



Policy Owner: Radiation Treatment Program

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Policy: Rectal Spacers Implementation Guidance Document for Prostate Cancer Patients in Ontario

Purpose:

To provide guidance in the usage of rectal spacers for prostate cancer patients in Ontario and allow for monitoring and equitable access to all cancer centres.

General Background:

Prostate cancer is one of the leading causes of death for men in Ontario. The Canadian Cancer Society statistics estimate that in 2022, 24,600 men will be diagnosed with prostate cancer. On average, 67 Canadian men will be diagnosed with prostate cancer every day¹. In the past 10 years, there has been extensive literature reviews and clinical trials examining the clinical efficacy of the hydrogel spacer. Clinical trials have been shown to provide meaningful dosimetric improvements for some prostate cancer patients undergoing radiotherapy treatment. The implementation of rectal spacers between the prostate and the rectum is a fairly low-risk procedure that produces meaningful clinical benefits for patients undergoing radiotherapy for localized prostate cancer. The placement of rectal spacers in patients with prostate cancer undergoing radiation therapy led to reductions in rectal radiation dose and a significant reduction in rectal toxicity for the patient^{2,3}.

Eligibility Criteria:

Patient Indications for Treatment Prioritization

A patient eligibility criterion for treatment prioritization has been developed based on the recommendations of authors and reviewers from the expert panel of the Quality Initiative of the Program in Evidence-Based Care guidance document (PEBC, 2019) on *Biodegradable Rectal Spacers for Prostate Cancer Radiotherapy*, and Radiation Oncologists from the genitourinary (GU) Disease Pathway Management program at Ontario Health.

The following criteria will be used to prioritize patients for the use of rectal spacers and to trigger funding. The objective is to support high quality and safe care and reduce complications with this patient population.

- 1) Patients with prostate cancer with conditions pre-disposing to extreme reactions of the rectum to radiotherapy irrespective of fractionation
 - Inflammatory Bowel Disease (e.g., Ulcerative Colitis and Crohn's Disease)³

¹ Canadian Cancer Society, 2022.

² Chung, Brown, D'Souza, Koll, Morgan, SPACER RRG, Cancer Care Ontario, 2019.

³ Payne, H. A., Jain, S., Peedell, C., Edwards, A., Thomas, J. A., Das, P., Hansson Hedblom, A., Woodward, E., Saunders, R., & Bahl, A. Delphi study to identify consensus on patient selection for hydrogel rectal spacer use during radiation therapy for prostate cancer in the UK. *BMJ open* (2022)



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- 2) Patients on chronic anti-coagulant therapy (anything other than acetylsalicylic acid (ASA)) for other medical conditions, thereby increasing the risk of significant post-radiotherapy rectal bleeding
- 3) Bilateral Hip Prosthesis
 - Situations in which dose delivery is limited to anterior/posterior angles, and hence depositing on rectum

Note: The indications for treatment prioritization and new clinical evidence are expected to evolve given the completion of clinical trials.

Special Access Program (SAP)

The Radiation Treatment Program (RTP) at Ontario Health will consider requests to the SAP for Rectal Spacers in accordance with the *SAP for Rectal Spacers Policy* for reimbursement of rectal spacers for prostate cancer patients that do not meet the current eligibility criteria for funding within the *Patient Indications for Treatment Prioritization*, and where other standard treatment approaches are not appropriate.

Clinician Training, Qualifications and Safety

To ensure safe administration/insertion of rectal spacers, the following training is recommended:

- Guidance from the Quality Initiative of the Program in Evidence-Based Care (PEBC, 2019)² recommend that prostate cancer patients should receive treatment by clinicians with training and experience in transperineal interventional procedures
- Training clinicians through certified supplier programs is strongly encouraged
- Each participating Regional Cancer Centre (RCC) is responsible to always have two clinicians who are fully trained on staff, in case of absences
- RCC's should ensure that they have one operator with certifying credentials for clinicians in training
- Participating RCC's without their own prostate brachytherapy program are responsible for partnering with centres that have programs for training purposes

Volume Monitoring and Equitable Distribution of Rectal Spacers

- Equitable distribution of rectal spacers for each Regional Cancer Centre depends on:
 - The existence of a spacer insertion program involving training clinicians
 - Patients chosen as a treatment candidate based on the *Patient Indications for Treatment Prioritization**
 - Patients eligible for funding through the Radiation Treatment Quality-Based Procedure

* Or are considered a successful candidate for treatment as per the *Special Access Program*



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Program Reporting:

- Patient eligibility and treatment data that is submitted to Ontario Health will be collected and used for:
 - Determining and verifying eligibility for reimbursement of rectal spacer requests based on the patient eligibility criterion, as per the *Patient Indications for Treatment Prioritization* or *Special Access Program*
 - Analysis or compiling statistical information with respect to the monitoring of the distribution of rectal spacers per treatment facility.
- To ensure accurate processing, only one rectal spacer and one patient indication code should be submitted per patient in databook. Submitting multiple rectal spacers or patient indication codes for the same patient will result in the submission being marked as non-funded.

Reimbursement:

- To support the implementation of funding for rectal spacers, the NHPIP code (399 – rectal spacer) is used to facilitate monitoring of volumes
- New NHPIP supplementary codes have been developed in alignment with each patient indication for treatment prioritization as well as an additional code for cases approved through the SAP
- Funding will be triggered when NHPIP code 399 is used in conjunction with at least one supplementary NHPIP code for patient indications or rectal spacer approved via SAP
- The reimbursement price includes the cost of the hydrogel rectal spacer kit and insertion procedure
- The cost of an incomplete/unsuccessful procedure will be covered if the patient met eligibility criteria