Louisiana Medicaid
Golodirsen (Vyondys 53®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for golodirsen (Vyondys 53®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Vyondys 53® is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Vyondys 53®. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Approval Criteria for Initiation of Therapy

- The following is true and is **stated on the request** - The recipient has a genetically-confirmed diagnosis of Duchenne muscular dystrophy and lab testing confirms that the mutation of the dystrophin (DMD) gene is amenable to exon 53 skipping; **AND**
- The recipient has been on a stable dose of corticosteroids for at least 6 months prior to the date of the request. Each medication and date range of treatment must be **listed on the request**; **AND**
- Vyondys 53® is prescribed by, or in consultation with, a neurologist experienced in the diagnosis and treatment of DMD; **AND**
- The recipient has functional status that can be preserved as demonstrated by a valid measuring tool (name and result of the valid measuring tool is **stated on the request)**; **AND**~~.~~
- The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial (6 months) of viltolarsen (Viltepso®).

Approval Criteria for Continuation of Therapy

- Vyondys 53® is prescribed by, or in consultation with, a neurologist experienced in the diagnosis and treatment of DMD; **AND**
- The following are true and the prescriber **states both on the request**:
  - **There has been a positive response to therapy**; **AND**
  - Functional status is reassessed with the same valid measuring tool, and the results show stable or improved functional status from baseline (**baseline and reassessment results** are stated on the request).

Duration of approval for initiation and continuation of therapy: 6 months

References

National Institute of Health, U.S. Department of Health & Human Services. Duchenne muscular dystrophy. (2017, September 28). https://rarediseases.info.nih.gov/diseases/6291/duchenne-muscular-dystrophy
Vyondys 53 (golodirsen) [package insert]. Cambridge, MA: Sarepta Therapeutics Inc; JuneFebruary 20241. https://www.vyondys53.com/static/patient/assets/Vyondys53_(golodirsen)_Prescribing_Information.pdf

Revision / Date	Implementation Date
Policy created / January 2020	May 2020
Removed dystrophin level requirement and updated reference / September 2020	January 2021
Removed age requirement from clinical criteria, formatting changes, updated references / January 2022	July 2022
Formatting changes / March 2024	July 2024
Added criterion for previous use of Viltepso®, updated references / November 2024	March 2025