



Policy owner: Radiation Treatment Program

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Contact: OH-CCO_RTP@ontariohealth.ca

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Policy: Special Access Program for Rectal Spacers

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

This *SAP for Rectal Spacers Policy (Policy)* outlines the case-by-case assessment process for the SAP for Rectal Spacers.

A. PURPOSE

The purpose of this Policy is to outline the review criteria and assessment process for requests submitted to the SAP for Rectal Spacers.

B. ELIGIBLE APPLICANTS

The SAP for Rectal Spacers applicant (**Applicant**) must be a physician who is a radiation oncologist that specializes in prostate cancer and is licensed to practice in Ontario (i.e., holds a valid license from the College of Physicians and Surgeons of Ontario). Patients (as well as family members, caregivers, etc.) cannot directly apply to the SAP for Rectal Spacers.

C. ELIGIBLE PATIENTS

The patient must be a resident of Ontario and have a valid Ontario Health Insurance Number.

D. REVIEW CRITERIA

Requests will be evaluated against the following review criteria to determine whether they will be funded under the SAP for Rectal Spacers:

I. DISEASE

- The request must be for a patient with prostate cancer.

II. PATIENT INDICATIONS

- The request must be for a patient that does not meet the criteria included in the current *Patient Indications for Treatment Prioritization* for funding.

These criteria include:

- 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)



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- 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
- Bilateral Hip Prosthesis
 - Situations in which dose delivery is limited to anterior/posterior angles, and hence depositing on rectum

E. DOCUMENTATION REQUIREMENTS

- I. The applicant must upload the request and forms to their assigned MFT folder. **The Applicant must NOT email Personal Health Information (PHI).**
- II. The Applicant must submit the following documentation for the request:
 - Completed **Special Access Form – Rectal Spacers Reimbursement Program**, including specific reasons why other standard treatment approaches are not appropriate
 - Clinical notes from the treating radiation oncologist (as appropriate)

F. ASSESSMENT

The assessment process is comprised of the following components:

I. COMPLETENESS

- Upon receipt, the RTP will screen each request for completeness against the documentation requirements in **Section E**. In the case of missing information, RTP will contact the Applicant as necessary. Requests which remain incomplete after 10 business days from the date of submission will be closed.

II. EVALUATION OF REVIEW CRITERIA

- **Disease:** Upon receipt of a complete request, RTP will assess the request against the review criteria in **Section D.I**. If necessary, RTP may consult with radiation oncologists with expertise in prostate cancer (**Reviewers**). Requests that do not meet the review criteria in **Section D.I** are ineligible and will not be further assessed.
- **Patient Indications:** If the request meets the review criteria in **Section D.I**, RTP will forward the request for external review against the review criteria in **Section D**. by a Reviewer. The Reviewer will provide a recommendation to RTP on whether the request meets the review criteria in **Section D**. If a decision cannot be reached by a Reviewer, the request will be automatically sent to an alternate Reviewer for consideration. In the case of two divergent clinical opinions from two Reviewers, an opinion by a third Reviewer will be obtained.



G. DECISIONS

The RTP will inform the Applicant in writing (i.e., email) of Ontario Health (Cancer Care Ontario)'s decision regarding the request as well as the rationale for the decision.

H. TIMELINES FOR REVIEW

The RTP will aim to provide a decision on a request as soon as possible. Due to the complexity of these cases and the need for external review, a decision may take up to 2 weeks. An incomplete **Special Access Form – Rectal Spacers Reimbursement Program** may result in longer turnaround times.

I. OPTIONS IN THE EVENT OF A NEGATIVE FUNDING DECISION

The RTP will accept requests for resubmissions or appeals within 30 days of the negative funding decision being communicated to the Applicant, which will be considered on a case-by-case basis in accordance with the *Special Access Program for Rectal Spacers – Resubmissions & Appeals Policy*.

J. PROGRAM REPORTING

In addition to collecting and using PHI in the application to verify eligibility, Ontario Health collects and uses PHI (from the Ministry and Applicants) for the purpose of health system planning. This aligns with Ontario Health's Prescribed Entity authority under section 45 of the Personal Health Information Protection Act, 2004 (PHIPA). Use of the data will include reporting to the Ministry on a regular basis on program indicators, which can include the program's turnaround times for evaluation, application volumes and financial indicators. Data needed for the report will be provided by the Ministry and collected from the referred applications pursuant to Ontario Health's Prescribed Entity authority under section 45 of PHIPA.

Comments or inquiries should be directed to the Radiation Treatment Program:

c/o: Radiation Treatment Program

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