Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Dinutuximab - Pediatric High-Risk Neuroblastoma

(This form must 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: ○ ANBL1531 ○ 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
- ○ 9-Supplemental doses requested
- ○ 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

The patient must meet the following criteria:

- In combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2) and retinoic acid (RA) for the treatment of pediatric patients who achieve a response to prior pediatric protocol first-line multi-agent, multimodal therapy. ☐ Yes

3. Baseline Information

a. Performance Status (Lansky or Karnofsky) at time of enrolment ○ 50 ○ 60 ○ 70 ○ 80 ○ 90 ○ 100

b. Response before autologous stem cell transplantation (ASCT)
○ Complete Response (CR)
○ Very Good Partial Response (VGPR)
○ Partial Response (PR)

4. Funded Dose

Dinutuximab
Cycles 1-5
17.5 mg/m^2 per day intravenously (IV) for 4 days during each of the cycles.

GM-CSF
Cycles 1, 3, 5
250 mcg/m^2/day subcutaneously (SC) for 14 days during each of the cycles, starting 3 days before the start of dinutuximab.

Treatment should be continued until unacceptable toxicity or disease progression to a maximum of six cycles of dinutuximab in combination with GM-CSF, IL-2 and RA. (I.e., for clarification, a maximum of five cycles of dinutuximab are administered. The sixth treatment cycle only includes RA.)

5. Notes

1. The High Cost Therapy Funding Program (HCTFP) will provide coverage of dinutuximab and GM-CSF in both the inpatient and outpatient settings, provided that funding criteria are met.

2. The HCTFP will allow funding of dinutuximab and GM-CSF when used in an adapted regimen where IL-2 is removed from Cycles 2 and 4 and GM-CSF is administered with all dinutuximab-containing cycles (i.e., up to 5 cycles (70 doses) of GM-CSF will be allowed).

3. Dinutuximab and GM-CSF will be reimbursed on a per vial basis.

4. Treatment with dinutuximab should only be delivered in specialized pediatric cancer centers with experience and knowledge of managing neuroblastoma.

6. FAQs

i. **My patient is currently receiving dinutuximab and/or GM-CSF through private means. Can my patient be transitioned over to receive funding under the HCTFP?**

Provided the funding 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 of dinutuximab and/or GM-CSF under the HCTFP.

ii. **Are dinutuximab and GM-CSF funded for relapsed/refractory neuroblastoma?**

Provided funding criteria are met, patients who have relapsed/refractory high-risk neuroblastoma may be eligible for dinutuximab and GM-CSF. Please enroll under the "Dinutuximab - Pediatric Relapsed or Refractory High-Risk Neuroblastoma" policy.

iii. **Why will the HCTFP fund the cost of dinutuximab and GM-CSF in the inpatient setting?**

The HCTFP recognizes that the administration of a dinutuximab-based regimen will require hospitalization for a portion of the treatment, while the remaining administration can occur in the outpatient setting. Given these challenges, the HCTFP will fund these drugs in both inpatient and outpatient settings.

iv. **How will claims for the inpatient use be managed in eClaims?**

For sites using OPIS with eClaims, the inpatient/outpatient status will be automatically captured when the claim is submitted; no additional work is required. Sites using DSP or HL7 must submit claims manually until March 13, 2023 (as per communication on August 10, 2022). For all sites submitting manually, please ensure the treatment setting is selected appropriately on the treatment claim within the eClaims web application. Once a patient is discharged from hospital, subsequent injections (i.e., for GM-CSF) are administered in the outpatient setting. Sites should select "Outpatient" as the treatment setting.

v. **How is the price of GM-CSF determined?**

GM-CSF is a drug made available to eligible patients in Canada under Health Canada’s Special Access Programme and is priced in USD. As a result, the HCTFP will recalibrate the best available price (“BAP”) for GM-CSF on an annual basis per fiscal year. Sites will be asked to upload their acquisition cost for GM-CSF and the HCTFP will arrive at an average price for the fiscal year. The annual average Bank of Canada exchange rate from the previous year will be used to determine the USD to CAD conversion.

7. Supporting Documents

None required for this policy.

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

- Clinic notes confirming the patient’s diagnosis and response to first-line multi-agent, multimodal therapy.

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

....
Day Month Year

Form 965