Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Sacituzumab Govitecan - Unresectable Locally Advanced or Metastatic Triple Negative 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

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 is used for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC*) who have received two or more therapies, with at least one therapy used to treat metastatic disease, and have a good performance status. ☐ Yes

Eligible patients must have adequate blood counts and organ function, stable or no brain metastases.

*Refers to lack of expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) as per the American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines.

3. Baseline Information

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

b. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

c. If yes, please indicate the funding source
○ Private payer
○ Manufacturer patient support program

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 documented radiographic disease progression, unacceptable toxicity, or clinical deterioration, whichever comes first.

[ST-QBP regimen code: SACI]

5. Notes

1. Functional TNBC is defined as hormone receptor (HR)-low disease (estrogen receptor and/or progesterone receptor 1-10% staining by IHC). According to the Canadian Agency for Drugs and Technologies in Health's provisional funding algorithm, patients with HR-low disease may be treated as functionally triple-negative and should consistently pursue treatments based on the same funding algorithm (i.e., TNBC), unless new information becomes available (e.g., new biopsy with updated biomarker results).

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 for sacituzumab govitecan 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:
   - A clinic note and imaging (if applicable) from treatment initiation
   - The most recent clinic note and imaging (if applicable)

   Please note: patients who meet NDFP criteria but who are enrolled and receiving treatment through the manufacturer's patient support program (PSP) are eligible to receive free drug through the PSP until **September 8, 2023, inclusive**. Hospitals/cancer centres should coordinate the supply of free drug between the PSP and their respective sites, if not done so already.

   After this date, patients who met public funding criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. **My patient was unable to receive a taxane in a previous line of therapy due to a contraindication. Would my patient be eligible for NDFP funding of sacituzumab govitecan?**

   Patients who were unable to receive a taxane due to a contraindication or who are intolerant to a taxane will be eligible for funding of sacituzumab govitecan provided that all other eligibility 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 TNBC as per ASCO/CAP guidelines.
- Clinic note(s) confirming treatment and patient history/response.
- CT and/or MRI scans confirming advanced disease.

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

Day Month Year