

## MEDICAL POLICY – 7.01.150


## Vagus Nerve Blocking Therapy for Treatment of Obesity

BCBSA Ref. Policy: 7.01.150

Effective Date:	May 1, 2018	RELATED MEDICAL POLICIES:	
Last Revised:	April 3, 2018	7.01.20	Vagus Nerve Stimulation
Replaces:	N/A	7.01.516	Bariatric Surgery
		7.01.522	Gastric Electrical Stimulation

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)  
[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

## Introduction

Obesity is a health hazard as it impacts the heart, lungs, muscles, and bones. Obesity also can lead to type 2 diabetes, heart disease, and high blood pressure. Changes to diet and exercise are the initial ways to treat obesity. Certain medications that make a person feel less hungry and feel fuller after eating may also be tried. When lifestyle changes do not work, some people have tried a treatment called intra-abdominal vagus nerve blocking therapy (vBloc). This treatment requires surgery to place a pacemaker-type device that sends an electrical signal to a specific nerve called the vagus nerve. The device blocks signals sent from the stomach to the brain. The goal is to promote weight loss by decreasing the feeling of hunger and increasing the feeling of fullness after eating. These types of devices are investigational (unproven). More studies are needed to see how effective they are in the long term.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Procedure	Investigational
<b>Intra-abdominal vagus nerve blocking therapy</b>	<p><b>Intra-abdominal vagus nerve blocking therapy is considered investigational in all situations, including but not limited to the treatment of obesity.</b></p> <p><b>Note:</b> Vagus nerve <u>stimulation</u> is addressed in a separate policy. (See <a href="#">Related Policies</a>)</p>

## Coding

Code	Description
<b>CPT</b>	
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
0313T	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
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed

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## Related Information

N/A



### Description

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 intermittently block signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety.

### Background

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/m<sup>2</sup> or more.<sup>1</sup> Fifteen percent of the adults had a BMI of 35 kg/m<sup>2</sup> or more and 6% had a BMI of 40 kg/m<sup>2</sup> or more. Among 2- to 19-year olds, 17% were obese, which is defined in this 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 was associated with higher all-cause mortality and death from cardiovascular disease.<sup>2</sup> 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 and/or by psychological interventions such as cognitive behavioral therapy. There are also prescription weight loss medications available, most notably orlistat (which blocks digestion and absorption of fat) and lorcaserin (which decreases appetite and promotes satiety). Weight



loss medications have limited evidence of efficacy and there are associated adverse effects (eg, oily stool, nausea, and 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 improve outcomes in select who choose that treatment. (Bariatric surgery is addressed separately. See [Related Policies](#).)

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 systems, 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 2015, the U.S. Food and Drug Administration (FDA) approved a medical device specifically designed to provide vagus nerve blocking therapy for weight regulation in obese patients. This device, the Maestro Rechargeable System, includes a neuroblocking 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 vagus nerve trunks. External components include a mobile charger, a transmit coil, a programmable microprocessor, and customized software. The system delivers high-frequency pulses of current to vagus 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.

Vagus nerve stimulation is approved by FDA to treat epilepsy and depression, but not obesity.

## *Outcomes*

To assess obesity treatments, a double-blind randomized controlled trial is optimal because these interventions require changes to patient behavior (ie, 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.

## Summary of Evidence

For individuals with obesity who receive vagus nerve blocking therapy, the evidence includes 2 sham-controlled randomized trials. 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 excess weight loss between groups at 12 months was 1%. In the more recent trial (ReCharge), the observed difference in excess weight loss between groups at 12 months was 8.5%; a post hoc analysis found this difference statistically significant, but the magnitude of change may not be viewed as clinically significant according to 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.

## Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in December 2016 did not identify any ongoing or unpublished trials that would likely influence this review.



## Practice Guidelines and Position Statements

### *American Society for Metabolic and Bariatric Surgery*

A 2016 position statement published by the American Society for Metabolic and Bariatric Surgery includes the following conclusions on vagus nerve blocking therapy for treatment of obesity<sup>8</sup>:

1. "Reversible vagal nerve blockade has been shown to result in statistically significant EWL [excess weight loss] 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 [vagus nerve blocking] 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

The U.S. Preventive Services Task Force published recommendations for screening and management of obesity in adults in 2012.<sup>9</sup> The Task Force recommended screening all adults for obesity and referring those with a body mass index of 30 kg/m<sup>2</sup> or higher to intensive, multicomponent behavioral interventions. Vagus nerve blocking therapy and other surgical interventions were not addressed in the recommendations or literature review. The recommendations are currently being updated.

## Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.



## Regulatory Status

In January 2015, the Maestro® Rechargeable System (EnteroMedics, St. Paul, MN) was approved by the FDA through the premarket approval process for use in adults ages 18 years and older who have BMI of 40 to 45 kg/m<sup>2</sup> or a BMI of 35 to 39.9 kg/m<sup>2</sup> with 1 or more obesity-related conditions such as high blood pressure or high cholesterol and have failed at least 1 supervised weight-management program within the past 5 years. Implantable components are incompatible with magnetic resonance imaging. 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. FDA product code: PIM.

## References

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## History



Date	Comments
07/14/15	New Policy. Policy created with literature review through March 30, 2015. Vagal nerve blocking therapy considered investigational in all situations.
05/01/16	Annual Review, changes approved April 12, 2016. Policy updated with literature review through December 13, 2015; reference 6 added. Policy statement unchanged.
05/01/17	Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 7-8 added. "Vagal" changed to "Vagus" in the policy Title and throughout the policy document when appropriate. Policy Statement unchanged.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; no references added. Policy statement unchanged.

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본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកតាមរយៈ Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ជំនួយចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਕੱਠ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਰਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).