

Fabrazyme® (agalsidase beta)



When requesting Fabrazyme® (agalsidase beta), 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

- Fabrazyme® (agalsidase beta) is indicated for the treatment of individuals with Fabry disease.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards

Coverage Guidelines

Fabry Disease

Has a diagnosis of Fabry Disease confirmed by enzyme assay demonstrating a deficiency of alpha-galactosidase A enzyme activity or by genetic testing^{1,3}

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 patients during Fabrazyme® (agalsidase beta) infusions. If severe allergic or anaphylactic reactions occur, Fabrazyme® (agalsidase beta) administration should be immediately discontinued and necessary emergency treatments should be provided.
- In patients experiencing infusion reactions, pretreatment with an antipyretic and antihistamine is recommended. If an infusion reaction occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administering additional antipyretic, antihistamines, and/or steroids may ameliorate the symptoms.
- There is a Fabry registry for women who are or may become pregnant. It monitors the effects of Fabrazyme® (agalsidase beta) on pregnant women and their offspring. For more information, visit www.fabryregistry.com or call (800) 745-4447.

References

1. Fabrazyme® prescribing information. Cambridge, MA: Genzyme Corporation: Revised May 2010. <https://fabrazyme.com/>. Accessed February 14, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 14, 2017. <https://www.micromedexsolutions.com>
3. Desnick RJ, Brady R, Barranger J, et al. Fabry disease, an under-recognized multisystemic disorder: expert recommendations for diagnosis, management, and enzyme replacement therapy. *Ann Intern Med*. 2003;138:338-346. Accessed February 14, 2017. <http://annals.org/aim/article/716074/fabry-disease-under-recognized-multisystemic-disorder-expert-recommendations-diagnosis-management>