

# BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit [Ministry of Health - PharmaCare](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an “indication”). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare’s drug coverage review process, see the last page of this information sheet.

| Information about the drug   |  |
|--|--|
| Generic name (scientific name)   | <b>galsulfase</b>  |
| Brand name   | <b>Naglazyme<sup>®</sup></b>   |
| Manufacturer   | BioMarin Pharmaceuticals Inc.  |
| Indication   | Naglazyme <sup>®</sup> is used to treat mucopolysaccharidosis type VI (Maroteaux-Lamy Syndrome).   |
| Has the drug been reviewed by the Common Drug Review (CDR)? (see the note below this table.) | Yes<br>For more information about the CDR’s review of galsulfase (Naglazyme <sup>®</sup> ), you can <a href="#">Search the CDR Reports</a> .                             |
| Public input start date  | Wednesday December 16, 2015  |
| Public input closing date  | Wednesday January 20, 2016 <b>AT MIDNIGHT</b>  |
| How is the drug taken?   | Naglazyme <sup>®</sup> is taken by intravenous infusion (a slow drip into a vein). Each infusion takes approximately 4 hours and is supervised by a health professional. |
| How often is the drug is taken?  | Naglazyme <sup>®</sup> is taken once a week. The recommended dose regimen is 1 mg/kg of body weight given once every week.   |

| Information about the drug                 |  |
|--|--|
| General drug and/or drug study information | <p>Mucopolysaccharidosis type VI (MPS VI, Maroteaux-Lamy Syndrome) is an inherited metabolic disease in which people are born with a gene that does not work properly. The gene results in low levels of the enzyme arylsulfatase B, which is responsible for breaking down glycosaminoglycan dermatin sulfate, a mucopolysaccharide. This incompletely broken down mucopolysaccharide remains stored in cells in the body causing progressive damage.</p> <p>Naglazyme® (galsulfase) is an enzyme replacement therapy that can help break down some of the glycosaminoglycans that cause the signs and symptoms of MPS VI.</p> <p>Studies looked at the following to assess if Naglazyme® is helpful and safe for the treatment of MPS VI:</p> <ul style="list-style-type: none"> <li>• Survival</li> <li>• Disease progression</li> <li>• 12 minute walk test</li> <li>• 3 minute stair climb test</li> <li>• Changes in height and weight</li> <li>• Quality of life</li> <li>• Lung function</li> <li>• Skeletal and soft tissue function</li> <li>• The frequency of antibiotic use and hospitalizations, days missed from school and/or work and the requirement for wheel chair or other ambulatory aids</li> <li>• Sleep and hearing function</li> <li>• Eye evaluation</li> <li>• Size of liver and spleen</li> <li>• Amount of glycosaminoglycans in the urine</li> <li>• Bad reactions/events</li> <li>• Leaving the trials due to the bad reactions</li> </ul> |
| Other considerations                       | None   |

**Note:**

The Common Drug Review (CDR) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare’s drug review process, including the role of the CDR in that process, see [The Drug Review Process in B.C. - Overview](#).

| Cost of the drug under review compared to other drugs used to treat the same indication |  |                                  |   |
|---|--|----------------------------------|---|
| generic name (Brand Name) of Drug Comparator  | PharmaCare Status (if and how the drug is already covered) | Usual Dose                       | Annual Cost of Therapy  |
| galsulfase (Naglazyme®)   | Under Review   | 1 mg/kg of body weight each week | \$234,671 - \$787,823 (Range is based on body weight from 14 kg to 47 kg) |

### 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 \(Council\)](#) gives advice to the Ministry. The Council 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 Council
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: [The Drug Review Process in B.C. - Overview](#).

**This document is intended for information only.**

It does not take the place of advice from a physician or other qualified health care provider.