

Louisiana Medicaid Enzyme Replacement Therapy

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred enzyme replacement therapy for Gaucher's Disease.

Additional Point-of-Sale edits may apply.

*Some of these agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Initial and Reauthorization Requests

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The recipient is established on the medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

References

Cerdelga (eliglustat) [package insert]. Waterford, Ireland: Genzyme Ireland Ltd; August 2018.
<http://products.sanofi.us/Cerdelga/cerdelga.html>

Cerezyme (imiglucerase) [package insert]. Cambridge, MA: Genzyme Corporation; April 2018.
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Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;
<https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill;
<https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

Elelyso (taliglucerase alfa) [package insert]. New York, NY: Pfizer Labs; November 2020.
<http://labeling.pfizer.com/ShowLabeling.aspx?id=798>

Miglustat [package insert]. South San Francisco, CA: Patriot Pharmaceuticals, LLC; November 2018. file:///C:/Users/Melissa%20Dear/Downloads/20200512_76eb7ac8-e0ee-4409-a4e7-e326c6725836.pdf

Vpriv (velaglucerase alfa) [package insert]. Lexington, MA: Shire Human Genetic Therapies Inc; November 2019. http://pi.shirecontent.com/PI/PDFs/Vpriv_USA_ENG.pdf

Zavesca (miglustat) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals; November 2017. <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ZAVESCA-pi.pdf>

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