

When requesting Vimizim® (elosulfase alfa), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- Vimizim® (elosulfase alfa) is indicated for the treatment of individuals with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

Approved Off-label Compendial use²

- No off-label uses meet evidence standards

Coverage Guidelines

Mucopolysaccharidosis Type IVA (Morquio A Syndrome)

The individual must meet the following criteria for approval:

- Has a diagnosis of mucopolysaccharidosis type IVA (Morquio A syndrome) confirmed by enzyme assay demonstrating a deficiency of galactose-6-sulfatase enzyme activity or by genetic testing^{1,3}
- Is 5 years old or older¹

Approval duration: 12 months

Additional Information for Prescribers

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Life-threatening anaphylactic and severe allergic reactions have been observed in some individuals during infusions.
- Cases of anaphylaxis have occurred as early as 30 minutes from the start of infusion and up to three hours after infusion. Anaphylaxis has occurred after multiple infusions.
- Because of the potential for hypersensitivity reactions, administer antihistamines with or without antipyretics prior to infusion.
- Individuals with acute febrile or respiratory illness may be at higher risk of life-threatening complications from hypersensitivity reactions. Careful consideration should be given to the patient's clinical status prior to administration of Vimizim® (elosulfase alfa) and consider delaying the infusion.

References

1. Vimizim® prescribing information. Novato, CA: BioMarin Pharmaceutical Inc.: Revised February 2014.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 14, 2017. <https://www.micromedexsolutions.com>
3. Tomatsu S, Yasuda E, Patel P, et al. Morquio A Syndrome: Diagnosis and Current and Future Therapies. *PediatrEndocrinol Rev.* 2014;12:141–151. Accessed February 14, 2016. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4259875/>