CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Vyondys 53 (golodirsen)
BILLING CODE	J1429 (1 unit = 10 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior authorization required (Non-Preferred Product) QUANTITY LIMIT – see dosage allowed
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Vyondys 53 (golodirsen) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

DUCHENNE MUSCULAR DYSTROPHY (DMD)

For **initial** authorization:

1. Member has a diagnosis of DMD with confirmed mutation of DMD gene that is amenable to exon 53 skipping (genetic testing results required); AND
2. Medication is being prescribed by or in consultation with a DMD specialist (i.e., neurologist); AND
3. Member is currently stable on corticosteroid for at least 6 months prior to starting therapy, unless not tolerated or contraindicated; AND
4. Member has had a 90-day trial and failure of, or contraindication to Viltepso; AND
5. Chart notes have been provided to show that the member is able to walk independently without assistive devices.
6. **Dosage allowed**: 30 mg per kg of body weight once weekly.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show stability or slowed rate of decline of the member's motor function compared to baseline; AND
2. Chart notes confirm that member remains able to walk independently without assistive devices.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Vyondys 53 (golodirsen) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
1/21/2020	New policy for Vyondys 53 created.
06/17/2020	Length of corticosteroid trial specified to be at least 3 months. Age requirement removed.
01/14/2021	Added prescriber requirement. Simplified ambulatory requirement. Added requirement of stability or slowed rate of decline of motor function in reauth section. Added a trial of Viltepso.

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04/06/2021	Increased duration of steroid trial to 6 months.

References:

1. Vyondys 53 [Package Insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; August 2020.
2. Sarepta Therapeutics, Inc. Phase I/II Study of SRP-4053 in DMD Patients. NLM Identifier: NCT02310906.
3. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. *Lancet Neurol*. 2018;17(3):251-267.
4. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(5):465-472.
5. Frank DE, Schnell FJ, Akana C, et al. Increased dystrophin production with golodirsen in patients with Duchenne muscular dystrophy. *Neurology*. 2020;94(21):e2270-e2282. doi:10.1212/WNL.0000000000009233

Effective date: 10/1/2021
Revised date: 04/06/2021