7.01.164 Hydrogel Spacer Use During Radiotherapy for Prostate Cancer

Original Policy Date: March 1, 2019  Effective Date: March 1, 2019
Section: 7.0 Surgery  Page: Page 1 of 9

Policy Statement

Hydrogel spacer use during radiotherapy for prostate cancer is considered investigational.

Use of a hydrogel spacer for any other indication is considered investigational.

Policy Guidelines

The following CPT code is specific to the SpaceOAR® System:

- **55874**: Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

Description

For low or intermediate risk prostate cancer, radiation therapy is an option. Because the rectum lies in close proximity to the prostate, the risk of rectal toxicity is high. One approach is to push the rectum away from the prostate, increasing the space between the two and reducing the radiation dose to the rectum. A variety of biomaterials, including polyethylene glycol hydrogels (e.g., SpaceOAR System) have been evaluated as perirectal spacers.

Related Policies

- Intensity-Modulated Radiotherapy of the Prostate

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In October 2014, SpaceOAR® (Augmenix, a subsidiary of Boston Scientific) was cleared by the Food and Drug Administration through the De Novo process (DEN140030). “SpaceOAR System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR System to reduce the radiation dose delivered to the anterior rectum.”
Rationale

Background Diagnosis

Prostate cancer is a complex, heterogeneous disease, ranging from microscopic tumors unlikely to be life-threatening to aggressive tumors that can metastasize, leading to morbidity or death. It is the second most common cancer in men, with over one in ten men diagnosed with prostate cancer over their lifetime. Cancer is typically suspected due to increased levels of prostate-specific antigen upon screening. A digital rectal exam may detect nodules, induration, or asymmetry, and followed by an ultrasound-guided biopsy with evaluation of the number and grade of positive biopsy cores.

Clinical staging is based on the digital rectal exam and biopsy results. T1 lesions are not palpable while T2 lesions are palpable but appear to be confined to the prostate. T3 lesions extend through the prostatic capsule, and T4 lesions are fixed to or invade adjacent structures. The most widely used grading scheme for a prostate biopsy is the Gleason system. It is an architectural grading system ranging from 1 (well differentiated) to 5 (poorly differentiated); the score is the sum of the primary and secondary patterns. A Gleason score of 6 or less is low-grade prostate cancer that usually grows slowly; 7 is an intermediate grade; 8 to 10 is high-grade cancer that grows more quickly. A revised prostate cancer grading system has been adopted by the National Cancer Institute and the World Health Organization. A cross-walk of these grading systems is shown in Table 1.

Table 1. Prostate Cancer Grading Systems

<table>
<thead>
<tr>
<th>Grade Group</th>
<th>Gleason Score (Primary and Secondary Pattern)</th>
<th>Cells</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6 or less</td>
<td>Well differentiated (low grade)</td>
</tr>
<tr>
<td>2</td>
<td>7 (3+4)</td>
<td>Moderately differentiated (moderate grade)</td>
</tr>
<tr>
<td>3</td>
<td>7 (4+3)</td>
<td>Poorly differentiated (high grade)</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>Undifferentiated (high grade)</td>
</tr>
<tr>
<td>5</td>
<td>9-10</td>
<td>Undifferentiated (high grade)</td>
</tr>
</tbody>
</table>

Treatment

Early localized disease can usually be treated with surgery and radiotherapy, although active surveillance may be adopted in men whose cancer is unlikely to cause major health problems during their lifespan or for whom the treatment might be dangerous. In patients with inoperable or metastatic disease, treatment consists of hormonal therapy and possibly chemotherapy. Treatment decisions are based on the anatomic extent of the lesion, the histologic grade from biopsy, and serum prostate-specific antigen level. Other factors in treatment decisions are expected outcomes, potential complications, along with medical condition, age, comorbidities, and personal preferences. For patients with clinically localized low-risk cancer (no palpable tumor and prostate-specific antigen of ten or less), active surveillance is an option. Definitive therapy with radical prostatectomy or radiation therapy (RT) with external beam and/or brachytherapy is also an option for low or intermediate risk disease. Dose escalation of RT improves cancer outcomes but also increases the risk of urinary or bowel toxicity. Image-guided RT and intensity-modulated RT may be used to limit margins and reduce toxicity but because the rectum lies in close proximity to the prostate, the risk of rectal toxicity remains high. Hypofractionation, dose escalation, and salvage RT protocols can be particularly prone to rectal toxicity.

Perirectal Spacers

One approach to the problem of rectal toxicity is to push the rectum away from the prostate, increasing the space between the two organs and reducing the radiation dose to the anterior rectal wall. A variety of biomaterials, including collagen, polyethylene glycol (PEG) hydrogels, and absorbable balloons have been evaluated as a means to reduce rectal radiation...
exposure. The SpaceOAR System is the first PEG hydrogel that was cleared by the US Food and Drug Administration specifically for use during RT of the prostate. The chemical composition of the SpaceOAR is similar to a PEG-based hydrogel that is Food and Drug Administration approved as a dural sealant. Hydrodissection is achieved with saline between the retroprostatic (Denonvilliers’) fascia and the anterior rectal wall using a transperineal approach. Once the needle placement is confirmed, two solutions in a two-channel syringe are injected into the perirectal space. The hydrogel then polymerizes to form a soft mass. The hydrogel maintains the space for approximately 3 months, the duration of radiotherapy, and is completely absorbed by 12 months. The PEG hydrogel may be injected at the same time as the placement of fiducial markers in the prostate.

**Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens, and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Hydrogel Perirectal Spacer**

**Clinical Context and Therapy Purpose**

The purpose of a hydrogel spacer in patients with prostate cancer who are being treated with external beam radiotherapy is to position the anterior rectal wall away from the prostate with the intent to reduce the radiation dose delivered to the rectum.

The question addressed in this evidence review is: Does the use of a hydrogel perirectal spacer improve the net health outcome in patients with prostate cancer who are being treated with external beam radiotherapy?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are men with prostate cancer who are being treated with external beam radiotherapy.

**Interventions**

The therapy being considered is a polyethylene glycol hydrogel (SpaceOAR System) that is placed between the prostate and rectum. The gel increases the space between the rectum and the prostate to about 12 mm. It maintains space for approximately three months and then is gradually absorbed and cleared.
Comparators
The following therapies are currently being used to make decisions about the treatment of prostate cancer: external beam radiotherapy without a spacer.

Outcomes
The outcomes of interest are symptoms of rectal toxicity, adverse events, and quality of life (QOL). Prostate cancer-specific QOL can be measured by the Expanded Prostate Cancer Index Composite health-related QOL questionnaire, with 5- and 10-point thresholds for minimum clinically important differences (MCID). Skolarus et al (2015) reported the bowel and vitality/hormonal domains had an MCID 4-6 point range, while the sexual domain had an MCID range of 10-12. Urinary incontinence had a greater MCID range (6-9) compared with the urinary irritation/obstruction domain (5-7). Although considered a surrogate outcome, studies may also report estimated radiation doses to the rectum from radiation planning, with the rectal volume predicted to receive a radiation dose over the threshold (e.g., rectal volume receiving 70 Gray [Gy]).

A beneficial outcome would be reduced rectal toxicity and reduced impairment in QOL following radiotherapy.

A harmful outcome would be adverse effects of the spacer, spacer insertion, or spacer absorption.

Timing
Follow-up should be for at least 2 years since the median time for the occurrence of radiation toxicity is 18 months.

Setting
The setting is outpatient care by a radiation oncologist.

Study Selection Criteria
To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs. To assess long-term outcomes and adverse effects, we sought single-arm studies that capture longer periods of follow-up and/or larger populations.

Review of Evidence
Results from the pivotal RCT for the SpaceOAR System were published by Mariados et al (2015), with 3-year follow-up published by Hamstra et al (2017) (see Table 2). A total of 222 men were randomized 2:1 to the spacer or control group. All men were implanted with fiducial markers for image-guided intensity-modulated radiation therapy (IG-IMRT) and received 79.2 Gy in 1.8-Gy fractions to the prostate. The primary outcome was the percent of the rectal volume receiving 70 Gy in dose planning studies, which was 3.3% with the peri-rectal spacer and 11.7% in the control group (p<0.001, see Table 3). Blinded adjudication identified no spacer-related adverse events. Grade ≥ 1 adverse events were similar between the groups at 6 and 15 months but were reduced at 3 years in the group with the SpaceOAR System (2% vs 9%, p<0.03) with a number needed to treat (NNT) of 14.3. Fewer patients reported a clinically significant decline in bowel or urinary-related QOL with an NNT of 6.3 and 6.7, respectively (see Table 2). Patients were not blinded to treatment at the three year follow-up.

Table 2. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Active</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mariados et al, (2015)</td>
<td>US</td>
<td>20</td>
<td>2012-2013</td>
<td>222 patients with clinical stage T1 or T2 prostate cancer with Gleason score of ≤7, PSA ≤20 ng/mL, Zubrod performance status 0 to 1, who were</td>
<td>149 patients who received perirectal injection of a hydrogel between the</td>
<td>73 patients who received only fiducial markers inserted in the prostate prior</td>
</tr>
</tbody>
</table>
Hydrogel Spacer Use During Radiotherapy for Prostate Cancer

Table 3. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Rectal Volume Receiving ≥70 Gy</th>
<th>Percent of Patients with ≥25% Reduction in Rectal Volume Receiving ≥70 Gy</th>
<th>Grade ≥21 Rectal or Procedure Adverse Events at 6 mo</th>
<th>Patients with Grade ≥1 Late Toxicity</th>
<th>10 Point Decline in Bowel QOL</th>
<th>10 to 12 Point Decline in Urinary QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mariados et al, (2015)4</td>
<td>219</td>
<td>3.3%</td>
<td>34.2%</td>
<td>66 (93.0%)</td>
<td>21.4%</td>
<td>≈12%</td>
</tr>
<tr>
<td>- N</td>
<td>219</td>
<td>97.3%</td>
<td>15 mo</td>
<td>0.087</td>
<td>NA</td>
<td>NS</td>
</tr>
<tr>
<td>- Hydrogel spacer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Control</td>
<td>N/A</td>
<td>31.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- P Value</td>
<td>&lt;0.001</td>
<td>0.70</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamstra et al (2017)5</td>
<td>140</td>
<td>2% (1 to 6)</td>
<td>21%</td>
<td>0.07</td>
<td>6.3</td>
<td>6.7</td>
</tr>
<tr>
<td>- N</td>
<td>140</td>
<td>5%</td>
<td>23%</td>
<td>0.03</td>
<td>0.28 (0.13 to 0.63)</td>
<td>0.31 (0.11 to 0.85)</td>
</tr>
<tr>
<td>- Hydrogel spacer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Control</td>
<td>9% (4 to 20)</td>
<td>2% (1 to 6)</td>
<td>21%</td>
<td>0.02</td>
<td>0.28 (0.13 to 0.63)</td>
<td>0.31 (0.11 to 0.85)</td>
</tr>
<tr>
<td>- P Value</td>
<td>&lt;0.03</td>
<td>5%</td>
<td>23%</td>
<td>0.03</td>
<td>0.28 (0.13 to 0.63)</td>
<td>0.31 (0.11 to 0.85)</td>
</tr>
<tr>
<td>- OR (95%CI)</td>
<td>14.3</td>
<td>6.3</td>
<td>6.7</td>
<td>6.3</td>
<td>6.3</td>
<td>6.7</td>
</tr>
<tr>
<td>- NNT</td>
<td>14.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CI: confidence interval; HR: hazard ratio; NA: not applicable; NNT: number needed to treat; OR: odds ratio; QOL: quality of life; RCT: randomized controlled trial

Gaps in relevance and design and conduct are shown in Tables 4 and 5. The primary gap in relevance was the population, which was restricted for this pivotal controlled trial. The primary gaps in design and conduct were the lack of investigator blinding and the loss to follow-up at three years.

Table 4. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mariados et al, (2015)4</td>
<td>4. Patients with prostate volumes &gt;80 mL, extracapsular extension, or prior radiation or surgery were excluded</td>
<td>prostate and rectum prior to IG-IMRT (79.2 Gy in 1.8-Gy fractions)</td>
<td>to IG-IMRT</td>
<td>1. 2. 15 month follow-up; 3 year follow-up was reported by Hamstra et al 2017</td>
<td></td>
</tr>
<tr>
<td>Hamstra et al (2017)5</td>
<td>4. Patients with prostate volumes &gt;80 mL, extracapsular extension, or prior radiation or surgery were excluded</td>
<td>prostate and rectum prior to IG-IMRT (79.2 Gy in 1.8-Gy fractions)</td>
<td>to IG-IMRT</td>
<td>1. 2. 15 month follow-up; 3 year follow-up was reported by Hamstra et al 2017</td>
<td></td>
</tr>
</tbody>
</table>
Table 5. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marliados et al (2015)</td>
<td>1, 3. Not blinded to treatment assignment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamstra et al (2017)</td>
<td>1, 2, 3. Not blinded to treatment assignment</td>
<td>1. 3 yr data were available for only 63% of patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- **Blinding key**: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
- **Selective Reporting key**: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- **Data Completeness key**: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
- **Power key**: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
- **Statistical key**: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Fischer-Valuck et al (2017) reported secondary analysis of magnetic resonance imaging for the 149 patients enrolled in the pivotal trial who received the hydrogel spacer. The spacer was symmetrically placed at midline for 71 (47.7%) patients, with 78 (50.9%) having some asymmetry and 3 (2.0%) with greater than 2 cm lateral distribution. The greater the asymmetry the lower the decrease in rectal radiation, although all but 4 patients achieved a 25% or greater reduction in rectal volume receiving 70 Gy. Infiltration of the rectal wall occurred in 9 (6%) patients but was not associated with procedure-related adverse events or acute or late rectal toxicity.

Summary of Evidence

For individuals who have prostate cancer and are undergoing radiation therapy who receive a hydrogel spacer, the evidence includes a pivotal RCT with a three year follow-up. The relevant outcomes include symptoms, QOL, and treatment-related morbidity. The pivotal RCT indicates the hydrogel spacer can reduce the radiation dose to the rectum with a statistically significant decrease in Grade 1 or greater late toxicity and an NNT of 14.3. There were few events of greater than Grade 1 toxicity in either group. Patient-reported declines in rectal and urinary QOL at three years were statistically lower in the spacer group and met the threshold for a clinically significant difference, although it is not clear if patients were blinded to treatment at the longer-term follow-up. The NNTs for late improvement in rectal and urinary QOL were 6.3 to 6.7, respectively. Limitations to the study include the lack of blinding and the exclusion of patients who might be at greater risk of rectal toxicity. Additional study is needed to corroborate the findings of the pivotal RCT, to identify the factors that increase the risk of rectal toxicity and
determine who is likely to benefit from the use of a spacer. The evidence is insufficient to
determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (V2.2018) provides the following
recommendation in principles of radiation therapy, “Perirectal spacer materials may be
employed when the previously mentioned techniques [highly conformal RT, photon or proton
beam, brachytherapy boost] are insufficient to improve oncologic cure rates and/or reduce
side effects due to anatomic geometry or other patient-related factors, such as medication
usage and/or comorbid conditions. Patients with obvious rectal invasion or visible T3 and
posterior extension should not undergo perirectal spacer implantation.”

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2017) published guidance on the
biodegradable spacer.9 The National Institute for Health and Care Excellence concluded that
“current evidence on the safety and efficacy of insertion of a biodegradable spacer to reduce
rectal toxicity during radiotherapy for prostate cancer is adequate to support the use of this
procedure.”

American Society of Clinical Oncology, the American Urological Association, and the American
Society for Radiation Oncology
The American Society of Clinical Oncology, the American Urological Association, and the
American Society for Radiation Oncology (2018) published a joint guideline on hypofractionated
radiation therapy for localized prostate cancer.8 The guideline recommends that men be
counseled about the small increased risk of acute gastrointestinal toxicity with
hypofractionation. “Moderately fractionated EBRT has a similar risk of acute and late
genitourinary and late GI toxicity compared with conventionally fractionated EBRT. However,
physicians should discuss the limited follow-up beyond 5 years for most existing RCTs [randomized
controlled trials] evaluating moderate hypofractionation.” This was a strong recommendation
based on high-quality evidence and 100% consensus.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage
determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>NCT01999660a Prospectiv eNational Post-marketing Surveillance for the</td>
<td>250</td>
<td>Jan 2019</td>
</tr>
<tr>
<td></td>
<td>Investigation of the Efficacy and Safety of SpaceOAR™ to Maintain Space</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Between the Rectum and Prostate During Radiation Therapy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial.  

a Denotes industry-sponsored or cosponsored trial.
References


Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>55874</td>
<td>Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed</td>
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</tbody>
</table>
**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/2019</td>
<td>BCBSA Medical Policy Adoption</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.