

ElELYso® (taliglucerase alfa) VPRIV® (velaglucerase alfa)



When requesting ElELYso® (taliglucerase alfa) or VPRIV® (velaglucerase 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 indications^{1,2}

- ElELYso® (taliglucerase alfa) and VPRIV® (velaglucerase alfa) are indicated for the treatment of individuals with Type 1 Gaucher disease.

Approved Off-label Compendial use³

- No off-label uses meet evidence standards

Coverage Guidelines

Type 1 Gaucher Disease

The individual must meet the following criteria for approval:

- Has a diagnosis of Type 1 Gaucher disease confirmed by enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity or by genetic testing^{1,2,4}
- Individual is 4 years of age or older^{1,2}

Approval duration: 12 months

Additional Information for Prescribers¹

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

- Hypersensitivity reactions including anaphylaxis can occur during and after the infusion. Infusion should be immediately discontinued if anaphylaxis occurs and appropriate treatment should be initiated
- Type III immune-mediated fixed drug eruption has been reported in patients receiving ElELYso® (taliglucerase alfa).

References

1. ElELYso® prescribing information. New York, NY: Pfizer Labs: Revised December 2016. <http://labeling.pfizer.com/ShowLabeling.aspx?id=798>. Accessed February 15, 2017.
2. VPRIV® prescribing information. Lexington, MA: Shire Human Genetic Therapies, Inc.: Revised April 2015. http://pi.shirecontent.com/PI/PDFs/Vpriv_USA_ENG.pdf. Accessed February 15, 2017.
3. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 15, 2017. <https://www.micromedexsolutions.com>
4. Thomas AS, Mehta AB, Hughes DA. Diagnosing gaucher disease: an on-going need for increased awareness among haematologists. *Blood Cells Mol Dis*. 2013;50(3):212-217.