Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Sacituzumab Govitecan - HR-positive HER2-negative Unresectable Locally Advanced or Metastatic Breast Cancer

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: .....

* Given Name: .....

* OHIN: ..... * Chart Number: .....

* Postal Code: .....

* Height (cm): ..... * Weight (kg): .....

* BSA (m^2): ..... * Gender: ○ Male ○ Female ○ Other

* Date of Birth: ....
Day Month Year

* Site:

* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

Other (specify): .....

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

- ○ 1-Unknown primary (submit pathology report and clinic note)
- ○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- ○ 3-Regimen modification - schedule (complete questions a and b)
- ○ 4-Regimen modification - drug substitutions (complete questions a and c)
- ○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- ○ 6-Maintenance therapy delay (submit clinic note)
- ○ 7-Prior systemic therapy clinical trials (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ Other (specify)

.....

All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: ....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

Sacituzumab govitecan will be used for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative breast cancer who have been treated with all of the following therapies: ☐ Yes

- At least 1 taxane,
- At least 1 prior anticancer hormonal treatment,
- At least 1 cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor; AND
- Refractory to or have relapsed after at least 2 systemic chemotherapy regimens for metastatic disease.

Patients must have a good performance status and must not have active central nervous system (CNS) metastases and/or carcinomatous meningitis.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Is the patient transitioning from a private payer? ○ Yes ○ No

d. If yes, please indicate the date of the last administered dose _____ _____ _____
Day Month Year

4. Funded Dose

Sacituzumab govitecan 10 mg/kg intravenously (IV) on days 1 and 8 of each 21-day cycle.

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: SACI]

5. Notes

1. (Neo)adjuvant therapy given for early-stage disease would qualify as one of the two required prior systemic therapies if the development of unresectable locally advanced or metastatic disease occurred within a 12-month period of initiation of the therapy.

2. Patients must not have received prior treatment with a topoisomerase 1 inhibitor as a free form or as part of other formulations. However, patients who experienced intolerance or severe toxicity to prior topoisomerase 1 inhibitor therapy may be considered for sacituzumab govitecan funding provided all other NDFP funding criteria are met.

3. Patients who have medical contraindications to taxanes may be considered for sacituzumab govitecan funding under this policy provided all other funding criteria are met.

4. Patients who progress on sacituzumab govitecan in the metastatic setting will be ineligible for NDFP funded trastuzumab deruxtecan for HER2-low disease as a subsequent line of therapy (and vice versa). However, patients who develop intolerance or toxicities while on sacituzumab govitecan may switch to trastuzumab deruxtecan (and vice versa) provided the patient meets the funding criteria and has experienced no disease progression.

5. According to the provisional funding algorithm from Canada's Drug Agency, patients must follow the treatment options outlined according to their breast cancer classification. Patients will be ineligible for public funding if the patient was treated using therapies for HR-positive, HER2-negative disease then switched to therapies used for triple negative disease (and vice versa). If new information regarding the patient's breast cancer classification becomes available (i.e., a new biopsy with updated biomarker results), your patient may be eligible to switch. In these circumstances, please submit a prior approval request including the new pathology results and clinic note(s) outlining the revised treatment plan.

6. FAQs

1. **My patient is currently receiving sacituzumab govitecan through non-publicly funded means (e.g. patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - Pathology report confirming diagnosis of HR-positive, HER2-negative breast cancer,
   - From treatment initiation, a clinic note outlining the patient's treatment history and imaging (if applicable), and
   - The most recent clinic note and imaging (if applicable).

3. **My patient was not able to receive prior therapy with a CDK4/6 inhibitor. Can they still be treated with sacituzumab govitecan?**

   On a time-limited basis, patients who were not able to access a CDK4/6 inhibitor as a prior line of therapy and are no longer eligible for it can be funded for sacituzumab govitecan, provided all other funding criteria are met.

Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Pathology report confirming diagnosis of HR-positive, HER2-negative breast cancer
- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.

Signature of Attending Physician (MRP-Most Responsible Physician): .....

Day Month Year

Form 1109