Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Dostarlimab - Primary Advanced or Recurrent MSI-H or dMMR Endometrial 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)

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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

* Dostarlimab will be used in combination with platinum doublet chemotherapy for the treatment of adult patients with primary advanced or recurrent mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) endometrial cancer that is not amenable to curative therapy. Patients must also have a good performance status.	☐ Yes
In addition to the above, the patient must meet one (or more) of the following eligibility criteria (select all that apply)	○ Have primary advanced (stage III or IV) endometrial cancer. ○ Have not received systemic anticancer therapy for advanced disease and this is the patient's first recurrence. ○ Have received (neo)adjuvant systemic anticancer therapy and the first recurrence is at least 6 months after completing (neo)adjuvant therapy.

Patients must not:

- Have experienced their first disease recurrence within 6 months of completing (neo)adjuvant systemic anticancer therapy; OR
- Been previously treated with an anti–PD-1, anti–PD-L1, or anti–PD-L2 drug for advanced disease; OR
- Have uncontrolled brain metastases.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment	○ 0	○ 1	○ 2
b. Stage of disease	○ Stage III	○ Stage IV	
c. Is the patient transitioning from a private payer or compassionate program?	○ Yes	○ No	
d. If yes, please indicate the funding source	○ Private payer	○ Manufacturer patient support program	

e. If yes, how many doses of dostarlimab did the patient receive prior to the transition?

○ N/A	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
○ 7	○ 8	○ 9	○ 10	○ 11	○ 12	○ 13
○ 14	○ 15	○ 16	○ 17	○ 18	○ 19	○ 20
○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28						

f. If yes, please indicate the date of the last administered dose.

Day ..... Month ..... Year .....

4. Funded Dose

Cycles 1 to 6 :
Dostarlimab (in combination with carboplatin and paclitaxel) 500 mg intravenously (IV) every 3 weeks

Cycles 7 to 29:
Dostarlimab 1000 mg IV every 6 weeks

Treatment should continue until disease progression or unacceptable toxicity up to a maximum of 3 years, whichever comes first.

[ST-QBP regimen code(s): CRBPPACL+DOST, DOST(MNT)]

5. Notes

1. Patients who complete 3 years' worth of dostarlimab without disease progression or recurrence may receive up to an additional 1 year's worth of dostarlimab (restarted with carboplatin and paclitaxel chemotherapy) at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for the initial course of treatment.

6. FAQs

1. **My patient is currently receiving dostarlimab 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:
   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

   Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until April 10, 2025, inclusive.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. **My patient has a contraindication to either a platinum or paclitaxel chemotherapy. Will my patient be eligible for dostarlimab funding if they cannot be initiated on both a platinum and paclitaxel? Can an alternate chemotherapy backbone be initiated with dostarlimab?**

   For patients who have a contraindication to platinum chemotherapy, single agent paclitaxel may be given with dostarlimab at the discretion of the treating clinician. Similarly, if a patient has a contraindication to paclitaxel, single agent platinum may be given with dostarlimab. Dostarlimab will not be funded if administered with an alternate chemotherapy backbone that does not include a platinum and/or paclitaxel.

4. **My patient is receiving carboplatin, paclitaxel, and dostarlimab but cannot tolerate the chemotherapy portion. Going forward, will dostarlimab be funded if given as a monotherapy?**

   For patients who have initiated treatment and cannot tolerate the chemotherapy portion, dostarlimab will be funded as monotherapy.

5. **My patient is currently receiving a platinum and paclitaxel. Can I add dostarlimab to the chemotherapy backbone?**

   Provided the patient has not progressed on treatment and meets all the eligibility criteria, the addition of dostarlimab may be funded under this policy. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history and response to treatment, if able to assess.

6. **My patient has been receiving maintenance dostarlimab and required a treatment interruption due to surgery or toxicity (i.e.: not due to disease progression). Can I restart dostarlimab in combination with carboplatin and paclitaxel?**

   Patients will be eligible to restart dostarlimab with carboplatin and paclitaxel provided the treatment interruption was not due to disease progression.

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:

- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.

- For instances where there is pseudoprogression:
  - o Clinic note documenting the assessment and decision to continue, AND
  - o Confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

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

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Day Month Year

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