Vimizim (elosulfase alfa)

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<th>Line(s) of Business:</th>
<th>Effective Date:</th>
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<td>HMO; PPO; QUEST Integration</td>
<td>10/01/2015</td>
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<td>Akamai Advantage</td>
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**POLICY**

**A. INDICATIONS**
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

**FDA-Approved Indication**
- Vimizim is indicated for patients with mucopolysaccharidosis IVA (MPS IVA, Morquio syndrome).

**B. REQUIRED DOCUMENTATION**
The following information is necessary to initiate the prior authorization review:
- Enzyme assay or DNA testing supporting the diagnosis

**C. CRITERIA FOR APPROVAL**

1. **MPS IVA**
   Authorization for 12 months may be granted to members with a diagnosis of mucopolysaccharidosis IVA which was confirmed by an enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase enzyme activity or by DNA testing who are prescribed Vimizim to be administered in a health care setting with the appropriate medical support in the event of an anaphylactic reaction.

**D. CONTINUATION OF THERAPY**
All members, including new members, requesting authorization for therapy must meet ALL initial authorization criteria.

Members who were previously approved for Vimizim by HMSA may request reauthorizations after their initial approval. Approval for an additional 12 months may be granted if the patient received benefit from Vimizim therapy.

**E. DOSING AND ADMINISTRATION**
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
F. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES