PROSTATE RECTAL SPACERS

Guideline Number: MPG375.02
Approval Date: November 13, 2019

Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY SUMMARY</td>
<td>1</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>1</td>
</tr>
<tr>
<td>PURPOSE</td>
<td>2</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>2</td>
</tr>
<tr>
<td>GUIDELINE HISTORY/REVISION INFORMATION</td>
<td>2</td>
</tr>
<tr>
<td>TERMS AND CONDITIONS</td>
<td>2</td>
</tr>
</tbody>
</table>

POLICY SUMMARY

Overview
Prostate rectal spacers are various materials or devices placed between the prostate and anterior wall of the rectum for use in men receiving radiation therapy for prostate cancer. The anterior wall of the rectum is considered a major dose-limiting factor in radiation therapy of prostate cancer. Physical separation is proposed to allow reduced toxicity and treatment intensification.

The SpaceOAR® System is made up of materials that break down naturally by the action of biological agents and is placed inside the patient through a needle. The system retains its position throughout the duration of the patient's radiotherapy treatments and, because the system is biodegradable, is absorbed by the patient's body over time.

Guidelines
For services performed on or after 10/15/2018, polyethylene-glycol (PEG) hydrogel is covered once in patients with clinically localized prostate cancer with both the following:
1. Inclusion criteria including all of the following:
   a. Low* or Favorable Intermediate Prostate Cancer Risk Group (AUA or NCCN criteria)
   b. Dose escalated (≥ 76 Gy) IG-IMRT planned
   c. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
   d. Modern localization techniques insufficient to improve oncologic cure rates and/or reduce side effects due to at least one of the following:
      i. Anatomic geometry precluding ideal rectal constraints (V70 <10%, V65 <20%, V40 <40%)
      ii. Medication usage (e.g., anticoagulants)
      iii. Comorbid conditions (e.g., increased age, Hx MI or CHF)
2. No Exclusion criteria including all of the following:
   a. Less than 5 year life expectancy and asymptomatic
   b. Prior prostate cancer treatment (surgery or RT)
   c. Active bleeding disorder or clinically significant coagulopathy
   d. Active inflammatory or infectious disease in the perineum or injection area (e.g., prostatitis, anorectal IBD)
   e. Prostate volume > 80 cc

*Life expectancy ≥ 20 y (very low risk); ≥ 10 y (low risk)

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.
### PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

### REFERENCES

#### CMS Local Coverage Determination (LCD)

<table>
<thead>
<tr>
<th>LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>L37485 (Prostate Rectal Spacers) NGS</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
</tr>
</tbody>
</table>

#### CMS Article

<table>
<thead>
<tr>
<th>Article</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>A56539 (Billing and Coding: Prostate Rectal Spacers) NGS</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
</tr>
</tbody>
</table>

#### CMS Transmittal

Transmittal 3940, Change Request 10385, Dated 12/22/2017 (January 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version 19.0)

### UnitedHealthcare Commercial Policy

Omnibus Codes

### GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/13/2019</td>
<td>• Annual review</td>
</tr>
</tbody>
</table>

### TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.
Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.