

Bulletin #721

July 30, 2008

BENEFIT CHANGES TO NBPDP

This update to the New Brunswick Prescription Drug Program (NBPDP) Formulary is effective July 30, 2008.

Included in this bulletin:

- Proton Pump Inhibitors (PPIs) follow-up information
- Regular Benefit Additions
- Special Authorization Additions and Revised Criteria
- Drugs Reviewed and Not Listed

To subscribe or unsubscribe from the Bulletin e-mail notification list, please send a message to BC_nbpdp@medavie.bluecross.ca or call 1-800-332-3691. Bulletins are also available on the NBPDP web page: www.gnb.ca/0051/0212/index-e.asp

If you have any questions or concerns, please contact our office at 1-800-332-3691.

Yours truly,



Debbie LeBlanc
New Brunswick Prescription Drug Program

PROTON PUMP INHIBITORS (PPIs) FOLLOW-UP INFORMATION

As previously announced, effective June 30, 2008, omeprazole and rabeprazole are listed as regular NBPDP benefits when prescribed in doses up to 20mg daily.

Special authorization is required for omeprazole and rabeprazole doses greater than 20mg daily and for lansoprazole and pantoprazole.

To facilitate the implementation of this change in benefit status, please note that:

- Patients with existing special authorization for PPIs will not be affected by the quantity limit until their current coverage period expires.
- Patients who have had a prescription for lansoprazole and pantoprazole from a gastroenterologist in the past 100 days will have a one year special authorization approval established based on their current dose. A new special authorization request will be required when either the coverage period expires or the quantity limit is reached.
- Starting October 1, 2008, the quantity limit for omeprazole and rabeprazole will be 200 x 20mg or 400 x 10mg tablets/capsules bi-annually rather than a floating time period.

REGULAR BENEFIT ADDITIONS

Drug/Form/Route/Strength	Brand Name	DIN	Manufacturer	Plans	\$	
Desmopressin						
Tab Orl	60mcg	DDAVP [®] Melt	2284995	FEI	EFG -18	AAC
	120mcg	DDAVP [®] Melt	2285002	FEI	EFG -18	
Dexamethasone						
Tab Orl	2mg	pms-Dexamethasone [®]	2279363	PMS	AEFGVW	AAC
Irbesartan / hydrochlorothiazide						
Tab Orl	300mg/25mg	Avalide [®]	2280213	BRI	AEFGVW	AAC
Lopinavir / ritonavir						
Tab Orl	200mg/50mg	Kaletra [®]	2285533	ABB	U	AAC

SPECIAL AUTHORIZATION ADDITIONS

Desmopressin
(DDAVP[®] Melt)
60mcg and 120mcg
tablets

For the management of diabetes insipidus.

Note: Desmopressin is a regular benefit for plans EFG -18.

SPECIAL AUTHORIZATION ADDITIONS

Itraconazole
(*Sporanox*[®])
100mg capsules

1. For the treatment of severe systemic fungal infections.
 2. For the treatment of severe or resistant fungal infections in immunocompromised patients.
 3. For the treatment of severe onychomycosis when used as pulse therapy;
 - Reimbursement for the treatment of fingernail mycosis is limited to 56 x 100mg capsules over an 8 week period.
 - Reimbursement for the treatment of toenail mycosis is limited to 84 x 100mg capsules over a 12 week period.
-

Alglucosidase alfa
(*Myozyme*[®])
50mg vial injection

For the treatment of infantile-onset Pompe disease, as demonstrated by onset of symptoms and confirmed cardiomyopathy within the first 12 months of life.

Monitoring of therapy

The monitoring of markers of disease severity and response to treatment must include at least:

1. Weight, length and head circumference.
2. Need for ventilatory assistance, including supplementary oxygen, CPAP, BiPAP, or endotracheal intubation and ventilation.
3. Left ventricular mass index (LVMI) as determined by echocardiography (not ECG alone).
4. Periodic consultation with cardiology.
5. Periodic consultation with respiratory.

Withdrawal of therapy

1. Patients to be considered for reimbursement of drug costs for alglucosidase alfa treatment must be willing to participate in the long-term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.
 2. The development of the need for continuing invasive ventilatory support after the initiation of ERT should be considered a treatment failure. Funding for ERT should not be continued for infants who fail to achieve ventilator-free status, or who deteriorate further, within 6 months after the initiation of ventilatory support.
 3. Deterioration of cardiac function, as shown by failure of LV hypertrophy (as indicated by LV mass index) to regress by more than Z=1 unit, or persistent clinical or echocardiographic findings of cardiac systolic or diastolic failure without evidence of improvement, in spite of 24 weeks of ERT, should be considered a treatment failure and funding for ERT should be discontinued.
-

SPECIAL AUTHORIZATION ADDITIONS

Pegfilgrastim
(Neulasta[®])
6mg prefilled syringe

Reimbursement of pegfilgrastim is available through special authorization as part of an NBPDP Pilot Project to monitor usage. See enclosed information sheet for details.

Requests will be considered when prescribed by, or on the advice of, a hematologist or medical oncologist for the following indications:

Chemotherapy Support

- **Primary prophylaxis:**
For use in previously untreated patients receiving a moderate to severely myelosuppressive chemotherapy regimen (i.e. $\geq 40\%$ incidence of febrile neutropenia). Febrile neutropenia is defined as a temperature $\geq 38.5^{\circ}\text{C}$ or $> 38.0^{\circ}\text{C}$ three times in a 24 hour period and neutropenia with an absolute neutrophil count (ANC) $< 0.5 \times 10^9/\text{L}$.
- **Secondary prophylaxis:**
 - For use in patients receiving myelosuppressive chemotherapy who have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or
 - For use in patients who have experienced a dose reduction or treatment delay longer than one week, due to neutropenia.
- **Dosing for chemotherapy support:**
The recommended dosage of pegfilgrastim is a single subcutaneous injection of 6mg, administered once per cycle of chemotherapy. Pegfilgrastim should be administered no sooner than 24 hours after the administration of cytotoxic chemotherapy.

Pegfilgrastim is not indicated and requests will not be considered for the following:

- Myeloid malignancies
- Pediatric patients with cancer receiving myelosuppressive chemotherapy
- Non-malignant neutropenias
- Stem-cell transplantation
- Treatment or prevention of febrile neutropenia in the palliative setting

Note: Filgrastim (Neupogen[®]) dosing is 5 mcg/kg/day. For patients ≤ 60 kg who are prescribed filgrastim 300mcg for 9 or fewer days, the cost for filgrastim therapy is less than the cost of pegfilgrastim 6mg.

SPECIAL AUTHORIZATION – REVISED CRITERIA

Carvedilol
(*Coreg*[®])
3.125mg, 6.25mg,
12.5mg and 25mg
tablets

For the treatment of stable symptomatic heart failure in patients with a left ventricular ejection fraction (LVEF) less than or equal to 40%.

Prescriptions written by cardiologists or internists do not require special authorization.

DRUGS REVIEWED AND NOT LISTED

The reviews of the following products found they did not offer a therapeutic and/or cost advantage over existing therapies. Requests for coverage through special authorization will not be considered.

Delta-9-tetrahydrocannabinol (THC) / Cannabidiol – in advanced cancer pain	(<i>Sativex</i> [®])	27mg/mL/25mg/mL – 5.5mL buccal spray
Lanthanum carbonate hydrate	(<i>Fosrenol</i> [®])	250mg, 500mg, 750mg and 1000mg chewable tablets
Posaconazole	(<i>Sprifil</i> [™])	40mg/mL oral suspension
Sitaxsentan	(<i>Thelin</i> [™])	100mg tablets

Pegfilgrastim (Neulasta®) Pilot Project to Assess Usage

BACKGROUND

Pegfilgrastim (Neulasta®) is a long-acting form of recombinant human granulocyte colony-stimulating factor. Pegfilgrastim is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs. Currently, NBPDP lists filgrastim (Neupogen®) under special authorization for this indication.

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that pegfilgrastim be listed for patients with non-myeloid cancer who are receiving regimens with curative intent who are at high risk of developing prolonged neutropenia. In cancer patients who have received myelosuppressive chemotherapy, filgrastim is administered once daily for a maximum of 14 days. Pegfilgrastim is administered as one single injection per cycle of chemotherapy. The cost of pegfilgrastim compared to that of filgrastim may be higher or lower depending on the dose, duration, patient and clinical practice.

PEGFILGRASTIM (Neulasta®) PROJECT

Effective August 1, 2008, a pilot project will be implemented to monitor the usage of pegfilgrastim. During the pilot project, NBPDP will provide coverage for pegfilgrastim through special authorization and assess its utilization in beneficiaries who meet the criteria. Upon completion of the pilot project, a determination will be made with respect to the benefit status for pegfilgrastim on the NBPDP formulary.

ROLE OF AMGEN CANADA PATIENT ASSISTANCE PROGRAM (VICTORY®)

Pegfilgrastim will be supplied to NBPDP beneficiaries through Amgen Canada's Victory Program Pharmacy (Keswick Pharmacy). Once the special authorization request has been approved, the prescribing physician or their delegate enrolls the patient in the manufacturer's Victory Program. The Victory Program enrolment form should be completed and faxed, along with a copy of the prescription, to 1-888-987-2201.

The prescribed quantity of pegfilgrastim is delivered by the Victory Program directly to the patient. The Victory Program pharmacist will provide pharmacy consultation to the patient regarding pegfilgrastim, schedule delivery to the patient, and fill the prescription via cold chain certified delivery.

Victory customer service representatives are available to answer questions from patients or healthcare providers at any time of the day or night at 1-888-706-4717.

MAXIMUM ALLOWABLE PRICE FOR PEGFILGRASTIM (Neulasta®)

A maximum allowable price (MAP) has been established for pegfilgrastim. Claims for pegfilgrastim submitted by pharmacies not associated with the Victory Program will be reimbursed up to the MAP, but no dispensing or other fees will be paid.

FILGRASTIM (Neupogen®) BENEFIT STATUS UNCHANGED

The special authorization criteria, approval process, dispensing and claims reimbursement process for filgrastim (Neupogen®) have not changed. Filgrastim is still listed as a special authorization benefit for NBPDP beneficiaries. Enrolment in the Victory Program is not required.

Filgrastim continues to be the preferred agent in a number of situations:

- Filgrastim is approved for additional indications which Pegfilgrastim has not received Health Canada approval.
- For patients ≤ 60 kg who are prescribed filgrastim 300mcg for 9 or fewer days, the cost of filgrastim therapy is less than the cost of pegfilgrastim 6mg.

FILGRASTIM / PEGFILGRASTIM SPECIAL AUTHORIZATION FORM

A form has been developed to assist with the submission of special authorization requests. This form is available on the NBPDP website at www.qnb.ca/0051/0212/index-e.asp. If you have any questions, please call the NBPDP Inquiry line at 1-800-332-3691.