

Bulletin #705

January 22, 2008

## BENEFIT CHANGES TO NBPDP

This update to the New Brunswick Prescription Drug Program (NBPDP) Formulary is effective January 22, 2008.

**Included in this bulletin:**

- **Special Authorization Additions and Revised Criteria**
- **Drugs Reviewed and Not Listed**

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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

## SPECIAL AUTHORIZATION ADDITIONS

### Adalimumab

(Humira™)

40mg/0.8mL (50mg/mL)

prefilled syringe, prefilled Pen

New indication added to criteria:

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score  $\geq 4$  on 10 point scale) who:
  - have axial symptoms\* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated OR
  - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- \* Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease, do not require a trial of NSAIDs alone.
- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score OR
  - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or “ability to return to work”)
- Approvals will be for a maximum dose of 40mg every two weeks
- Adalimumab will not be reimbursed in combination with other anti-TNF agents

**Cost Comparison of Biologic Response Modifiers in the Treatment of Ankylosing Spondylitis**

Generic Name	Brand Name	Strength	Dose	Dosing Interval	Cost*	Annual Cost
adalimumab	Humira™	40mg	40mg	bi-weekly	\$ 759.12	\$ 19,736.99
etanercept	Enbrel®	50mg	50mg	weekly	\$ 395.25	\$ 20,552.74
infliximab	Remicade®	100mg	5 mg/kg	week 0,2,6 and every 8 weeks thereafter <b>or</b> week 0,2,6 and every 6 weeks thereafter	\$ 1,019.90	\$ 32,636.80  \$ 40,796.00

**Note:** Infliximab cost is for 4 vials per infusion. This is sufficient drug to treat patients who weigh between 70kg and 80kg

\*Source: McKesson Canada Maritimes Price Catalogue February - April 2008

## SPECIAL AUTHORIZATION ADDITIONS

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### **Darbepoetin**

(*Aranesp*<sup>®</sup>)

10,20,30,40,50,60,80,100,130, 150, 200, 300 and 500mcg SingleJect<sup>®</sup> prefilled syringes

New indication added to criteria:

For the treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are  $\geq 2$  units of packed red blood cells per month over 3 months.

- Initial approval for 12 weeks
  - Approval of further 12 week cycles is dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.
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### **Efalizumab**

(*Raptiva*<sup>®</sup>)

150mg vial for subcutaneous injection

For patients with severe debilitating psoriasis who meet all of the following criteria:

1. Body surface area (BSA) involvement of  $>10\%$  and/or significant involvement of the face, hands, feet or genital region
2. Failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine
3. Failure to respond to, intolerant to or unable to access phototherapy

Coverage will be approved initially for 12 weeks. Continued coverage can be approved in patients who have responded to therapy. A response is defined as patients who have achieved a  $\geq 75\%$  reduction in Psoriasis Area Severity Index (PASI) score, or a  $\geq 50\%$  reduction in PASI with a  $\geq 5$  point improvement in Dermatology Life Quality Index (DLQI) or a quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet or genital region.

Patient enrolment in the manufacturer's RESTORE registry program to collect effectiveness and harm outcome information is encouraged.

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## SPECIAL AUTHORIZATION ADDITIONS

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### **Epoetin Alfa**

(Eprex<sup>®</sup>)

1,000IU/0.5mL; 2,000IU/0.5mL;  
3,000IU/0.3mL; 4,000IU/0.4mL;  
5,000IU/0.5mL; 6,000IU/0.6mL;  
8,000IU/0.8mL; 10,000IU/mL;  
20,000IU/mL and 40,000IU/mL  
vials & prefilled syringes

New indication added to criteria:

For the treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are  $\geq 2$  units of packed red blood cells per month over 3 months.

- Initial approval for 12 weeks
  - Approval of further 12 week cycles is dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly
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### **Lanreotide acetate**

(Somatuline<sup>®</sup> Autogel<sup>®</sup>)

60mg, 90mg and 120mg prefilled syringes

For the treatment of acromegaly.

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## SPECIAL AUTHORIZATION – REVISED CRITERIA

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### **Bosentan**

(Tracleer<sup>®</sup>)

62.5mg and 125mg tablets

For treatment of pulmonary arterial hypertension (PAH) in patients with:

- World Health Organization (WHO) functional class III or IV idiopathic pulmonary arterial hypertension (IPAH) in patients who do not demonstrate vasoreactivity on testing or who demonstrate vasoreactivity on testing but fail a trial of, or are intolerant to, calcium channel blockers
  - WHO class III or IV pulmonary arterial hypertension associated with connective tissue disease who do not respond adequately to conventional therapy.
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## 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.

**Bupropion** (*Wellbutrin XL*<sup>®</sup>) 150mg and 300mg extended release tablets

**Lumiracoxib** (*Prexige*<sup>™</sup>) 100mg tablets  
(Lumiracoxib was removed from the market in October 2007)

The following product was recommended for listing, however, smoking cessation products are not eligible NBPDP benefits.

**Varenicline** (*Champix*<sup>™</sup>) 0.5mg and 1mg tablets