Maryland
DEPARTMENT OF HEALTH

Vimizim (elosulfase alfa)

Vimizim is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

I. Criteria for Initial Approval

Vimizim will be considered for coverage when all of the criteria below are met, confirmed with supporting medical documentation.

- Patient is 5 years of age or older.
- Prescribed by a specialist familiar with Mucopolysaccharidosis. Typically either a biochemical geneticist or metabolic disease physician.
- Documented diagnosis of MPS IVA with biochemical/genetic confirmation by one of the following:
    - Absence or marked reduction in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity; OR
    - Sequence analysis and/or deletion/duplication analysis of the GALNS gene for biallelic mutation.
- Documented clinical signs and symptoms of Morquio A syndrome (e.g., knee deformity, corneal opacity or pectus carinatum.)
- Documented baseline value for one or more of the following:
    - Endurance tests (e.g., six minute walk test (6-MWT) or timed 25-foot walk test (T25FW)).
    - Pulmonary function tests (e.g., FVC.)

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in **Section I.**) must be met; **AND** the provider attests to the following;

- Absence of unacceptable toxicity from the drug.
- Patient has shown a response to therapy as evidenced by one or more of the following markers when compared to pretreatment baseline values:
    - Stability or improvement on endurance tests.
    - Stability or improvement in pulmonary function tests.

III. Dosing/Administration

Vimizim must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- 2 mg per kg body weight administered once every week as an intravenous infusion over a minimum of 3.5 to 4.5 hours, based on infusion volume.

IV. Length of Authorization for Initial Therapy

Vimizim will be authorized for 6 months when criteria for initial approval are met. Continuing therapy with Vimizim will be authorized for 12 months.

V. Billing Code/Information

J1322 – Injection, elosulfase alfa, 1 mg; 1 billable unit = 1 mg.

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 5/25/2021
Last Reviewed Date: 6/30/2021