

## Prostate Rectal Spacers

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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.

### I. Criteria for Initial Approval

Application of a prostate rectal spacer - Polyethylene-glycol (PEG) hydrogel will be considered for coverage when **ALL** of the criteria below are met and confirmed with supporting medical documentation, once, in patients with clinically localized prostate cancer.

- Inclusion criteria, including all of the following:
  - Adult male patients >18 years old.
  - Low\* or Favorable Intermediate Prostate Cancer Risk Group (AUA or NCCN criteria).
  - Dose escalated ( $\geq 76$  Gy) conventional fractionation (1.8-2 Gy fractions) or moderate hypofractionation (HFX) (2.4-3.4 Gy fractions) IG-IMRT planned.
  - Eastern Cooperative Oncology Group (ECOG) performance status  $\leq 1$ .
  - Modern localization techniques insufficient to improve oncologic cure rates and/or reduce side effects due to at least one of the following:
    - Anatomic geometry precluding ideal rectal constraints - Conventional fractionation (V70 <10%, V65 <20%, V40 <40%) - Moderate HPX (dose constraints not yet standardized; employ those used in the supporting phase III trials).
    - Medication usage (e.g., anticoagulants).
    - Comorbid conditions (e.g., increased age, history of MI or CHF).
- No exclusion criteria, including all of the following:
  - Less than 5 year life-expectancy and asymptomatic.
  - Prior prostate cancer treatment (surgery or RT).
  - Active bleeding disorder or clinically significant coagulopathy.
  - Active inflammatory or infectious disease in the perineum or injection area (e.g., prostatitis, anorectal IBD).

- Prostate volume > 80 cc.

\*Life expectancy  $\geq$  20 y (very low risk);  $\geq$  10 y (low risk)

## II. Required Clinical Information

Documentation of ***all*** of the following:

- A recent History and Physical exam, and any medical progress notes related to the medical treatment and planned surgical and radiation interventions.

## III. Coverage Limitations and Exclusions

Placement of a Prostate Rectal Spacer - Polyethylene-glycol (PEG) hydrogel - must be administered according to the criteria for approval (**Section 1.**) listed above. The recommended use is once in a lifetime.

## IV. Length of Authorization For initial therapy

Polyethylene-glycol (PEG) hydrogel will be authorized for a one time patient application.

## V. Billing Code/Information

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

*Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.*

**Approved by MDH Clinical Criteria Committee: 1/1/2021**

**Last Reviewed Date: 2/18/2021**