Transperineal Placement of Biodegradable Material for Prostate Cancer

Policy Number: M20240924031

Effective Date: 11/1/2024

Sponsoring Department: Health Care Services

Impacted Department(s): Health Care Services

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)

✦ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan

✦ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP

✦ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual

☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for transperineal placement of biodegradable material for prostate cancer utilizing **Barrigel**.

Policy:

Commercial, Self-Funded and Medicare Advantage:

Biocompatible and biodegradable perirectal spacer materials (Barrigel) may be implanted between the prostate and rectum in patients:

- undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions.

- Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation and is not covered.
- Imaging must be provided indicating the cancer has not invaded into the rectum or extended beyond the posterior region of the prostate.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:
Biocompatible and biodegradable perirectal spacer materials (Barrigel) are not covered for MediSource, MediSource Connect, Child Health Plus and Essential Plan members.

Background:

Prostate radiation therapy rectal toxicity is largely due to the prostate-rectum proximity. Signs of rectal damage can include diarrhea, incontinence, proctitis and ulceration of the rectal mucosa. Injecting a biodegradable substance or inserting and inflating a biodegradable balloon spacer in the space between the rectum and prostate is done to temporarily increase the distance between them, reduce the amount of radiation delivered to the rectum and reduce the toxicity profile during prostate radiotherapy.

Barrigel is an injectable gel spacer that is used for separation of the prostate and rectum during radiotherapy. It is indicated to temporarily position the anterior wall of the rectum away from the prostate during radiotherapy for localized prostate cancer to reduce the radiation dose delivered to the anterior rectum. Barrigel is composed of biodegradable hyaluronic acid and maintains space for the entire course of prostate radiotherapy treatment. Before a member receives radiation therapy, Barrigel is injected under local or general anesthesia using transrectal ultrasound guidance. It is delivered via a syringe and pushes the rectal tissue away to reduce radiation exposure to the anterior rectal wall, providing protection throughout the duration of radiation therapy. Composed of biodegradable polyethylene glycol, this hydrogel maintains the space for the 3 months during treatment, after which it spontaneously breaks down by hydrolysis and is excreted renally after 6 months. Barrigel was approved by the Food and Drug Administration May 26, 2022.

According to the National Comprehensive Cancer Network's Prostate Cancer Guidelines "… biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation."

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Preauthorization is required for this service.

Definitions

Barrigel injectable gel is a biodegradable rectal spacer for protection of the rectal wall when treating prostate cancer with radiation therapy, composed of nonanimal stabilized hyaluronic acid (NASHA) at a concentration of 20 mg/mL in phosphate buffered saline.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory References

DiBiase S, Roach III, M. External beam radiation therapy for localized prostate cancer. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on August 28, 2024)

Gejerman G, Goldstein MM, Chao M, et al. Barrigel Spacer Injection Technique. Pract Radiat Oncol. 2024 Jan-Feb;14(1):e57-e61.

Hayes, Inc. Evidence Analysis Research Brief Barrigel Absorbable Perirectal Spacer (Teleflex Inc.) During Radiation Therapy for Prostate Cancer. Lansdale, PA: July 2024.

Karsh LI, Gross ET, Pieczonka CM, et al. Absorbable Hydrogel Spacer Use in Prostate Radiotherapy: A Comprehensive Review of Phase 3 Clinical Trial Published Data. Urology. 2018 May;115:39-44.

Mariados N, Sylvester J, Shah D, et al. Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. Int J Radiat Oncol Biol Phys. 2015 Aug 1;92(5):971-977.

Morgan SC, Hoffman K, Loblaw DA, et al. Hypofractionated Radiation Therapy for Localized Prostate Cancer: An ASTRO, ASCO, and AUA Evidence-Based Guideline. J Clin Oncol. 2018 Oct 11;36(34):JCO1801097.

National Comprehensive Cancer Network (NCCN) [web site]. Prostate Cancer Version 4.2024 — May 17, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf Accessed August 27, 2024.

Regulatory References

United States Food and Drug Administration (FDA) [web site]. 510(k) approval. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220641.pdf Accessed August 28, 2024.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Policy Author / Owner	Notes
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