Louisiana Medicaid
Enzyme Replacements

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred enzyme replacement agents.

Additional Point-of-Sale edits may apply.~~.~~

*T~~Some of t~~hese 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

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- For generic and authorized generic miglustat capsule (generic and authorized generic for Zavesca®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Zavesca®; **OR**
- 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 all of 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. HYPERLINK "http://products.sanofi.us/Cerdelga/cerdelga.html" http://products.sanofi.us/Cerdelga/cerdelga.html~~

~~Cerezyme (imiglucerase) [package insert]. Cambridge, MA: Genzyme Corportation; April 2018. HYPERLINK "http://products.sanofi.us/Cerezyme/cerezyme.pdf" http://products.sanofi.us/Cerezyme/cerezyme.pdf~~

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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. HYPERLINK "http://labeling.pfizer.com/ShowLabeling.aspx?id=798" http://labeling.pfizer.com/ShowLabeling.aspx?id=798~~

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~~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~~

Revision / Date	**~~Date~~Implementation Date**
Policy created	November 2020
Formatting changes, removed specific references, added specific wording for use of Zavesca® / September 2021	January 2022