Français

Preamble

Daratumumab (Darzalex®) for intravenous infusion has been approved for addition to the New Brunswick Hospital Formulary in combination with Bortezomib and Dexamethasone for the treatment of multiple myeloma after at least one prior treatment. The formulary approval process by the Provincial Drugs and Therapeutics Committee includes recommendations by the New Brunswick Cancer Network (NBCN), the Provincial Oncology Formulary Advisory Committee which is advisory to NBCN and, the Canadian Agency for Drugs and Technologies in Health (CADTH) Expert Review Committee of the pan-Canadian Oncology Drug Review (pCODR). The pCODR is the national process for the review and assessment of oncology drugs, which considers the available information about new oncology drugs and/or indications, including clinical evidence, cost-effectiveness and patient perspectives.

Further information about the pCODR recommendation and supporting documentation can be obtained on the pCODR website:

https://www.cadth.ca/darzalex-multiple-myeloma-second-line-or-beyond-details

Policy Statement

Daratumumab (Darzalex®) will be funded by the Department of Health (DH) when used according to the following criteria:

In combination with Bortezomib and Dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Patients must have a good performance status. Treatment with daratumumab should be discontinued upon disease progression or unacceptable toxicity.

Note:

- DH funding is limited to one triplet therapy for patients with relapsed/refractory multiple myeloma (i.e., daratumumab or carfilzomib based triplet therapy).

Regional Health Authorities (RHAs) will be reimbursed for daratumumab costs associated with the treatment of eligible patients. **Reimbursement will occur on a 'mg per mg' basis**. The Eligibility Form must be completed and submitted to the Department of Health.

Privacy/Security Statement:

While it is recognized that processes may differ between and within RHAs, it is essential that procedures and systems are in place to protect the privacy of personal health information. Refer to Health System Bulletin FN1006 for procedures on submitting budget amendment requests. DH will accept electronic submission of budget amendment requests via email at dhbars@gnb.ca. The following are recommended when emailing personal health information:

1. Email to be sent from a GNB managed device to another GNB managed device
2. Email to be sent only to a GNB email account
3. Do not put personal health information in the subject line
4. Mark the email as CONFIDENTIAL in the subject line
5. Double-check recipient's email address

Eligibility Form: Daratumumab (Darzalex®) in combination with Bortezomib and dexamethasone for relapsed/refractory multiple myeloma

1. Patient Initials (First/Middle/Last): _____

2. Date of Birth: _____ - _____ - _____
   Day Month Year

3. **NB** Medicare Number: _____

4. Regional Health Authority: _____ Initial _____ Subsequent

   Treatment Facility: _____ Initial _____ Subsequent

5. Attending Physician: _____

6. Eligibility Criteria - **Each** of the following criteria must be met:

   i. Patient is diagnosed with multiple myeloma and has received at least one prior therapy ☐ Yes

   ii. Patient will receive daratumumab in combination with Bortezomib and dexamethasone. ☐ Yes

   iii. Patient has not experienced disease progression during treatment with a proteasome inhibitor ☐ Yes

   iv. Patient has not been previously treated with daratumumab triplet therapy or carfilzomib triplet therapy in the relapsed/refractory setting ☐ Yes

   v. Patient has a good performance status ☐ Yes

   Daratumumab dosing – refer to appropriate protocol. Treatment should be discontinued upon disease progression or unacceptable toxicity.

   Note: Type and screen is recommended prior to initiating therapy due to interaction with blood compatibility testing.

7. Planned date of first dose: _____ - _____ - _____
   Day Month Year

_____ _____
Prescribing Physician (Signature) Date

Completed form and Budget Amendment Request to be submitted to Department of Health in a secure & confidential manner. **Reference: Hospital Services Bulletin PS 2077**