All requests for Vimizim® (Elosulfase alpha) require prior authorization and will be screened for medical necessity and appropriateness using the non-formulary criteria listed below.

Vimizim® (Elosulfase alfa) Prior Authorization Criteria:

- Coverage may be provided when the indication is **Mucopolysaccharidosis Type IV A (Morquio Syndrome)** AND
  - The patient is age 5 years or older but is not over age 65 years
  - The diagnosis has been confirmed by a specialist conducting a biochemical evaluation, a peripheral blood leukocyte enzyme analysis demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase activity, and a radiographic skeletal survey OR by performing DNA testing
  - The prescriber is a biochemical geneticist or metabolic physician
  - The product will be prepared and administered under the supervision of a healthcare professional able to manage medical emergencies in the event of an anaphylactic reaction
  - The patient has some ability to walk at least 30 meters prior to treatment initiation:
    - Documentation of a baseline 6-minute walking test must be provided
  - The dosing is within the following prescribing-supported parameters:
    - Does not exceed 2mg/kg every week.

- All other indications not otherwise listed are considered experimental/investigational unless peer reviewed medical literature or guidelines are provided to support its use.
- Benefit is approved for a 6 month duration.
- Reauthorization is considered when there is chart documentation of clinical improvement in walking ability and tolerance to medication.
- When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must over ride criteria when, in their professional judgment, the requested medication is medically necessary.

References:
1) Vimizim® (Elosulfase alpha) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc; 02/2014