Gastric Pacing/Gastric Electrical Stimulation

Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies
Related Documents
Description
Coverage Determination
Coverage Limitations
Coding Information
References
Change Summary

Disclaimer
The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member’s coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medical/Pharmacy Coverage Policies
None

Related Documents
There are no NCDs or LCDs for this service.

Description
Gastric pacing (also known as gastric electrical stimulation) is a treatment for an individual with chronic, intractable or drug-refractory nausea and vomiting secondary to gastroparesis, which could be caused by diabetes or idiopathic (unknown) reasons. A gastric pacing system delivers electrical stimulation to the gastric muscles by means of two leads that are implanted directly into the stomach and connected to a generator that is implanted into the abdominal area. The electrical impulses that are delivered to the gastric muscles are intended to stimulate gastric myoelectric activity with the goal of improving stomach emptying and relieving symptoms. The device is regulated by an external programmer that noninvasively
adjusts the level of gastric stimulation and allows the device to be completely turned off at any time. Internal battery replacement is required every 5 to 10 years. The Enterra Therapy II system is approved under a Humanitarian Device Exemption (HDE) by the US Food & Drug Administration (FDA) and is the only gastric pacing system approved for marketing.

A temporary trial of gastric pacing is being investigated to determine the response and benefit of this treatment prior to placing a permanent device. A cannula with an internal needle is inserted through the skin and placed in the gastric submucosa. A self-anchoring electrode is passed through the needle, which delivers electrical stimulation up to 8 weeks.

**Coverage Determination**

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:*

**Gastric pacing** will be considered medically reasonable and necessary when **ALL** the following criteria are met:

- Chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; **AND**
- Diagnosis confirmed by gastric emptying scintigraphy and/or radiopaque marker testing; **AND**
- Refractory or intolerant to diet modification and pharmaceutical therapy (eg, antiemetics, prokinetics)

**Gastric pacing revision or removal** of previously approved implantation will be considered medically reasonable and necessary for complications associated with gastric pacing (eg, bowel obstruction, gastric wall perforation, infection, lead dislodgement or lead erosion into the small intestine).

**Replacement of a gastric pacing device** will be considered medically reasonable and necessary if required for battery depletion (generally no more frequently than every 5 to 10 years).

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

**Coverage Limitations**
The following gastric pacing indications will not be considered medically reasonable and necessary:

- Initial treatment for gastroparesis; OR
- Temporary trial of gastric pacing; OR
- Treatment of obesity

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

**Summary of Evidence**

A review of the current medical literature demonstrates a lack of evidence or unclear utility regarding the use of gastric pacing for the initial treatment of gastroparesis. Gastric electrical stimulation should only be used for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. There is a lack of evidence to support the use of a temporary trial of gastric pacing. The FDA approval of the only available device (Enterra) states it is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The indications do not reference the use of a temporary trial. There were no recommendations from the American College of Gastroenterology guidelines. The American Gastroenterological Association states temporary electrical stimulation may predict a response to gastric electrical stimulation and if available, should be offered. However, this statement was based on only one clinical trial of 58 subjects in which it was concluded that overall treatment effects were not significant.

There are no FDA approved gastric electrical stimulation devices for the treatment of obesity.

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

<table>
<thead>
<tr>
<th>CPT® Code(s)</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>43647</td>
<td>Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum</td>
<td></td>
</tr>
<tr>
<td>43648</td>
<td>Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum</td>
<td></td>
</tr>
<tr>
<td>CPT® Category III Code(s)</td>
<td>Description</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>43881</td>
<td>Implantation or replacement of gastric neurostimulator electrodes, antrum, open</td>
<td></td>
</tr>
<tr>
<td>43882</td>
<td>Revision or removal of gastric neurostimulator electrodes, antrum, open</td>
<td></td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
<td></td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
<td></td>
</tr>
<tr>
<td>95980</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming</td>
<td></td>
</tr>
<tr>
<td>95981</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming</td>
<td></td>
</tr>
<tr>
<td>95982</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming</td>
<td></td>
</tr>
<tr>
<td>C1767</td>
<td>Generator, neurostimulator (implantable), nonrechargeable</td>
<td></td>
</tr>
<tr>
<td>C1778</td>
<td>Lead, neurostimulator (implantable)</td>
<td></td>
</tr>
<tr>
<td>C1827</td>
<td>Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller</td>
<td></td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
<td></td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
<td>Not Covered</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension</td>
<td>Not Covered</td>
</tr>
</tbody>
</table>
References


Change Summary

- Click or tap to enter a date. New Policy.