Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Vagus Nerve Blocking Therapy for Treatment of Obesity

Policy #: 598
Latest Review Date: March 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 24, 2020:

Blue Advantage will treat **intra-abdominal vagus nerve blocking therapy** in all situations, including but not limited to the treatment of obesity as a **non-covered benefit** and as **investigational**.

Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCD L34555.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **intra-abdominal vagus nerve blocking therapy** in all situations, including but not limited to the treatment of obesity as a **non-covered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Vagus nerve blocking therapy for obesity consists of an implantable device that delivers electrical stimulation to branches of the vagus nerve on the anterior abdominal wall. The intent is to cause intermittent blocking of signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety.

Obesity

Obesity is a common condition in the United States. A large nationally representative survey conducted in 2009 to 2010 found that 36% of American adults age 20 and older were obese, defined as body mass index (BMI) of 30 kg/m2 or more. Fifteen percent of adults had a BMI of 35 kg/m2 or more and 6% had a BMI of 40 kg/m2 or more. Among children age 2 to 19 years, 17% were obese, defined in the population as being at or above the 95% percentile in sex-specific BMI for corresponding age (based on the U.S. Centers for Disease Control and Prevention age growth charts).

Obesity is a major cause of premature death and is linked to serious illnesses including heart disease, Type 2 diabetes, sleep apnea, osteoarthritis, and certain types of cancer. In a 2013 systematic review, being obese has been associated with higher all-cause mortality and death

from cardiovascular disease. In that same year, the American Medical Association officially recognized obesity itself as a disease.

Management and Treatment
Lifestyle interventions, specifically changes to diet and exercise, are the first-line treatment of obesity. These interventions can be enhanced by participation in a structured weight loss program. There are also prescription weight loss medications available, but they have limited evidence of efficacy and there are adverse effects (e.g., oily stool, nausea, dizziness) associated with their use.

Weight loss (bariatric) surgery is a potential option for obese patients who have failed conservative treatments. Common procedures include gastric bypass surgery (open or laparoscopic approaches), sleeve gastrectomy, and laparoscopic adjustable gastric banding. Certain types of bariatric surgery have been found to improve outcomes in selected patients who choose that treatment. (Refer to medical policy #053 Surgical Management of Morbid Obesity for additional information.)

Vagus nerve blocking therapy is another potential treatment option for obese patients. The vagus nerve consists of two long cranial nerves that extend from the brain stem to the viscera. The term vagus is Latin for wandering and the vagus nerve winds through the abdomen and has branches that come in contact with the heart, lung, stomach and other body parts. The vagus nerve plays a major role in autonomic and sympathetic nervous system functioning, including regulation of heartbeat and breathing. It is also involved in regulation of the digestive system, although its exact role in controlling appetite and feelings of satiety is unknown. Vagus nerve blocking therapy involves intermittent blocking of signals to the intra-abdominal vagus nerve, with the intent disrupting hunger sensations and inducing feelings of satiety.

In January 2015, FDA approved a medical device specifically designed to provide vagal nerve blocking therapy for weight regulation in obese patients. This device, the Maestro® Rechargeable System, includes a neuro-blocking pulse generator that is implanted subcutaneously on the thoracic sidewall, and flexible leads approximately 47 cm in length that are placed on the abdominal anterior and posterior vagal nerve trunks. External components include a mobile charger, a transmit coil, a programmable microprocessor and customized software. The system delivers high-frequency pulses of electrical current to vagal nerve trunks; therapy parameters and the treatment schedule can be customized by a clinician. Like other surgical interventions, there is the potential for adverse effects. In addition, there may be other unintended consequences of disrupting signals to a particular portion of the vagus nerve.

Stimulation of the vagus nerve via a device implanted within the carotid artery sheath has also been evaluated as a treatment for obesity. Refer to medical policy #260 Vagus Nerve Stimulation for additional information. Vagus nerve stimulation is FDA-approved to treat epilepsy and depression, not for obesity treatment.

Outcomes
To assess obesity treatments, a double-blind randomized controlled trial is optimal because these interventions require changes to patient behavior (i.e., diet, exercise) that are subject to the

placebo effect. Health outcomes such as mortality, cardiovascular events, and rates of type 2 diabetes would be optimal, but are difficult to use as study end points due to the need for a large sample size and long follow-up period. Cardiovascular risk factors, such as changes in blood pressure, glucose, and lipid levels, are good intermediate measures because they have been linked with these health outcomes, and would require smaller sample sizes. Weight loss outcomes, reported as absolute change in weight or BMI, or as percent excess weight loss or percent BMI are acceptable intermediate outcome measures and are commonly used in obesity studies. Weight loss has been linked to improvements in cardiovascular risk factors. While no generally accepted threshold of percent excess weight loss is considered clinically significant, bariatric surgery trials generally define clinical success as at least 50% excess weight loss. The amount of weight loss is expected to be lower for other, less dramatic weight loss interventions.

Sham controls are useful for establishing the efficacy of an intervention beyond the placebo effect and for controlling for other nonspecific effects of interventions including disease natural history and regression to the mean. Because there are so many existing treatment options for weight loss, if sham-controlled weight loss intervention studies are positive, trials using an active comparator, such as medication or other types of surgery, are desirable.

KEY POINTS:

The most recent literature review was updated through March 2, 2023.

Summary of Evidence

For individuals with obesity who receive vagus nerve blocking therapy, the evidence includes 2 sham-controlled randomized controlled trials (RCTs). Relevant outcomes are change in disease status, morbid events, quality of life and treatment-related morbidity. The primary efficacy outcome, at least a 10% difference between groups at 12 months, was not met for either trial. In the first trial (EMPOWER), the observed difference in EWL between groups at 12 months was 1%. In the more recent trial (ReCharge), the observed difference in EWL between groups at 12 months was 8.5%. In a post hoc analysis, the 8.5% EWL was statistically significant, but this magnitude of change may not be clinically significant according to the investigators' original trial design decisions. Post hoc analyses of longer-term data have been published and are subject to various biases including missing data and unblinding at 12 months. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Society for Metabolic and Bariatric Surgery

A position statement published in 2016 by the American Society for Metabolic and Bariatric Surgery includes the following conclusions and recommendations on vagus nerve blocking therapy for treatment of obesity:

> "1. Reversible vagal nerve blockade has been shown to result in statistically significant EWL at 1 year compared with a control group in one of 2 prospective randomized trials.

2. Reversible vagal nerve blockage has been shown to have a reasonable safety profile with a low incidence of severe adverse events and a low revisional rate in the short term. More studies are needed to determine long-term reoperation and explantation rates.
3. The prospective collection of VBLOC outcomes as part of the national center of excellence databases is encouraged to establish the long-term efficacy of this new technology."

U.S. Preventive Services Task Force Recommendations
In 2018, the U.S. Preventive Services Task Force updated recommendations for screening and management of obesity in adults. The Task Force recommended screening all adults for obesity and referring those with a body mass index of 30 kg/m2 or higher to intensive, multicomponent behavioral interventions. Vagus nerve blocking therapy and other surgical interventions were not addressed in the recommendations or literature review.

KEY WORDS:
Vagus nerve blocking therapy, Maestro, obesity, neurostimulator, Maestro® System

APPROVED BY GOVERNING BODIES:
FDA approved the Maestro Rechargeable System, (Enteromedics, St. Paul, MN) through the premarket approval process on January 14, 2015. The device is indicated for use in adults age 18 years and older who have a BMI of 40 to 45 kg/m2 or a BMI of 35 to 39.9 kg/m2 with one or more obesity-related conditions such as high blood pressure or high cholesterol and have failed at least one supervised weight management program within the past five years. Implantable components are incompatible with magnetic resonance imaging (MRI). Additional contraindications to use of the device include conditions such as cirrhosis of the liver, portal hypertension and clinically significant hiatal hernia, and the presence of a previously implanted medical device.

The commercial availability of the Maestro® System is unclear. On the FDA's Weight-Loss and Weight-Management Devices webpage (content noted as current as of 09/05/2019), the Maestro® Rechargeable System is described as "no longer marketed as of September 2018". Additionally, on the ReShape LifesciencesTM website (previously EnteroMedics), the Maestro® Rechargeable System, is not listed among their current portfolio of medical devices to treat obesity and metabolic disease. However, updates to the Maestro® Rechargeable System were noted in the FDA Premarket Approval database (P130019) subsequent to September 2018, including updates to the circuit assembly and application firmware of the mobile charger (01/25/2019) and approval of modifications to the follow-up schedule for the post-approval study protocol.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

There are no specific CPT codes for this procedure. This would likely be reported with an unlisted procedure code.

PREVIOUS CODING:

0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming (Deleted 12/31/22)
0313T	laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator (Deleted 12/31/22)
0314T	laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator (Deleted 12/31/22)
0315T	removal of pulse generator (Deleted 12/31/22)
0316T	replacement of pulse generator (Deleted 12/31/22)
0317T	neurostimulator pulse generator electronic analysis, includes reprogramming when performed (Deleted 12/31/22)

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POLICY HISTORY:

Adopted for Blue Advantage, June 2015
Available for comment June 4 through July 18, 2015
Medical Policy Group, February 2016
Medical Policy Group, February 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, March 2021
Medical Policy Group, March 2022: Reviewed by consensus. No new literature identified that would alter coverage statement at this time.
Medical Policy Group, November 2022: 2023 Annual Coding Update. Created Previous Coding section to include the following deleted codes: 0312T, 0313T, 0314T, 0315T, 0316T, 0317T. No change to policy statement.
Medical Policy Group, March 2023: Reviewed by consensus. No new literature identified that would alter coverage statement at this time.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
