** with 19303 for complete mastectomy +19350 for nipple/areola reconstruction.

CPT CODES

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00926	Anesthesia for procedures on male genitalia (including open urethral procedures); radical orchiectomy, inguinal
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
15100-15101	Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children + each additional 1%
15120	Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less. of wound surface area.

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15272	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with mocrovascular anastomosis
15860	Intravenous injection of agent (eg, fluorescein) to test vascular flow in flap or graft
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19318	Reduction mammaplasty
19325	Breast augmentation with implant
19350	Nipple/areola reconstruction
35236	Repair blood vessel with vein graft; upper extremity
35256	(Repair blood vessel with vein graft; lower extremity)
51102	Aspiration of bladder; with insertion of suprapubic catheter
53405	Urethroplasty; second stage (formation of urethra), including urinary diversion
53410	Urethroplasty, 1-hyphenstage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
53450	Urethromeatoplasty with mucosal advancement
54120	Partial amputation of the penis
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach

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54660	Insertion of testicular prosthesis
54690	Laparoscopy, surgical; orchiectomy
55150	Resection of scrotum
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy, simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57210	Colpoperineorrhaphy, suture of injury of vagina and/or perineum (nonobstetrical)y
57282	Colpopexy, vaginal; extra-hyphenperitoneal approach (sacrospinous, iliococcygeus)
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s);
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and /or ovary(s);
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
58999	Unlisted procedure, female genital system (nonobstetrical) [metoidioplasty]
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64859	Suture of each additional major peripheral nerve
64874	Suture of nerve; requiring extensive mobilization, or transposition of nerve

HCPCS CODES

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Gender Affirming Medical and Surgical Treatment for Colorado Based Plans, continued

C1789	Prosthesis, breast (implantable)
C1813	Prosthesis, penile, inflatable
L8600	Implantable breast prosthesis, silicone or equal
S0189	Testosterone pellet, 75 mg

Key References

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MEDICAL POLICY

GYNECOMASTIA SURGERY

Policy # 124
Implementation Date: 4/15/02
Review Dates: 5/16/03, 6/25/03, 4/22/04, 1/13/05, 1/3/06, 12/20/07, 12/18/08, 12/17/09, 6/20/13, 5/7/15, 4/14/16, 4/27/17, 6/21/18, 5/5/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23, 4/2/24
Revision Dates: 4/22/02, 7/24/06, 10/21/10, 10/21/11, 4/19/12, 11/1/23, 4/4/24

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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

Gynecomastia is excessive development of the male mammary glands, due mainly to ductal proliferation with periductal edema; frequently, secondary to increased estrogen levels, but mild gynecomastia may occur in normal adolescence. Gynecomastia surgery is the removal of breast tissue from one or both male breasts that is persistent from either physiological or pathological reasons.

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 surgery for gynecomastia as medically necessary when certain criteria have been met.

Criteria for coverage (either 1 or 2 must be met):

1. Klinefelter's syndrome; **OR**
2. Either pubertal (adolescent) onset gynecomastia that has persisted for at least 2 years; **OR** post pubertal-onset gynecomastia that has persisted for 1 year, when **ALL** the following criteria are met:
   a) Glandular breast tissue confirming true gynecomastia is documented on physical exam and/or by mammography.
   b) The gynecomastia is classified as Grade II or greater, per the American Society of Plastic Surgeons classification*
   c) The condition is associated with persistent breast pain, despite the use of analgesics.
   d) The use of potential gynecomastia-inducing drugs and substances has been identified and discontinued for at least 1 year, when medically appropriate**
   e) The gynecomastia persists, despite correction of any underlying causes.
   f) Hormonal causes, including hyperthyroidism, estrogen excess, prolactinomas, and hypogonadism have been excluded by appropriate laboratory testing (e.g., with levels of thyroid stimulating hormone [TSH], estradiol, prolactin, testosterone and/or luteinizing hormone, [LH]), and if present, have been treated for at least 12 months before surgery has been considered.
   g) Patient's BMI is < 30

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*Gynecomastia *Scale adapted from the McKinney and Simon, Hoffman and Kohn scales*

Grade I *Small breast enlargement with localized button of tissue that is concentrated around the areola.*

Grade II *Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.*

Grade III *Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present.*

Grade IV *Marked breast enlargement with skin redundancy and feminization of the breast.*

***This indication is waived with written statement from patient's prescribing physician that this medicine is mandatory and cannot be changed to an alternative medication*

Select Health does NOT cover suction lipectomy or ultrasonically-assisted suction lipectomy (liposuction) as a sole method of treatment for gynecomastia, because such treatments are considered unproven in the treatment of gynecomastia.

Select Health does NOT cover surgical treatment of gynecomastia under EITHER of the following conditions, as it is considered cosmetic in nature and not medically necessary:

- When performed primarily to improve appearance of the male breast or to alter contours of the breast wall
- When performed solely to treat psychological or psychosocial complaints

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

Physiological pubertal gynecomastia occurs in teenage boys, usually between the ages of 13 and 14. In more than 90% of these boys, the condition resolves within a year. This temporary development of breast tissue is probably related to normal development of testicular tissue and the short-lived increase in plasma estrogen relative to plasma testosterone. In adults, gynecomastia is associated with increasing age. This is due to the onset of testicular hypofunction and increased adiposity, which enhances the atomization of androgens to estrogens. Certain medications or drugs can lead to the development of gynecomastia.

In some instances, adolescent gynecomastia may be reported as tender or painful, and the presence of these symptoms may be presented as a rationale for the medical necessity of surgical treatment. However, the pain associated with adolescent gynecomastia is typically self-limiting or responds to analgesic therapy.

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Gynecomastia Surgery, continued

Billing/Coding Information

Covered: For the indications outlined above

CPT CODES

19300 Mastectomy for gynecomastia

HCPCS CODES

No specific codes identified

Key References

1. American Society of Plastic Surgeons (ASPS). (2002). ASPS Recommended Insurance Coverage Criteria for Third-Party Payers. Date Accessed: October 21, 2010. Available: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/insurance/Gynecomastia-Insurance-Coverage.pdf.
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MEDICAL POLICY

INTRATHECAL BACLOFEN THERAPY

Policy # 137

Implementation Date: 1/4/00

Review Dates: 2/27/01, 6/5/02, 10/23/03, 11/18/04, 11/7/05, 10/19/06, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23

Revision Dates: 11/18/04, 9/14/06, 9/4/08, 11/12/11, 10/19/17

Related Medical Policies:

#609 Infusion Pumps (External or Implantable)

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

Intrathecal baclofen therapy is administered to patients with chronic, intractable spasticity. It is based on the surgical implantation of a programmable infusion pump and placement of a catheter into the intrathecal space, the primary site of action, for the delivery of baclofen. The pump is implanted on an indefinite basis, depending on patient response and prognosis. Baclofen (trade name, Lioresal) is a muscle relaxant and anti-spasmodic agent and is the most used anti-spastic drug; other drugs can be added to the pump to improve management of these patients.

In some patients with severe spasticity who are on oral baclofen, the amount of drug that penetrates the blood-brain barrier is insufficient to provide adequate relief. Thus, the achievement of a satisfactory therapeutic response involves high oral dose regimens, which can cause intolerable central nervous system (CNS) side effects or systemic toxicity. Such patients often benefit from long-term intrathecal administration of baclofen.

Intrathecal baclofen (IB) therapy, in contrast to oral baclofen, permits effective levels to be obtained at the site of action without concomitant high levels in non-target tissues (e.g., blood). Thus, plasma concentrations of patients on IB therapy can be 100 times less than those of patients on oral baclofen, with equivalent therapeutic effect, dramatically reducing potential side effects and increasing functional status of the patient.

Side effects of this drug therapy are related to its CNS depressant characteristics and include sedation, drug tolerance, sleepiness, ataxia, and respiratory and cardiovascular depression. The patient population is primarily those with spasticity of spinal or cerebral origin (e.g., due to spinal cord trauma, degenerative spinal disease [multiple sclerosis], cerebral palsy, or brain injury).

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 intrathecal baclofen therapy for the treatment of spasticity in *limited circumstances*.

Criteria for placement of trial (temporary) pump:

1. Patient has intractable spasticity of cerebral or spinal origin.

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2. Documentation of failure, contraindication, or intolerance to at least a 6-week trial of oral antispasmodic drugs and physical therapy.

Criteria for placement of permanent pump:

1. **ALL** the above, **AND**
2. Patient has a favorable response to a trial intrathecal dosage of the anti-spasmodic drug prior to pump and demonstrates improvement of the Ashworth Scale, Spasm Scale, or ADLs (Activities of Daily Living) implantation as evidenced by the following:

Ashworth Scale:

1- No increase in muscle tone.

2 - Slight increase in tone giving a "catch" when affected part is moved in flexion or extension.

3 - More marked increase in tone but affected part is easily flexed.

4 - Considerable increase in tone; passive movement difficult.

5 - Affected part is rigid in flexion or extension; and

Spasm Scale:

Spasms are measured by the number of spontaneous muscle spasms that occur over a 1-hour period:

0 - None.

1 - No spontaneous spasms; but vigorous sensory or motor stimulation results in spasms.

2 - Occasional spontaneous spasms or easily induced spasms.

3 - Greater than 1 but less than 10 spontaneous spasms per hour.

4 - Greater than 10 spontaneous spasms per hour.

Contraindications:

- Hypersensitivity to baclofen
- Presence of general contraindications to a surgical procedure (e.g., sepsis, coagulopathy).

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

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Summary of Medical Information

Boviatsis et al. estimated the functional benefit in 22 patients with severe and disabling pharmaceutically intractable spasticity treated with intrathecal baclofen infusion through an implantable pump. Fifteen patients had multiple sclerosis and seven had suffered a spinal cord injury at different levels (from C4 to T11). Postoperatively, all patients reported reduced spasticity, spasm frequency, and pain, improved functional status, and enhanced quality of life. In a placebo-controlled trial by Van Schaeybroeck et al., 11 patients with spasticity of cerebral origin (mainly cerebral palsy) underwent bolus injections of baclofen and placebo. Eight patients were considered good responders and received a subcutaneous device for intrathecal drug delivery. Six of these were followed-up on for 2 years during which they were subjected to a blinded dose reduction test. The authors reported a noticeable placebo effect on spasticity scores during tests with bolus injections, suggesting the need for double-blind screening in each patient. Eight patients demonstrated a significant beneficial effect of intrathecal bolus injections compared with this placebo effect. Functional improvements were noted in most patients. During continuous infusion, Ashworth scale scores were less favorable but still significantly lower than at baseline.

Sampson et al. conducted a systematic literature review to estimate the effect of continuous intrathecal baclofen infusion on function and quality-of-life (QoL) measures in patients with severe spasticity. Health and cost data were obtained from hospitals in the United Kingdom. Results indicated that intrathecal baclofen improves mobility in bedbound patients and significantly reduce or eliminate pain in persons with severe spasm-related pain. Estimated costs per quality adjusted life year ranged between $10,550 to $19,570. Sampson et al. concluded that in carefully selected patients who have not responded to less invasive treatments, continuous intrathecal baclofen infusion is likely to lead to worthwhile functional benefits. Continuous intrathecal baclofen infusion has an acceptable cost/benefit ratio compared with other interventions that are funded by the health service.

A literature review performed in October 2011 identified Brennan et al. (2010), who found continuous infusion of intrathecal baclofen (ITB) via a subcutaneously implanted pump has developed over the past 2 decades as a powerful tool in the management of spasticity in various adult and pediatric neurological conditions. Acting more focally on spinal GABA receptors, ITB causes fewer systemic side effects than orally administered baclofen. The result is facilitation of daily caring, and symptomatic relief from painful spasm. With increasing experience of ITB use, novel applications and indications are emerging. These include the management of dystonia and chronic neuropathic pain. However, despite some recent authoritative reviews, there is still uncertainty about optimal use and evaluation of this therapy.

Billing/Coding Information

CPT CODES

Catheter Placement

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

Reservoir/Pump Placement

62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	; 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

Analysis/Reprogramming

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

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62368	; with reprogramming
62369	; with reprogramming and refill
62370	; with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

Refilling

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 physician's skill 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)

HCPCS CODES

This list is not all-inclusive

J0475	Injection, baclofen, 10 mg
J0476	Injection, baclofen, 50 mcg for intrathecal trial
A4220	Refill kit for implantable infusion pump
A4221	Supplies for maintenance of drug infusion catheter, per week (list drug separately)
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, non-programmable, permanent (implantable)
C2626	Infusion pump, non-programmable, temporary (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)

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Intrathecal Baclofen Therapy, continued

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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MEDICAL POLICY

KIDNEY TRANSPLANT AND RE-TRANSPLANTATION

Policy # 141

Implementation Date: 11/94
Review Dates: 1/4/00, 2/27/01, 5/21/01, 5/13/02, 6/25/03, 6/24/04, 6/16/05, 10/18/07, 10/23/08, 7/18/13, 6/11/15, 6/16/16, 6/15/17, 6/21/18, 6/20/19, 6/2/20, 6/17/21, 6/2/22, 6/2/23
Revision Dates: 9/19/06, 1/28/10, 1/17/11, 7/15/11, 7/23/11, 9/12/11, 6/19/20, 12/10/21, 6/8/22, 11/1/23

Related Medical Policies:

#142 Liver Transplant (Adult, Cadaveric)
#143 Liver Transplant-Adult Living Donor Liver Transplantation (aLDLT)
#144 Simultaneous Liver and Kidney Transplant (SLK)

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

Kidney transplantation should be strongly considered for all patients who are medically suitable with chronic and end-stage renal disease (ESRD). A successful kidney transplant offers enhanced quality and duration of life and is more effective (medically and economically) than chronic dialysis therapy. Transplantation is the renal replacement modality of choice for patients with diabetic nephropathy and pediatric patients.

In the United States, potentially more than 100,000 persons may have lived with a functioning kidney transplant each year. This number represents 27% of the nearly 350,000 persons who may have been enrolled in the U.S. ESRD program.

Kidney transplantation is the treatment of choice for end-stage renal disease. A successful kidney transplant improves the quality of life and reduces the mortality risk for most patients, when compared with maintenance dialysis.

Patients who have been so diagnosed usually qualify for Medicare coverage, either as secondary or primary coverage depending on their Medicare eligibility date and type of coverage. Medicare does not cover immunosuppressive drugs more than 1-year post-transplant.

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.

Kidney transplants will be approved If recommended by Intermountain Healthcare Renal Transplant Clinical Program; **OR**

For all other clinicians, Select Health covers renal transplants if the following criteria are met:

Criteria for coverage (must meet 1, and EITHER 2 or 3, AND 4 through 9 below):

1. Provided by In-Network Providers in an In-Network Facility* unless otherwise approved in writing in advance by Select Health. *This criterion does not apply to Idaho commercial plans. Members on Idaho commercial plans may use their out-of-network benefits with an out-of-network provider if all other criteria are met.

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2. Acute trauma with irreversible impairment of renal function where no therapeutic alternative is available; **or**
3. Chronic renal impairment is irreversible; permanent; has progressed to the point of significant interference with the patient's quality of life, and for which no other effective medical or surgical therapeutic alternative is available; **and**
4. The patient has one of the following:
   a. On dialysis; or
   b. The dialysis need is imminent; or
   c. The patient has a living-related donor (the transplant may be done before dialysis is necessary); or
   d. The patient may have a history of a renal transplant, but due to progressive graft failure is approaching the need for dialysis.
5. A reasonable expectation that the patient's quality of life (e.g., physical and social function suited to activities of daily living), will be improved.
6. Strong motivation by the patient to undergo the procedure and a thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
7. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would preclude surgery or a reasonable survival.
8. Medical and social assessment that the patient has sufficient social stability to provide assurance that they will cooperate with the long-term follow-up and the immunosuppressive program, which is required.
9. No uncontrolled and/or untreated psychiatric disorder or substance use disorder that would interfere with compliance to a treatment regimen.

Absolute Contraindications:

1. Advanced respiratory failure.
2. Myocardial infarction within 6 months
3. Intractable life-threatening cardiac arrhythmias
4. Severe generalized arteriosclerosis
5. Active severe hemodynamic compromise at the time of transplantation if accompanied by significant compromise of one or more non-renal end-organs.
6. Unmanageable active infection
7. Cancer, (except skin cancer) unless treated and eradicated for 2 or more years
8. Unresolved GI hemorrhage
9. Debilitating and/or irreversible brain damage
10. Life-threatening extra-renal congenital abnormalities
11. Persistent coagulation disorder

Relative Contraindications:

12. Age at the time of transplant: greater than 70 years or less than 18 years
13. Clinical evidence of peripheral vascular disease, specifically, cerebral vascular disease, ischemic ulcers, or previous amputations secondary to vascular disease
14. Diabetic patient with poor control (hgbA1c >9%) who has documentation of poor medication adherence/compliance and/or lifestyle management based on clinical documentation or prescription refills
15. Active peptic ulcer disease
16. Hypertension poorly controlled by medication
17. Morbid obesity

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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

Candidates for renal transplantation undergo an extensive evaluation to identify factors that may have an adverse effect on outcome. Virtually all transplant programs have a formal committee that meets regularly to discuss the results of evaluation and select medically suitable candidates to place on the waiting list. Most programs perform the evaluation in the outpatient setting and possess a relatively uniform approach to the diagnosis and treatment of the pertinent medical and psychosocial issues affecting candidacy.

The primary goal of short-term and long-term medical follow-up is enabling surveillance for signs and symptoms of renal allograft dysfunction. Renal parenchymal dysfunction has many etiologies. The clinical manifestation is typically an increase in serum creatinine. The most common causes of allograft dysfunction are rejection, nephrotoxicity of calcineurin inhibitors, and recurrence of native kidney disease. The time interval between transplantation and the rise in serum creatinine often is helpful to determine the etiology graft dysfunction.

Despite these complications, the 1-year life expectancy after kidney transplantation is 95%−98%.

Billing/Coding Information

CPT CODES

50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)

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50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor
90951-90970	ESRD Services

HCPCS CODES

S2065	Simultaneous pancreas kidney transplantation
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s) , procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition
S9339	Home therapy; peritoneal dialysis, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately

Key References

1. Fabrizii V, Winkelmayer WC, Klauser R, et al. (2004). Patient and graft survival in older kidney transplant recipients: does age matter? J Am Soc Nephrol.15(4):1052.
2. Ismail, N. (2011). Renal transplantation and the elderly patient. UpToDate. 19.2. May. Last Update: June 4, 2011. Available: http://www.uptodate.com/contents/renal-transplantation-and-the-elderly-patient?source=see_link. Date Accessed: September 12, 2011.
3. Kaufman DB. (2011). Renal Transplantation (Medical). Medscape Reference. September. Last Update: September 8, 2011. Available: http://emedicine.medscape.com/article/429314-overview. Date Accessed: September 12, 2011.
4. Post, TW and Vella, J. (2011). Patient survival after renal transplantation. UpToDate. 19.2. May. Last Update: February 13, 2011. Available: http://www.uptodate.com/contents/patient-survival-after-renal-transplantation?source=search_result&search=Patient+survival+after+renal+transplantation&selectedTitle=1%7E150. Date Accessed: September 12, 2011.
5. Ramos, E and Brennan, DC. (2011). Evaluation of the potential renal transplant recipient. UpToDate. 19.2. May. Last Update: May 6, 2010. Available: http://www.uptodate.com/contents/evaluation-of-the-potential-renal-transplant-recipient?source=search_result&search=kidney+transplantation+adult&selectedTitle=16%7E150#H5. Date Accessed: September 12, 2011.

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Kidney Transplant And Re-Transplantation, continued

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MEDICAL POLICY

LIVER TRANSPLANT (CADAVERIC)

Policy # 142

Implementation Date: 1/4/00
Review Dates: 2/27/01, 6/21/01, 5/13/02, 6/25/03, 6/24/04, 6/16/05, 12/18/08, 12/16/10, 12/15/11, 7/18/13, 8/28/14, 10/20/16, 10/19/17, 10/4/18, 10/15/19, 10/15/20, 11/22/21, 9/15/22, 10/2/23
Revision Dates: 9/20/06, 10/18/07, 1/28/10, 3/12/10, 12/04/14, 1/5/15, 3/9/17, 11/1/17, 11/20/19, 1/24/22, 6/30/22, 11/1/23

Related Medical Policies:
#141 Kidney Transplant and Re-Transplantation
#143 Liver Transplant-Adult Living Donor Liver Transplantation (aLDLT)
#144 Combined Liver/Kidney Transplant

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

Liver transplantation has emerged as a practical and established medical therapy for patients with fulminant hepatic failure and end-stage liver disease. Initially progress and growth in offering liver transplantation were limited by technical difficulties, an inherent learning curve in the management of patients both pre- and post-transplantation. Now liver transplantation is the standard of care for managing end stage liver disease complications in the context of chronic liver disease, liver tumors and acute liver failure that will not recover. Although this therapy could theoretically be used for every patient with terminal liver disease it is offered to only those with a clear transplant benefit and to those likely to survive for an extended period post-transplant. Liver transplantation should not be considered as either the initial or primary treatment modality for most liver diseases and candidates for liver transplant must have a low probability for recurrent disease to preserve the utility of a scarce resource; the organ donated.

The probability of success with liver transplantation is inversely related to the severity of illness the patient suffers from. The probability of a successful outcome is lower than for patients less severely ill and accordingly in some instances the severity of the patient's clinical state may prevent transplantation as the "***Final Rule***" dictates that an adequate probability of survival after transplantation must before a transplant can be performed.

The challenge for the transplant team is to choose their candidates wisely, to choose the donor organs selectively, and to optimize utility of the scarce supply of donor organs. Allocation of donor organs will remain problematic until the donor liver supply can meet demands and to address the supply demand mismatch and the issue that nationally approximately 30% listed never realize a transplant opportunity, living donor transplantation is explored and nationally recognized as essential to providing the best care to patients who are wait listed. Other techniques to improve supply include such techniques as split liver transplantation and domino liver transplantation.

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.

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Select Health covers cadaveric liver transplantation in *limited circumstances,* where the medical literature has demonstrated a reasonable probability of improvement in the member's health outcome. The following coverage criteria reflect this policy.

Criteria for coverage: (Patient must meet **A or B**)

A. Procedure has been endorsed, recommended, and will be performed by Intermountain Healthcare Liver Transplant Services

OR

B. For service being requested outside of Intermountain Healthcare:

1. The patient is under case management with Select Health.

2. The transplant team has documented the following:

a. The patient has irreversible, end-stage or chronic liver disease which has progressed to the point of significant interference with the patient's life activities (e.g., the patient is unable to work, attend school, or perform housework duties).

b. There is no other effective medical or surgical therapeutic alternative available.

c. There is a reasonable expectation that the patient's quality of life (i.e., physical and social function required to perform activities of daily living will be significantly improved).

d. One of the following (i–iv):

i) The patient's MELD (Model for End-State Liver Disease as maintained by the United Network for Organ Sharing, [UNOS]) score is **15** or higher, or

ii) The patient meets criteria for an Organ Procurement and Transplantation Network (OPTN) approved MELD exception (T2 tumor or a tumor downstaged and stable within Milan criteria, hepatopulmonary syndrome, portopulmonary hypertension, etc.) requiring transplantation to reverse the process, or

iii) The patient has a genetically derived metabolic condition with clear benefit from transplantation, or

iv) The patient has experienced life-threatening complications of end stage liver disease where their mortality exceeds that predicted by their MELD score.

e. The patient and the patient's family have demonstrated sufficient motivation to undergo the preoperative preparation, the operative procedure, and the postoperative lifetime follow-up.

f. In its decision to recommend that the patient be a liver transplant recipient, the transplant team has considered and evaluated any evidence for non-compliance with medical care.

g. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would preclude surgery or a reasonable survival.

h. Medical and social assessment that the patient has sufficient social stability to provide assurance that they will cooperate with the long-term follow-up and the immunosuppressive program, which is required.

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i. No uncontrolled and/or untreated psychiatric disorder or substance use disorder that would interfere with compliance to a treatment regimen.

j. If the patient has diabetes mellitus, a comprehensive clinical assessment and cardiology specialist has cleared the patient for transplant surgery.

k. None of the below listed "Absolute Contraindications" apply to or characterize the patient.

3. The transplant team and the Select Health Medical Director (or their designee), concur that none of the following relative contraindications preclude acceptance of the patient as a liver transplant recipient:
   a. Age under 18 or over 65 years (Liver failure patients who are less than 18 years are referred to a participating pediatric liver transplant program. Those patients age > 65 must be otherwise healthy and evaluated on a case-by-case basis).

   b. Insulin dependent diabetes mellitus with complications.

   c. Extrahepatic or biliary sepsis.

Absolute Contraindications:

1. Irreversible musculoskeletal disease resulting in bed confinement.
2. Irreversible pulmonary disease as listed below:
   a. Cystic fibrosis with severe or incapacitating disease. Mild cystic fibrosis lung disease with severe liver disease can be considered on a case-by-case basis
   b. Obstructive pulmonary disease (FEV1 < 55% of predicted)
   c. Restrictive lung disease (FVC < 50% of predicted)
   d. Lung cancer
3. Metastatic cancer
4. Life-threatening and unmanageable bacterial or fungal infection outside the hepatobiliary system
5. Cardiovascular disease as listed below:
   a. Myocardial infarction within 3 months
   b. Intractable life-threatening cardiac arrhythmias
   c. NYHA Class IV heart disease
   d. Severe and non-bipassable occlusive peripheral vascular, coronary vascular disease, or cerebrovascular disease
   e. Severe generalized arteriosclerosis
6. Irreversible terminal state (extreme cachexia)
7. Severe extrahepatic disease which would likely limit life expectancy to less than 2½ years
8. Long-standing major psychosis; lack of social or family support systems; significant history of non-compliance
9. Incarceration
10. Dementia

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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 2002 Hayes technology evaluation concluded the following about adult liver transplantation: "Based on available data, the following HAYES Ratings have been assigned: 'A' for liver transplantation in adults who experience life-threatening complications of chronic liver disease, a decompensation of previously stable liver disease, or severe impairment of quality of life directly related to liver disease caused by primary biliary cirrhosis, primary sclerosing cholangitis, alcoholic cirrhosis, alpha-1 antitrypsin deficiency disease, or Wilson's disease; 'B' for liver transplantation in adults who experience life-threatening complications caused by hepatitis and who receive adequate immuno- and antiviral therapy following transplantation; 'B' for selected patients diagnosed with hepatocellular carcinoma; 'C' for reduced-size liver transplantation in adults; 'D' for patients with hepatocellular carcinoma who are candidates for subtotal liver resection, or whose tumor is greater than 5 cm in diameter, or have macrovascular involvement or extrahepatic spread of tumor; and 'D' for any type of liver transplantation in patients with absolute contraindications."

Another 2002 Hayes technology evaluation concluded the following about liver transplantation in pediatric patients: "Conclusions: Evidence from these studies suggests that liver transplantation is a feasible alternative for pediatric patients with end-stage liver disease, with outcomes comparable to those seen in adult populations. Most of the available data are from cadaver organ transplants; the available data are insufficient to provide a definitive conclusion regarding which specific type of liver transplant provides the best long-term outcome. The primary indications for liver transplantation in children include a life-threatening complication of chronic liver disease, a decompensation of previously stable liver disease, or the severe impairment of quality of life related to liver disease. Current United Network for Organ Sharing (UNOS) criteria for prioritization of transplant candidates have been developed to include all potential patients and allow for the distribution of organs to patients who are most able to benefit from them. Based on the available evidence, a Hayes Rating of 'A' has been assigned to cadaveric donor liver transplantation in children with acute or chronic end-stage liver disease or failure for whom transplant is deemed likely to succeed by a panel of experts (see the Hayes Medical Technology Directory® report entitled Living Donor Liver Transplantation for Hayes Ratings for pediatric living donor liver transplantation). A Hayes Rating of 'D' has been assigned for any type of liver transplantation in patients with hepatocellular carcinoma, who are candidates for subtotal liver resection, or whose tumor is greater than 5 cm in diameter, or has macrovascular involvement, or extrahepatic spread of tumor. A Hayes Rating of D has also been assigned for any type of liver transplantation in patients with absolute contraindications, e.g., active HIV infection, non-hepatic malignancy other than skin cancer, severe pulmonary disease, or severe cardiovascular disease; and for any type of liver transplantation in patients unwilling or unable to adhere to post-transplant lifestyle restrictions and medical regimen."

Billing/Coding Information

CPT CODES

47133	Donor hepatectomy (including cold preservation), from cadaver donor

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47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	; with trisegment split of whole liver graft into two partial liver grafts (i.e., left lateral segment (segments II and III) and right trisegment [segments I and IV through VIII])
47145	; with lobe split of whole liver graft into two partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe [segments I and V through VIII])
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	; arterial anastomosis, each
47399	Unlisted procedure, liver

HCPCS CODES

No specific codes identified

Key References

1. Di Dove LM & Brown RS. 2006. Patient selection for liver transplantation. UpToDate. http://www.utdol.com/utd/content/topic.do?topicKey=livertrn/4482&type=A&selectedTitle=5~144. Date accessed: 9/20/06.
2. Hayes Directory. 2002. Liver Transplantation, Adult. Lansdale, PA.
3. Hayes Directory. 2002. Liver Transplantation, Pediatric. Lansdale, PA.
4. Intermountain Healthcare's LDS Hospital Liver Transplant Listing Criteria Protocol document (revised 9/14/2006)
5. Murray KF, Carithers Jr. RL. AASLD Practice Guidelines: Evaluation of the Patient for Liver Transplantation/ (2005) Hepatology. Jun;41(6):1407-32.
6. United Network for Organ Sharing [UNOS] Liver transplant criteria (see http://www.unos.org/ and http://www.optn.org/organDatasource/about.asp?display=Liver)

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MEDICAL POLICY

LIVER TRANSPLANT – LIVING DONOR LIVER TRANSPLANTATION

Policy # 143

Implementation Date: 4/3/01

Review Dates: 5/13/02, 6/25/03, 4/22/04, 6/24/04, 6/16/05, 6/22/06, 7/12/07, 6/19/08, 6/11/09, 5/19/11, 6/21/12, 6/20/13, 6/19/14, 4/14/16, 6/16/16, 6/15/17, 2/18/19, 2/17/20, 2/18/21, 1/20/22, 2/16/23, 2/25/24

Revision Dates: 5/27/04, 1/28/10, 1/5/15, 3/9/18, 2/25/21, 12/10/21, 6/10/22, 4/16/24

Related Medical Policies:

#141 Kidney Transplant and Re-Transplantation

#142 Liver Transplant (Adult, Cadaveric)

#144 Simultaneous Liver and Kidney Transplant (SLK)

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

Living donor liver transplantation requires a careful donor selection and screening process to select a prospective donor who will not only be able to provide a donor graft segment of adequate function to ensure patient/recipient benefit, but also to ensure that the donor also survives and fully recovers from the hepatectomy. The liver segment donation requires removal of either the left lobe or combinations of right segments of the donor liver and simultaneous transplant into the waiting patient/recipient. Donors include parents, siblings, or adult children (> 18 years), as well as donors who have only an "emotional connection" to the recipient (e.g., friends, more distant relatives).

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 living donor liver transplantation, when both the recipient and donor meet qualification criteria. Coverage is allowed in these circumstances as the medical literature has shown an improvement in survival for the recipient, without undue risk to the donor. Applications of this procedure outside of these guidelines are not covered as the medical literature has not demonstrated improved outcomes for the recipient and/or acceptable morbidity/mortality to the donor when these transplants are performed.

Criteria for coverage:

A. Both the recipient and donor requirements have been endorsed and recommended, and the procedure will be performed by Intermountain Healthcare Liver Transplant Services;

OR

B. Fulfills liver transplant criteria (outlined in medical policy #142).

***Donor Criteria**:*

1. The prospective donor is age > 18 and < 60;

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2. No uncontrolled and/or untreated psychiatric disorder or substance use disorder that would interfere with compliance to a treatment regimen
3. Documentation supports **ALL** the following:
    a. The prospective donor initiated the contact stating interest in donating a liver segment;
    b. The prospective donor is in excellent psychological health;
    c. The prospective donor's decision to donate has been established to be entirely voluntary and without direct or indirect coercion, including informed consent;
    d. The prospective donor has a demonstrable, significant long-term relationship with the recipient;
    e. The prospective donor will not benefit financially from the organ donation;
    f. The prospective donor is in excellent medical health with no major medical problems (e.g., diabetes, severe or uncontrolled hypertension; cardiac, renal, or pulmonary disease; or active infection) and is free from any clinically significant abnormalities as determined by the following work-up criteria:
        i. Thorough history and physical examination;
        ii. Lab tests: ABO, hematology, chem12 panel, glucose tolerance test, coagulation profile, protein C, antithrombin III, Factor V, VII, and VIII, C-reactive protein (CRP), thyroid function tests (TSH, T3, T4), alpha-1-antitrypsin, transferrin, ferritin, tumor markers (e.g., AFP, CEA), U-sediment, and pregnancy test;
        iii. Serology tests: Hepatitis A, B, and C, CMV IgG, IgM, HSV, EBV IgG, IgM, VDRL, and HIV (by PCR);
        iv. Imaging studies: CT and abdominal ultrasound.
    g. The prospective donor is ABO compatible with recipient;
    h. The planned donor hepatectomy will:
        i. Provide a segmental graft of at least 0.55% of the recipient's body mass based on appropriate pre-operative imaging studies AND is expected to satisfy the physiologic needs of the recipient;
        ii. Allow for a residual donor liver volume of greater than 30%.
    i. All members of the Transplant Team agree on the appropriateness of the prospective donor.

Contraindications:

1. Donor has risk factors and/or significant medical co-morbidities that substantially increase the likelihood of surgical complications.
2. Donor demonstrates marginal psychosocial function.

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

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

Summary of Medical Information
The scarcity of donor organs is the limiting factor in liver transplantation. While over 5,000 transplants are performed annually in the United States, more than 1,000 candidates die each year on the liver transplant waiting list. Adult living donor liver transplantation (ALDLT) provides one means to expand organ availability. Living donation of the lateral segment of the left lobe of the liver has become highly successful in pediatric transplantation. An increasing number of transplant centers are starting to perform adult-to-adult right lobe ALDLT. Advantages of ALDLT include thorough donor screening, optimization of timing for transplantation, minimal cold ischemia time, and decreased cost. However, ALDLT poses a risk to the donor.

Living donors are usually close family members or spouses, although some transplant programs do accept unrelated "good Samaritan" living donors. ABO blood type compatibility is preferable, and donors are usually less than 60 years of age.

The first step in the screening process is education regarding the risks of living donation. A thorough psychosocial assessment is performed. Every effort should be made to confirm that consent is informed and to ensure that the prospective donor has adequate time to contemplate the risks of the procedure and to decline participation, if desired. Typically, separate teams evaluate the donor and the transplant candidate to limit any perceived pressure from the medical staff to comply with living donation.

The medical evaluation of the donor includes a comprehensive history and physical examination. Routine chemistries, a complete blood count, and liver enzymes are measured in addition to testing for Hepatitis B, Hepatitis C, and human immunodeficiency virus (HIV). A chest radiograph and an EKG are performed. CT or MR imaging provides means to estimate the volume of the left lateral segment or right lobe to assess whether the mass is sufficient to support a particular recipient. CT or MR further serves to identify space-occupying lesions and give an indication of the presence of steatosis. MR also provides a noninvasive method to obtain a preoperative cholangiogram. Conventional celiac and mesenteric angiography remains the gold standard for imaging the donor's abdominal vasculature. Some centers are gaining experience with CT or MR angiography, which are less invasive. More extensive cardiac and pulmonary testing is performed in selected cases. Liver biopsy is a routine part of the donor evaluation at some centers, while other programs reserve biopsy for potential donors with elevated liver enzymes or suspected steatosis. The degree of steatosis identified on liver biopsy may be used to correct volumetric estimates of hepatic mass. Suitable donors can use autologous blood banking to prepare for surgery.

Graft size constraints have generally limited the use of left lobe ALDLT to recipients who weigh less than 60 kg. The Kyoto group analyzed outcomes of 276 ALDLT recipients as a function of graft-to-recipient weight ratio. Patients who received grafts that were less than 1% of body weight had prolonged biochemical evidence of graft dysfunction, and a lower rate of graft survival.

The San Francisco program observed similar results in a smaller series. Grafts consisting of 60% or more of expected liver weight were successful, while graft failure occurred in 2 out of 5 patients who received transplants that were 50% or less of expected liver weight. Another group reported that a graft as small as 32% of predicted volume provided adequate metabolic function in some patients.

Transplantation of a thick, left-sided caudate lobe in addition to the left hepatic lobe has also been described. However, harvesting the caudate lobe along with the left lobe is technically difficult and applicable to only a limited number of patients.

There has been increasing interest in the use of the right hepatic lobe in adult LDLT. The right lobe accounts for approximately two-thirds of the liver mass and provides adequate tissue to support the metabolic needs of an adult recipient. The right lobe also fits correctly into the right subphrenic space, making the vascular anastomoses easier to perform. However, the extent of the resection may put the donor at increased risk. One known donor death has occurred during the early experience with right lobe ALDLT in the U.S.

The first series of adult-to-adult right lobe ALDLT was published in 1997. Seven procedures were reported with no donor mortality. Two donors had complications requiring surgical intervention including 1 bile duct stricture and 1 incisional hernia. Recipients in this early study experienced a high degree of

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morbidity. Six required re-operation for causes including biliary leakage, sepsis, and bleeding. Two recipients underwent later reoperation for management of biliary strictures.

A subsequent report included 25 adult-to-adult right lobe ALDLT. Four donors experienced minor complications including pressure sores, atelectasis, phlebitis, and prolonged ileus. No donor required heterologous blood transfusion and the average length of hospital stay for donors was 5.7 days. Graft and recipient survival were 88%. Six recipients (24%) had biliary complications and 5 of these required re-operation for management. The incidence of biliary complications was decreased in the last 15 cases with improvement of the parenchymal dissection and use of biliary stenting. Additional major complications in recipients included sepsis, gastrointestinal bleeding, and seizures. Similar findings have been observed in other series.

A series from the University of Colorado described the outcome in their first 41 transplants using right-lobe grafts. Most transplant recipients (93%) were alive and well after a mean follow-up of 9.6 months, although 4 patients required re-transplantation secondary to technical problems. Donor complications include bile leaks (3 patients) requiring reoperation in 2, an incisional hernia requiring surgical repair (1 patient), transient neuropraxia (1 patient), reoperation to retrieve a drain (1 patient), and hemothorax from venous access (1 patient). All donors had returned to their normal pre-transplantation activity. Similar experience has been described in other reports.

Donor mortality and morbidity have not been systematically collected or reported. The available evidence suggests that while right lobe donation appears to be safe, it can be associated with significant morbidity, and can affect quality of life. Donor deaths have also been reported.

The University of Chicago group reported complications in 100 adult donors who underwent left lateral segmentectomy (n = 91) or left lobectomy (n = 9) between 1989 and 1996. There were 14 major complications requiring operative or invasive intervention. Seven donors had biliary complications, 2 had wound dehiscences, and 1 each had hepatic artery thrombosis, intra-abdominal abscess, splenectomy, perforated duodenal ulcer, and gastric outlet obstruction. Twenty percent of recipients had minor complications that were managed conservatively, including pneumothorax, infections, and post-operative ileus. Left lobe resections were associated with a higher rate of morbidity than left lateral segmentectomy. Donor outcomes improved with experience. The second 50 donors analyzed had fewer complications and a shorter length of stay than the first cohort of donors. No donor deaths occurred in the study population. However, 1 death due to pulmonary embolus was previously reported in a pediatric LDLT donor, and other donor deaths have occurred, not all of which have been reported.

Right hepatic lobe donation may also have long-term consequences on quality of life. One study included 24 donors who were followed for 4 months or longer. Subjects were interviewed and asked to complete the Medical Outcomes Study 36-Item Short-Form Survey regarding psychosocial outcomes and symptoms after surgery. Major and minor complications each occurred in 4 patients (16% each). Complete recovery occurred in 75% of subjects at a mean time of 3.4 months. The majority (96%) returned to the same pre-donation job at an average of 2.4 months. A change in body image was reported in 42% of patients while 71% reported mild ongoing symptoms (mostly abdominal discomfort), which they related to the donor surgery. The mean out-of-pocket cost to the donors was $3,660. Despite these problems, all donors stated that they would donate again if necessary.

Similar conclusions were reached in another study in which the Medical Outcomes Study 15-Item Short-Form Survey was administered to 27 adult patients, one-half of whom had donated a right lobe. An event deemed to be an immediate complication was reported by 64% of the respondents. Complications requiring readmission occurred in 29% of patients. The mean recovery time was 18 weeks. No significant change was described in physical or social activity, and 92% resumed their pre-donation occupation. All patients said they would donate again and would recommend living donor transplantation to other potential donors.

A survey study summarized the experience of 449 adult-to-adult transplantations from living donors from 84 programs in the United States. The authors estimated that the overall mortality rate for the donor was 0.2%. In addition, at least 1 donor required liver transplantation. The most common complications were biliary (22%) and vascular (10%); approximately 9% of donors required rehospitalization. Complications occurred more often in centers performing the fewest transplants.

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No recent (i.e., useful) systematic reviews which address the clinical effectiveness and cost-effectiveness of this procedure have been identified. The Hayes review, below, is now old enough to be functionally out-of-date. The bulk of the published work on ALDLT for adults has been published since the Hayes review of the literature was completed. Thus, the primary evidence guiding conclusions for this assessment is the primary literature. From that primary literature, the following conclusions can be made.

The risk to donors in ALDLT seems to be about 1 in 500 deaths (0.2%). Reported 1-year and 5-year survival rates of ALDLT recipients are virtually equivalent to that of cadaveric liver transplant recipients.

Several authors have recommended that ALDLTs should only be performed in transplant centers in which the surgeons are vastly experienced in liver transplantation and major liver surgery. Selection criteria for recipients varies; some would suggest retaining the standard criteria/indications for cadaveric transplants while others suggest an expanded set of criteria because use of living donors changes many aspects of both clinical and non-clinical issues. The primary remaining controversies seems to lie with the substantial risk to (healthy) organ donors, selection and evaluation of prospective donors, the patient indications to whom the procedure would be made available, specifics of surgical technique, and the cost-effectiveness of the procedure.

No reports have been identified reporting survival rates/outcomes beyond 1-year in adults, though, several case series have reported survival of individual patients of several years, without overall rates. However, outcomes from LRLT performed in kids over the past 10 years have been as good as or better than liver transplants from cadaveric transplants. While it may be tempting to assume the same will occur in adults; at least 1 author has suggested there is a "… tendency of inferior results in adults … that is considered to be specific to ALRLT (probably due to size mismatching of donor liver)."

Costs: There are now published data with cost comparisons between living and deceased donor liver transplants, and post-transplant outcomes data pertinent to ALDLT, adult, and pediatric. A study from Yagi et al. stated that: "… the mean initial monthly cost in the adult group was significantly higher than that in the pediatric group ($123,000 vs. $41,500)." The Hayes report reviews several studies of standard liver transplant costs, which range between about $200,000–$400,000 (in 1988). Additional substantial costs would be incurred for screening/work-up of potential donors (about 30% of prospects "qualify"; 70% fail), collection of the donor liver (8–9 hr. surgery, 5 to 10 days in-patient recovery, and follow-up care of the donor, including a substantial rate of complications. However, although this initial experience suggests that some costs will be retrieved by reducing costs associated with maintaining patients in end-stage liver failure while awaiting an available organ, more recent data from the A2ALL North American Consortium and single center experience data from the largest living donor program in the United States details that the cost concerns previously voiced did not appear, and that there are potential cost savings with living donor liver transplantation when compared to deceased donor transplantation.

Billing/Coding Information

CPT CODES

47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
47399	Unlisted procedure, liver

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

LUNG (SINGLE OR DOUBLE) TRANSPLANT

Policy # 146

Implementation Date: 1/4/00

Review Dates: 105/21/01, 5/13/02, 6/25/03, 4/22/04, 4/20/05, 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, 6/21/18, 4/17/19, 4/15/20, 4/15/21, 3/18/22, 4/24/23

Revision Dates: 9/20/06, 12/2/20

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

More than 1,400 lung transplants were performed in 2007, according to the National Organ Procurement and Transplantation Network. The number of both single and double lung transplants has increased dramatically since 1990. While more recently, the number of lung transplantations has remained stable for several years, the proportion of bilateral lung transplants has increased and surpassed the number of single lung transplants.

In the United States, nearly 1,700 candidates were awaiting lung transplantation in mid-2011. In contrast to this rise in demand, the annual number of cadaveric lung donors in the United States has been relatively stable at approximately 1,700.

To alleviate the donor organ shortage, alternatives to cadaveric lung transplants, including living donor lobar lung transplantation, have been investigated. For living donor lobar lung transplantation, the right or left lower lung lobe is removed from the adult donor and transplanted into an adult or pediatric recipient. In some cases, 2 donors may be used, which permits bilateral transplant.

The indications for lung transplantation span the spectrum of lung diseases, but the most common diagnoses, in order of frequency, are chronic obstructive pulmonary disease (COPD), emphysema due to alpha-1 antitrypsin deficiency, idiopathic pulmonary fibrosis (IPF), cystic fibrosis (CF), idiopathic pulmonary arterial hypertension (IPAH), and Eisenmenger syndrome. Less common indications have included bronchiectasis, sarcoidosis, lymphangioleiomyomatosis (LAM), and pulmonary Langerhans cell histiocytosis.

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 lung transplantation *in limited circumstances*; it has been demonstrated in the medical literature to improve the health outcomes of members.

Criteria for coverage:

1. The patient has been evaluated and accepted for transplant with a transplant team participating with Select Health.

2. The patient must meet the established criteria of the transplant center the referring team has recommended.

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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

CADAVERIC LUNG TRANSPLANTATION: The first human lung transplant was performed in 1963, with the recipient dying 18 days later. Few lung transplants were performed thereafter, until the introduction of both improved surgical techniques and cyclosporine in the 1980s. Between 1988 and 1993, the number of lung transplants performed worldwide increased dramatically and the procedure has become an accepted treatment for end-stage lung disease.

There was a moderate increase from 1993–2005. The introduction of a lung allocation system in the United States in 2005 caused another rapid rise in the number of lung transplantations being performed; however, donor shortage remains a limiting factor.

LIVING DONOR LUNG TRANSPLANTATION: In Hayes' 2003 technology review, they concluded the following about living donor lung transplantation.

"Evidence from the available, peer-reviewed published studies suggests that living donor lobar lung transplantation is a reasonable treatment option for carefully selected patients with end-stage lung disease who are unlikely to survive or who may deteriorate clinically to the point of transplant ineligibility during the wait for a compatible cadaveric donor but who are otherwise eligible candidates for unilateral or bilateral lung transplantation. The surgery provides health benefits by improving respiratory and cardiac function and quality of life, and by prolonging survival in patients who otherwise are likely to die. While a number of recipients experience complications, or die, the likelihood of survival without transplant is extremely low. There is some evidence that living donor lobar lung transplants may be more efficacious than cadaveric lung transplants for certain patients, e.g., it leads to greater improvement in respiratory function, and that the incidence of chronic rejection, for which there is no effective therapy, is lower than that for cadaveric transplantation.

While the benefits to the recipient must be weighed against the risks to the healthy donor(s), to date, there have been no reports of donor deaths, and the majorities of lung lobe donors have a full recovery and return to their normal activities.

Despite these promising findings, living donor lobar lung transplantation is a relatively new procedure and is performed at only a few specialized centers. There is a need for additional, well-designed clinical trials to answer questions regarding long-term survival of recipients and safety for donors, as well as studies employing subgroup analyses to determine which recipients have the best prognosis and, therefore, would derive the most benefit from this procedure."

Based on this review of the available evidence, living donor lobar lung transplantation is assigned a Hayes Rating of 'B' for patients with end-stage lung disease with no other medical or surgical treatment options and who meet the criteria for cadaveric lung transplantation but are unlikely to survive the wait for a cadaveric lung allograft or may become ineligible for lung transplantation due to clinical deterioration. A

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Hayes Rating of 'D' is assigned for patients with contraindications to lung transplantation and for those whose prognosis is extremely poor despite transplantation, due to the risks to the healthy donor(s).

COST-EFFECTIVENESS OF LUNG TRANSPLANTATION: A 2002 study from Anyanwu et al. evaluated the cost-effectiveness of lung transplantation. The study estimated that over 15 years, lung transplantation yields mean improvement in quality-adjusted life-years (relative to medical treatment) of 2.1, 3.3, and 3.6 quality-adjusted life-years for single-lung, double-lung, and heart-lung transplantation, respectively. During the same period the mean cost of medical treatment was estimated at $73,564, compared with $176,640, $180,528, and $178,387 for single-lung, double-lung, and heart-lung transplantation, respectively. The costs per quality-adjusted life-year gained were $48,241 for single-lung, $32,803 for double-lung, and $29,285 for heart-lung transplantation. The authors concluded that survival and quality of life gains from lung transplantation are offset by its high cost, mortality, and morbidity.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

32850	Donor pneumonectomy (ies) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	; with cardiopulmonary bypass
32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral
35856	; bilateral

HCPCS CODES

S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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MEDICAL POLICY

LUNG VOLUME REDUCTION SURGERY

Policy # 197
Implementation Date: 10/15/03
Review Dates: 11/18/04; 11/18/05, 12/21/06, 4/23/07, 2/21/08, 2/26/09, 2/18/10, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/5/19, 2/11/20, 2/18/21, 1/18/22, 2/16/23, 2/7/24
Revision Dates: 2/17/11

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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
Lung volume reduction surgery (LVRS), or reduction pneumoplasty (also called lung shaving or lung contouring), unilateral or bilateral, by open or thoracoscopic approach for treatment of emphysema or chronic obstructive pulmonary disease, is a surgical technique that involves reducing lung volume by multiple wedge excisions. It can be done using either an open or thoracoscopic approach. It is also done either bilaterally or unilaterally. Persistent air leaks limited early success, however, the use of bovine pericardial strips and/or other materials to buttress the staple line, and improvements in surgical technique, have greatly improved success rates from the surgery itself. Randomized, controlled trials in patients with severe disease have demonstrated an appreciable operative mortality, without substantial improvements in lung function or symptoms, except in a select subgroup of patients.

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 lung volume reduction surgery *in limited circumstances.* This is based upon the select subgroup of patients that was shown to receive limited benefit in the National Emphysema Treatment Trial (NETT) Study.

Criteria for coverage: (Member must meet ALL the following)

1. Age < 75 years
2. History and physical examination consistent with emphysema
3. Severe dyspnea despite optimal medical therapy and maximal pulmonary rehabilitation
4. Has not smoked for 6 or more months
5. For members with cardiac ejection fraction less than 45%, there is no history of congestive heart failure or myocardial infarction within 6 months of consideration for surgery
6. The member has all the following on pre-operative work-up:
   a. Forced expiratory volume in 1 second (FEV1) (maximum of pre- and post-bronchodilator values) ≤ 45% of predicted and, if age 70 years or older, FEV1 15% of predicted or more

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b. Post-bronchodilator total lung capacity (TLC) greater than or equal to 100% of the predicted value and residual volume (RV) ≥ 150% of predicted value
c. Resting partial pressure of oxygen (PaO^2) 45 mmHg or greater
d. Resting partial pressure of carbon dioxide ($PaCO^2$) ≤ 60 mmHg on room air
e. CT scan evidence of bilateral emphysema (see exclusion criterion #14 below)
f. Plasma nicotine ≤ 13.7 ng/ml (if not using nicotine products) or carboxyhemoglobin ≤ 2.5% (if using nicotine products)
g. 6-minute walk test > 140 meters

Select Health does NOT cover lung volume reduction surgery if the member meets any one or more of the follow exclusion criteria:

1. Previous lung volume reduction surgery (laser or excision)
2. Pleural or interstitial disease which precludes surgery
3. Giant bullae (greater than 1/3 the volume of the lung in which the bulla is located)
4. Clinically significant bronchiectasis
5. Pulmonary nodule requiring surgery
6. Previous lobectomy
7. Uncontrolled hypertension (systolic greater than 200 mmHg or diastolic greater than 110 mmHg)
8. Oxygen requirement > 6 liters per minute during resting to keep oxygen saturation greater than or equal to 90%
9. History of recurrent infections with clinically significant production of sputum
10. Unplanned weight loss greater than 10% within 3 months prior to consideration for surgery
11. Pulmonary hypertension, defined as mean pulmonary artery pressure of 35 mmHg or greater on right heart catheterization or peak systolic pulmonary artery pressure of 45 mmHg or greater (right heart catheterization is required to rule out pulmonary hypertension if peak systolic pulmonary artery pressure is greater than 45 mmHg on echocardiogram)
12. Resting bradycardia (less than 50 beats per minute), frequent multifocal premature ventricular contractions (PVCs), complex ventricular arrhythmia or sustained supraventricular tachycardia (SVT)
13. Evidence of systemic disease or neoplasia that is expected to compromise survival.
14. Post-bronchodilator FEV1 is 20% or less than its predicted value and member has either
    a. A homogenous distribution of emphysema on CT scan; or
    b. A carbon monoxide diffusion capacity (DLCO) is 20% or less than its predicted value (persons in this category have been found to be at high risk for death after lung-volume reduction surgery, with little chance of functional benefit).
15. Member has predominantly non-upper lobe emphysema and a high maximal workload.
    a. For purposes of this policy, a high maximal workload is defined as a maximal workload (on cycle ergometry with an increment of 5 or 10 W per minute after 3 minutes of pedaling with the ergometer set at 0 W and the person breathing 30% oxygen) above the sex-specific 40th percentile (25 W for women, 40 W for men).
    b. For purposes of this policy, predominantly non-upper lobe predominance of emphysema is defined to exclude disease on CT that is judged by the radiologist as affecting primarily the upper lobes of the lung, and to include disease that is judged

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to be predominantly lower lobe, diffuse, or predominantly affecting the superior segments of the lower lobes.

(Persons with predominantly non-upper-lobe emphysema and a high maximal workload have been found to have higher mortality from lung-volume reduction surgery than from medical therapy alone and have been found to have little chance of functional improvement regardless of the treatment they receive.)

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

Emphysema represents the pathologic enlargement of air spaces beyond the terminal bronchiole, associated with destruction of the alveolar wall. The main treatments for emphysema are preventive (e.g., avoidance of smoking) and pharmacologic measures. Several forms of surgical therapy: bullectomy for giant bullae, bilateral pneumectomy (also called pneumoplasty or lung volume reduction surgery), and lung transplantation are options that are applicable to only a small number of patients with this disorder.

Based on results reported in peer-reviewed journals, abstracts, and presentations at national meetings, lung volume reduction surgery appears efficacious for a small group of patients with severe emphysema.

Several centers have documented post-operative improvement in exertional dyspnea, measurements of pulmonary function, exercise capacity, and objectively scored quality of life indices. Improvements in exercise capacity have been reported in patients undergoing a comprehensive program of pulmonary rehabilitation in preparation for surgery.

It appears that bilateral pneumectomy yields improvements in spirometry that are roughly twice as great as unilateral procedures.

In the one available randomized prospective trial that compared stapled lung reduction to laser bullectomy surgery, patients who received the latter procedure were more likely to develop a delayed pneumothorax and less likely to eliminate dependency on supplemental oxygen. Also, the mean post-operative improvement in the FEV1 at 6 months was greater in those who received the stapled lung reduction technique (32.9% improvement) than the laser treatment (13.4% improvement).

Fishman et al., reported on the results of the National Emphysema Treatment Trial, a randomized, multicenter clinical trial comparing lung volume reduction surgery with medical treatment. A total of 1,218 patients with severe emphysema were randomly assigned to undergo lung-volume-reduction surgery or to receive continued medical treatment. Lung volume reduction surgery was found to improve exercise capacity in a significant proportion of patients, but to have no significant effect on overall mortality. After 24 months, exercise capacity had improved by more than 10 W in 15% of the patients in the surgery group, as compared with 3% of patients in the medical-therapy group.

Lung volume reduction surgery was found to yield a survival advantage for patients with both predominantly upper-lobe emphysema and low base-line exercise capacity. Among patients with

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predominantly upper-lobe emphysema and low exercise capacity, mortality was more than 50% lower in the surgery group than in the medical-therapy group.

In contrast, LVRS was associated with an increase in mortality and negligible functional gain among patients with predominantly non-upper lobe emphysema and a high baseline exercise capacity. Among patients with non-upper-lobe emphysema and high exercise capacity, mortality was twice as high in the surgery group as in the medical therapy group.

Lung volume reduction surgery was also associated with an increase in mortality among persons who were, in previous reports considered to be at high risk of death after surgery, namely patients with a low FEV1 (20% or less than predicted) and either homogenous emphysema or a very low carbon monoxide diffusing capacity (20% or less than predicted).

Functional benefits, but no improvements in survival, were found in patients with predominantly upper-lobe emphysema and a high baseline exercise capacity and patients with non-upper lobe emphysema and a low baseline exercise capacity.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

32491	Removal of lung, other than pneumonectomy; with resection-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure, when performed
32672	Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed

HCPCS CODES

No specific codes identified

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Select Health

MEDICAL POLICY

MEDIAN ARCUATE LIGAMENT SYNDROME (MALS)

Policy # 658
Implementation Date: 10/27/22
Review Dates: 1/2/24
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

Median arcuate ligament syndrome (MALS) (also referred to as celiac artery compression syndrome or Dunbar syndrome) is a diagnosis of exclusion. Pertinent workup of this condition may include simple tests to rule out other etiologies. Several diagnostic modalities can be employed to make a diagnosis of celiac artery compression syndrome. These can be categorized as non-invasive and invasive modalities.

MALS was initially proposed as a vascular disease with etiology secondary to compression of the celiac artery and resultant intermittent gastric ischemia, typically characterized by postprandial abdominal pain, nausea and vomiting, and often weight loss. This is referred to as vascular MALS (vMALS). Over the past decade, most literature supports an etiology of compression of the celiac plexus between the celiac artery and the median arcuate ligament as the primary cause of these symptoms. This is referred to as neurogenic MALS (nMALS) and has the same symptoms described above but may lack some of the vascular compression findings on imaging studies. The diagnosis of vMALS and nMALS may be made by selective angiography, magnetic resonance angiography, spiral computed tomographic angiography, Doppler ultrasound, and Celiac Plexus bock. Symptomatic patients with celiac artery compression confirmed by CT-angiography or doppler ultrasound, and transient amelioration of symptoms with celiac plexus block, will benefit more from surgical treatment.

Additionally, the following findings may also be encountered: the abnormal origin of the celiac artery, flow reversal in the hepatic artery and lowering of velocity in the celiac artery when the patient stands erect. Conventional visceral angiography shows partial to complete stenosis of the celiac artery secondary to extrinsic compression with possible post-stenotic dilation and retrograde filling of the celiac artery. During visceral angiography, intravascular ultrasound can be used to demonstrate ostial compression of the celiac artery with expiration. CTA shows compression of the celiac axis with focal stenosis and post-stenotic dilation in vMALS, or a low-riding diaphragm where the inferior diaphragm/median arcuate ligament terminates along the course of the celiac artery instead of superior to the celiac artery insertion.

On ultrasound, there is a demonstration of elevated celiac artery peak systolic velocities with deep expiration. More specifically, the following two criteria are supportive for the diagnosis of MALS on ultrasound: expiratory peak velocity of greater than 200 cm/s and deflection angle greater than 50 degrees. Percutaneous celiac ganglion block is diagnostic for nMALS and is the best predictor of surgical outcomes in patients whose studies demonstrate celiac artery compression.

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.

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Select Health covers surgical treatment of median arcuate ligament syndrome (MALS) for members who meet ALL the following criteria:

A. Vascular MALS

1) Symptomatic, with these potential symptoms: postprandial or exercise-induced epigastric pain, which may be associated with nausea, vomiting, and weight loss; and
2) Normal gallbladder, normal EGD, normal CT scan; and
3) CTA, MRA, doppler ultrasound, or abdominal angiography, with three-dimensional reconstruction of the celiac axis with compression noted on ventilatory expiration; and
4) Positive ganglion nerve block, relieving the discomfort.
5) Functional causes (i.e., behavioral, psychiatric issues) of abdominal pain have been excluded.

B. Neurogenic MALS

1) Symptomatic, with these potential symptoms: postprandial or exercise-induced epigastric pain, which may be associated with nausea, vomiting, and weight loss; and
2) Normal gallbladder, normal EGD, normal CT scan; and
3) Positive ganglion nerve block, relieving the discomfort.
4) Functional causes (i.e., behavioral, psychiatric issues) of abdominal pain have been excluded.

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

CPT CODES

35701	Exploration not followed by surgical repair, artery; neck (eg, carotid, subclavian)
37799	Unlisted procedure, vascular surgery
39541	Repair, diaphragmatic hernia (other than neonatal), traumatic
39599	Unlisted procedure, diaphragm
49329	Unlisted laparoscopy procedure, abdomen, peritoneum and omentum

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MEDICAL POLICY

NANOKNIFE ONCOBIONIC SYSTEM

Policy # 604
Implementation Date: 5/24/17
Review Dates: 7/25/18, 6/20/19, 6/18/20, 6/17/21, 5/4/22, 6/21/23
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

Irreversible electroporation (IRE) is a minimally invasive procedure that uses a low-energy, direct-current, non-thermal technology, to ablative soft tissue lesions through permeabilization of the cell membrane. The NanoKnife Oncobionic System uses brief and controlled electric pulses to open microscopic pores in a targeted area. By increasing the number, strength, and duration of electric pulses, electroporation can be made permanent or irreversible. This procedure is being used in conjunction with chemotherapeutic drugs for cancer treatment (electochemotherapy). Use of the NanoKnife System for cancer treatment is currently controversial because the technology is not approved by the FDA specifically for this indication, and no randomized trials or large comparative studies have been performed that evaluate the device for cancer treatment.

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

Select Health does NOT cover the NanoKnife Oncobionic System for cancer treatment as it is 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

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 NanoKnife Oncobionic System received initial clearance from the U.S. Food and Drug Administration (FDA) as a tissue ablation system indicated for surgical ablation of soft tissue, including cardiac and smooth muscle. It is classified by the FDA as an electrosurgical cutting and coagulation device. According

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to the FDA information available online: "It has not received clearance for the therapy or treatment of any specific disease or condition."

In January 2011, the FDA issued a warning letter to AngioDynamics for inappropriate marketing of the NanoKnife for unapproved clinical indications. Because the device is approved for surgical ablation, off-label use for cancer treatment is expected to continue, even in the absence of evidence, because the NanoKnife offers a non-invasive alternative to chemotherapy, radiation therapy, surgical, and minimally invasive ablative treatments.

In 2013, the National Institute for Health and Clinical Excellence (NICE) issued updated interventional procedure guidance documents for the use of IRE for treating renal cancer, primary lung cancer/metastases in the lung, pancreatic cancer and liver metastases whose findings on the evidence for safety and efficacy of irreversible electroporation is inadequate in quantity and quality. Therefore, NICE reported this procedure should only be used in the context of research; studies should report the effect of the procedure on local tumor control and patient survival.

Billing/Coding Information

CPT CODES

(Use the unlisted codes below if they are specified as ablation by irreversible electroporation)

32999	Unlisted procedure, lungs and pleura
47399	Unlisted procedure, liver
48999	Unlisted procedure, pancreas
53899	Unlisted procedure, urinary system
99199	Unlisted special service, procedure or report

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

NEUROMONITORING DURING SPINAL SURGERY (PEDIGUARD PROBE AND EMG)

Policy # 639

Implementation Date: 4/16/20
Review Dates: 1/11/22, 2/16/23, 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

The PediGuard is a battery-powered, single-use tool for drilling pilot holes in spinal pedicles into which pedicle screws can be inserted during spinal surgery. Small comparative trials in different populations of adults and children show that the PediGuard can reduce exposure to fluoroscopy, has high sensitivity and specificity for detecting pedicle perforations, and can significantly reduce the number of malpositioned screws. It can be used to drill multiple pilot holes in a single patient, if the device is wiped with a saline-impregnated cloth between uses.

The PediGuard would be used in place of a standard pedicle awl in secondary and tertiary care during spinal surgery in which pedicle screws are placed; this would include spinal decompression or correction surgery where fusion and instrumentation are needed. The PediGuard should not be used on people with pacemakers or any other active implantable medical device, or in patients with severely osteoporotic vertebrae. This tool is intended for use in secondary and tertiary care settings, specifically, it would be used in operating theaters by appropriately qualified orthopedic surgeons or neurosurgeons.

Electromyography (EMG) measures muscle response or electrical activity in response to a nerve's stimulation of the muscle; the test is used to help detect neuromuscular abnormalities. During the test, one or more small needles (also called electrodes) are inserted through the skin into the muscle. The electrical activity picked up by the electrodes is then displayed on an oscilloscope (a monitor that displays electrical activity in the form of waves); an audio-amplifier is used so the activity can be heard.

EMG measures the electrical activity of muscle during rest, slight contraction, and forceful contraction. Muscle tissue does not normally produce electrical signals during rest. When an electrode is inserted, a brief period of activity can be seen on the oscilloscope, but after that, no signal should be present.

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 the use of the PediGuard Probe for spinal surgery when pedicle screws are being placed.

Select Health will cover either the PediGuard Probe or electromyography (EMG) testing during spinal surgery, but not both modalities.

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Neuromonitoring During Spinal Surgery (PediGuard and EMG), 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

The PediGuard is similar in appearance to a pedicle awl; it has a stainless-steel shaft with a pointed tip capable of boring through bone. The tip houses an electromagnetic bipolar sensor that responds to the electrical conductivity of the surrounding tissue. The handle contains a battery, speaker, and LED: these provide audio and visual feedback in response to tissue conductivity.

There are 3 types of PediGuard available; straight and curved, for open surgeries, and cannulated for minimally invasive approaches. Each has several tip length and diameter options to provide flexibility. The smaller sizes (Tri Tip 2.5XS and CurvXS) are designed to be used in small pedicles, such as in cervical vertebrae or in those of children and young people.

Fluoroscopy (or, less often, intraoperative CT imaging) is commonly used to aid the placement of pedicle screws by providing real time anatomical information, as well as information on screw trajectory and position (Patel et al. 2011). Fluoroscopy is quantified by the number of 'shots' used; every fluoroscopy shot exposes the patient to radiation. Neuromonitoring can also be used to help drill pilot holes; this is done to test the integrity of the pedicle wall without exposing the patient to ionising radiation (Mattei et al. 2009). Some tertiary care facilities may use spinal cord monitoring, which is a type of neuromonitoring, for complex cases, such as deformity, fracture, and metastatic spinal cord compression cases; as well as significant proportion of degenerative spinal cases.

Evidence for the PediGuard comes from 4 controlled studies of variable design and quality, involving a total of 405 patients. Two randomized controlled trials (n = 42 people with 694 pedicle screws and n = 18 with 78 pedicle screws) comparing the PediGuard with the standard method for drilling pilot holes demonstrated a statistically significant reduction in the number of fluoroscopy exposures needed when using the PediGuard. Accuracy of pedicle screw placement was significantly improved in the first study ($p = 0.001$) and non-inferior in the second study ($p > 0.05$). A multicenter, non-randomized controlled trial (n = 97,571 pedicle screws inserted) showed that the PediGuard detected 22 of 23 pedicle perforations compared with 10 of 23 using other methods of detection. Overall, the PediGuard had a 94% positive predictive value and 100% negative predictive value, yielding 99% specificity and 98% sensitivity. A retrospective controlled study (n = 248) compared the PediGuard with a standard method for drilling pilot holes to insert pedicle screws in children and young people with scoliosis. There was a statistically significant reduction in the number of clinically relevant malpositioned screws when the PediGuard was used.

Billing/Coding Information

CPT CODES

22899	Unlisted procedure, spine

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95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)

HCPCS CODES

G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)

Key References

1. NICE (National Institute for Health and Care Excellence). The PediGuard for placing pedicle screws during spinal surgery. 25 March 2015.

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MEDICAL POLICY

PANCREAS/PANCREAS-KIDNEY TRANSPLANTS

Policy # 610

Implementation Date: 4/18/17
Review Dates: 6/17/18, 4/17/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23
Revision Dates: 9/27/19, 11/17/21, 12/10/21

Related Medical Policies:

#190 Pancreatic Islet Cell Transplants

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

Pancreas transplantation was developed in the United States primarily as a procedure performed in tandem with kidney transplantation for diabetic patients who had developed end-stage renal failure and were considered suitable for renal transplantation. Pancreas transplantation may be performed alone (PTA), simultaneously with a kidney transplant (simultaneous pancreas/kidney, SPK), or following a successful kidney transplant (pancreas-after-kidney, PAK). Pancreas transplantation alone is performed in patients who show little (preuremic) or no kidney insufficiency (nonuremic), as determined by laboratory tests. SPK and PAK are performed in patients who have confirmed kidney dysfunction. Since kidney failure is one of the major diabetic complications, most potential pancreas graft recipients are uremic and eligible for either of the combined pancreas-kidney transplantation procedures. However, PAK is generally reserved for patients with a suitable replacement kidney from a living related donor, which is associated with increased kidney graft survival, compared with a cadaver kidney. Most pancreas transplantation procedures involve SPK grafting, which represents 78% of the more than 15,300 cadaver pancreas transplants reported to United Network for Organ Sharing (UNOS) between October 1987 and June 2004. While SPK transplants occurring in the United States have only increased marginally, PTA has increased by a factor of 4.3. In 2004, there were 604 pancreas transplants, 116 of those were repeat transplants and 28 were in the pediatric population.

Combined kidney-pancreas transplant employs grafts harvested from a single deceased donor. Patient survival is higher with SPK vs. that observed with deceased donor kidney transplantation alone but is similar with living donor kidney transplant alone. Nevertheless, there may be no survival benefit with SKP vs. deceased donor kidney transplantation among young (age < 45 years) diabetic recipients of kidneys from young (age < 36 years) donors. The major benefit of combined pancreas/kidney transplantation is an improved quality of life due to freedom from both insulin therapy and dialysis, stabilization of neuropathy and improvement in nephropathy, and protection of a simultaneously transplanted kidney from the adverse effects of hyperglycemia. The results of studies of secondary complications of diabetes must be interpreted in the light of the fact that most patients undergoing pancreas transplantation have had diabetes for over 2 decades. Beneficial responses in insulin, glucose, and lipid metabolism have been maintained for up to 20 years or longer after pancreas transplantation.

Most pancreas transplants have been performed in conjunction with kidney transplantation, with the idea that the risks associated with major surgery and immunosuppression are subsumed by the kidney transplant. However, given the frequent availability of a live-donor kidney for transplant and the lack of an available cadaveric pancreas at the same time, an increasing number of situations have arisen in which a pancreas becomes available for transplant after the patient has already undergone a kidney transplant (hence the name, pancreas after kidney transplant [PAK]). In PAK procedures, there is a modest increase in surgical risk, as well as increased postoperative infections and complications, and a need for more intensive immunosuppression, attending simultaneous pancreas-kidney transplantation compared with

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kidney transplantation alone. These risks have been balanced by improved quality of life and by the potential for reduced complications, including a decrease and even reversal of neuropathy, as well as by decreased pathologic changes in the transplanted kidney. The data to balance the risks and benefits of pancreatic transplantation are limited, owing to the absence of controlled trials.

Pancreas transplantation alone is not a treatment option for most diabetic patients because of the potential significant complications associated with immunosuppression following transplantation. A total pancreatectomy is a major operation reserved for patients who have failed medical management and who are not candidates for less extensive surgery. Most total pancreatectomies are planned for benign (e.g., chronic pancreatitis), premalignant (e.g., intraductal papillary mucinous neoplasm), or malignant indications (e.g., pancreatic cancer). A completion total pancreatectomy may be required as a rescue operation to treat severe complications (e.g., uncontrolled sepsis, massive hemorrhage) of a prior, more limited pancreatic resection. During the PTA procedure, an incision is made in the lower abdomen, and the cadaveric pancreas is inserted into an intraperitoneal location and attached to the blood vessels, intestine, or bladder; the diseased pancreas is left in place. As the pancreas performs both an exocrine and endocrine function, each must be connected to the most appropriate physiological outlet. The exocrine secretions are managed with either a duodenocystostomy or a duodenojejunostomy, whereas, the endocrine secretions, such as insulin, can be either systemic drainage or portal venous drainage. The recent literature has reported a physiological benefit with portal venous drainage combined with enteric drainage; this is referred to in the literature as portal-enteric drainage.

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 pancreas-after-kidney (PAK) transplant or combined pancreas/kidney transplantation in members who meet either of the following criteria listed below.

Criteria for coverage: (Patient must meet **A or B**)

A. Procedure has been endorsed, recommended, and will be performed by Intermountain Health Renal Transplant Services;

OR

B. For service being requested outside of Intermountain Health:

1. Insulin-dependent diabetes mellitus (IDDM) with end-stage renal failure or irreversible chronic renal failure with impending end-stage renal failure (refer to renal transplant criteria for medical indications); and
2. Complications of poorly controlled diabetes, despite an appropriate insulin regimen, such as severe bouts of unexplained ketoacidosis or hypoglycemic episodes, requiring hospitalizations; and
3. a) Acute trauma with irreversible impairment of renal function where no therapeutic alternative is available;

   OR

   b) Chronic renal impairment is irreversible; permanent; requires a regular course of dialysis; has progressed to the point of significant interference with the patient's quality of life, and for which no other effective medical or surgical therapeutic alternative is available; and
4. The patient must meet one of the following:
   a. On dialysis
   b. Dialysis considered imminent, eGFR ≤ 20
   c. The member meets criteria for simultaneous pancreas/kidney transplant and eGFR 20 to 25 and transplant organs has zero antigen mismatch, which meets UNOS criteria
   d. The patient has a living related donor (the transplant may be done before dialysis is necessary)

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e. The patient may have a history of a renal transplant, but due to progressive graft failure, is approaching the need for dialysis; and

5. A reasonable expectation that the patient's quality of life, e.g., physical and social function suited to activities of daily living, will be improved; and
6. Strong motivation by the patient to undergo the procedure and a thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up; and
7. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would preclude surgery or a reasonable survival; and
8. Medical and social assessment that the patient has sufficient social stability to provide assurance that they will cooperate with the long-term follow-up and the immunosuppressive program, which is required; and
9. No uncontrolled and/or untreated psychiatric disorder or substance use disorder that would interfere with compliance to a treatment regimen.

Absolute Contraindications:

1. Advanced respiratory failure;
2. Cardiovascular diseases as listed below:
   a. Myocardial infarction within 6 months;
   b. Intractable cardiac arrhythmias;
   c. Symptomatic or occlusive peripheral vascular disease;
   d. Severe generalized arteriosclerosis;
3. Active severe hemodynamic compromise at the time of transplantation if accompanied by significant compromise of one or more non-renal end-organs;
4. Any other contraindications for transplantation as listed below:
   a. Active infection;
   b. Cancer, (except skin cancer) unless treated and eradicated for 2 or more years;
   c. Unresolved GI hemorrhage;
   d. Debilitating and/or irreversible brain damage;
   e. Life-threatening extra-renal congenital abnormalities;
   f. HIV positive;
   g. Hepatitis B antigen positive and active liver failure;
   h. Positive Hepatitis C serology with abnormal liver biopsy and/or elevated transaminases;
   i. Persistent coagulation disorder.

Age at the time of Relative Contraindications:

5. Transplant: greater than 60 years or less than 18 years.
6. Clinical evidence of peripheral vascular disease, specifically, cerebral vascular disease, ischemic ulcers, or previous amputations secondary to vascular disease.
7. Active peptic ulcer disease.
8. Hypertension poorly controlled by medication.
9. Hepatitis B antigen positive.
10. Morbid obesity.

Select Health covers pancreas transplantation alone *in limited circumstances*; it has been proven in the medical literature to improve health outcomes for members.

Coverage Criteria:

1. Patients must have a diagnosis of type I diabetes:

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a) Patient with diabetes must be beta cell autoantibody positive; or
b) Patient must demonstrate insulinopenia, defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL; and

2. Patients must have a history of medically uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia, unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks; and
3. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months, with the most medically recognized advanced insulin formulations and delivery systems; and
4. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and
5. Patients must otherwise be a suitable candidate for transplantation.

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

Combined Pancreas/Kidney Transplant

A 1995 technology assessment by the Agency for Healthcare Research and Quality observed the following from the literature on kidney-pancreas transplant: "Patient selection criteria were not explicit, although it appears that many SPK/PAK recipients have had mild or moderate clinical problems with hyper- or hyperglycemia. Pancreas graft survival averaged 74%, 71%, and 64% at 1–3 years post-transplant. Morbidity following SPK or PAK is significantly greater than that following renal transplant.

In general, patient survival is similar with both SPK and living donor transplantation alone, but survival is higher versus that observed with deceased donor kidney transplantation alone. As examples:

- A small 10-year study evaluated outcomes after SPK in 14 patients with Type 1 diabetes and end-stage diabetic nephropathy vs. 15 diabetics subjected to deceased donor kidney transplantation alone. Mortality was significantly lower among those who underwent SPK (20% vs. 80%).
- A retrospective study of 18,549 patients with Type 1 diabetes reported that 8-year survival was similar for SPK (72%) and living donor kidney recipients (72%), which was higher than that observed for deceased donor kidney recipients (55%).
- Patient survival was evaluated among 130, 379, and 296 recipients of living related donor kidneys, SPKs, and deceased donor kidneys, respectively. Patient survival was significantly lower for the deceased donor group versus that observed with recipients of living related donor kidneys and SPKs.

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The best patient survival may be observed in recipients of SPKs with prolonged pancreas graft function. However, there may be no survival benefit with SPK vs. deceased donor kidney transplantation among young diabetic recipients of kidneys from young donors. As an example, survival outcomes were examined in a retrospective study of 3,642 SPK and 2,374 deceased donor renal transplant recipients. Although overall 5-year patient survival was superior among those who received SPK (85% vs. 76%), there was no difference in survival between the 2 groups among recipients less than 14 years of age who received a kidney from a donor under the age of 36 years.

The best candidates for pancreas transplantation are younger (age < 45 years) type 1 diabetics without cardiac risk factors who are to receive SPK transplants. Recipients over age 45 carry a two-fold greater risk of graft loss, most often due to technical failure, and a three-fold greater risk of dying than younger patients.

Pancreas transplant candidates can be informed that the major benefits they can expect from the addition of a pancreas to a kidney transplant are an improved quality of life, stabilization of neuropathy and improvement in nephropathy, and protection of a simultaneously transplanted kidney from the adverse effects of hyperglycemia.

Pancreas Transplant Alone (PTA)

Review of the literature has identified 21 primary studies and 3 systematic reviews on pancreas transplant also published since 2003. In all, > 7,000 patients were evaluated, of which > 6,800 (97%) were PTA-treated; patients were followed between 6 months and 10 years.

The majority of the studies were not randomized against standards of care (90.5% did not compare PTA to non-PTA therapies). Most were concerned with native kidney function, estimated glomerular filtration rate (eGFR), and end-stage renal disease (ESRD), all after PTA. Key take-away points from the studies included normalization or amelioration of glucose metabolism, pancreatic graft survival was better in SPK and PAK, and PTA improves diabetic nephropathy. Four papers identified the frequency of renal transplant occurring due to ESRD at 4.3% at 1 year, 6% at 5 years, 9.7% at 5 years, and 10.6% at 4.6 years.

Evidence out to 10 years has shown that PTA may result in outcomes commensurate with SPK, particularly, if preoperative eGFR is high.

Pancreas after Transplant (PAK)

Reported in 1993, the Diabetes Control and Complications Trial Study conclusively showed that tight glucose control significantly decreases nephropathy, retinopathy, and neuropathy in patients with type 1 diabetes, and this provided the impetus for combining pancreas transplantation with kidney transplantation. In selected patients and without compromising survival rates, both type 1 diabetes and ESRD can be eliminated by LRD kidney transplantation alone, followed by a solitary cadaver-donor pancreas transplant (sequential pancreas after kidney [PAK] transplantation). Though SPK transplantation may offer an immunologic advantage, some advocate PAK transplantation if there is a willing LRD. Use of a well-matched living-donor kidney offers the potential benefits of shorter waiting time, expansion of the organ donor pool, and improved short-term and long-term renal graft function. SPK pancreas graft survival has historically exceeded that of solitary pancreas transplantation; however, recent improvements in solitary pancreas transplant survival rates have narrowed the advantage seen with SPK. Both SPK and PAK impose greater immunologic risks over kidney transplant alone.

The goal of these transplants is to produce a lasting normoglycemic state that enhances quality of life and prevents, arrests, or perhaps even reverses the otherwise inexorable progression of the destructive effects of diabetes. As demonstrated in a number of studies, this resumption of normal glucose homeostasis achieved provides several benefits: 1) quality of life is improved since it usually removes dependence on both insulin and dialysis; 2) recurrence of diabetic nephropathy is attenuated; 3) diabetic retinopathy is reduced; 4) progression of diabetic neuropathy may be halted and in some cases reversed, including improvements in autonomic neuropathy, enhancing both cardiac reflex function and gastric motility in some cases; and 5) beneficially affects patient survival even though this glycemic control is given as a late intervention in a diabetic patient's lifetime. More importantly, studies show that diabetic patients who receive a successful SPK transplant do not develop diabetic complications in their newly transplanted kidney, unlike persons with diabetes who receive a kidney transplant alone. Even diabetic

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vesicopathy has been shown to improve after transplantation, as well as attenuation of diabetic cardiovascular disease.

The American Diabetes Association (2003) has concluded that pancreas-kidney transplantation is indicated in patients with insulin-dependent diabetes and end-stage renal disease:

> "Pancreas transplantation should be considered an acceptable therapeutic alternative to continued insulin therapy in diabetic patients with imminent or established end-stage renal disease who have had or plan to have a kidney transplant, because the successful addition of a pancreas does not jeopardize patient survival, may improve kidney survival, and will restore normal glycemia."

The pros and cons of PAK must be weighed in each individual patient to determine proper treatment. The graft survival rate of living related kidney allografts significantly exceed that of cadaveric renal transplants because they have less immunologic disparity and comparatively minimal preservation injury. However, in the setting of diabetes, with the possibility of recurrent diabetic nephropathy and other disabling complications, the medical literature indicates that the addition of a pancreas transplant might provide benefits that outweigh the advantages of LRD renal transplantation.

With improved surgical technique and better organ preservation, the remaining obstacle was a high rejection rate of both the kidney and the pancreas. However, with the introduction of more immunosuppressant alternatives over the past ten years, rejection rates have now been reduced. The addition of mycophenolate mofetil (CellCept) and tacrolimus (Prograf) have been extremely helpful options in the immunosuppressive management. Furthermore, induction protocols utilizing basiliximab (Simulect) or daclizumab (Zenapax) are less complicated and have been shown to be better tolerated than the previous induction protocols with antilymphocyte globulin (ALG) or OKT3 (Muromonab-CD3). The results of PAK have lagged behind the excellent results of SPK transplantation. During the past 3 to 4 years, the reported 1-year pancreas graft survival rate for PAK recipients has improved from 54% survival to 71%, shrinking the "immunologic advantage" of combining a cadaver pancreas with a kidney from the same donor.

Members referred for SPK transplantation, who are acceptable candidates by all criteria, should be counseled about possible living donor kidney transplantation. Since there is an extreme shortage of cadaver kidneys in the United States and because living donor kidneys have a survival advantage over cadaver kidneys, generally accepted guidelines state that persons with diabetes with ESRD referred for SPK transplantation should consider living donor kidney transplant alone (LDKTA) followed by a pancreas after kidney (PAK) procedure. Studies show that the LDKTA and PAK option carries equal pancreatic transplant success as SPK transplantation combined with the added survival advantage of LDKTA.

Billing/Coding Information

CPT CODES

48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islets cells
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft (recipient)
48556	Removal of transplanted pancreatic allograft
48999	Unlisted procedure, pancreas

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MEDICAL POLICY

PANCREATIC ISLET CELL TRANSPLANTS

Policy # 190
Implementation Date: 8/30/03
Review Dates: 8/26/04, 8/10/05, 10/18/07, 10/23/08, 10/22/09, 10/08/10, 8/16/11, 8/16/12, 7/18/13, 6/19/14, 6/16/16, 3/3/19, 2/17/20, 2/18/21, 1/18/22, 2/16/23, 2/15/24
Revision Dates: 10/31/06, 4/12/17

Related Medical Policies:
#610 Pancreas Transplants

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 islet cell transplantation procedure involves acquiring and isolating pancreatic islet cells from donor pancreases and infusing them into the recipient via a portal vein infusion. The donated cells implant in the wall of the portal vein and begin to secrete insulin into the blood stream in an autoregulated fashion, similar to a native pancreas. Islet cell transplantation can be either an auto-transplantation (transplantation within the same individual) or an allotransplantation (transplantation from a donor). If the individual receives any allotransplant, they must remain on life-long immunosuppression in an effort to avoid rejection of the implants and maintain the insulin secreting function of these cells.

Autologous islet cell transplantation is an alternative for persons undergoing total pancreatectomy for severe, refractory chronic pancreatitis. Near total or total pancreatic resection can alleviate pain in patients with severe chronic pancreatitis. Allogeneic islet cell transplantation is being investigated as an alternative means of restoring normoglycemia, without the attendant morbidity of the whole-organ procedure, and potentially with significantly less need for immunosuppression than pancreas transplantation. In autologous islet transplantation, during the pancreatectomy procedure, islet cells are isolated from the resected pancreas using enzymes, and a suspension of the cells is injected into the portal vein of the patient's liver. Once implanted, the beta cells in these islets begin to make and release insulin. In the case of allogeneic islet cell transplantation, cells are harvested from the deceased donor's pancreas, processed, and injected into the recipient's portal vein. Up to 3 donor pancreas transplants may be required to achieve insulin independence. Allogeneic transplantation may be performed in the radiology department.

Allogeneic islet transplantation has been used for type 1 diabetes to restore normoglycemia and, ultimately, reduce or eliminate the long-term complications of diabetes such as retinopathy, neuropathy, nephropathy, and cardiovascular disease. Islet transplantation potentially offers an alternative to whole-organ pancreas transplantation. However, a limitation of islet transplantation is that 2 or more donor organs are usually required for successful transplantation, although experimentation with single-donor transplantation is occurring. A pancreas that is rejected for whole-organ transplant is typically used for islet transplantation. Therefore, islet transplantation has generally been reserved for patients with frequent and severe metabolic complications who have consistently failed to achieve control with insulin-based management.

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

Select Health will cover autologous pancreas islet transplantation for patients undergoing a near-total or total pancreatectomy for severe refractory chronic pancreatitis.

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Select Health

MEDICAL POLICY

PANCREATIC ISLET CELL TRANSPLANTS

Policy # 190
Implementation Date: 8/30/03
Review Dates: 8/26/04, 8/10/05, 10/18/07, 10/23/08, 10/22/09, 10/08/10, 8/16/11, 8/16/12, 7/18/13, 6/19/14, 6/16/16, 3/3/19, 2/17/20, 2/18/21, 1/18/22, 2/16/23, 2/15/24
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Select Health will cover autologous pancreas islet transplantation for patients undergoing a near-total or total pancreatectomy for severe refractory chronic pancreatitis.

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The Edmonton Protocol

In July 2000, Shapiro and his colleagues published results of successful islet transplantation in 7 non-uremic type 1 diabetic patients who had recurrent severe hypoglycemia or metabolic instability and did not respond to treatment with exogenous insulin. All 7 patients achieved insulin independence at one year after transplantation. The protocol adopted by the Edmonton team incorporated several new approaches to islet transplantation, and is known as the Edmonton protocol.

The National Institutes of Health states in its March 2007 Publication No. 07-4693: "In its 2006 annual report, the Collaborative Islet Transplant Registry, which is funded by the National Institute of Diabetes and Digestive and Kidney Diseases, presented data from 23 islet transplant programs on 225 patients who received islet transplants between 1999 and 2005. According to the report, nearly two-thirds of recipients achieved "insulin independence"—defined as being able to stop insulin injections for at least 14 days—during the year following transplantation. However, other data from the report showed that insulin independence is difficult to maintain over time. Six months after their last infusion of islets, more than half of recipients were free of the need for insulin injections, but at 2-year follow-up, the proportion dropped to about one-third of recipients. The report described other benefits of islet transplantation, including reduced need for insulin among recipients who still needed insulin, improved blood glucose control, and greatly reduced risk of episodes of severe hypoglycemia."

Novel immunosuppressive regimens

Immunosuppression has been based on triple therapy with azathioprine, prednisolone, and cyclosporine A (CsA) for the last two decades. It is now recognized that CsA impairs islet replication, islet engraftment, and beta cell function. Both CsA and tacrolimus treatment are associated with nephrotoxicity. Tacrolimus is also more neurotoxic and more diabetogenic compared to CsA. The combination of steroids and high dose tacrolimus and CsA induced a marked insulin resistance and direct beta cell toxicity.

The Edmonton group used a steroid-free immunosuppressive regimen comprised of a combination of sirolimus, low dose tacrolimus, and daclizumab. This immunosuppressive regimen is less likely to cause diabetes after transplantation and is also less harmful to the kidney.

Preparation of islet cells

In the past, xenoprotein products, such as fetal calf serum, were used in many islet transplantation centers to isolate and purify donor islet cells. Islets were often transplanted after several days in culture.

In the Edmonton series, donor islet cells were isolated and purified in xenoprotein-free medium to avoid targeting by formed antibodies that facilitate cell destruction by complement activation or antibody-dependent cellular cytotoxicity. Cold ischemic time was kept short and islet cells were transplanted less than 12 hours after harvesting them from cadaver donor organs.

Delivery of an adequate number of viable islet cells

In the past, the threshold of 360,000 islets (6,000 IE/kg), which represents the approximate number of islets currently isolated from a pancreas, was considered necessary for graft function. In the Edmonton series more islets (approximated 11,000 IE/kg) were extracted from at least two pancreas donors and were given to recipients several weeks apart. The number of islets used by the Edmonton team was therefore almost double that was previously used.

Evidence on the efficacy/effectiveness of ITA for this group of patients is limited. To date, no randomized controlled trials have been reported to compare the efficacy of ITA to other treatments such as intensive insulin therapy or whole pancreas transplantation for controlling hyper- and hypoglycemia.

Limited evidence suggests that ITA is effective in controlling labile diabetes and protects against unrecognized hypoglycemia in highly selected patients in the short term. The long-term effects of ITA on metabolic control remain to be proven.

Based on the limited published evidence, ITA for non-uremic type 1 diabetic patients with severe hypoglycemia or uncontrolled diabetes is still an evolving procedure with promising results and not considered standard of care at this stage for this group of patients.

A single-centered study (Chinnakotla (2015), analyzed the records of 581 patients with Chronic Pancreatitis (CP) who underwent a total pancreatectomy and islet autotransplantation (TP-IAT). The patients' duration (mean±SD) of CP before their TP-IAT was 7.1±0.3 years and narcotic usage of

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3.3±0.2 years. Pediatric patients had better postoperative outcomes. Among adult patients, the odds of narcotic use at 1 year were increased by previous endoscopic retrograde cholangiopancreatography (ERCP) and stent placement, and a high number of previous stents (> 3). Independent risk factors for pancreatic pain at 1 year were pancreas divisum, previous body mass index > 30, and a high number of previous stents (> 3). The strongest independent risk factor for islet graft failure was a low islet yield—in islet equivalents (IEQ)—per kilogram of body weight. We noted a strong dose-response relationship between the lowest-yield category (< 2000 IEQ) and the highest (≥ 5000 IEQ or more). Islet graft failure was 25-fold more likely in the lowest-yield category. This represents the largest study of factors predicting outcomes after a TP-IAT so far. However, the patient subgroups warrant further attention.

Billing/Coding Information

CPT CODES

48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islets cells
48999	Unlisted procedure, pancreas
86341	Islet cell antibody

HCPCS CODES

G0341	Percutaneous Islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy Islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy Islet cell transplant, includes portal vein catheterization and infusion
S2102	Islet cell tissue transplant from pancreas; allogeneic

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MEDICAL POLICY

PANNICULECTOMY/ABDOMINOPLASTY

Policy # 463
Implementation Date: 9/21/10
Review Dates: 9/15/11, 11/29/12, 12/19/13, 10/20/16, 12/13/18, 12/18/19, 12/17/20, 11/28/21, 1/13/23
Revision Dates: 4/27/17

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Description

The panniculus adiposus is a layer of tissue bearing deposits of fat underneath the skin. After significant weight loss in men or women, particularly those with morbid obesity, an overhanging "apron" of redundant skin and fat may develop in the lower abdominal area. Created by the lack of underlying supportive tissue, these redundant skin folds do not respond to weight loss methods or exercise. Hanging like an apron over the abdominal wall the pannus may result in significant skin-related problems due to the accumulation of bacteria, fungi, debrided skin, and moisture, resulting in intertrigo, recurring cellulitis, and ulcerations. These recurring problems may temporarily respond to improved hygiene and topical or systemic antimicrobial therapies, but for some individuals becomes a chronic recurrent problem unresponsive to medical management. For those individuals, removal of the pannus (panniculectomy) may be the only solution to resolve the problem.

Panniculectomy is a surgical procedure in which this large, redundant apron of subcutaneous fat and abdominal skin is removed from the lower abdomen. Under most circumstances, panniculectomy is a cosmetic service. For patients with significant functional impairment, such as considerable difficulty with persistent infection, panniculectomy may be indicated.

Abdominoplasty, also referred to as a "tummy tuck," is a surgical procedure that tightens lax anterior abdominal wall muscles and removes excess abdominal skin and fat. This recontouring of the abdominal wall area is often performed solely to improve the appearance of a protuberant abdomen by creating a flatter, firmer abdomen. The standard abdominoplasty involves plication of the anterior rectus sheath for muscle diastasis (i.e., repair of diastasis recti) and removal of excess fat and skin. Traditional abdominoplasty can be performed as an open procedure or endoscopically. Abdominoplasty completed by endoscopic guidance is usually reserved for those patients who seek less extensive contouring of the abdominal wall. Mini-abdominoplasty, with or without liposuction, is a partial abdominoplasty involving the incision of the lower abdomen only. The procedure is generally performed solely for cosmetic purposes, in order to improve the appearance of the abdominal area and may be done at the same time as a panniculectomy.

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 panniculectomy surgery in *limited circumstances.*

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Panniculectomy/Abdominoplasty, continued

Criteria for coverage:

Patients who have undergone substantial weight loss (e.g., bariatric surgery) resulting in an overhanging "apron" of redundant skin and fat (panniculus) in the lower abdominal area, when ALL the following clinical criteria are met:

1. Documented weight loss > 100 lbs.; and
2. The individual has reached a body mass index (BMI) less than or equal to 30 kg/m^2; and
3. The individual has maintained a stable weight (BMI ≤ 30 kg/m^2) for at least 6 months; and
4. If the individual has had bariatric surgery, he/she is at least 18 months post-operative; and
5. Panniculus hangs to or below the level of the pubis is documented; and
6. There is documented evidence of any of the following chronic or recurring conditions refractory to appropriate medical therapy (e.g., analgesics, antibacterials, antifungals, cortisone ointments, drying agents, strict attention to hygiene, topically applied skin barriers, and supportive garments) for a period of at least 6 months as documented in office notes:
    a. Intertrigo (bacterial or fungal infections)
    b. Cellulitis
    c. Folliculitis
    d. Skin ulceration
    e. Skin/subcutaneous abscesses not responsive to conventional medical therapy, including a trial of oral antibiotics and topical therapies
    f. Monilial infestation/fungal dermatitis
    e. Skin necrosis

Select Health does NOT cover panniculectomy surgery for all other circumstances, as other reasons are cosmetic in nature. This meets the plan's definition of not medically necessary.

The following are considered not medically necessary (this list is not all-inclusive):

7. The procedure(s) is performed solely to enhance the patient's appearance, as this is considered cosmetic in nature
8. Permanent overstretching, with or without diastasis recti, of the anterior abdominal wall secondary to massive weight loss or pregnancy resulting in a large pendulous or protruding abdomen
9. Suction-assisted lipectomy (liposuction) as a primary procedure because it is considered cosmetic
10. Abdominoplasty performed by liposuction only for localized areas of fat deposits
11. Panniculectomy/liposuction performed in the arms and/or legs (e.g., brachioplasty)
12. Correction of low back pain because in most individuals this condition is multi-factorial and the primary cause may not be the abdominal panniculus
13. Poorly fitting clothes
14. Problems with hygiene
15. Difficulty exercising
16. Breathing difficulties
17. Trouble bending to put on socks and shoes, and to wash lower extremities
18. Walking, sitting, or even eating meals at a table
19. Stretch marks that sometimes open and bleed
20. Patient is no longer able to work

Select Health does NOT cover abdominoplasty for any indication, as it is considered cosmetic.

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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 current medical evidence addressing the efficacy of panniculectomy consists mostly of individual case reports and review articles. A limited number of small-scale controlled trials exist. In one study, Arthurs et al. performed a retrospective cohort series of post-bariatric panniculectomy patients (n = 126), and the only factor that independently predicted postoperative complications after panniculectomy was pre-panniculectomy body mass index (BMI). Patients with a BMI greater than 25 kg/m^2 were at nearly three times the risk of postoperative wound complications. Although patients who experienced a plateau in weight loss at a BMI of 30–35kg/m^2 did have the largest functional improvement from a panniculectomy, they also experienced the highest risk postoperatively. In this series, the average weight loss following bariatric surgery prior to panniculectomy was 116 ± 35 lbs. A limitation of this study is its retrospective design.

In a similar retrospective study, Acarturk et al. compared the surgical outcomes of panniculectomy following bariatric surgery in a series of 123 patients, with a mean age of 44.5 years. The outcomes of 21 patients with panniculectomy done at the time of bariatric surgery were compared with the surgical outcomes of 102 patients who waited a time period of 17 ± 11 months to have the panniculectomy performed. Overall, patients who had panniculectomy simultaneously with bariatric surgery had more complications. Wound infections were 48% vs. 16%, wound dehiscence 33% vs.13%, and there was a higher incidence (24% vs. 0%) of post-operative respiratory distress seen in patients with the combined procedures. There were 3 postoperative deaths in the combined procedure cohort and none in the group that delayed panniculectomy until an average weight loss of 126 ± 59 lbs. was achieved. The authors concluded that an initial period of substantial weight loss prior to the procedure makes panniculectomy safer and more effective.

The American Society of Plastic Surgeons (ASPS) recommends that body contouring surgery including panniculectomy be performed only after the patient maintains a stable weight for 2–6 months. For post bariatric surgery patients, this is reported to occur 12–18 months after surgery when the BMI has reached the 25–30 kg/m^2 range. If performed prematurely, a potential exists for a second panniculus to develop once additional weight loss has occurred and the risks of postoperative complications are increased. Although it has been suggested that the presence of a large overhanging panniculus may interfere with the surgery or compromise post-operative recovery, there is insufficient evidence to support the proposed benefits of improved surgical site access or improved health outcomes.

Most recently, a Hayes Technology Brief identified a number of studies, but they were limited to retrospective studies focused almost entirely on surgical complications, with little or no documentation of other clinical outcomes such as resolution of panniculus-related skin disorders or pain. The Hayes Brief concluded that there is a substantial risk of complications associated with panniculectomy; reported overall complication rates ranged from 12.0%–51.6%, although major complications that required hospitalization or surgical reintervention occurred at a rate of 10%–15%. Complication rates were highest when panniculectomy was performed concurrently with bariatric surgery, or other procedures such as hernia repair, and were generally increased in patients with anesthesia risk factors, larger panniculi, and

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in those with a higher BMI. Patients who had undergone previous bariatric surgery appeared to be at higher risk of bleeding, and some authors hypothesized that wound healing may be impaired in patients who are obese or were obese, compared with patients who have no history of obesity. The risk associated with higher BMI is unclear; study results were conflicting, and some found no correlation between BMI and complication rate. The majority of the studies evaluating panniculectomy after weight loss are retrospective designs, which are methodologically weak, and subject to bias. None of the studies provided data regarding impact of panniculectomy on clinical outcomes other than complications, making it difficult to determine if this procedure effectively addresses medical conditions associated with a large panniculus such as back or groin pain, or serious skin conditions. However, there are no nonsurgical alternatives to panniculectomy, and it must be assumed that the observed successful removal of the panniculus in the majority of patients will resolve issues associated with its presence including skin conditions and hampered activities of daily living. In many cases, bariatric surgery and plastic/reconstructive surgery following massive weight loss should be considered parts of a whole and complete treatment for morbid obesity.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

RADIOFREQUENCY ABLATION FOR BENIGN THYROID NODULES

Policy # 646
Implementation Date: 4/17/21
Review Dates: 3/15/22, 4/3/23
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

Thyroid nodules are common and occur in up to 50% of individuals. Most are benign (non-cancerous) and only require monitoring. However, sometimes even benign nodules become large enough to either cause pressure symptoms in the neck or be otherwise bothersome to the patient. Surgery is then an option, but leaves a scar, and, depending upon the extent of surgery needed, can result in hypothyroidism and rarely problems with the parathyroid glands that control calcium in the blood.

When nodules are cystic, ethanol infusion can be used to decrease the size. However, with solid nodules, other methods, such as radiofrequency ablation (RFA) and laser ablation (LA), have been used.

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

Select Health covers radiofrequency ablation of thyroid nodules for symptomatic benign thyroid nodules.

Select Health does not cover radiofrequency ablation of thyroid nodules for cosmetic purposes or as a primary cancer treatment.

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

Both RFA and LA have been shown to be effective in many studies including a recent meta-analysis with volume reduction rates at 6 months, 1 year, and 2 years were 68%, 75%, and 87% for RFA and 48%, 52%, and 45% for LA. However, the two techniques have not been compared head-to-head.

This study was done to directly compare RFA and LA in their ability to decrease the size and symptoms of benign, solid thyroid nodules.

Billing/Coding Information

CPT CODES

60699 Unlisted procedure, endocrine system

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MEDICAL POLICY

RADIOFREQUENCY ABLATION (RFA) OF LIVER TUMORS

Policy # 204
Implementation Date: 11/11/03
Review Dates: 11/18/04, 12/15/05, 12/15/06, 12/20/07, 12/18/08, 4/23/09, 2/18/10, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 8/3/18, 4/23/19, 4/6/20, 4/15/21, 3/18/22, 4/20/23
Revision Dates: 11/24/03

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Description

Radiofrequency ablation (RFA) is a method of utilizing electrically generated radiofrequency thermal energy to ablate (destroy) localized lesions, including primary and metastatic liver tumors. Tissue ablation occurs when high frequency alternating current moves from the tip of an electrode (the probe) into the tissue surrounding that electrode. As the ions within the tissue attempt to follow the change in the direction of the alternating current, their movement results in frictional heating of the tissue. As the temperature within the tissue becomes elevated beyond 60º C, cells begin to die, resulting in a region of necrosis surrounding the electrode.

RFA is a reasonable option for patients who do not meet resectability criteria for primary or metastatic liver tumors and yet are candidates for a liver-directed procedure based upon the presence of liver-only disease. Although there is no absolute tumor size beyond which RFA should not be considered, the best outcomes are in patients with a single tumor < 4 cm in diameter.

The RFA probe is placed directly into the tumor under direct vision by laparoscopy or laparotomy and with the aid of intraoperative ultrasound. The probe rapidly heats the tissue to a very high temperature resulting in a region of necrosis surrounding the probe. Depending upon the power applied and the electrical resistance of the tissues, heat falls off rapidly at a specific distance from the electrode tip. The size of the ultimate region of necrosis is determined by the size of the probe. Normally, the process requires less than 15 minutes exposure time and does not sacrifice surrounding normal liver tissue. Most patients are treated on an outpatient or short hospital stay basis.

When feasible, surgical resection remains the treatment of choice for patients with isolated primary or metastatic liver tumors. There are, however, no randomized trials directly comparing RFA with surgical resection (with or without postresection chemotherapy).

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

Select Health covers radiofrequency ablation of both primary and secondary non-resectable malignant liver tumors.

Select Health does NOT cover radiofrequency ablation of liver tumors for any other indication.

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Radiofrequency Ablation (RFA) of Liver Tumors, continued

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Summary of Medical Information

The results of preliminary clinical studies demonstrate that RFA of unresectable primary or metastatic liver cancers is a relatively safe and efficacious procedure for the short-term local control of single or multiple tumors. Histopathological examination of cancer specimens and normal liver tissues following RFA demonstrates that the procedure induces well-circumscribed areas of coagulative necrosis and adequate tumor-negative margins. Thus, RFA has joined liver cryosurgery and ethanol injection as an alternative technique for reducing tumor burden in patients whose tumors have been deemed unresectable.

Some evidence suggests that RFA increases the chances of survival in some patients with hepatocellular carcinoma (HCC), but no existing data supports a similar conclusion for metastatic liver cancer. More evidence from studies of both types of liver cancer is needed before firm conclusions can be drawn about the effect of RFA on long-term patient survival. Even if all tumors are destroyed, tumor recurrence or new tumor development occurs in some cases. This raises the possibility that RFA will ultimately have only minimal impact on long-term patient survival rates.

There is evidence that RFA results in destruction of tumors, which may be associated with higher survival rates. Most of this evidence is reported in patients with hepatocellular carcinoma.

Although RFA is a relatively well-tolerated, serious and potentially fatal complications have been reported. An American Society of Clinical Oncology (ASCO) panel of experts reviewed the RFA literature and reported the mortality rate was 0−2%, and the major complication rate was between 6−9% in most studies. The largest series to address complications included 312 patients with hepatic tumors (predominantly colorectal metastases) who underwent 350 procedures (226 percutaneous and the remainder intraoperative). The mortality rate was 1.6%. The serious complication rate was 10.6%.

Most of the evidence on RFA is limited by small sample size, short follow-up times, and a lack of comparability between the outcome measures. Despite the limitations of the data, RFA generally resulted in larger and more complete areas of ablation and also was associated with higher survival rates compared to the other ablative techniques assessed in this review. Surgical resection was associated with a lower rate of recurrence and an increased time interval to recurrence compared to RFA. However, these 2 procedures are usually performed on different patient groups, with RFA being performed on patients who are unable to undergo surgical resection.

The current AASLD guidelines (Bruis J et al.) for hepatocellular carcinoma (HCC) recommend the use of RFA for patients who are not liver transplant candidates (due to comorbidities) but who have early stage disease with single lesion < 5 cm or up to 3 nodules <3 cm (Milan Criteria). While the use of RFA for lesions up to 4 cm is practiced, it appears to be safe and tolerable for certain larger lesions. To elaborate further, a study by Zhang X et al. revealed RFA was used successfully with less blood loss and operative time as well as improved recovery times as compared to open surgical resection of enlarging symptomatic hepatic hemangiomas up to 10 cm. However, with respect to malignant tumors, especially

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HCC, not much data is available to determine a size cutoff. Several RCTs have been performed, but these studies are limited by small sample sizes and a general lack of comparability.

One RCT by Feng et al. comparing surgical resection to RFA (n=168 total) of small (< 4 cm) HCC lesions showed increased survival rates (both overall and recurrence-free) in the surgical resection group, though neither reached statistical significance. Of note, the authors concluded that RFA was more likely to be an incomplete therapy for HCC at specific liver sites. A similar conclusion was arrived at by Liu et al. and Huang et al. for HCC lesions within Milan criteria. A recent, and first of its kind, phase II RCT by Ruers et al. compared RFA+ chemotherapy (FOLFOX with bevacizumab) vs. chemotherapy alone for non-resectable colorectal liver metastases (up to 10 lesions, largest 4 cm or less). In this study, which looked at 30-month overall survival as the primary endpoint, the combined therapy was numerically higher (45.3 months) than chemotherapy alone (40.5 months), though it did not reach statistical significance. The progression-free survival was significantly higher in the combined group, at 16.8 months vs. 9.9 months.

The body of evidence presented along with the low morbidity/mortality rates in experienced hands appears to reinforce RFAs place in management of liver lesions deemed risky or not meeting criteria for surgical resection, though its benefit for other malignancies remains unestablished.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

47370	Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency
47380	Ablation, open, of one or more liver tumor(s); radiofrequency
47382	Ablation, one or more liver tumor(s), percutaneous, radiofrequency
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation

HCPCS CODES

No specific codes identified

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Radiofrequency Ablation (RFA) of Liver Tumors, continued

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MEDICAL POLICY

REDUCTION MAMMOPLASTY (BREAST REDUCTION)

Policy # 172
Implementation Date: 4/10/02
Review Dates: 10/10/02, 6/25/03, 6/24/04, 5/4/06, 2/21/08, 2/26/09, 4/21/11, 6/21/12, 6/20/13, 4/17/14, 4/27/17, 5/5/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23, 4/2/24
Revision Dates: 7/1/02, 2/15/05, 3/7/06, 6/8/06, 3/27/07, 4/13/09, 5/8/15, 8/11/15, 3/18/16, 8/7/18, 7/1/20, 2/8/24

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Description

Female breast hypertrophy, macromastia, is the development of abnormally large breasts in the female. This condition can cause significant clinical manifestations when the excessive breast weight adversely affects the supporting structures of the shoulders, neck, and trunk. Macromastia is distinguished from large normal breasts by the presence of persistent, painful symptoms and physical signs. This condition can be improved, and the associated clinical signs and symptoms can be alleviated by reduction mammoplasty surgery.

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 reduction mammoplasty in *limited circumstances*, when the following criteria are met.

Coverage Criteria (Must meet ALL)

1. Documentation provided by a qualified medical practitioner independent of the requesting surgeon's practice, showing both a and b:
   a. One or more of the following conditions due to female breast hypertrophy:
      i. Chronic postural backache
      ii. Chronic neck pain
      iii. Chronic upper back pain
      iv. Shoulder grooving from bra straps
      v. Chronic/recurrent breast intertrigo

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b. Practitioner has provided or recommended conservative treatment for the above condition and member has not responded to treatment.

2. The member has no competing conditions that are more likely causing or significantly contributing to the member's signs/symptoms.
3. The surgeon's estimate of weight and grams of the breast tissue to be removed meets the Select Health Patient BSA/Tissue Removal Weight Standards outlined below:

Select Health Patient BSA / Tissue Removal Weight Standards for Reduction Mammoplasty

4. The following documentation must be submitted to determine if member meets criteria below in Table 1 or 2:
   a. Member's height and weight
   b. Surgeon's estimate of the weight (in grams) of the breast tissue to be removed from each breast
   c. The proposed amount of tissue to be removed can be from each breast, or the average amount from both breasts. In either situation, the amount must meet or exceed the parameters established in 1 of the following 2 tables.

TABLE 1: Body Surface Area* (BSA) Table:

- BSA < 1.35---------200 grams/breast
- BSA 1.40---------- 218 grams/breast
- BSA 1.45---------- 238 grams/breast
- BSA 1.50---------- 260 grams/breast
- BSA 1.55---------- 284 grams/breast
- BSA 1.60---------- 310 grams/breast
- BSA 1.65---------- 338 grams/breast
- BSA 1.70---------- 370 grams/breast
- BSA 1.75---------- 404 grams/breast
- BSA 1.80---------- 441 grams/breast
- BSA 1.85---------- 482 grams/breast
- BSA 1.90---------- 527 grams/breast
- BSA 1.95---------- 575 grams/breast
- BSA > 2.00----------600 grams/breast

**Body Surface Area (BSA) is calculated using the following formula:*

$$BSA\ (m^2) = \text{the square root of: } \frac{Ht.\ (in\ inches)\ x\ Wt.\ (in\ lbs.)}{3{,}131}$$

An Internet BSA calculator is at: http://www.halls.md/body-surface-area/bsa.htm

TABLE 2: Body Mass Index (BMI) Table

(This is an alternative for members with a BMI < 30)

• < 60kg (≤ 132 lbs.) body weight	225 grams/breast
• 61 - 79kg (133 - 174 lbs.) body weight	360 grams/breast
• > 80kg (≥ 175 lbs.) body weight	575 grams/breast

To help determine if the member's BMI is less than 30, use the Internet BMI calculator at:
http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html

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Reduction Mammoplasty (Breast Reduction), continued

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

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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

Reduction mammoplasty is among the most performed breast procedures in the United States. Reduction mammoplasty has been performed to relieve back and shoulder pain on the theory that reducing breast weight will relieve this pain. For pain interventions, evidence of effectiveness is necessary from well-controlled, randomized prospective clinical trials assessing effects on pain, disability, and function. Well-designed trials are especially important in assessing pain management interventions to isolate the contribution of the intervention from placebo effects, the effects of other concurrently administered pain management interventions, and the natural history of the medical condition. Because of their inherently subjective nature, pain symptoms are especially prone to placebo effects.

In the case of reduction mammoplasty for relief of back, neck, and shoulder pain, Schnur et al. demonstrated in their study that there was a direct correlation between the amount of breast tissue removed and the amelioration of an individual's symptoms. Other clinical trial data, however, are lacking. Logic even in the absence of firm clinical trial evidence, suggests that this excessive weight could contribute to back and shoulder pain, and that removal of this excessive breast tissue would potentially provide substantial pain relief, reductions in disability, and improvements in function.

The goal of medically necessary breast reduction surgery is to relieve symptoms of pain and disability. If an insufficient amount of breast tissue is removed, the surgery is less likely to be successful in relieving pain and any related symptoms from excessive breast weight (e.g., excoriations, rash).

Some studies, however, have argued that reduction mammoplasty may be indicated in any woman who suffers from back and shoulder pain, regardless of how small her breasts are or how little tissue is to be removed. They have argued that removal of even a few hundred grams of breast tissue can result in substantial pain relief. These studies cite evidence from subjective, observational studies to support this position. These studies did not find a relationship between breast weight or amount of breast tissue removed and the likelihood of response or magnitude of relief of pain after reduction mammoplasty.

It is not intuitively obvious, however, that breast weight would substantially contribute to back, neck, and shoulder pain in women with normal or small breasts. Nor is it intuitively obvious that removal of smaller amounts of breast tissue would offer significant relief of back, shoulder, or neck pain. Furthermore, the lack of an expected "dose-response" relationship between the amount of breast tissue removed and the magnitude of symptomatic relief in these studies raises questions about the validity of these studies and the effectiveness of breast reduction as a method of relieving shoulder and back pain.

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The studies used to support the arguments for the medical necessity of breast reduction surgery are poorly controlled, and therefore, subject to a substantial risk of bias in the interpretation of results. Well-designed, prospective, controlled clinical studies have not been performed to assess the effectiveness of surgical removal of modest amounts of breast tissue in reducing neck, shoulder, and back pain and related disability in women. In addition, reduction mammoplasty needs to be compared with other established methods of relieving back, neck, and shoulder pain. Well-designed clinical trials provide reliable information about the effectiveness of an intervention and provide valid information about the characteristics of patients who would benefit from that intervention.

For these reasons, there is insufficient evidence to support the use of reduction mammoplasty, without regards to the size of the breasts or amount of breast tissue to be removed, as a method of relieving chronic back, neck, or shoulder pain.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

19318 Reduction mammoplasty

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

RENAL AUTOTRANSPLANTATION

Policy # 606

Implementation Date: 1/24/17
Review Dates: 12/21/17, 12/13/18, 12/12/19, 12/17/20, 11/18/21, 1/13/23, 12/29/23
Revision Dates: 8/24/20, 10/15/20, 5/20/21, 9/23/22, 2/22/24

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Description

Renal autotransplantation is a method of removing a kidney from its place of origin, repairing it, and transplanting it in another location of the body (most commonly, the iliac fossa) of the same patient. Renal autotransplantation has been described in the treatment of renal arterial disease (e.g., arterial aneurysm), complex urological reconstruction (e.g., ureteral stenosis due to retroperitoneal fibrosis), renal cell carcinoma (primarily in patients with a solitary kidney), advanced nephrolithiasis, and loin pain hematuria syndrome and Nutcracker Syndrome. Utility of this procedure is best described in recalcitrant Nutcracker Syndrome and Loin Pain Hematuria Syndrome.

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. Coverage for auto transplantation; must meet **ALL** the following in members with **Nutcracker Syndrome**:

1. Urology and/or gynecology consultation has ruled out other etiologies
2. Triphasic Imaging abdomen and pelvis is positive
    a. Positive test is indicated by one of the following:
        i. Retro-aortic renal vein or renal vein narrowing on venous phase, or
        ii. Multiple retroperitoneal collaterals
3. Other causes of lumbar pain have been ruled out
4. Renal artery anatomy has been evaluated and is normal
5. Left renal venogram with pressure gradient, or injection is positive
    a. Positive test is indicated by one of the following:
        i. Pressure gradient of 2 or greater between left renal vein and IVC, or
        ii. Multiple collaterals seen around the renal vein, or
        iii. Stasis of contrast inside the kidney after injection
6. Left renal lidocaine block is positive with immediate pain relief more than 50% from baseline, and pain relief duration < 24 hours
   Adequate anatomy for autotransplant

*May-Thurner syndrome (MTS) is defined as extrinsic venous compression by the arterial system against bony structures in the iliocaval territory. MTS is also referred to as iliocaval venous compression syndrome, iliac vein compression syndrome, Cockett's syndrome, and venous spur. The most common variant of MTS is due to compression of the left iliac vein between the overlying right common iliac artery and the fifth lumbar vertebrae, but

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others exist. **For patients with moderate-to-severe symptoms and a demonstrable significant venous stenosis associated with May-Thurner's syndrome, then stenting is the preferred treatment.**

B. Coverage for auto transplantation; must meet **ALL** the following in members with **Loin Pain Hematuria Syndrome:**

1. Unilateral or bilateral lumbar pain > 6 months
2. Hematuria, gross or microscopic
3. Normal triphasic CT scan to exclude other causes
4. Urology and/or gynecology consultation to rule out pelvic, ureteral, and bladder disease
5. Nephrology consultation to rule out glomerular disease
6. Renal block is positive, immediate pain relief more than 50% from baseline, and pain relief duration is less than 24 hours
7. Adequate anatomy for autotransplant

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

In reviewing the literature related to renal autotransplantation, there are systematic reviews for Nutcracker Syndrome, but not loin pain hematuria syndrome.

The studies assessed renal autotransplantation in a range of conditions. The most frequently studied diagnosis was loin pain hematuria syndrome and Nutcracker syndrome, but other etiologies included renal or ureteral cancer angiomyolipoma of the renal sinus, renovascular hypertension, metabolic stone disease. The studies are small and lack randomization, however, in selected patients who have failed all other therapies, including endovascular procedures, autotransplantation may be effective.

Billing/Coding Information

CPT CODES

50380 Renal autotransplantation, reimplantation of kidney

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

SACRAL NERVE STIMULATION (SNS)

Policy # 173

Implementation Date: 11/20/00

Review Dates: 2/27/01, 8/30/01, 3/3/02, 10/23/03, 11/18/04, 11/30/05, 12/20/07, 12/18/08, 12/17/09, 12/16/10, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 12/21/17, 2/13/19, 2/18/20, 2/18/21, 1/10/22, 2/16/23, 2/15/24

Revision Dates: 7/24/06, 4/11/11, 4/28/11, 1/27/14, 12/6/16, 10/9/23, 12/14/23, 2/22/24

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Description

Urinary Incontinence/Retention

Urinary incontinence is the complaint of involuntary loss of urine. While a specific etiologic cause of urinary incontinence is often identifiable in younger persons, a multifactorial syndrome is more likely in older persons. In the older population, urinary incontinence may represent the intersection of neuro-urinary pathology, age-related factors, comorbid conditions, medications, and functional and cognitive impairments. Providers may underestimate the prevalence of incontinence in their patients because at least one-half of people with incontinence do not report the problem to healthcare personnel.

Urinary retention from neurologic causes occurs equally in men and women. Although most patients with neurogenic bladder will experience incontinence, a significant number might also have urinary retention. Up to 45% of patients with diabetes mellitus and 75%–100% of patients with diabetic peripheral neuropathy will experience bladder dysfunction, which is likely to include urinary retention. Voiding dysfunction tends to correlate with the severity of multiple sclerosis and occurs in up to 80% of patients, with urinary retention being present in approximately 20%. Disk herniation, spinal trauma, and cord compression from benign or malignant tumors may cause urinary retention through interruption of spinal pathways.

Conservative treatment for urinary disorders depends upon the etiology. In the case of urge urinary incontinence/overactive bladder, the usual conservative therapies include anticholinergic medications, pelvic floor rehabilitation, collagen injections, Kegel exercises, and chronic catheterization. For non-obstructive urinary retention, the standard treatment is intermittent self-catheterization. Electrical bladder stimulation has emerged as a possible alternative to surgery for patients who fail to respond to standard treatment.

Fecal Incontinence

Fecal incontinence (FI) is the inability to control bowel movements, causing stool to leak unexpectedly from the rectum. Also called bowel incontinence, fecal incontinence ranges from an occasional leakage of stool while passing gas to a complete loss of bowel control in someone who is older than four years old.

Common causes of fecal incontinence include constipation, diarrhea, and muscle or nerve damage. FI may be due to a weakened anal sphincter associated with aging or to damage to the nerves and muscles of the rectum and anus from giving birth. A broad range of conditions and disorders can cause fecal incontinence.

The treatment of fecal incontinence varies depending upon the etiology and severity of the problem. For some patients, medications to treat underlying constipation may resolve the problem. For those who have had muscle or nerve damage, behavioral modification including biofeedback may be used. For those failing to respond to conservative therapy, surgery may be considered.

Sacral nerve stimulation (SNS), or sacral nerve neuromodulation, is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder and sphincter function. This treatment is one of several alternative modalities for patients with urinary incontinence, urinary retention, and fecal incontinence, who have failed conservative measures. It is also potentially a treatment for patients with other types of chronic voiding dysfunction, such as the urge-frequency syndrome interstitial cystitis, and idiopathic chronic urinary retention.

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 sacral nerve stimulation (SNS) for the treatment of patients with disabling urge incontinence, non-obstructive urinary retention, or fecal incontinence *in limited circumstances*.

Criteria for placement of a ***trial*** sacral nerve stimulator:

Urinary:

1. Urine testing performed in the last 4 weeks has demonstrated absence of urinary infection; and
2. Documentation has demonstrated cystoscopy has been performed within the past 2 years and alternative causes of problem have been excluded; and
3. Symptoms have been present for at least 12 months; and
4. Documented failure or intolerance to conventional therapy (e.g., 2 different anticholinergic drugs or a combination of an anticholinergic and a tricyclic antidepressant, or other standard pharmacologic treatment regimens, pelvic muscle exercises, timed-voids, and fluid management); and
5. The patient has demonstrated the ability to operate the implantable pulse generator (IPG); and
6. Patient is at least 16 years of age; and
7. Appropriate documentation in the patient's record must support the condition to be disabling.

Fecal:

1. Chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth; and
2. Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy performed more than 12 months [or 24 months in case of cancer] previously); and
3. The patient has demonstrated the ability to operate the implantable pulse generator (IPG); and
4. Patient is at least 16 years of age; and
5. Appropriate documentation in the patient's record must support the condition to be disabling.

Criteria for placement of a ***permanent*** sacral nerve stimulator***:***

1. The member must have met all the above criteria prior to the placement of a permanent stimulator; **AND**
2. Patient experienced at least a 50% reduction in incontinence symptoms with a trial of a percutaneous sacral stimulator; **AND**
3. Trial period is within 3 months of placement.

Contraindications:

- Patients with cardiac demand pacemakers and internal defibrillators

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- For patients with urge incontinence, the presence of neurological conditions (e.g., multiple sclerosis, diabetes with peripheral nerve involvement, spinal cord injury, stroke, detrusor hyperreflexia).
- Patients with primary pelvic pain.
- Patients with mechanical obstruction (e.g., BPH, cancer, or urethral stricture)
- Patients with anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60°; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease

Note: Cardioverter defibrillators, diathermy, electrocautery, external defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors, and screening devices (e.g., those used in airports to screen luggage, etc.) can interfere with the device.

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

Urge Incontinence

A prospective randomized controlled trial by Schmidt et al. conducted at 23 worldwide centers examined the effectiveness of sacral nerve stimulation in treating urinary urge incontinence. All candidates underwent baseline screening to determine their eligibility for the study, and almost all had undergone previous medical treatment that had failed in alleviating their condition. Out of a pool of 155 urge incontinence patients, 98 were pre-screened as viable candidates for the study. The 98 patients were then randomized into 2 groups, where 52 patients were scheduled for implant of the system and 46 patients were followed as a control group. Control patients underwent standard medical therapy for 6 months, and thereafter, could cross over to the implant group to receive sacral nerve stimulation therapy. All patients who were enrolled agreed to keep diaries of their condition throughout the duration of the study. After 6 months of sacral nerve stimulation therapy, a therapy evaluation test was performed, where stimulation was turned off to determine the effects of discontinued therapy.

After 6 months of treatment, the number of daily incontinence episodes, the severity of episodes, and the frequency of absorbent pads or diapers requiring replacement due to incontinence were significantly reduced in the implant group when compared with the control group. In the implant group, 47% were completely dry at 6 months, and these results were sustained at 12 months after receiving the therapy. Furthermore, an additional 28% of the implant group had a 50% or greater reduction in the number of leaking episodes they experienced. Control group patients demonstrated no clinical improvement at 6 months.

Additionally, when stimulation was deactivated during the therapy evaluation test 6 months after implantation, voiding diaries indicated a return towards baseline urge incontinence, with no adverse effect on baseline voiding function. This illustrated the reversible nature of the therapy and demonstrated that the therapeutic results were attributed to the application of the therapy.

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About a third of the patients who received devices underwent subsequent surgery to reposition or to replace elements of their systems. The adjustments were intended to resolve device or therapy-related adverse side effects. The most reported adverse events included pain at the implant site (19.1%), pain at the neurostimulator site (15.9%) and lead migration (7%). The surgical revisions did not preclude a favorable clinical outcome for the patient. No adverse events resulted in permanent injury, however, 9% remained unresolved at the time of database closure.

A 1998 BCBS and Kaiser Permanente Review concluded the following about sacral nerve stimulation:

> Sacral nerve stimulation meets the TEC criteria for patients with urge incontinence that is not due to a neurologic condition, who have failed previous conservative treatments, and who have had a successful peripheral nerve evaluation test. SNS does not meet the TEC criteria in patients with urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia), or in patients with other types of chronic voiding dysfunction.

A 1998 Hayes Directory Report concluded the following:

> The future of bladder stimulation will depend upon more data from larger blinded studies with greater follow-up time that randomize patients to either a placebo group or to a control group employing conventional treatment. The development of new alternative treatments, such as collagen injections, also will affect the extent to which bladder stimulation becomes a standard procedure. Based on the findings reviewed in this report, a Hayes Rating of 'B' is assigned for anal and vaginal electrode placement in the treatment of genuine stress incontinence, a 'C' for anal and vaginal electrode placement in the treatment of detrusor instability, a 'C' for anal and vaginal electrode placement in the treatment of mixed incontinence, a 'C' for percutaneous placement of electrodes in the treatment of neuropathic-induced detrusor instability, a 'C' for sacral nerve stimulation in the treatment of urinary incontinence and detrusor instability, and a 'C' for intravesical electrode placement in the treatment of neurogenic detrusor instability.

Urinary Retention

A Medical Technology Assessment performed in March 2011 focusing on SNS for non-obstructive urinary retention identified 2 systematic reviews and 1 primary study. One systematic review was performed by Hayes and was published in November of 2010. This review provided a 'C' rating for the use of SNS for urinary retention and stated: "Long-term outcomes from randomized controlled trials (RCTs) of SNS are lacking; however, evidence from prospective and retrospective long-term follow-up studies of the available RCT shows sustained control of intractable urinary symptoms for up to 2 years and, in a small patient group, for up to 11 years. Although the results of a few studies indicate that SNS may be effective for some patients with neurogenic urinary retention and mixed urinary incontinence, there is insufficient data for these conditions."

The other systematic review published in 2009 by the Cochrane Database, noted: "In spite of methodological problems, it would appear that some people benefit from implants which provide continuous nerve stimulation. More research is needed on the best way to improve patient selection, carry out the implant, and to find why so many fail. The effectiveness of implants should be tested against other interventions, particularly in people with an overactive bladder."

As for the data contained in the primary literature, it is inconsistent as it pertains to safety, efficacy, explantation rates, and patient satisfaction. Al-Zahrani et al. published an explantation rate that was 20.8%, and a median time to removal of 18.5 months. Blandon et al. reported a 33% revision rate and a 15% explant rate after only 17 months. Vaarala et al. published a surgical revision rate of 20.3% after 41 months. In contrast to these dismal reports, Leong et al. published in 2011 a report that overall satisfaction with sacral neuromodulation was high at 90%, and that of the patients who had a significant side effect, 89% did not seek further therapy.

Fecal Incontinence

The review for sacral nerve stimulation for the treatment of fecal incontinence identified four systematic reviews and 20 primary literature articles which met inclusion. The systematic reviews date from 2004 for the review by National Institute for Clinical Excellence (NICE) to the 2010 Cochrane Review. Uniformly, these systematic reviews support SNS for fecal incontinence (SNS for FI) as safe and effective in patients failing conservative therapy. Specifically, the NICE (2004) found that current evidence on the safety and

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efficacy of sacral nerve stimulation for fecal incontinence appears adequate to support the use of this procedure. In all, 2 peer reviewed papers were found concerning SNS for FI. These range in size from as few as 9 individuals to large as 665 patients

Of note, the Dudding et al. published a paper in 2010 prefaced by the statement that surgical repair of the internal anal sphincter is not successful, and therefore, a clinical investigation of SNS was needed. Though the group studied a small number of patients (n = 9), a large decrease in the number of FI episodes per week was found after implantation of a sacral nerve stimulator. Similar decreases in the number of episodes were seen in 6 other studies.

Related to complications, the most common need for revision of the procedure noted in the studies included infection, electrode displacement, electrode breakage, dysfunction owing to impedance increase, adverse stimulation with pain, battery depletion, or total or partial loss of clinical efficacy.

Unlike many other new technologies, 5 of the papers (none of which gave figures in USD) addressed cost-effectiveness of SNS for FI. All five stated that the treatment was cost-effective. For example, Dudding et al. (2008), published in the British Journal of Surgery, that SNS for FI is 16% under the NICE threshold for justification of usage within their healthcare system. Furthermore, Hetzer et al. (2006) showed that SNS can be performed for 35% less than colostomy and 30% less than graciloplasty.

In short, as stated by NICE (2004), current evidence on the safety and efficacy of SNS for FI appears adequate to support the use of this procedure for patients failing conservative therapy. However, as indicated by the Medical Advisory Secretariat, and supported by the literature, to qualify for SNS, patients must meet the following criteria:

- Be able to record voiding diary data, so that clinical results of the implantation can be evaluated; and
- Be refractory to behavior and/or drug therapy; and

Have had a successful test stimulation before implantation; successful test stimulation is defined by a 50% or greater improvement in voiding function based on the results of a voiding diary.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

HCPCS CODES

A4290	Sacral nerve stimulation test lead, each
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

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MEDICAL POLICY

SCLEROTHERAPY FOR THE MANAGEMENT OF LYMPHANGIOMATA

Policy # 424
Implementation Date: 10/12/09
Review Dates: 4/12/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 7/20/18, 4/15/19, 4/15/20, 4/15/21, 3/18/22, 6/12/23
Revision Dates: 4/21/11

Related Medical Policies:
#147 Lymphedema 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

LA lymphatic malformation (LM) is also known as a lymphangioma or a cystic hygroma. LMs usually appear in young children. These lesions, also called "lymphatic birthmarks," come in various forms, including localized, small lesions, and large (diffuse) lesions, involving an extremity or particular body part of organ system. LMs are usually classified as microcystic (usually small and not easily compressed), macrocystic (usually large and easily compressed), or mixed. The term cystic hygroma is commonly applied to macrocystic LMs located in the neck. About 75% of LMs occur in the cervico-facial region. Diagnostic imaging may be required to distinguish a lymphatic malformation from venous malformation (cavernous hemangioma).

The superficial lymphatic system originates from the epidermis. Valveless lymphatic channels drain into deeper, valve precollectors. One-way valves permit forward flow into subcutaneous collectors and smooth muscle further aids in peristaltic movement of lymph fluid. The lymphatic fluid then travels into major regional lymph node groups via the subcutaneous collectors or by way of deep lymphatics that run with local neurovascular bundles.

Lymphangiomata are rare congenital malformations of the lymphatic system that involve the skin and subcutaneous tissues. They account for 4% of all vascular tumors and approximately 25% of all benign vascular tumors in children. The classification most frequently used divides these lesions into 2 major groups based on the depth and the size of these abnormal lymph vessels. The superficial vesicles are called lymphangioma circumscriptum. The more deep-seated group includes cavernous lymphangioma and cystic hygroma. The classification of lymphangiomata lacks a standard clear definition and universal application, in part, because of the diverse nature of underlying cellular abnormality causing the formation of lymphangiomata. Lymphangiomata may manifest as lymphedema, and larger lesions can involve the skeletal system and cause gross disfigurement. Large malformations in the neck or mediastinum can compromise the airway, leading to stridor, dysphonia, or dyspnea.

Lymphangiomata can occur anywhere in the skin and the mucous membranes. The most common sites are the head and the neck, followed by the proximal extremities, the buttocks, and the trunk. However, they sometimes can be found in the intestines, the pancreas, and the mesentery. Deeper cystic lesions usually occur in areas of loose and areolar tissue, typically the neck, the axilla, and the groin. Their skin involvement ranges from small, well-demarcated areas to large, diffuse regions with unclear borders.

Sclerotherapy is a nonsurgical treatment option that involves the injection of an inflammatory solution, or sclerosant, directly into a vascular cavitary structure. The sclerosant causes irritation and damage to the tissues lining the lymphatic vessels. As a result, the vessels harden or scleroses, and closing the lumen

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of the vessel, which is eventually replaced by scar tissue and/or absorbed into the body. Following surgery or sclerotherapy, the remaining vessels in the lymphatic system may compensate over time for the absent, or treated lymphatic channel(s), by creating or enlarging collateral lymphatics.

No standard sclerotherapy technique has been identified. Needle positioning is performed with or without ultrasonic guidance. Once the optimal needle position is determined, the needle is advanced into the vessel wall. With slow and steady pressure, the sclerosant is injected into the vessel, taking care that no sclerosant is injected into the surrounding tissue.

For the treatment of **lymphedema,** see Policy # 147 "Lymphedema Therapy."

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

Select Health covers sclerotherapy for lymphangiomata and associated lymphedema. Current evidence demonstrates equal efficacy and improved morbidity compared to surgical excision.

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

One systematic review from 2008 was identified. Acevedo reviewed 22 studies examining percutaneous sclerotherapy with a variety of sclerotic agents. The aggregate outcomes indicated that 43% of patients treated with OK-432, also known as picibanil, achieved a complete/excellent response, 23.5% achieved a good response, and 15.4% had not observed response. OK-432 is a lyophilized incubation mixture of group A Streptococcus Pyogenes of human origin, inactivated by heating with penicillin G, which has lost its streptolysin producing ability, but retains activities to produce local inflammatory mediators. In the bleomycin (an established antineoplastic drug which has been used as a locally injected sclerosing agent) group, the results were: 35.2% excellent, 37.1% good, 18.4% fair/poor, and 11.6% no response. Seven major complications were noted out of the 289 patients in the series, including 2 mortalities.

Twenty-eight studies met criteria for inclusion; all of these were focused on treatment of lymphangiomata, and one of these was a randomized controlled trial. Giguere et al. randomly assigned 30 patients to a 4-dose series of OK-432 or to an observation control group for 6 months. Of the 22 patients with macrocystic lymmphangiomata, 19 (86%) had a successful outcome (defined as complete or a substantial (> 60%) reduction in lymphangiomata size). Though the remaining studies are not randomized, they all arrive at the same conclusion, namely that sclerotherapy is a safe, effective treatment for lymphangiomata. Furthermore, many studies recommend this treatment as first-line therapy. There are no cost studies examining cost-effectiveness of this therapy relative to surgical excision or other therapies. However, overall, the large body of literature suggests that this therapy is a safe and effective alternative to surgical excision.

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Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the invervention; venous, other than hemorrhage (e.g. congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method

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MEDICAL POLICY

SIMULTANEOUS LIVER AND KIDNEY TRANSPLANTATION (SLK)

Policy # 144

Implementation Date: 1/4/00
Review Dates: 2/27/01, 5/21/01, 5/13/02, 6/25/03, 6/24/04, 6/16/05, 10/18/07, 10/23/08, 4/21/11, 2/15/12, 4/25/13, 2/20/14, 3/19/15, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/22/21, 9/15/22, 10/2/23
Revision Dates: 9/20/06, 1/28/10, 7/1/10, 3/9/18, 11/20/19, 1/24/22, 12/1/22, 11/1/23

Related Medical Policies:
#141 Kidney Transplant and Re-Transplantation
#142 Liver Transplant (Adult, Cadaveric)
#143 Liver Transplant-Adult Living Donor Liver Transplantation (aLDLT)

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

Simultaneous liver and kidney transplantation (SLK) involves the removal of both organs, ideally from a single donor, and transplantation into a single recipient, with the goal of correcting specific pathological processes in the recipient that pertain to liver and kidney function.

Adequate kidney and liver function are vital to sustaining life. While kidney function can be somewhat improved by dialysis, for many, this procedure is inadequate to ensure long-term health. In instances of advance chronic kidney disease or in instance where hepatorenal syndrome of an extended duration leads to renal failure unlikely to recover following liver transplantation an SLK is required for those with indication for liver transplantation (see policy on liver transplantation #142). SLK procedures are required to address pathological processes that lead to failure or severe compromise of these two organs.

Renal and hepatic failure may result from a single disease process (e.g., polycystic disease), a disease may be the consequence of another pathologic process (e.g., postviral hepatic cirrhosis in a dialysis patient), or related or unrelated concomitant diseases. (Hepatitis C causing both cirrhosis with MPGN of the kidney) or Cirrhosis leading to long-standing Hepatorenal Syndrome on dialysis for more than 4 weeks).

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 simultaneous liver and kidney transplantation (SLK transplantation) in patients who meet United Network for Organ Sharing (UNOS)/Organ Procurement and Transplantation Network (OPTN) eligibility criteria for both the liver and kidney transplants. Candidates for SLK transplantation must also satisfy the criteria established for the separate transplant procedures (e.g., liver and kidney) and those for SLK transplantation in keeping with the OPTN policy; those criteria are presented here. Transplantation benefits and coverage will be determined only after the review of the work-up from the requesting transplant team has been completed.

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All requests for transplant benefits, coverage, or preauthorization, should be sent to case management.

Liver Transplant Criteria (Policy #142)

Select Health covers cadaveric liver transplantation in *limited circumstances,* where the medical literature has demonstrated a reasonable probability of improvement in the member's health outcome. The following coverage criteria reflect this policy.

Criteria for coverage: (Patient must meet **A or B**)

A. Procedure has been endorsed, recommended, and will be performed by Intermountain Healthcare Liver Transplant Services

OR

B. For service being requested outside of Intermountain Healthcare:

1. The patient is under case management with Select Health.

2. The transplant team has documented the following:

a. The patient has irreversible, end-stage or chronic liver disease which has progressed to the point of significant interference with the patient's life activities (e.g., the patient is unable to work, attend school, or perform housework duties).

b. There is no other effective medical or surgical therapeutic alternative available.

c. There is a reasonable expectation that the patient's quality of life (i.e., physical and social function required to perform activities of daily living will be significantly improved).

d. One of the following (i–iv):

i) The patient's MELD (Model for End-State Liver Disease as maintained by the United Network for Organ Sharing, [UNOS]) score is **15** or higher, or

ii) The patient meets criteria for an Organ Procurement and Transplantation Network (OPTN) approved MELD exception (T2 tumor or a tumor downstaged and stable within Milan criteria, hepatopulmonary syndrome, portopulmonary hypertension, etc.) requiring transplantation to reverse the process, or

iii) The patient has a genetically derived metabolic condition with clear benefit from transplantation, or

iv) The patient has experienced life-threatening complications of end stage liver disease where their mortality exceeds that predicted by their MELD score.

e. The patient and the patient's family have demonstrated sufficient motivation to undergo the preoperative preparation, the operative procedure, and the postoperative lifetime follow-up.

f. In its decision to recommend that the patient be a liver transplant recipient, the transplant team has considered and evaluated any evidence for non-compliance with medical care.

g. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would

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preclude surgery or a reasonable survival.

h. Medical and social assessment that the patient has sufficient social stability to provide assurance that they will cooperate with the long-term follow-up and the immunosuppressive program, which is required.

i. No uncontrolled and/or untreated psychiatric disorder or substance use disorder that would interfere with compliance to a treatment regimen.

j. If the patient has diabetes mellitus, a comprehensive clinical assessment and cardiology specialist has cleared the patient for transplant surgery.

k. None of the below listed "Absolute Contraindications" apply to or characterize the patient.

3. The transplant team and the Select Health Medical Director (or their designee), concur that none of the following relative contraindications preclude acceptance of the patient as a liver transplant recipient:
   a. Age under 18 or over 65 years (Liver failure patients who are less than 18 years are referred to a participating pediatric liver transplant program. Those patients age > 65 must be otherwise healthy and evaluated on a case-by-case basis).

   b. Insulin dependent diabetes mellitus with complications.

   c. Extrahepatic or biliary sepsis.

Absolute Contraindications:

1. Irreversible musculoskeletal disease resulting in bed confinement.
2. Irreversible pulmonary disease as listed below:
   a. Cystic fibrosis with severe or incapacitating disease. Mild cystic fibrosis lung disease with severe liver disease can be considered on a case-by-case basis
   b. Obstructive pulmonary disease (FEV1 < 55% of predicted)
   c. Restrictive lung disease (FVC < 50% of predicted)
   d. Lung cancer
3. Metastatic cancer
4. Life-threatening and unmanageable bacterial or fungal infection outside the hepatobiliary system
5. Cardiovascular disease as listed below:
   a. Myocardial infarction within 3 months
   b. Intractable life-threatening cardiac arrhythmias
   c. NYHA Class IV heart disease
   d. Severe and non-bipassable occlusive peripheral vascular, coronary vascular disease, or cerebrovascular disease
   e. Severe generalized arteriosclerosis
6. Irreversible terminal state (extreme cachexia)
7. Severe extrahepatic disease which would likely limit life expectancy to less than 2½ years
8. Long-standing major psychosis; lack of social or family support systems; significant history of non-compliance
9. Incarceration
10. Dementia

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Simultaneous Liver and Kidney Transplantation (SLK), continued

Kidney Transplant and Re-Transplantation Criteria (Policy #141)

Kidney transplants will be approved If recommended by Intermountain Healthcare Renal Transplant Clinical Program; **OR**

For all other clinicians, Select Health covers renal transplants if the following criteria are met:

Criteria for coverage (must meet 1, and EITHER 2 or 3, AND 4 through 9 below):

1. Provided by In-Network Providers in an In-Network Facility* unless otherwise approved in writing in advance by Select Health. *This criterion does not apply to Idaho commercial plans. Members on Idaho commercial plans may use their out-of-network benefits with an out-of-network provider if all other criteria are met.
2. Acute trauma with irreversible impairment of renal function where no therapeutic alternative is available; **or**
3. Chronic renal impairment is irreversible; permanent; has progressed to the point of significant interference with the patient's quality of life, and for which no other effective medical or surgical therapeutic alternative is available; **and**
4. The patient has one of the following:
   a. On dialysis; or
   b. The dialysis need is imminent; or
   c. The patient has a living-related donor (the transplant may be done before dialysis is necessary); or
   d. The patient may have a history of a renal transplant, but due to progressive graft failure is approaching the need for dialysis.
5. A reasonable expectation that the patient's quality of life (e.g., physical and social function suited to activities of daily living), will be improved.
6. Strong motivation by the patient to undergo the procedure and a thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
7. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would preclude surgery or a reasonable survival.
8. Medical and social assessment that the patient has sufficient social stability to provide assurance that they will cooperate with the long-term follow-up and the immunosuppressive program, which is required.
9. No uncontrolled and/or untreated psychiatric disorder or substance use disorder that would interfere with compliance to a treatment regimen.

Absolute Contraindications:

1. Advanced respiratory failure.
2. Myocardial infarction within 6 months
3. Intractable life-threatening cardiac arrhythmias
4. Severe generalized arteriosclerosis
5. Active severe hemodynamic compromise at the time of transplantation if accompanied by significant compromise of one or more non-renal end-organs.
6. Unmanageable active infection
7. Cancer, (except skin cancer) unless treated and eradicated for 2 or more years
8. Unresolved GI hemorrhage
9. Debilitating and/or irreversible brain damage
10. Life-threatening extra-renal congenital abnormalities
11. Persistent coagulation disorder

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Simultaneous Liver and Kidney Transplantation (SLK), continued

Relative Contraindications:

12. Age at the time of transplant: greater than 70 years or less than 18 years
13. Clinical evidence of peripheral vascular disease, specifically, cerebral vascular disease, ischemic ulcers, or previous amputations secondary to vascular disease
14. Diabetic patient with poor control (hgbA1c >9%) who has documentation of poor medication adherence/compliance and/or lifestyle management based on clinical documentation or prescription refills
15. Active peptic ulcer disease
16. Hypertension poorly controlled by medication
17. Morbid obesity

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

An AHRQ technology review in 1995 reported patient survival for simultaneous kidney and liver (SLK) transplant in 5 studies with 4−38 patients, ranged from 68%−100% for periods of time ranging from 6 weeks to 7 years. Patient survival of 217 patients from the Scientific Registry for Organ Transplantation was 74% with no prior transplant and 50% with a prior liver transplant. One-year patient survival in the United Network for Organ Sharing Registry for isolated liver transplant was 75% with no prior transplant and 51% with a prior transplant. The review concluded that SLK transplant performed as the initial transplant procedure appears to provide patients with both kidney and liver failure a 1-year survival probability equivalent to that following isolated liver transplantation in patients with liver failure alone. SLK following prior liver transplant appears to be associated with a significant decrement in survival.

Ruiz et al. retrospectively analyzed health outcomes for 98 patients who underwent 99 SLK transplants over a 16-year period. Overall patient survival was 76%, 72%, and 70% at 1, 3, and 5 years, respectively; liver graft survival was 70%, 65%, and 65%; and kidney graft survival was 76%, 72%, and 70%. No risk factors analyzed for recipients or donors were associated significantly with early post- transplantation mortality or graft loss. In 28 patients who received monoclonal antibody induction therapy with interleukin 2 blockers, there were significantly fewer episodes of acute liver rejection.

Billing/Coding Information

Covered: For the indications outlined above

CPT CODES

47133 Donor hepatectomy (including cold preservation), from cadaver donor

47135 Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any

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	age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	; with trisegment split of whole liver graft into two partial liver grafts (i.e., left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII])
47145	; with lobe split of whole liver graft into two partial liver grafts (i.e., left lobe [segments II, III, and IV] and right lobe [segments I and V through VIII])
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	; arterial anastomosis, each
47399	Unlisted procedure, liver
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	; arterial anastomosis, each
50329	; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

HCPCS CODES

S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s) , procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic,

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emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition

Key References

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2. Ruiz R, Kunitake H, Wilkinson AH, et al. "Long-term analysis of combined liver and kidney transplantation at a single center." Arch Surg 141.8 (2006): 735-41; discussion 741-2.

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MEDICAL POLICY

SMALL BOWEL TRANSPLANT

Policy # 640
Implementation Date: 5/18/20
Review Dates: 1/20/22, 2/16/23, 2/15/24
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

Patients with small bowel disease may need to consider a small bowel transplant or intestinal surgery. In a small bowel transplant, the diseased portion of the small intestine is removed and replaced with a healthy small intestine from a donor. This procedure can be lifesaving for patients with irreversible intestinal failure that has become life-threatening.

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 small bowel transplantation for members who have failed TPN (total parental nutrition); reasons for TPN failure may include one of the following (this list is not all-inclusive):

1) Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN;
2) Frequent line infection and sepsis;
3) Impending or overt liver failure due to TPN-induced liver injury;
4) Other complications leading to loss of vascular access;
5) Thrombosis of the major central venous channels, jugular, subclavian, and femoral veins; or
6) Member is incapable of utilizing TPN

*Members must also meet the transplant institution's criteria.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

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

Billing/Coding Information

CPT CODES

44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete

HCPCS CODES

S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre and posttransplant care in the global definition

Key References

1. Small Bowel Transplant. Med Star St. Mary's Hospital. Retrieved from: https://www.medstarstmarys.org/our-services/transplant/treatments/small-bowel-transplant/

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MEDICAL POLICY

VARICOSE VEIN PROCEDURES

Policy # 193

Implementation Date: 8/30/03
Review Dates: 8/26/04, 8/3/05, 8/17/06, 8/23/07, 8/21/08, 8/13/09, 8/19/10, 12/15/11, 10/11/18, 1/16/20, 2/18/21, 1/20/22, 2/15/23
Revision Dates: 9/20/05, 9/23/13, 8/5/14, 11/6/14, 12/16/14, 10/13/15, 10/29/15, 11/23/15, 1/11/16, 9/21/16, 5/11/17, 5/25/17, 3/6/18, 4/15/20, 1/1/21

Related Medical Policies:

#268 Pelvic Vein Procedures for Pelvic Congestion Syndrome and Varix

#88 In-Network Coverage of Medical Services with an Out-of-Network Provider

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 venous anatomy of the lower limbs consists of three major divisions, including a deep system (femoral, popliteal, and sural veins) that generally parallel the arteries within the muscular system, the superficial system (great, small, accessory saphenous, and inter-saphenous veins) located closer to the skin, and the subcutaneous tissues and perforating veins that connect with deep and superficial systems. The primary return of blood to the heart is via the deep venous system. The superficial veins serve as a conduit to gather blood from the surrounding tissues and direct it into the deep system via the perforator connections. Malfunction of these veins at any level contributes to chronic venous disease and pathology that manifests as clinically important disease. A major component of the veins is a series of valves that prevent reflux into the distal aspects of the venous system when the limbs are in a dependent position. Abnormal function of these valves creates venous hypertension and its sequelae including varicose veins, lipodermatosclerosis, and venous ulceration. The term varicose vein is used to designate enlarged, tortuous veins that are typically secondary to valve incompetence. Treatments in the past typically revolved around removal of the incompetent axial veins (vein stripping). Percutaneous catheter-based treatments, approved by the FDA, use radiofrequency or laser generated heat to create endothelial damage and sclerosis of the treated veins, effectively removing them from circulation without need for surgical excision. Newer, non-thermal techniques, also FDA-approved, include mechanico-chemical endovenous ablation and cyanoacrylate adhesive ablation of the incompetent veins. These treatments can be performed in an outpatient setting and typically have a much shorter recovery time. The durability of the therapies has been well established for both radiofrequency and laser therapy (endothermal ablation).

Endothermal ablation using either the radiofrequency catheter or the laser fiber technique is typically performed in an outpatient setting with mild-to-moderate conscious sedation. Ultrasound imaging is used to evaluate the axial vein to be treated, including the adjacent deep venous system. Through a small access dermatotomy, using standard Seldinger technique, the vein is accessed under ultrasound guidance and a sheath introduced into the vein. Through this sheath, the catheter is inserted into the vein and positioned approximately 2 cm from the junction with the deep venous system. Tumescent, local anesthesia is then delivered around the vein through a series of needle sticks for anesthesia and to act as a heat sump to reduce adjacent tissue heat damage. The generator is activated, and the catheter withdrawn at a specific rate to deliver an appropriate quantity of heat to the vein to achieve closure. Ultrasound is then used to reevaluate the vein and assess for closure.

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There are multiple FDA-approved laser devices for endothermal ablation, each of which uses different light wavelength. These include 810 nm, 940 nm, 980 nm, and 1470 nm. One radiofrequency catheter is available.

Cyanoacrylate and mechanico-chemical therapies are more recent developments in the treatment of incompetent axial veins also performed in outpatient settings with little or no sedation. These are also minimally invasive but are non-thermal procedures. Cyanoacrylate is a medical adhesive use to occlude the vein and create a fibrotic reaction, treating the incompetent vein. Mechanico-chemical ablation uses a catheter with a rotating wire (that causes damage to the vein) combined with a sclerosant to close the diseased vein. Unlike other procedures, these treatments do not require tumescent anesthesia, allowing patients to return to their normal activities following the procedure more quickly. Since these techniques are non-thermal, the risk of nerve or other heat-related injuries associated with laser and radiofrequency procedures are eliminated.

Removal of varicosed venous tributaries (varicose veins) is also frequently necessary for complete treatment of chronic venous insufficiency associated with incompetence of the truncal, axial veins (great, small, and accessory saphenous veins). This procedure ("ambulatory"-, "stab"-, or "micro-phlebotomy") is commonly performed after tumescent local anesthesia infiltrated into the tissue surrounding the varicosed veins. Through additional small incisions adjacent to the dilated, malfunctioning veins, they are removed, improving overall venous function of the system. This is an adjunct to the treatment of the axial veins and can be performed simultaneously or at a subsequent procedure. This procedure is most often performed in an outpatient setting with mild-to-moderate conscious sedation.

Transilluminated power phlebectomy has been introduced as a means of improving ambulatory phlebectomy. This procedure involves the use of transillumination and tumescent anesthesia, coupled with subcutaneous vein ablation using a powered resector. Once adequate tumescent infiltration is achieved, the resector and illuminator are inserted and positioned underneath the skin through small incisions near the varicosities to be treated. The targeted tissue is drawn into the cutting window of the blade under suction, where the rotating inner blade shears off the tissue. To avulse the vessel away from the adjacent tissue and remove as much vein tissue as possible, the resector is gently passed along the side and underneath the varicosities for removal. This procedure may require general or spinal anesthesia, performed in an outpatient setting.

The VenaSeal Closure System (Sapheon Inc., Morrisville, NC) is a minimally invasive, non-tumescent, non-thermal and non-sclerosant procedure that uses a medical adhesive to close the diseased vein in patients with symptomatic venous reflux disease. Unlike other treatments, the VenaSeal Closure System does not require tumescent anesthesia, allowing patients to return to their normal activities following the procedure; it also eliminates the risk of nerve or other heat-related injuries associated with thermal-based procedures, and thus may reduce the need for compression stockings post-procedure.

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.

(Effective January 1, 2021) SelectHealth covers varicose vein treatment when performed in an IAC (Intersocietal Accreditation Commission)-accredited center.

SelectHealth covers varicose vein treatment at a non-IAC accredited center when either A or B are met:

A. All the following criteria must be met (1−7):

1. There are no IAC-accredited centers within the distance guidelines outlined in coding/reimbursement policy #88. (***This criterion is not applicable for members on the Fidelity, Hexcel, Granite School District, Revere Health, Marriot Vacations Worldwide, or St. Luke's Health System employer plans***)

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2. The member is at least 18 years old.
3. The varicose vein(s) are associated with any one of the following symptoms:
    a. Itching, discomfort, or heaviness in the legs
4. The varicose vein(s) are associated with least one of the following physical findings:
    a. Lipodermatosclerosis, hyperpigmentation, or eczema
5. Symptoms of the varicose vein(s) interfere with ADLs (activities of daily living).
6. Symptoms of the varicose vein(s) continue after activity modification for at least 6 weeks.
7. Treated veins are required to have superficial venous reflux ≥ 500 milliseconds by duplex ultrasound

OR

B. Both of the following criteria must be met (1 and 2):

1. a. There are no IAC-accredited centers within the distance guidelines outlined in coding/reimbursement policy #88. (***This criterion is not applicable for members on the Fidelity, Hexcel, Granite School District, Revere Health, Marriot Vacations Worldwide, or St. Luke's Health System employer plans***)

2. Documentation supports presence of any one of the following:

    a. Recurrent thrombophlebitis or persistent thrombophlebitis despite anticoagulants; **or**
    b. Severe or recurrent bleeding from the varicosities; **or**
    c. Recurrent or residual varicose vein post-varicose vein procedure; **or**
    d. Venous insufficiency with venous ulcer.

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

In 2011, the Society for Vascular Surgery and the American Venous Forum (Gloviczki. et al., 2011) developed clinical practice guidelines for care of patients with varicose veins of the lower limbs and pelvis. Although not all-inclusive, the main recommendations of the committee may be summarized as follows:

1. in patients with varicose veins or more severe chronic venous disease (CVD), a complete history and detailed physical examination are complemented by duplex ultrasound scanning of the deep and superficial veins
2. the use of CEAP classification for patients with CVD and the revised Venous Clinical Severity Score to assess treatment outcome
3. regarding Duplex scanning results:

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- a cutoff value of 1 second for abnormally reversed flow (reflux) in the femoral and popliteal veins
- a cutoff value of 500 ms for abnormally reversed flow (reflux)for the great saphenous vein, the small saphenous vein, the tibial, deep femoral, and the perforating veins
- in patients with chronic venous insufficiency, duplex scanning of the perforating veins is performed selectively; the definition of "pathologic" perforating veins includes those with an outward flow of duration of ≤ 500 ms, with a diameter of ≤ 3.5 mm and a location beneath healed or open venous ulcers (CEAP class C5-C6)

4. compression therapy (pressure 20−30 mm Hg):
   - is suggested for patients with symptomatic varicose veins
   - as the primary treatment to aid healing of venous ulceration
   - in addition to ablation of incompetent superficial veins in order to decrease the recurrence of venous ulcers
   - is not recommended as the primary treatment if the patient is a candidate for saphenous vein ablation
5. ligation and stripping for the treatment of incompetent great, small saphenous and superficial veins recommend the following:
   - endovenous thermal ablation (radiofrequency or laser) for treatment of incompetent saphenous vein rather than high ligation and inversion stripping of the saphenous vein to the level of the knee
   - phlebectomy or sclerotherapy to treat varicose tributaries
   - foam sclerotherapy as *an option* for the treatment of the incompetent saphenous vein (endovenous thermal ablation is recommended over foam sclerotherapy)
   - treatment of pathologic perforating veins (outward flow duration >500 ms, vein diameter > 3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6)
6. recommend against selective treatment of perforating vein incompetence in patients with simple varicose veins (CEAP class C2)

Radiofrequency Ablation (RFA) of Greater Saphenous Vein
The VNUS Closure System received U.S Food and Drug Administration (FDA) 510k clearance in 1999. VNUS has been evaluated as an alternative to vein ligation and stripping or stripping alone, for the treatment of saphenofemoral or saphenopopliteal junction incompetence and saphenous vein reflux. Endoluminal RF ablation of the saphenous vein is based on the principle of treating reflux disease by control of the point of reflux and isolation of the refluxing saphenous vein from circulation. The current evidence suggests that this procedure has success rates similar to those reported for surgical ligation and stripping with less postoperative pain and faster postoperative recovery.

Venacure EVLT received FDA 510k clearance in 2002. EVLT of the greater saphenous vein has been studied in two large-scale case series studies and several smaller case series studies. These studies demonstrate lower relapse rates when compared to ligation and stripping, as well as comparable symptom relief and complication rates similar to endoluminal radiofrequency ablation. With respect to long-term outcomes and comparison to other therapies, including ligation and stripping or RF ablation, the data is not adequate to make sufficient comparisons.

One study reported that the literature supported minimally invasive interventions in the treatment of lower extremity varicosities despite the lack of large-controlled studies. However, comparing the outcomes of RF and laser ablation showed that laser ablation was more effective than RF ablation. They also stated that larger controlled studies are necessary to validate the clinical efficacy of RF and laser procedures.

With regards to use of RF ablation for perforator veins of the saphenous vein, the literature is limited but supportive. In a published study RF ablation of 14 incompetent perforator veins in 12 individuals was studied. At three months, nine (64%) of the 14 perforators treated were obliterated on ultrasound examination and the other five showed remaining reflux. The authors found that while RF ablation of perforator veins may be a promising procedure, further standardization of the procedure is required as well as comparative clinical trials between RF ablation and standard therapies. In a small study reported laser and sclerotherapy ablation of the Giacomini vein in fourteen individuals. The ablations were successful and without complications. No recanalization occurred during a 2−4-year follow-up.

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Additionally, a 2011 Cochrane review compared endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus ligation/stripping for saphenous vein varices. Included in the review were 13 reports from 5 studies with a combined total of 450 patients. Many of the comparisons between endovenous ablation and ligation/stripping failed to reach statistical significance. The authors concluded that current evidence suggests that endovenous radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) are at least as effective as surgery in the treatment of great saphenous varicose veins.

With regards to short/lesser/small saphenous and accessory saphenous vein endovenous ablation procedures the evidence also remains limited and of relatively poor quality. Review of the literature completed in December 2014 identified only, seven systematic reviews and 18 peer-reviewed articles since 2005 relevant to use of this technology for these specific veins. None of the systematic reviews were specific to ASV or SSV veins. All 7 spoke generally to the use of ablation in the treatment of varicose veins and all concluded endovenous ablation is as safe and effective as surgery.

Fourteen of the 18 primary studies assessed endovascular ablation of the GSV, ASV and SSV veins primarily in cohort studies. Both EVLA and EVRFA were used evenly throughout the 18 studies. Only one study, Merchant et al., assessed the use of endovascular ablation in ASV varicose veins. All 18 noted improved outcomes from baseline and low complication rates. These studies identified high levels of target vein closure at rates typically ranging from 89 to 100 percent. A study by Park et al., published in 2008 identified a lower closure rate of 57 percent but this study extended out to 3 years whereas most studies only had result out to one year. The one-year closure rate for this study was 96 percent. None of these studies had direct comparisons performed to standard ligation and phlebectomy.

Three published studies identified completed head-to-head comparison to standard ligation and phlebectomy (Roopram et al., Samuel et al., and Van Groenendael et al.). With follow-up periods of 12−18 months, all studies demonstrated superior clinical outcomes related to venous occlusion over ligation and phlebectomy. Notably, some measure of heterogeneity exists between the three head-to-head trials accounting for some difference in the findings.

Surgical Stripping and Ligation

In patients with symptoms caused by primary varicose veins who have evidence of saphenofemoral junction or sapheno-popliteal junction reflux, there is clear evidence in the literature to support the use of surgical treatment. Surgery is also indicated in patients without evidence of reflux in the large veins but with large tributaries feeding varicose veins. Complications of surgery include saphenous vein and saphenous nerve injury in up to 39% of patients after total long-saphenous vein stripping, a 2%−15% risk of infection, an up to 7% risk of phlebitis. Reported patient satisfaction ranged from 75%−90%.

Studies indicate a similar healing rate of venous ulcers with superficial vein surgery and conservative compression treatments but a reduction in ulcer recurrence rate with surgery. In general, recurrence rates after ligation and stripping are estimated at around 20%. Jones and colleagues reported on the results of a study that randomized 100 patients with varicose veins to undergo either ligation alone or ligation in conjunction with stripping. At 1 year, reflux was detected in 9% of patients, rising to 26% at 2 years. Rutgers and Kitslaar reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with sclerotherapy. At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

No randomized trials comparing sclerotherapy with ligation/stripping met the study inclusion criteria, and there were thus insufficient data to comment on ultrasound-guided sclerotherapy.

Cryostripping

Cryoablation uses extreme cold to cause injury to the vessel. Cryostripping of the GSV may be considered an alternative approach to traditional ligation and stripping. During this procedure, a cryoprobe is passed through the GSV, the probe freeze attaches to the GSV, and stripping is performed by pulling back the probe. In one randomized clinical trial (n=494) comparing cryostripping with conventional stripping of the GSV (Klem, et al., 2009) the authors reported that cryostripping accounted for higher failures and residual GSV and offered no benefits over conventional stripping. Menyhei et al. (2008) compared conventional stripping and cryostripping and assessed quality of life outcomes and complications (n=160) in a randomized trial. The authors reported significantly improved quality of life scores for both groups, with no difference between the two groups at six months. There was less bruising in the cryo group but no difference in post-operative pain scores between the two groups. The results of another randomized trial (n=120) indicated that EVLT and cryostripping were similarly effective at two

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years follow-up (recurrent incompetence 77% and 66%, for EVLT and cryostripping, respectively), however EVLT was superior with regard to duration of operation, post procedural pain, induration and resumption of normal activity (Disselhoff, et al., 2008). The published evidence is mixed and does not lend strong support to improved clinical outcomes when compared to more conventional methods of varicose vein treatment.

Endovenous Laser Therapy
EVLT, also commonly referred to as endovenous laser ablation of the saphenous vein (ELAS), is a treatment alternative to surgical stripping of the greater saphenous vein. EVLT is also considered an effective treatment for the SSV (Bhayani, Lippitz, 2009) however it is not typically used for smaller veins. EVLT is performed by threading a catheter through the greater saphenous vein and inserting an optical fiber through the catheter. The optical fiber is then connected to a surgical laser, allowing high-intensity laser light to induce photocoagulation of blood and occlusion of the vein. As the catheter is withdrawn, light pulses can be repeated at regular intervals to prevent any further blood flow through the vein. The procedure is typically used to treat larger varicose veins since catheters cannot be easily passed through a tortuous vein or a vein with several turns or bends. Small-dilated branches that persist after EVLT may require additional treatments with sclerotherapy or phlebectomy (Radiological Society of North America, 2009).

The FDA has granted several approvals for ablative technologies, including: Diomed 810nm laser (Diomed, Inc.); Dornier diode laser systems (Dornier MedTech, Kennesaw, GA); Biolitec, Inc. (East Longmeadow, MA); Angiodynamics, Inc. and Vascular Solutions Inc. (Minneapolis, MN).

Evidence in the medical literature evaluating EVLT for the treatment of saphenous vein reflux consists of both retrospective and prospective case series, published reviews, and randomized controlled clinical trials (Disselhoff, et al., 2011; Huisman, et al., 2009; Nijsten, et al., 2009; Kalteis, et al., 2008; Darwood, et al., 2008; Desmyttrere, et al., 2007; Sharif, et al., 2007; Gibson, et al., 2007; Rasmussen, et al., 2007; Ravi, et al., 2006; Puggioni, et al., 2006; Min, et al., 2003; Ho, 2003; Chang and Chua, 2002; Proebstle, et al., 2002; Navarro and Min, 2001). There is a growing body of evidence to suggest that more minimally invasive techniques, which include both RFA and EVLT, are beneficial in the treatment of varicose veins when used alone (van den Bos, et al, 2009; Ravi et al., 2006; Sadick, 2005; Beale, et al., 2004; Teruya and Ballard, 2004; Elias and Frasier, 2004). Sample size and follow-up periods vary widely across studies; follow-up periods typically range at least one to four years on average. In some of the studies, duplex ultrasound demonstrated successful vein occlusion after initial treatment and throughout the various follow-up periods (Kalteis, et al., 2008; Gibson, et al., 2007; Desmyttrere, et al., 2007; Ravi, et al., 2006; Puggioni, et al., 2006; Min, et al., 2003). Some of the measured outcomes, such as complication rates, return to work, patient satisfaction and quality of scores, are mixed—some authors report improvement compared to traditional surgical methods while others have not. Success rates and recurrence rates have been promising with several studies supporting clinical efficacy. Van den Bos, et al. (2009) published the results of meta-analysis demonstrating success rates of 78%, 84%, and 95% for ultrasound guided sclerotherapy, RFA and EVLT respectively, after three years. Min and associates (2003) reported a recurrence rate of less than 7% at a two-year follow-up, although the study had a significant number of patients lost to follow-up. Nonetheless, the authors noted their results were comparable or superior to those reported for other treatment options, including surgery, ultrasound-guided sclerotherapy, and radiofrequency ablation. Puggioni et al. (2006) concluded from a retrospective review that the overall success rate of endovenous ablation techniques for occluding the incompetent greater saphenous vein was 94% at one month, although the EVLT group developed more frequent postoperative complications compared to an RFA group. Ravi et al., (2006) reported that no GSV recanalization was found at three years post EVLT and that no saphenous vein could be identified in 82.5% of limbs in their study group. Closure rates at one-month, one-year, two-year, three-year, and four-year follow-up were reported by Desmyttrere, et al. (2007) as follows: 98.4%, 96.8%, 97.8%, 99.3% and 97.1%, respectively. Overall, much of the evidence available suggests that endovenous closure

Transilluminated Powered Phlebectomy (TIPP)
TIPP, which is similar to ambulatory phlebectomy, is another minimally invasive alternative to standard surgery for the treatment of symptomatic varicosities. Also known as the TriVex (Smith & Nephew Inc., Andover, MA) procedure, TIPP involves endoscopic resection and ablation of the superficial varicosity. Subcutaneous transillumination and tumescent anesthesia help visualize and locate the varicosity, while subcutaneous vein ablation is performed using a powered resector to obliterate the vein. Tumescent

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anesthesia involves the infusion of large amounts of saline and lidocaine to reduce hemorrhage and of epinephrine to delay absorption of the lidocaine. During this procedure, the veins are marked with a marker, and a bright light is introduced into the leg through a small incision (2–3 cm) to enhance visualization of the veins. The power vein resector is then inserted to cut and remove the vein through suction.

Proponents of this method suggest that the illuminating light allows quicker and more accurate removal of the vein, leading to a more effective yet less traumatic procedure. TIPP is intended for patients who are suitable candidates for conventional ambulatory phlebectomy and may also be used as an adjunctive method to other varicose vein treatments, such as ligation and stripping.

The individual components of the TriVex system were approved for use by the FDA in 1999, however since that time, several other illumination and powered-resection devices have been approved and are available for use.

Evidence evaluating TIPP for the treatment of varicose veins is primarily in the form of published reviews, few comparative trials (few involving randomized groups) and both retrospective and prospective case series involving small populations and evaluating short-term outcomes (Kim, et al., 2012; Franz and Knapp, 2008; Passman, et al., 2007; Scavee, 2006; Chetter, et al., 2006; Aremu, et al., 2004; Shamiyeh, et al., 2003; Scavee, et al., 2003; Chesire, et al., 2002; Spitz, et al., 2000). Two controlled studies specifically compared TIPP to phlebectomy (Aremu, et al., 2004; Scavee, et al., 2003), although neither of these studies were blinded. In addition, the outcomes measured in most studies include operative time, number of incisions, complications, and cosmetic satisfaction with few patient-oriented outcomes being reported. Generally, the results of these studies demonstrate that TIPP is associated with fewer incisions (Luebke, et al., 2008; Chetter, et al., 2006; Aremu, et al., 2004; Shamiyeh, et al., 2003; Scavee, et al., 2003; Spitz, et al., 2000). Operative time varies among authors and with experience. Despite reports in the published literature of a reduced number of incisions, an increase in bruising, postoperative pain and decreased quality of life during the early postoperative period has been reported. Moreover, it has been reported in the literature that technical complications may be associated with inexperience. The published, peer-reviewed, scientific literature does not lead to strong conclusions that TIPP results in clinical outcomes (e.g., improved pain, less varicose vein recurrence) that are as good as treatment with standard conventional methods (i.e., hook phlebectomy). Furthermore, long-term safety and efficacy of the procedure has not been adequately demonstrated. ECRI Institute published an emerging technology report (2008) evaluating TIPP for treatment of varicose veins. According to the report, the available data are promising for demonstrating the safety and efficacy of TIPP relative to hook phlebectomy and stab avulsion to treat varicose veins. However, ECRI also reported that the available evidence is inadequate to draw firm conclusions about its relative short- and long-term effectiveness, or its purported advantages over existing methods in terms of complications, operating time, pain, varicose vein recurrence, and cosmetic outcomes.

In 2004, NICE issued an Interventional Procedure Guidance for TIPP. The advisory committee indicated that, although the evidence suggested that the procedure is effective, the data are too limited to be conclusive and there are no long-term follow-up data (NICE, 2004a).

Cyanoacrylate Adhesive (VenaSeal Closure system)

In 2015, the VenaSeal Closure System (Sapheon, a part of Medtronic) was approved by the FDA through the premarket approval process for the permanent closure of clinically significant venous reflux through endovascular embolization with coaptation.

Lawson et al (2013) noted that less invasive endovenous techniques have been shown to be as effective as open surgery in the treatment of varicose veins. Furthermore, they cause less post-operative bruising and pain and enable early return to normal activities and work. Tumescent anesthesia is safe and obviates complications of general or spinal anesthesia. Drawbacks are a steep learning curve and painful administration during treatment. Tumescentless techniques like ClariVein or VenaSeal Sapheon Closure System are recently under investigation. Short-term results of VenaSeal are comparable with thermal ablation. The procedure is safe without serious adverse events. Peri-operative pain and patient discomfort with this tumescentless approach is minimal but post-operative recovery is temporarily hindered by thrombophlebitis in 14 to 15% of patients. One-year results in a small feasibility study has

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demonstrated durable closure at this endpoint. No longer-term results are available. A randomized control trial between VenaSeal and Covidien ClosureFast is in a preparatory phase.

Toonder et al. (2014), noted that percutaneous thermo-ablation techniques are still being used today and seem more effective than non-thermal techniques. However, thermal techniques require anesthesia and potentially may cause inadvertent damage to surrounding tissues such as nerves. Cyanoacrylate adhesive has a proven record, but not for the treatment of chronic venous disease of the leg. Researchers examined the feasibility of ultrasound-guided cyanoacrylate adhesive perforator embolization (CAPE). The authors stated that results of this feasibility study showed a 76 % occlusion rate of incompetent perforating veins without serious complications; further investigation with a dedicated delivery device in a larger patient population is needed.

McHugh and Leahy (2014) stated that endothermal treatment of the great saphenous vein has become the first line of treatment for superficial venous reflux. Newer treatments, especially non-thermal ablation have potential benefits both for patient acceptability and decreased risk of nerve injury. These researchers described the current non-thermal options available including advantages and disadvantages. Ultrasound-guided foam sclerotherapy avoids the risk of nerve injury; however, it is not as effective as endothermal ablation. Mechano-chemical endovenous ablation combines mechanical endothelial damage using a rotating wire, with the infusion of a liquid sclerosant (the ClariVein System). Reports suggested that this system is safe and effective, eliminating the need for tumescent anesthesia with no reported case of nerve injury. Finally, the VenaSeal Closure System comprises the endovenous delivery of cyanoacrylate tissue adhesive to the vein causing fibrosis. Peri-operative discomfort seems to be minimal, but the complication of thrombophlebitis has been reported in up to 15 % of patients. The authors concluded that non-thermal options promise comparable treatment efficacy without the added morbidity associated with high thermal energies. They stated that the potential of treating venous reflux without the risk of nerve damage may change how many surgeons approach venous disease.

Morrison and colleagues (2015) noted that preliminary evidence suggests that CAPE may be effective in the treatment of incompetent GSVs. These investigators reported early results of an RCT of CAPE versus RFA for the treatment of symptomatic incompetent GSVs. A total of 222 subjects with symptomatic GSV incompetence were randomly assigned to receive either CAPE (n = 108) with the VenaSeal Closure System or RFA (n = 114) with the ClosureFast System. After discharge, subjects returned to the clinic on day 3 and again at months 1 and 3. The study's primary endpoint was closure of the target vein at month 3 as assessed by duplex ultrasound and adjudicated by an independent vascular ultrasound core laboratory. Statistical testing focused on showing non-inferiority with a 10 % delta conditionally followed by superiority testing. No adjunctive procedures were allowed until after the month 3 visit, and missing month 3 data were imputed by various methods. Secondary endpoints included patient-reported pain during vein treatment and extent of ecchymosis at day 3. Additional assessments included general and disease-specific quality of life surveys and adverse event rates. All subjects received the assigned intervention. By use of the predictive method for imputing missing data, 3-month closure rates were 99 % for CAPE and 96 % for RFA. All primary endpoint analyses, which used various methods to account for the missing data rate (14 %), showed evidence to support the study's non-inferiority hypothesis (all $p < 0.01$); some of these analyses supported a trend toward superiority ($p = 0.07$ in the predictive model). Pain experienced during the procedure was mild and similar between treatment groups (2.2 and 2.4 for CAPE and RFA, respectively, on a 10-point scale; $p = 0.11$). At day 3, less ecchymosis in the treated region was present after CAPE compared with RFA ($p < 0.01$). Other adverse events occurred at a similar rate between groups and were generally mild and well-tolerated. The authors concluded that CAPE was proven to be non-inferior to RFA for the treatment of incompetent GSVs at month 3 after the procedure. Both treatment methods showed good safety profiles; CAPE does not require tumescent anesthesia and is associated with less post-procedure ecchymosis. While these findings supported non-inferiority, the reliability of this approach is unclear. These early results need to be validated by well-designed studies with lower rates of data loss and longer follow-up.

Furthermore, an UpToDate review on cyanoacrylate glue describes it as a system that ablates the treated vein using an adhesive agent (VenaSeal) has been approved for use in the United States. The use of glue was initially described for treatment of saphenous incompetence in 2013. The procedure is performed like radiofrequency and laser ablation, but without the need for tumescent anesthesia. In a randomized trial comparing this system with radiofrequency ablation, short-term outcomes at three months were similar. Longer term follow-up is needed to determine the durability of the results.

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The agent is injected sequentially through a catheter followed by compression along the length of the vein from proximal to distal. If the first injection is near the saphenofemoral junction, the vein above the catheter is compressed with the ultrasound probe prior to injection to prevent injection into the deep veins. The feasibility of the use of this system for perforating veins was investigated in a separate study; there were no serious complications.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein
36466	; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718	Ligation, division, and stripping, short saphenous vein

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37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37735	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
37760	Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
37766	; more than 20 incisions
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg

HCPCS CODES

A6530	Gradient compression stocking, below knee, 18-30 mm Hg, each
A6531	Gradient compression stocking, below knee, 30-40 mm Hg, each
A6533	Gradient compression stocking, thigh length, 18-30 mm Hg, each
A6534	Gradient compression stocking, thigh length, 30-40 mm Hg, each
A6536	Gradient compression stocking, full-length/chap style, 18-30 mm Hg, each
A6537	Gradient compression stocking, full-length/chap style, 30-40 mm Hg, each
A6539	Gradient compression stocking, waist length, 18-30 mm Hg, each
A6540	Gradient compression stocking, waist length, 30-40 mm Hg, each
A6544	Gradient compression stocking, garter belt
A6545	Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each

Not covered: Investigational/Experimental/Unproven for this indication

HCPCS CODES

S2202	Echosclerotherapy

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