

January 2008 US Myozyme Supply Update

In April 2007, Genzyme implemented measures to manage the limited supply of Myozyme[®] (alglucosidase alfa) in the United States in order to ensure uninterrupted treatment for as many patients as possible. Since April, both the patient and physician communities have worked diligently to enroll the majority of adults into the Myozyme Temporary Access Program (MTAP) and have greatly reduced the number of individuals at risk of an interruption in treatment. In spite of this achievement, not enough adults were transitioned into MTAP to ensure that the remaining infants, children and adults would have a steady supply of commercial Myozyme until the larger scale manufacturing process is approved by the FDA. Unfortunately, it is necessary to take immediate additional measures to manage the current limited commercial supply of Myozyme.

As of February 1, 2008, Genzyme will no longer be shipping commercial Myozyme for adults 18 years of age and older in the United States who are currently on treatment but not yet enrolled in MTAP.

The rationale behind stopping commercial shipments for the remaining adults not yet enrolled in MTAP is that it allows Genzyme to be in a better position to ensure continued access to Myozyme for infants and children not eligible for MTAP.

All eligible adults continue to have the option to enroll into MTAP. Shipments of Myozyme to adults not enrolled in MTAP will not be resumed until we receive FDA approval of the larger scale manufacturing process. We currently anticipate a decision from the FDA regarding this approval during the first half of 2008.

YOU ARE AFFECTED BY THIS CHANGE:

A) If you are 18 years of age and older and currently on Myozyme but not enrolled in MTAP

Alternative ways of continuing treatment with Myozyme at this time are:

- 1) Working with your treating physician to enroll into MTAP as quickly as possible for continued access to Myozyme. Please note that you will not be able to receive commercial Myozyme after February 1, 2008.
- 2) If your physician is not able to implement MTAP before February 1st, you may be able to temporarily receive infusions at another MTAP location. Please refer to www.myozyme.com for the most updated list of approved MTAP sites and speak with your treating physician about this option.
- 3) In the event that options 1 and 2 are not attainable, your treating physician may be able to gain emergency approval from the FDA for you to receive temporary doses of Myozyme under Emergency Use regulations. This procedure is generally reserved for emergency situations for patients with life-threatening or severely debilitating conditions. Your

treating physician should contact Genzyme directly for more information on Emergency Use submissions.

B) If you are 18 years of age older, not on Myozyme and do not meet the MTAP criteria

For patients not yet on treatment who do not meet these MTAP entry criteria, Myozyme treatment will continue to be delayed until the larger scale manufacturing process is approved for commercial use.

YOU ARE NOT AFFECTED BY THIS CHANGE:

A) If you are currently enrolled in MTAP

You will continue to receive your infusions via MTAP until FDA approval of the larger scale manufacturing process, at which time Genzyme will work to transition you back to commercial therapy. Please note that you are considered to be enrolled in MTAP once you have signed an informed consent and are receiving infusions via the MTAP program.

B) If you are 18 years of age and older, not on treatment, but are eligible for MTAP

Patients 18 years of age and older who have not yet begun treatment with Myozyme and meet either of the following criteria may be eligible for enrollment into MTAP: (1) require ventilation assistance for breathing, **or** (2) require a wheelchair for ambulation. Please have your treating physician contact Genzyme Medical Information at 1-800-745-4447 for more information.

C) If you are 17 years of age or younger and currently receiving Myozyme

You are not impacted by this change. You will continue to receive your infusions via regular commercial channels.

D) If you are 17 years of age and younger and are interested in seeking Myozyme treatment

Please have your physician contact Genzyme Treatment Support directly at 1-800-745-4447, option 3. Due to the urgent need to treat infants, please follow the regular route to access commercial treatment for infants to prevent any delay in the initiation of treatment.

E) If you are currently enrolled in a Myozyme Clinical Trial

You are not impacted by this change. You will continue to receive Myozyme through the clinical trial you are participating in.

We will continue to keep you updated on developments related to the US Myozyme supply. Please feel free to contact your Genzyme Treatment Support case manager at 1-800-745-4447, option 3 with questions or speak with your local Genzyme representative.