



PHARMACY POLICY STATEMENT Ohio Medicaid

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| 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 – Based on weight |
| 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 confirmed mutation of DMD gene that is amenable to exon 53 skipping (chart/lab notes required); AND
2. Member is currently stable on corticosteroid for at least 3 months, unless not tolerated or contraindicated; AND
3. Chart notes have been provided that show the member is ambulatory and walks independently (i.e. without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Vyondys 53 therapy.
4. **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. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member's status has been reviewed within 30 days of the reauthorization request confirming that the member remains ambulatory and walks independently (i.e. without side-by-side assist, cane, walker, wheelchair, etc.).

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. |

References:

1. Vyondys 53 [Package Insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; December 2019.
2. Sarepta Therapeutics, Inc. Phase I/II Study of SRP-4053 in DMD Patients. NLM Identifier: NCT02310906.



3. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne Muscular Dystrophy. *Neurology*. 2016 Nov 15;87(20):2123-2131.

Effective date: 07/20/2020

Revised date: 06/17/2020