

Policy owner: Radiation Treatment Program Effective Date: April 1, 2022

Contact: OH-CCO_RTP@ontariohealth.ca Revised Date:

Policy: Special Access Program for Rectal Spacers – Resubmission & Appeals

The Radiation Treatment Program (RTP) at Ontario Health (Cancer Care Ontario) will consider requests to the Special Access Program (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 Patient Indications for Treatment Prioritization for funding and where other standard treatment approaches are not appropriate.

This SAP for Rectal Spacers – Resubmission & Appeals Policy (**Policy**) outlines the case-by-case Resubmission and Appeals process of the SAP for Rectal Spacers.

A. OVERVIEW

There are two options available to an Applicant who has received a negative funding decision from the SAP for Rectal Spacers:

- I. **Resubmission**: The Applicant may request a Resubmission if he/she has new evidence or pertinent medical documentation that he/she believes may change the decision.
- II. **Appeal**: The Applicant may Appeal if he/she believes that the *SAP for Rectal Spacers Policy* was wrongfully applied but does not have new evidence or pertinent medical documentation that may change the decision.

B. PURPOSE

The purpose of this Policy is to:

- I. ensure that Ontario Health (Cancer Care Ontario) clearly defines the eligibility criteria for Resubmissions and Appeals; and
- II. outline the assessment process for eligible Resubmissions and Appeals.

C. DEFINITIONS

Defined terms not otherwise defined in this Policy have the meanings set out in the SAP for Rectal Spacers Policy.

Appeal: An Initial Request or Resubmission has been denied funding, and the Applicant requests a review of the previous decision(s) because he/she believes the *SAP for Rectal Spacers Policy* was wrongfully applied but does not have new evidence or pertinent medical documentation that may change the decision.

Applicant: The patient's treating radiation oncologist who submitted the Initial Request.

Initial Request: A request submitted pursuant to the SAP for Rectal Spacers Policy.

Resubmission: An Initial Request has been denied funding and the Applicant requests a review by the same Reviewers because he/she has new evidence or pertinent medical documentation that he/she believes may change the decision.

Reviewer: A radiation oncologist with expertise in prostate cancer who provides a recommendation as to whether the Applicant's request meets the criteria of the *SAP for Rectal Spacers Policy* or this Policy.

D. ELIGIBLE APPLICANTS

In order to be eligible to request a Resubmission or Appeal a negative funding decision, the Applicant for the Resubmission or Appeal must be the same individual who applied to the SAP for Rectal Spacers initially (i.e., the treating radiation oncologist who submitted the Initial Request). Patients (as well as family members, caregivers, etc.) cannot directly request a Resubmission or Appeal a negative funding decision.

E. FILING PROCESS

- I. The Applicant must upload a file a request for a Resubmission or Appeal to their assigned MFT folder. **PHI must NOT** be sent via email.
- II. The Applicant must identify whether the request is for a Resubmission or Appeal.
- III. Upon receipt, the RTP will screen the request against the eligibility criteria for Resubmissions or Appeals as applicable (see **Sections F and G**).

F. RESUBMISSIONS

Eligibility Criteria:

- I. An Applicant may request a Resubmission of a negative funding decision rendered after an Initial Request, if he/she has new evidence or pertinent medical documentation that he/she believes may change the decision.
- II. The Applicant must submit the request for Resubmission within 30 days of notification of the negative funding decision by the RTP.
- III. The Applicant must use the **Special Access Form Rectal Spacers Reimbursement Program** to request a Resubmission. In the "Other Information" section of the form, the Applicant must include the date of the Initial Request and must clearly:
 - list of all of the SAP for Rectal Spacers Policy criteria that the Initial Request failed to satisfy; and
 - describe how the new evidence or pertinent medical documentation should change the decision.

Process:

- I. The RTP will forward eligible Resubmission requests to the same Reviewers who assessed the Initial Request.
- II. The Reviewers will:
 - review the Initial Request with the new evidence or pertinent medical documentation against the SAP for Rectal Spacers Policy; and
 - make a recommendation to approve or reject funding.
- III. If the Initial Request was originally reviewed by two Reviewers and there are divergent clinical opinions by the two original Reviewers, the RTP will obtain an opinion by a third Reviewer.
- IV. Ontario Health (Cancer Care Ontario) will make the funding decision, taking into consideration the recommendations from the Reviewers.
- V. The RTP will inform the Applicant in writing (i.e. email) of the funding decision and rationale for the decision.

G. APPEALS

Eligibility Criteria:

- I. An Applicant may Appeal a negative funding decision rendered after an Initial Request or Resubmission, if he/she believes that the *SAP for Rectal Spacers Policy* was wrongfully applied but he/she does not have new evidence or pertinent medical documentation that may change the decision.
- II. The Applicant must submit the Appeal within 30 days of notification of the negative funding decision by the RTP.
- III. The Applicant must use the **Special Access Form Rectal Spacers Reimbursement Program** to submit an Appeal. In the "Other Information" section of the form, the Applicant must clearly:
 - list the SAP for Rectal Spacers Policy criteria that the Initial Request failed to satisfy;
 - describe how the SAP for Rectal Spacers Policy was incorrectly applied or interpreted;
 and
 - comprehensively refute the grounds for rejection.

Process

- I. RTP will forward eligible Appeals for independent external review by at least two Reviewers who did not assess the Initial Request.
- II. The Reviewers will:



- review the Appeal and Initial Request against the review criteria in the SAP for Rectal Spacers Policy;
- determine whether the grounds for Appeal are reasonable and just, given the evidence and the review criteria; and
- make a recommendation to approve or reject funding.
- III. 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 by the Reviewers, RTP will obtain an opinion by a third Reviewer who did not assess the Initial Request.
- IV. Ontario Health (Cancer Care Ontario) will make the final decision to either uphold or overturn the negative funding decision, taking into consideration the recommendations from the Reviewers.
- V. The RTP will inform the Applicant in writing (i.e. email) of the final funding decision and rationale for the decision.

H. TIMELINES FOR REVIEW

- I. The RTP will aim to provide a decision on a Resubmission or Appeal as soon as possible. Due to the complexity of these cases and the need for external review, a final decision may take up to 2 weeks.
- II. An incomplete request for Resubmission or Appeal may result in longer turnaround times.

I. PROGRAM REPORTING

In addition to collecting and using PHI in the application to verify eligibility, Ontario Health (Cancer Care Ontario) collects and uses PHI (from the Ministry and Applicants) for the purpose of health system planning. This aligns with Ontario Health (Cancer Care Ontario)'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 (Cancer Care Ontario)'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

Email: OH-CCO RTP@ontariohealth.ca