Medical and Behavioral Health Policy Activity

Policies Effective: October 7, 2024 Notification Posted: August 1, 2024

Policies Developed
None

Policies Revised

- **Cryoablation of Solid Tumors, IV-05**

I. Cryoablation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the following indications:

- Treatment of primary or metastatic **intrahepatic cholangiocarcinoma** when both of the following criteria are met:
  - A single tumor of ≤ 3 cm; **AND**
  - Tumor should be amenable to complete ablation so that the tumor and a margin of normal tissue up to 1 cm can be treated.
- Treatment of **lung cancer** under the following circumstances:
  - Patient with early-stage non-small cell lung cancer (NSCLC) who is a poor candidate for surgical resection; **OR**
  - Palliation of a central airway obstruction lesion.
- Treatment of **prostate cancer** for whole-gland ablation under the following circumstances:
  - Primary treatment for clinically localized prostate cancer; **OR**
  - Salvage treatment for recurrent prostate cancer following failed radiation therapy.
- Treatment of **localized renal cell carcinoma** when tumor size is ≤ 4 cm and either of the following criteria are met:
  - Preservation of kidney function is necessary (i.e., the patient has one kidney or renal insufficiency, defined as a glomerular filtration rate [GFR] of < 60 mL/min/m^2) and standard surgical approaches would compromise kidney function; **OR**
  - Patient is not considered a surgical candidate due to co-morbid disease.

II. Cryoablation is considered **EXPERIMENTAL/INVESTIGATIVE** for treatment of all other solid tumors or metastases due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Bariatric Surgery, IV-19**

I. **<u>Patient Selection Criteria: Initial Procedure</u>**

The surgical treatment of morbid obesity may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients who meet **ALL** the following criteria:

- Meets one of the following:
  - Age 18 years or older; OR
  - Bone age of ≥ 13 years in girls or ≥ 15 years in boys; OR
  - Attainment of 95% of adult height based on estimates of bone age;

  AND
- Body mass index (BMI) at initial evaluation of **ONE** of the following:
  - BMI of ≥ 40 kg/m^2 OR
  - BMI of 35 kg/m^2 to < 40 kg/m^2 with **AT LEAST ONE** of the following comorbid conditions:
    - Hypertension refractory to standard treatment; OR
    - Cardiovascular disease; OR
    - Type 2 diabetes mellitus; OR

- Obstructive sleep apnea requiring continuous positive airway pressure (CPAP) or other related treatment; OR
- Obesity-hypoventilation syndrome (OHS); OR
- Pickwickian syndrome (a combination of OSA and OHS); OR
- Nonalcoholic fatty liver disease (NAFLD); OR
- Nonalcoholic steatohepatitis (NASH); OR
- Pseudotumor cerebri; OR
- Gastroesophageal reflux disease (GERD);

OR

- BMI 30 kg/m^2-34.9 kg/m^2 with type 2 diabetes mellitus, with inadequate glycemic control (HbA1c ≥8%)

AND

- Patient has been evaluated by an eligible licensed mental health professional within 12 months prior to the surgery. The mental health professional's notes must document **ALL** of the following:
  - Absence of active substance use disorder; AND
  - If a mental health condition is present, it is under successful treatment; AND
  - Patient able to provide informed consent; AND
  - Personal barriers to making and continuing required life changes have been identified, and strategies to overcome those barriers have been recommended; AND
  - Family and social supports have been assessed, and strategies to strengthen those supports have been recommended;

  AND
- Patient has actively participated in a preoperative program supervised by a physician, physician's assistant, nurse practitioner/advanced practice nurse, or registered dietician. The supervising medical professional's notes must document **ALL** of the following:
  - Correctable endocrine disorders and other medical conditions have been ruled out, or are under successful treatment; AND
  - Medications that may contribute to the patient's obesity, such as antipsychotic medications, have been identified; AND
  - Patient has demonstrated at least 6 months of ongoing adherence to recommended behavior and nutrition modifications; AND
  - Compliance with recommended strategies to address identified personal barriers to making and continuing needed life changes;

  AND
- Patient has completed a surgical preparatory program. The surgical preparatory program's notes must document that the patient has been informed of **BOTH** of the following:
  - Required appointments with the surgery team the patient will need to attend before and after surgery; AND
  - Life changes patient must make and continue to make, including diet and exercise programs before and after surgery;

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products~~,~~ (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- Initial bariatric surgery is considered **NOT MEDICALLY NECESSARY** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes

II. Patient Selection Criteria: Reoperation

- Revision bariatric surgery OR conversion of one type of bariatric surgery to a different procedure may be considered **MEDICALLY NECESSARY AND APPROPRIATE** using one of the procedures identified in section III as medically necessary, for **EITHER** of the following indications:

- Treatment of surgical complications or technical failures following the original bariatric surgery (e.g., staple line failure, band migration or slippage, pouch dilation, narrowing or constriction of the stoma, prolonged GERD causing esophagitis); OR
- Inadequate weight loss following the original surgery when **ALL** the following criteria are met:
  - At least two (2) years have elapsed since the original bariatric surgery; AND
  - Patient has been and continues to be compliant with the required appointments with the surgery team and the required life changes including diet and exercise recommended by the surgery team from the time of surgery up to the present time without any period of non-compliance; AND
  - Patient currently has a BMI ≥ 40 kg/m^2 OR a BMI of 35 kg/m^2 to < 40 kg/m^2 with an obesity related comorbid condition as described in section I OR a BMI 30 kg/m^2 – 34.9 kg/m^2 with type 2 diabetes mellitus and inadequate glycemic control. (HbA1c ≥8%); AND
  - Evaluation by a mental health professional indicates any barriers to successful reoperation have been identified and addressed; AND
  - Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products, (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- Revision or conversion surgery is considered **NOT MEDICALLY NECESSARY** when performed for inadequate weight loss due to documentation of individual noncompliance with prescribed postoperative nutrition and exercise.

- Revision bariatric surgery is considered **NOT MEDICALLY NECESSARY** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes

III. Surgical Procedures

- The following surgical procedures may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in the treatment of morbid obesity when the previous patient selection criteria in section I have been met:
  - Open gastric bypass using a Roux-en-Y anastomosis with an alimentary or Roux limb of ≤ 150 cm
  - Laparoscopic gastric bypass using a Roux-en-Y anastomosis
  - Open or laparoscopic sleeve gastrectomy (SG)
  - Open or laparoscopic biliopancreatic diversion (i.e., Scopinaro procedure) with duodenal switch
  - Laparoscopic adjustable gastric banding, (i.e., Lap-Band® and REALIZE Band)

- Any other surgical or minimally invasive procedure is considered **EXPERIMENTAL/INVESTIGATIVE** as a treatment of morbid obesity including but not limited to the following due to the lack of evidence demonstrating an impact on improved health outcomes:
  - Open or laparoscopic vertical banded gastroplasty
  - Open adjustable gastric banding
  - Gastric bypass using a Billroth II type of anastomosis, known as the mini-gastric bypass one anastomosis gastric bypass (OAGB)
  - Biliopancreatic diversion (i.e., the Scopinaro procedure) without duodenal switch
  - Long limb gastric bypass procedure (i.e., > 150 cm)
  - Single anastomosis duodenal switch (i.e., stomach intestinal pylorus-sparing surgery [SIPS] single anastomosis duodeno-ileal bypass with sleeve gastrectomy [SADI-S])
  - Laproscopic gastric plication
  - Bariatric surgery (any procedure) for patients with a BMI < 30 kg/m^2 including but not limited to solely as a cure for type 2 diabetes mellitus
  - Endoluminal (also called endosurgical, endoscopic, sclerosing endotherapy or natural orifice transluminal endoscopic) procedure as a primary bariatric procedure or as a revision procedure by any method including but not limited to:

- Aspiration therapy device (e.g., AspireAssist® Weight Loss Therapy System)
- Duodenal-jejunal sleeve
- Intragastric balloon therapy (e.g., Obalon, Orbera®, ReShape™ Duo systems, Spatz3 Adjustable Gastric Balloon)
- Primary Obesity Surgery, Endoluminal (POSE)
- StomaphyX™
- OverStitch™
- Transpyloric Shuttle

Documentation Submission:
Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. **Initial Procedure**
   - Documentation requirements described in Patient Selection criteria (section I) must be included in the prior authorization; **AND**
   - Documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

2. **Reoperation Procedure**
   - Date of previous bariatric surgery or surgeries; **AND**
   - Initial procedure(s) performed; **AND**
   - ONE of the following:
     - Description of surgical complication(s) or technical failure; OR
     - If reoperation due to inadequate weight loss, clinic notes from the past 2 years including **ALL** of the following:
       - Patient's current BMI; **AND**
       - Obesity-related comorbid conditions; **AND**
       - Record of psychological evaluation for reoperation; **AND**
       - Copy of the surgery team's standard required appointments after surgery including and documentation of the following at each visit:
         - Patient's weight;
         - Patient's eating and exercise habits;
         - Progress toward achieving life changes the patient was instructed to make.

     AND
   - Documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- **Left Atrial Appendage Closure Devices, IV-169**

I. Percutaneous Left Atrial Appendage Closure Devices

The use of a device with U.S. Food and Drug Administration (FDA) approval for percutaneous left atrial appendage closure may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the prevention of stroke in patients when **ALL** of the following criteria are met:

- Diagnosis of non-valvular atrial fibrillation; **AND**
- Increased risk of stroke and systemic embolism based on $CHADS_2$ (score ≥2) or CHA_2DS_2 VASc score (score ≥3);

AND

- Clinical documentation that the patient is suitable for short-term anticoagulation (30 days) but unable to take long-term oral anticoagulation following the conclusion of a formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation; **AND**
- Procedure is performed by an interventional cardiologist, electrophysiologist, or cardiovascular surgeon experienced in performing interventional cardiac procedures that involve transeptal puncture through an intact septum.

All other uses for percutaneous left atrial appendage closure devices, including but not limited to the use of non-FDA approved percutaneous left atrial appendage closure devices, are considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

II. Surgical Left Atrial Appendage Closure Devices

The use of surgical left atrial appendage closure devices as a standalone procedure for the prevention of stroke is considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

The use of surgical left atrial appendage closure devices in conjunction with open or thoracoscopic cardiac procedures for the prevention of stroke is considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes describing diagnosis and features of the diagnosis.
2. The FDA approved device to be utilized.
3. Documentation that supports an increased risk of stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc score.
4. Documentation indicating that the patient is suitable for short-term anticoagulation but unable to take long-term oral anticoagulation, including the evidence as to why the patient is unable to take long-term oral anticoagulation therapy.
5. Documentation of the shared decision-making interaction in the medical record.
6. Attestation from provider describing personal experience in performing interventional cardiac procedures that involve transeptal puncture through an intact septum.

- **Compression Devices in the Outpatient or Home Setting**

NOTE: Coverage may be subject to legislative mandates, including but not limited to the following, which apply prior to the policy statements:

- Federal Women's Health and Cancer Rights Act (WHCRA).

I. Lymphedema

The use of segmented or non-segmented pneumatic compression devices without calibrated gradient pressure (non-programmable pumps) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of lymphedema of the upper or lower limbs in the outpatient or home setting when **ALL** of the following criteria are met:

- The patient has undergone a four-week trial of conservative therapy which includes:
  - Use of an appropriate compression bandage system or compression garment; **AND**

- Exercise; **AND**
- Elevation of the limb;

AND

- The treating physician determines that no significant improvement has occurred or significant symptoms remain following the four-week trial.

The use of segmented pneumatic compression therapy devices with calibrated gradient pressure (programmable pumps) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of lymphedema of the upper or lower limbs in the outpatient or home setting when the patient meets criteria for a device without calibrated gradient pressure (non-programmable pumps) and either of the following criteria are met:

- The patient's medical condition has failed to respond to therapy using segmented or non-segmented pneumatic compression devices without calibrated gradient pressure (non-programmable pumps); **OR**
- The individual has unique characteristics (e.g., significant scarring) that prevent satisfactory pneumatic compression treatment using segmented or non-segmented pneumatic compression devices without calibrated gradient pressure (non-programmable pumps).

II. Chronic Venous Insufficiency

The use of segmented or non-segmented pneumatic compression devices without calibrated gradient pressure (non-programmable pumps) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of chronic venous insufficiency of the lower extremities in the outpatient or home setting when **ALL** of the following criteria are met:

- The patient has one or more venous stasis ulcers; **AND**
- The patient has undergone a trial of conservative therapy for a minimum of six months which includes **ALL** of the following:
  - The use of an appropriate compression bandage system or compression garment; **AND**
  - Appropriate dressings for the wound; **AND**
  - Exercise; **AND**
  - Elevation of the limb;

  AND
- The treating physician determines that the venous stasis ulcer has failed to heal.

The use of segmented pneumatic compression therapy devices with calibrated gradient pressure (programmable pumps) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of chronic venous insufficiency of the lower extremities in the outpatient or home setting when the patient meets criteria for a device without calibrated gradient pressure (non-programmable pumps) and either of the following criteria are met:

- The patient's medical condition has failed to respond to therapy using segmented or non-segmented pneumatic compression devices without calibrated gradient pressure (non-programmable pumps)~~;~~ **OR**
- The individual has unique characteristics (e.g., significant scarring) that prevent satisfactory pneumatic compression treatment using segmented or non-segmented pneumatic compression devices without calibrated gradient pressure (non-programmable pumps).

III. Post-Surgical Venous Thromboembolism (VTE) Prophylaxis

The use of pneumatic compression devices in the outpatient or home setting may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in patients who have undergone a surgical procedure when **BOTH 1 and 2 are met**:

1. Patient meets ONE OR MORE of the following:
   - Major surgery (e.g., total hip arthroplasty, total knee arthroplasty, hip fracture repair, open abdominal or open pelvic procedure); **OR**
   - Patient is at moderate to severe risk of VTE. Examples include:
     - Patient is not able to walk unassisted or is bedridden
     - Age greater than 60 years, anesthesia at least 2 hours and bed rest at least 4 days during current episode of care
     - Inpatient stay of more than 2 days during current episode of care
     - Central venous access during current episode of care
     - Sepsis during current episode of care
     - Active cancer or cancer treatment
     - Significant comorbidity such as recent myocardial infarction, congestive heart failure, cerebrovascular disease, moderate to severe chronic obstructive pulmonary disease, moderate to severe liver disease, moderate to severe chronic kidney disease
     - Pregnancy or post-partum state (<1 month)
     - Hypercoagulable state (e.g., Factor V Leiden, antithrombin III deficiency, protein C or S deficiency, antiphospholipid syndrome, dysfibrinolysis, prothrombin 20210 defect)
     - Prior VTE;

   AND
2. The patient has a contraindication to pharmacologic anticoagulants, such as being at high-risk for bleeding. Risk factors for bleeding include:
   - Bleeding disorder such as hemophilia
   - Active liver disease
   - Severe renal failure
   - Previous major bleed (and previous bleeding risk similar to current risk)
   - Concomitant antiplatelet agent
   - History of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery.

Outpatient or home use of pneumatic compression devices for post-surgical VTE prophylaxis is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE** for patients who have undergone a surgical procedure with a low risk of VTE and who have no additional risk factors for VTE. Examples of lower risk surgical procedures include, but are not limited to, laparoscopic cholecystectomy, appendectomy, transurethral prostatectomy, and inguinal herniorrhaphy.

IV. Experimental/Investigative Uses

The use of pneumatic compression devices in the outpatient or home setting is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- treatment of arterial insufficiency (e.g., peripheral arterial disease) and restless legs syndrome;
- treatment of the head, neck, trunk, or chest for lymphedema.

The use of non-pneumatic compression devices in the outpatient or home setting is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies Inactivated
None

Policies Delegated to eviCore
None