B.C. Ministry of Health Services Drug Coverage Decisions

About PharmaCare

B.C. PharmaCare helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

PharmaCare Coverage

The Ministry of Health Services (Ministry) makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs and resources and the evidence-based recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including available clinical and pharmacoeconomic evidence, clinical practice and ethical considerations, and the recommendations of the national Common Drug Review, when applicable.

Inside

Page 1 includes the Ministry decision and reasons in wording that is easier for readers without a medical background to understand. **Page 2** summarizes the DBC recommendation, the Ministry's decision and the reasons for the Ministry's decision.

Interferon beta-1b injection (Betaseron®) for early treatment before a definite diagnosis of multiple sclerosis

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- **Multiple sclerosis (MS)** is a condition where the protective covering of the nerve cells (myelin) in the brain and spinal cord breaks down. This may be caused by a problem with the immune system, and results in spots or patches called lesions. Lesions can be seen with **magnetic resonance imaging** (MRI). MRI technology makes it possible to take detailed pictures of the brain and spinal cord.
  - Symptoms include muscle weakness, poor muscle control, and problems with vision.
  - MS is different for each person. Some patients have mild symptoms and others have serious symptoms affecting their daily lives.
  - Most patients with MS have symptoms that progress from mild to serious at a very slow rate. There may be times of no symptoms or only mild symptoms. A flare-up occurs when symptoms suddenly get worse.
  - The diagnosis of MS is not easy. It may take several months to years to confirm a **definite diagnosis**.
- **Interferon beta-1b** has the brand name **Betaseron® .**
  - **Interferon** occurs naturally in the body. One of its roles is to protect the body from disease.
  - In MS, treatment with interferon beta-1b has been shown to decrease the number of flare-ups and slow the progress after a definite diagnosis. The drug is given by needle into the outer layer of the skin (**subcutaneous injection**).
  - Interferon beta-1b has **limited coverage** for patients with a definite diagnosis of MS.
  - Interferon beta-1b has been shown to affect the immune system but it is not known how it works in MS.

Why was this drug reviewed?

Drug company request for early treatment before a definite diagnosis of MS.

What did the review find?

- One study shows that interferon beta-1b may slow the progress to MS before a definite diagnosis. The study did not show that interferon beta-1b led to better function or quality of life for patients.
- Approximately 50% of patients with initial symptoms of MS, but without definite diagnosis of MS, will not develop MS. The long-term effects of the drug in these patients are not known.
- The study also shows that patients taking the drug had more side effects such as flu-like symptoms, injection site reactions, headache and changes in liver function tests. Patients taking the drug were more likely to stop because of side effects.
- The side effects and safety concerns suggest there is no clear advantage to using interferon beta-1b for early treatment before a definite diagnosis of MS.
- Interferon beta-1b is not cost-effective in this setting.

What decision was made?

- Interferon beta-1b will not be covered for suspected or early stages of MS before definite diagnosis.
- Each request will be reviewed by te MS Advisory Committee.
- No change to current **limited coverage**.

Key Term(s)

- **Limited Coverage** drugs are not normally considered the first choice in treatment, or other drugs may offer better value. To receive coverage, the patient's physician must submit a Special Authority request to PharmaCare. If the request is approved, the drug is covered up to the usual PharmaCare coverage limits. Actual reimbursement depends on the rules of a patient's PharmaCare plan including any annual deductible requirement.

Please visit us online to find out more about the Pharmaceutical Services Division and the PharmaCare program at www.health.gov.bc.ca/pharme. To find out more about how drugs are considered for PharmaCare coverage, visit www.health.gov.bc.ca/pharme/formulary.

BRITISH COLUMBIA
The Best Place on Earth

Interferon beta-1b injection (Betaseron®) for early treatment before a definite diagnosis of multiple sclerosis

Drug Class

- Immunomodulator

Available Dosage Forms

- Lyophilized powder for subcutaneous injection 0.3mg single-use vial

Sponsor/Requestor

- Berlex Canada Inc.

Submission (Request) to PharmaCare

- Drug review of interferon beta-1b for the following Health Canada-approved indication:
  - Treatment of patients with a single demyelinating event, accompanied by at least two clinically silent lesions typical of multiple sclerosis (MS) on magnetic resonance imaging, to delay progression to definite MS.

Drug Benefit Council (DBC) Recommendations

- Interferon beta-1b not be listed for suspected or early stages of MS before definite diagnosis.

Reasons for the Ministry of Health Services Decision

- One double-blind, randomized controlled trial (DB RCT) compared early treatment with interferon beta-1b to placebo in adult patients with clinically isolated syndrome (CIS) over a 2-year period. Based on this trial, there is sufficient evidence that treatment with interferon beta-1b has an advantage over placebo in delaying the development of MS.
  The delay in development in MS did not translate into significant benefits over placebo in functional status, quality of life, morbidity, or mortality. In order to fully interpret the clinical importance of this benefit, information on subsequent demyelinating events needs to be reported. Approximately 50 percent of the CIS population do not develop MS, and the long-term clinical impact of exposure to interferon beta-1b in patients without MS is unknown.
  - Compared to the placebo group, significantly more patients in the interferon beta-1b group reported flu-like syndrome, injection site reactions, headache, and elevated liver enzymes. Patients in the interferon beta-1b group also had higher withdrawal rates due to adverse effects than the placebo group. Therefore, there is sufficient evidence that interferon beta-1b provides a therapeutic disadvantage in terms of safety and serious morbidity compared to placebo.
- The annual drug acquisition cost for this drug is approximately $19, 281 per patient. The economic evaluation submitted by the manufacturer assumed that all patients with a single demyelinating event are currently receiving interferon beta-1a. As this patient population is not currently receiving interferon therapy, this assumption is questionable and would significantly underestimate the overall budget impact. Based on this information, the drug was also not cost-effective.
- Any requests received by PharmaCare for exceptional coverage of interferon beta-1b for CIS will be referred to the MS Advisory Committee on a case-by-case basis.

Decision and Status

- **Limited coverage.** No change to current Special Authority criteria.
- Effective July 8, 2008

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