

Field Name	Field Description
Prior Authorization Group Description	<b>Vimizim (elosulfase alfa)</b>
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	<p><b><u>Initial Authorization (new to therapy):</u></b></p> <ul style="list-style-type: none"> <li>• Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> <li>○ Genetic testing</li> <li>○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts</li> </ul> </li> <li>• Dosage does not exceed 2 mg/kg once a week.</li> <li>• Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) and be able to walk a minimum of 30 meters at baseline.</li> </ul> <p><b><u>Re-Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Dosage does not exceed 2 mg/kg once a week.</li> <li>• Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request)</li> </ul> <p><b><u>Re-authorization for members new to the plan previously treated with Vimizim:</u></b></p> <ul style="list-style-type: none"> <li>• Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> <li>○ Genetic testing</li> <li>○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts</li> </ul> </li> <li>• Dosage does not exceed 2 mg/kg once a week.</li> <li>• Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request).</li> <li>• If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then:</li> </ul>

<p>Revision/Review Date 7/2023</p>	<ul style="list-style-type: none"> <li>○ A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request).</li> <li>○ Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk a minimum of 30 meters in subsequent evaluations.</li> <li>○ If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk a minimum of 30 meters, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy.</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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PerformRx recommends approving the Vimizim prior authorization criteria for ACOH with no changes.