Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Dinutuximab - Pediatric Relapsed or Refractory 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: ○ ANBL1821 ○ 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

Dinutuximab is used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), irinotecan and temozolomide for the treatment of patients with high-risk neuroblastoma in first relapse or with refractory disease. ☐ Yes

3. Baseline Information

a. Karnofsky (for patients 16 years old and older) or Lansky (for patients under 16 years old) Performance Status ○ 50 ○ 60 ○ 70 ○ 80 ○ 90 ○ 100

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

c. If yes, how many cycles of dinutuximab did the patient have prior to the transition?
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10
○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16

4. Funded Dose

Dinutuximab
17.5 mg/m^2/day intravenously (IV) for 4 days during each cycle.

GM-CSF
250 mcg/m^2/day subcutaneously (SC) for 7 days during each cycle.

All cycles are given in combination with temozolomide and irinotecan as part of an every 21-day cycle.

Treatment should be continued until unacceptable toxicity or disease progression to a maximum of 17 cycles of dinutuximab in combination with GM-CSF, irinotecan and temozolomide.

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

3. Patients with high-risk neuroblastoma who were previously treated for refractory or relapsed disease will not be eligible for funding under this policy.

4. Refractory disease is defined as inadequate response to treatment that included at least 4 cycles of 2 or more chemotherapy agents, including an alkylator and a platinum agent.

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

6. Treatment beyond 6 cycles requires documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation must be submitted with the treatment claims.

6. FAQs

i. **My patient is currently receiving dinutuximab and GM-CSF for relapsed or refractory high-risk neuroblastoma that is paid for by alternate means (e.g., patient support program, private insurance, hospital budget, etc.). Can my patient be transitioned over to receive funding under the High-Cost Therapy Funding Program (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 GM-CSF under the HCTFP. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the response to treatment, if able to assess, and the number of cycles of dinutuximab and GM-CSF received to date.

Funding is for a maximum of 17 cycles, regardless of funding source.

ii. **My patient received dinutuximab and GM-CSF as a part of their upfront treatment for high-risk neuroblastoma. Will they be eligible for dinutuximab and GM-CSF in the relapsed or refractory setting?**

Provided that the patient did not have a severe reaction or progressive disease during upfront therapy with dinutuximab, and they have not received any treatment for relapsed or refractory high-risk neuroblastoma, they may be eligible for funding under this 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 list price of GM-CSF determined?**

GM-CSF is a drug made available to eligible patients in Canada under Health Canada’s Special Access Program 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 at enrolment. For treatment beyond 6 cycles, documentation showing continued evidence of benefit must be submitted.

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

- Clinic notes confirming the patient’s diagnosis, and imaging demonstrating response to therapy.

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

....
Day Month Year