CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Vyondys 53 (golodirsen)
BILLING CODE	J3490
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 must be 6-15 years of age; AND
2. Member has confirmed mutation of DMD gene that is amenable to exon 53 skipping (chart/lab notes required); AND
3. Member is currently taking a corticosteroid or has a contraindication to corticosteroids; AND
4. 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.
5. **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.

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.

Effective date: 05/25/2020
Revised date: 01/21/2020