

Vyondys 53[®] (golodirsen) Injection

When requesting Vyondys 53[®] (golodirsen), the individual requiring treatment must be diagnosed with FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication

- Treatment of Duchenne Muscular Dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

Coverage Guidelines

The individual must meet **all** of the following criteria for initial approval:

- Diagnosis of Duchenne muscular dystrophy
- Confirmed mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 53 skipping

The individual must meet the following criteria for reauthorization:

- Individual has shown benefit from the drug (eg, improvement in dystrophin levels or in 6-minute walk distance [6MWD])

Approval duration (initial and renewal): 12 months

Dosing Recommendation

- 30 mg/kg administered intravenously once weekly

References

1. Vyondys 53[™] prescribing information. Cambridge, MA: Sarepta Therapeutics; Revised December 2019. Accessed January 14, 2020.
2. Klasco RK (Ed): DRUGDEX[®] system. Thomson Micromedex, Greenwood Village, CO. Accessed January 14, 2020.