Vagus Nerve Blocking Therapy for Treatment of Obesity

Effective Date: May 1, 2017
Last Revised: April 11, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.20 Vagus Nerve Stimulation
7.01.516 Bariatric Surgery
7.01.522 Gastric Electrical Stimulation

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.

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**

**Intra-abdominal vagus nerve blocking therapy**

Intra-abdominal vagus nerve blocking therapy is considered investigational in all situations, including but not limited to the treatment of obesity.

**Note:** Vagus nerve stimulation is addressed in a separate policy. (See Related Policies)

**Coding**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tr>
<td>0312T</td>
<td>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</td>
</tr>
<tr>
<td>0313T</td>
<td>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</td>
</tr>
<tr>
<td>0314T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator</td>
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<tr>
<td>0315T</td>
<td>Vagus nerve blocking therapy (morbid obesity); removal of pulse generator</td>
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<tr>
<td>0316T</td>
<td>Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator</td>
</tr>
<tr>
<td>0317T</td>
<td>Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed</td>
</tr>
</tbody>
</table>

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**Related Information**

N/A
Evidence Review

This policy was created with a search of the MEDLINE database through March 30, 2015. It was updated with a MEDLINE search through December 20, 2016.

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes compared with available alternatives.

In the case of interventions to treat obesity, a double-blind RCT 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 body mass index (BMI), or as percent excess weight loss (EWL) 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 EWL is considered clinically significant, bariatric surgery trials generally define clinical success as at least 50% EWL. 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 such as natural history, regression to the mean, etc. 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.

Description

Intra-abdominal vagus nerve blocking therapy (vBloc) for morbid obesity consists of an implanted neurostimulator/pulse generator device that delivers intermittent electrical stimulation to the vagus nerve branches on the anterior abdominal wall. The programmable pacemaker-like device blocks signals sent from the stomach to the brain. The intent is to decrease sensations of hunger and increase feelings of fullness after eating (satiety) to promote weight loss.
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/m² or more.¹ 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 pediatric population as 95% percentile or more in BMI for 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 meta-analyses, being obese has been associated with higher all-cause mortality and death from cardiovascular disease.² In 2013, the American Medical Association officially recognized obesity itself as a disease.

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, 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 been found to improve outcomes in selected patients 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, 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 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, transmit coils, 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 Blocking Therapy for Obesity

The published literature on vagus nerve blockade for obesity consists of 2 RCTs, both of which were industry-sponsored, multicenter, double-blind and sham controlled. Although both trials included a sham treatment group, protocols differed. In the 2012 EMPOWER trial, all participants had devices implanted and leads placed. However, external controllers were programmed differently such that if the controllers were worn for 10 hours per day, the total charge delivered was 3.9 Coulombs (C) to patients in the treatment group and a negligible amount, 0.0014 C, to the sham group. In the 2014 ReCharge trial, all participants had devices implanted but no leads were placed in the sham group.

Study characteristics and results of the two clinical trials are summarized in Table 1.

Table 1. RCTs Evaluating Vagus Nerve Blockade for Treatment of Morbid Obesity

<table>
<thead>
<tr>
<th>Variables</th>
<th>EMPOWER³</th>
<th>ReCharge⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td>No patients randomized</td>
<td>294</td>
<td>239</td>
</tr>
<tr>
<td>Age range, y</td>
<td>18-65</td>
<td>18-65</td>
</tr>
</tbody>
</table>
| Key eligibility criteria   | • BMI 40-45 kg/m² or 35-39.9 kg/m² with ≥1 obesity-related comorbid conditions  
                          • Failed to respond to supervised diet/exercise program (timeframe not specified)  
                          | • BMI 40-45 kg/m² or 35-40 kg/m² with ≥1 obesity-related comorbid conditions  
                          • Failed to respond to supervised diet/exercise program within past 5 y |
<table>
<thead>
<tr>
<th>Variables</th>
<th>EMPOWER³</th>
<th>ReCharge⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Active treatment with Maestro device plus 15 weight management counseling sessions (n=192)</td>
<td>Active treatment with Maestro device plus 17 weight management counseling sessions (n=162)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Sham treatment with Maestro device plus 15 weight management counseling sessions (n=102)</td>
<td>Sham treatment with Maestro device plus 17 weight management counseling sessions (n=77)</td>
</tr>
</tbody>
</table>
| Primary outcome measures | Difference in mean percent EWL at 12 mo (superiority margin: 10%) | Coprimary outcomes:  
  - Difference in mean percent EWL at 12 mo (superiority margin: 10%)  
  - ≥55% of patients in active treatment group achieved 20% EWL; ≥45% achieved 25% EWL |
| Secondary outcome measure | Difference in percent of patients who achieved ≥25% EWL | \[ \text{Percentage of SAEs} \] |
| Primary safety outcome | Rate of SAEs | SAEs <15% in active treatment group |
| Length of follow-up, mo | 12 | 12 |

BMI: body mass index; EWL: excess weight loss (calculated as difference between pre- and posttreatment weights divided by difference between pretreatment weight and ideal body weight. BMI of 25 kg/m² was considered ideal); NA: not applicable; RCT: randomized controlled trial; SAE: serious adverse event.

Table 2: RCTs Evaluating Vagus Nerve Blocking for Treatment of Morbid Obesity: Results

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>EMPOWER³</th>
<th>ReCharge⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active</td>
<td>Sham</td>
</tr>
<tr>
<td>Mean Percent EWL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary efficacy</td>
<td>17%</td>
<td>16%</td>
</tr>
<tr>
<td>≥25% EWL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary efficacy</td>
<td>22%</td>
<td>25%</td>
</tr>
<tr>
<td>No. of SAEs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td>23</td>
<td>12</td>
</tr>
</tbody>
</table>

EWL: excess weight loss (calculated as difference between pre- and posttreatment weights divided by difference between pretreatment weight and ideal body weight. BMI of 25 kg/m² was considered ideal); NR: not reported; RCT: randomized controlled trial; SAE: serious adverse event.
a For a >10% difference.
b Met objective of <15%.

The primary efficacy outcomes were not met in either of the 2 RCTs. The difference in mean percent excess weight loss (EWL) was the sole primary efficacy outcome in the EMPOWER study and a coprimary outcome in the ReCharge study. This outcome was evaluated in both trials using a superiority margin of 10%, ie, the efficacy objective would only be met if there was more than a 10% difference between groups in EWL. U.S. Food and Drug Administration (FDA) documents state that the 10% margin, which was not attained in either trial, was considered to indicate a clinically meaningful difference in weight loss between active and sham treatment groups.5

For the ReCharge trial, however, in addition to the primary efficacy analysis, the authors also conducted a post hoc analysis that evaluated the difference in EWL between groups using a 2-sided t test with no superiority margin. In this post hoc analysis, the difference between groups, 8.5% EWL was statistically significant. (The difference between groups in percent EWL in the EMPOWER study was only 1%.)

The outcome used in these studies was percent EWL and modest changes in this outcome may translate to a relatively small amount of weight loss relative to total weight for patients with morbid obesity. Mean initial body weight in the ReCharge trial was 249 pounds in the active treatment group and 255 pounds in the sham group. Mean excess body weight was 97 pounds in the treatment group and 99 pounds in the sham group. Thus, a difference of 10% EWL, used in the primary analyses, represents only about a 10 pounds difference in absolute weight loss and a 4% difference in absolute body weight.

The ReCharge study had a second primary outcome that was met if at least 55% patients in the active treatment group achieved at least 20% EWL and at least 45% achieved at least 25% EWL. This outcome was not achieved; the data showed that 52% of patients in the active treatment group achieved at least 20% EWL and 38% achieved at least 25% EWL. In the EMPOWER study, groups did not differ significantly on the secondary outcome measure, percent of patients achieving at least 25% EWL.

In a post hoc subgroup analysis of the EMPOWER trial, longer duration of device use per day was related to a larger percentage of EWL. This association, however, occurred in the sham group, as well as the active treatment group. For example, EWL among patients who used the device fewer than 6 hours was 5% in the active treatment group and 6% in the sham group whereas EWL among patients who used the device at least 12 h/d was 30% and 22%, respectively. This finding suggests a substantial placebo effect associated with device use.
Both trials met their primary safety end points that related to SAEs. However, there were nonserious adverse events that occurred frequently. Rates of key adverse events (all severity levels) in the ReCharge trial are shown in Table 3. Most of these were of mild or moderate severity. The authors of the EMPOWER trial did not report individual adverse events.

### Table 3: Most Common Adverse Events, ReCharge Trial

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Treatment Group No. (%) Patients</th>
<th>Sham Group No. (%) Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, neuroregulator site</td>
<td>61 (38%)</td>
<td>32 (42%)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>38 (23%)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Pain, other</td>
<td>37 (23%)</td>
<td>0</td>
</tr>
<tr>
<td>Pain, abdominal</td>
<td>20 (12%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>11 (7%)</td>
<td>0</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>13 (8%)</td>
<td>0</td>
</tr>
<tr>
<td>Belching</td>
<td>13 (8%)</td>
<td>0</td>
</tr>
</tbody>
</table>

Additional information on ReCharge trial design and findings was reported in FDA documents. The study was designed to evaluate primary end points at 12 months and to follow patients to 5 years post implant. Patients were blinded until 12 months and unblinding began once all patients had completed the 12-month follow-up. After the 12-month follow-up, sham patients had the option to cross over into the active treatment group. At 18 months, follow-up data were reported for 117 (72%) patients initially assigned to the active treatment group and 42 (55%) assigned to the sham treatment group. The number of patients in the sham group who crossed over to active treatment and the timing of unblinding were not reported. At 18 months, the mean percent EWL was 25.3% in the active treatment group and 11.7% in the sham group; the mean between-group difference was 13.5% (95% confidence interval [CI], 5.7% to 21.3%). In this analysis, the treatment group sustained the weight loss they achieved at 12 months, and the control group gained weight. Nearly half of the patients initially randomized to the sham group were not included in the 18-month analysis, which limits ability to draw conclusions about these data. In addition, the 18-month analysis could be biased by unblinding, which occurred after all patients completed the 12-month follow-up. In the 12-month sham intervention phase of the trial, patients in both groups experienced decreased hunger, increased cognitive restraint, and decreased food intake. It is likely that unblinding could have an impact on these factors. FDA documents also report longer term safety data. Analyses of data up to 48 months from the
EMPOWER trial and 18-month data from the ReCharge trial did not identify any deaths or unanticipated SAEs. There were 13 surgical explants through 12 months (5 in active treatment group, 8 in sham group) and an additional 16 explants between 12 and 18. Reasons for explant included patient decision, pain, and need for magnetic resonance imaging.

Eighteen-month follow-up data from the ReCharge trial were published in the peer-reviewed literature by Shikora et al in 2015. The authors reported on a larger proportion of the patient population than that discussed in the FDA documents: in addition to the 159 (67%) of 239 randomized patients who completed the 18-month follow-up, the 2015 analysis included another 30 patients who missed the 18-month analysis but had a visit at 16 or 17 months. The additional patients included 11 from the active treatment group and 19 from the sham group, comprising a total of 188 patients (79% of those originally randomized). At 18 months, the mean percent EWL noted was 23.5% (95% CI, 20.8% to 26.3%) in the active treatment group and 10.2% (95% CI, 6.0% to 14.4%) in the sham group. The mean between-group difference in percent EWL was 13.4% (95% CI, 8.4% to 18.4%). The authors also evaluated the potential impact of blinding and found no statistically significant impact of blinding on their findings, which were also similar when the analysis was restricted to patients who remained blinded at 18 months. The degree of EWL at 18 months in this analysis of ReCharge trial data are similar to those previously published in the FDA documents, although this sample size is larger, reducing potential bias from missing data. However, as this was a post hoc analysis that incorporated 16- and 17-month data in addition to 18-month data, results are considered preliminary or hypothesis-generating. Long-term findings need to be replicated in additional appropriately designed RCTs.

Twenty-four-month outcomes from ReCharge were published by Apovian et al in 2016. The investigators noted that the sham arm was no longer a valid comparator at 24 months due to crossovers, dropouts, and patient unblinded at 12 months. There was no prespecified statistical analysis plan for assessments after the 12-month primary outcome assessment, including those in this 2016 article. A total of 103 (43%) patients of 239 randomized patients completed the 24-month follow-up. Their mean EWL was 21% (95% CI, 16% to 26%) and mean total weight loss was 8% (95% CI, 6% to 10%). No serious treatment-related adverse events were reported in the 18- to 24-month time period. The analysis lacked a blinded comparison group, and, like the 18-month data, was post hoc.

**Vagus Nerve Stimulation (VNS)**

Vagus nerve stimulation uses a device implanted in the chest with wire leads (electrodes) that are wound around the vagus nerve in the left neck area. These types of stimulators are different from the device used as a treatment for obesity and are addressed in another policy.
Related Policies). VNS of the carotid artery in the neck area is FDA-approved to treat epilepsy and depression, not for obesity treatment.

Section Summary

Two sham-controlled RCTs have been published evaluating vagus nerve blocking. The primary efficacy outcome (at least a 10% difference between groups) 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%; 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. Additional analyses of data from ReCharge found a difference in EWL at 18 months of approximately 13% in 79% of initially randomized patients and a mean EWL of 21% at 24 months in 43% of initially randomized patients. However, analyses beyond 12 months were post hoc, considered preliminary and need to be replicated in other appropriately designed RCTs. In addition, the 18- and 24-month data have potential biases, including missing data and unblinding. Moreover, the 18-month analysis combined data from different follow-up visits and the 24-month analysis lacked a control group. The 2 RCTs found that vagus nerve blocking was reasonably safe in terms of serious adverse events during follow-up, although a substantial number of mild and moderate adverse events were reported.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in December 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary of Evidence

For individuals who have 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 (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%; 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.

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 [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 (USPSTF) published recommendations for screening and management of obesity in adults in 2012. USPSTF 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. As of December 30, 2016, the recommendations were being updated; no release date for the updated recommendations was provided.
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 U.S. Food and Drug Administration (FDA) through the premarket approval process for use in adults ages 18 years and older who have a body mass index (BMI) of 40 to 45 kg/m2 or a BMI of 35 to 39.9 kg/m2 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


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
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<td>07/14/15</td>
<td>New Policy. Policy created with literature review through March 30, 2015. Vagal nerve blocking therapy considered investigational in all situations.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, changes approved April 12, 2016. Policy updated with literature review through December 13, 2015; reference 6 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>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.</td>
</tr>
</tbody>
</table>

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