

## Rectal Spacers Reimbursement Program Frequently Asked Questions (FAQ)

The purpose of the frequently asked questions (FAQ) document is to provide information on common questions about the Rectal Spacers Reimbursement Program.

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### **Rectal Spacers Reimbursement Program Overview**

#### 1. What is the purpose of a rectal spacer?

In the past 10 years, there has been extensive literature reviews and clinical trials examining the clinical efficacy of the rectal spacer for prostate cancer patients. 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 low-risk procedure that reduces rectal toxicity during radiation therapy and maintains the quality of life in appropriately selected patients with prostate cancer. Please see the guidance document on the <u>Radiation Treatment Program (RTP) Resource Hub</u> under the Rectal Spacers Reimbursement Program dropdown for more information.

#### 2. What is the purpose of the Rectal Spacers Reimbursement Program?

The purpose of the Rectal Spacers Reimbursement Program is for Ontario Health-Cancer Care Ontario (OH-CCO) to provide reimbursement to the Regional Cancer Centres for the use of rectal spacers with eligible prostate cancer patients.

Centres will be funded for rectal spacers for patients that fall within the approved eligibility criteria for funding within the Patient Indications for Treatment Prioritization through the Cancer QBP Agreement:

- NHPIP 399 + 726x Patients with prostate cancer with conditions pre-disposing to extreme reactions
  of the rectum (inflammatory bowel disease IBD) to radiotherapy irrespective of fractionation (e.g.,
  Ulcerative Colitis and Crohn's Disease)
- NHPIP 399 + 727x Patients with prostate cancer 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
- NHPIP 399 + 728x- Patients with prostate cancer with bilateral hip prosthesis.

For patients that do not meet the current rectal spacers eligibility criteria, centres can submit a Special Access Program (SAP) request. SAP requests are assessed on a case-by-case basis for rectal spacers for prostate cancer patients that do not meet the current eligibility criteria for funding within the *Patient Indications for Treatment Prioritization* (*listed above*), and where other standard treatment approaches are not appropriate.

3. What are the National Hospital Product Improvement Program (NHPIP) codes associated with the current eligible patient indications to receive funding for rectal spacers?

The NHPIP codes are aligned with the four eligible patient indications for treatment prioritization including 726x, 727x, 728x, and 729x for approved SAP submissions. Centres <u>must</u> submit code 399-Rectal Spacer (Insertion of rectal spacer) with the corresponding code that applies to the patient's presenting criterion (e.g., 399 + 726x) to receive funding.



Please note that the code 399 + 729x must **only** be submitted if the patient was approved through the SAP. If the SAP submission is not approved, no NHPIP code is to be submitted.

NHPIP_ACT_CD	NHPIP_SHORT_DESC	NHPIP_ACT_DESC
726X	Pts with IBD	Patients with prostate cancer with conditions pre-disposing to extreme reactions of the rectum (inflammatory bowel disease - IBD) to radiotherapy irrespective of fractionation (e.g., Ulcerative Colitis and Crohn's Disease)
727X	Pts on chronic anti- coagulant therapy	Patients with prostate cancer 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
728X	Pts with bilat Hip Prosthesis	Patients with prostate cancer with bilateral hip prosthesis
729X	RC SAP Approved	Rectal spacer approved via Special Access Program (SAP)

## 4. At what time in the patient's treatment journey should the NHPIP codes for eligible patient criteria (726x,727x,728x) be submitted?

The NHPIP code for eligible patient criteria (726x,727x,728x) should be submitted on the same day as the rectal spacer insertion code (399) for the same course number and protocol. Any activity submitted after the course is flagged as complete is not counted.

# 5. Who was involved with developing the Guidance Documentation for the Implementation of Rectal Spacers for Prostate Cancer Patients in Ontario?

In 2022/2023, OH-CCO formed a GU Working Group to support the development and endorsement of the Guidance Documentation for the Implementation of Rectal Spacers for Prostate Cancer Patients in Ontario. The purpose of the guidance document is to ensure the appropriate patient selection and funding criteria for rectal spacers were met. The GU Working Group had an existing membership that was formed in 2018 and was originally selected by the Regional Vice-Presidents and Regional Directors to guide the work of the RT-QBP. The working group membership is made up of Medical Physicists, Radiation Oncologists and Radiation Therapists.

#### 6. How was patient eligibility criteria for funding Rectal Spacers developed?

A guidance document (Guidance Documentation for the Implementation of Rectal Spacers for Prostate Cancer Patients in Ontario) with patient eligibility criterion for treatment prioritization was developed based on the recommendations of authors and reviewers from the expert panel of the Quality Initiative of the Program in



Evidence-Based Care (PEBC, 2019) guidance document on *Biodegradable Rectal Spacers for Prostate Cancer Radiotherapy*, and Radiation Oncologists from the Genitourinary (GU) Disease Pathway Management program at OH-CCO.

#### 7. Where can I find the rectal spacers resources?

The following resources for the rectal spacers reimbursement program can found can be found on the <a href="RTP">RTP</a>
<a href="RTP">Resource Hub</a> under the tab, "Rectal Spacers Reimbursement Program". The following rectal spacers resources are available:</a>

- PEBC Biodegradable Rectal Spacers for Prostate Cancer Radiotherapy
- Special Access Program Form Rectal Spacers Reimbursement Form for Prostate Cancer Patients
- Policy: Special Access Program for Rectal Spacers
- Policy: Special Access Program for Rectal Spacers Resubmission & Appeals
- Policy: Rectal Spacers Implementation Guidance Document for Prostate Cancer Patients in Ontario
- Rectal Spacers Reimbursement Program Frequently Asked Questions (FAQ)

#### 8. How will funding be allocated if treatment is split between two Regional Cancer Centres?

In a case where a region has received a request from another Regional Cancer Centre for insertion of a rectal spacer, it is recommended that the centres establish a local funding agreement between the two regions. Funding will only be provided to the facility completing the radiation treatment protocol.

For example, a prostate cancer patient receives Stereotactic Body Radiation Therapy (SBRT) treatment at Regional Cancer Centre 1 but the rectal spacer is inserted at Regional Cancer Centre 2. In this example, centre 1 receives the RT-QBP treatment funding for the RT protocol as well as the cost of the rectal spacer and insertion. As such, it is recommended that a funding agreement is established between the two centres to divide the funding allocation as required.

#### 9. Who can I contact for questions about the Rectal Spacers Reimbursement Program?

For any inquiries or questions related to rectal spacers, please contact the RTP inbox:

c/o: Radiation Treatment Program

• E-mail: OH-CCO\_RTP@ontariohealth.ca



### **Special Access Program for Rectal Spacers**

#### 10. What is the Special Access Program (SAP) for Rectal Spacers?

The SAP for rectal spacers assesses requests for rectal spacers for prostate cancer patients on a case-by-case basis that do not meet the current eligibility criteria for the RT-QBP funding and where other standard treatment approaches are not appropriate. SAP requests for rectal spacers are reviewed by a clinical expert, who can take up to two weeks to review and provide a decision (please see question 14 and 15 for more information on regarding the reviewal process, approval, and timelines). In the case where the SAP request is denied, the applicant can choose to re-submit through the Rectal Spacers Resubmission and Appeals Policy (please see question 10 for more information).

#### 11. What is the Rectal Spacers Resubmission and Appeals Policy?

If the SAP request is denied, the applicant will be informed via email by the Radiation Treatment Program (RTP) of the decision, and the SAP form will be left in the MFT folder for the centre to access. The applicant can choose to re-submit through the Resubmissions and Appeals policy and may choose one of the following options:

- I. **Resubmission**: The applicant may request a resubmission if they have new evidence or medical documentation that may change the decision.
- II. **Appeal**: The applicant may appeal if the *SAP for Rectal Spacers Policy* was wrongfully applied but does not have new evidence or pertinent medical documentation that may change the decision.

#### 12. Who completes and submits the SAP form for the patient?

The SAP Rectal Spacers applicant (completing the form and submitting) 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.

#### 13. Where do I submit my SAP form once it is complete?

SAP form submissions must be uploaded via the Regional Cancer Centre's MFT folder under Rectal Spacer SAP that is designated to assigned members of each centre. We ask that the Regional Cancer Centre informs the Radiation Treatment Program (RTP) via email (OH-CCO\_RTP@ontariohealth.ca) that an SAP form has been added to the Rectal Spacer MFT SAP folder for review. It is important to note that SAP form submissions cannot be submitted via email as they contain PHI.



#### 14. What is the process once an application is submitted to the SAP?

Once a form has been submitted for review, the Radiation Treatment Program (RTP) will send the SAP Form (removing all PHI) to the Clinical Expert Reviewer, who can take up to two weeks to review and provide a decision. Clinical Expert Reviewers are responsible for providing clinical expertise to the Provincial Head of Radiation Treatment Program to determine if the request should or should not receive funding. (*Please see question 15 for process diagram*).



#### 15. What is the process and timelines associated with the Rectal Spacers SAP?





