Drug Coverage Decision for B.C. PharmaCare

About PharmaCare B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	**natalizumab**
Brand Name	Tysabri®
Dosage Form(s)	300 mg/ 15 ml Intravenous Infusion
Manufacturer	Biogen Canada Inc.
Submission Type	**Modification of Criteria**
Use Reviewed	Relapsing Remitting Multiple Sclerosis
Common Drug Review (CDR)	No, CDR did not review
Mininstry Intiated Review	In 2010, natalizumab was made a Limited Coverage Drug but the Drug Benefit Council had ongoing concerns about the cost of natalizumab. The cost of natalizumab is significantly higher than the cost of other disease modifying agents but does not appear to have the comparative clinical advantage data to justify the higher price. Therefore the Ministry initated to modify the criteria of natalizumab, to reflect the clinical and economic changes.
Drug Coverage Decision	**Modificaiont of Critieria.** **Access the natalizumab criteria from www.gov.bc.ca/pharmacarespecialauthority**
Date	March 26, 2019
Reason(s)	• The Ministry was able to address the concerns identified by the CDR and DBC in previous reviews regarding the cost-effectiveness and value for money. • The modification of criteria is supported by clinical evidence anad clinical practice.
Other Information	None.

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the Common Drug Review (CDR)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit the The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL
RESUBMISSION

Natalizumab (Tysabri®)
Biogen Idec Canada

Description:

Drug review of natalizumab (Tysabri) resubmission for the following:

For patients who have confirmed diagnosis of relapsing remitting multiple sclerosis (MS) and who met the following criteria:

1. Failure to respond to full and adequate courses of treatment with at least two Disease Modifying Agents or have contraindications to or be intolerant of these therapies
2. Significant increase in T2 lesion load compared to a previous MRI or at least one gadolinium enhancing lesion
3. Two or more disabling relapses in the previous year.

The DBC has previously reviewed this information in April, 2009 and recommended not to list. In December, the ministry issued its decision not to list and advised that if the company was interested in resubmitting, that it should include additional product information around the clinical efficacy or effectiveness, long term safety and pharmacoeconomic information.

In this review of the resubmission, the DBC reviewed the manufacturer submission and also considered the review completed by the Common Drug Review (CDR) in February, 2009, which included evidence review material and the recommendation from the Canadian Expert Drug Advisory Committee (CEDAC). The DBC also considered Clinical Practice Reviews provided by two BC practicing physicians (two specialists who practice in the area of multiple sclerosis).

Dosage Forms:

300mg/15mL vial

Recommendation:

The Drug Benefit Council (DBC) recommends that natalizumab (Tysabri) be listed as a Limited Coverage, third line monotherapy agent in patients with diagnosed MS with the following criteria:

1. Failure to respond to full and adequate courses of treatment with at least two Disease Modifying Agents or have contraindications to or be intolerant of these therapies
2. Significant increase in T2 lesion load compared to a previous MRI or at least one gadolinium enhancing lesion
3. Two or more disabling relapses in the previous year.

The DBC recommended that the Ministry of Health Services (Ministry) work with relevant stakeholders (MS specialists) to develop specific criteria for use and relevant definitions.

The DBC also recommends that the Ministry aggressively seek the best value possible for natalizumab to improve the cost-effectiveness of the product.

Reasons for the Recommendation:

- The manufacturer provided some data in response to the additional data requested by the DBC during the natalizumab review in 2009.
- The DBC acknowledges that there are significant limitations to the available evidence, but it recognizes that some of the observational evidence of efficacy may support the use of natalizumab in select patients who have been unresponsive to other therapies.
- The DBC acknowledges that there is limited Canadian pharmacoeconomic data and is concerned about the continued accrual of progressive multifocal leukoencephalopathy cases.
- Although the clinical practice reviews suggest approval of natalizumab after failure on one disease modifying agent, the DBC felt that based on clinical and pharmacoeconomic evidence, two disease modifying agents should be tried prior to treatment with natalizumab.
- The DBC feels that the overall evidence for the use of natalizumab as a third line agent may justify its use in select patients.
- The DBC had ongoing concerns about the cost of natalizumab, as it did previously when the product was reviewed in 2009. The cost of natalizumab is significantly higher than the cost of other disease modifying agents but does not appear to have the comparative clinical advantage data to justify the higher price. This comparison is based upon product dosing as outlined in the product monograph.