Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization  Number: 07.170

Title: elosulfase alfa (Vimizim™)  Page 1 of 3

Approval: Robert Bonnell, M.D., Med. Dir.  DATES - Origination: 08/27/14
Responsible Party: CPM Director  Revised:  Effective: 09/29/14
Distribution: Medical Department  P&T Review: 08/24/16  Annual Review: 08/23/17

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department:

   1.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
Background Information, continued:

Medication Summary

- Elosulfase alfa is a purified human enzyme for the treatment of patients with Mucopolysaccharidos type IVA (MPS IVA; Morquio A syndrome).

- MPS IVA is a very rare and debilitating genetic disorder which is caused by a deficiency of the enzyme, N-acetylgalactosamine-6 sulfatase, which results in excessive lysosomal storage of keratan sulfate in many tissues and organs. Accumulation of keratan sulfate causes systemic skeletal dysplasia, short stature, and joint abnormalities, which limit mobility and endurance. Malformation of thorax impairs respiratory function and malformation of neck vertebrae and ligament weakness causes cervical spinal instability and, potentially, cord compression. Other symptoms include hearing loss, corneal clouding, and heart valve disease.

Coverage Guidelines

- Member must be eligible and have applicable benefits.

- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Members less than five (5) years old.

- Members with Mucopolysaccharidosis IV B.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.

- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
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Procedure:

1.0 Request for initial therapy with Vimizim for the treatment of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Prescriber must be a specialist; AND

1.2 Documented diagnosis of MPS IVA; Morquio A syndrome (genetic testing confirmation required); AND

1.3 Documentation of a baseline 6-minute walk test (6-MWT) indicating the Member walked at least 30 meters in six (6) minutes;

1.4 If criteria are met, Vimizim™ may be approved at 2mg/kg given once a week for up to six (6) months.

2.0 Request for continuation of therapy with Vimizim™ for the treatment of MPS IVA; Morquio A syndrome beyond the initial authorization period requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

2.1 Member is deriving clinical benefit from therapy:
   2.1.1 Medical records indicate tolerance and effectiveness of therapy based on results of the comparison of baseline and current 6-minute walk test (6-MWT); AND
   2.1.2 Must maintain sustained walking improvement farther than before he or she started treatment; AND

2.2 If criteria are met, Vimizim™ may be approved at 2mg/kg given once a week for 12 months.

Reference: