

**VYONDYS 53
(golodirsen)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 20 years of age or younger

Diagnosis

Patient must have the following:

Duchenne muscular dystrophy (DMD)

AND ALL of the following:

1. Confirmed mutation of the DMD gene that is amenable to exon 53 skipping
2. Prescribed by or in consultation with a neurologist specializing in DMD
3. Prescriber agrees to measure glomerular filtration rate prior to initiation of therapy and monitor for renal toxicity during treatment
4. Patient will be advised to monitor for hypersensitivity reactions
5. Obtain a baseline muscle strength score from **ONE** of the following:
 - a. 6-minute walk test (6MWT)
 - b. North Star ambulatory assessment (NSAA)
 - c. Motor Function Measure (MFM)
6. NO concurrent therapy with another exon skipping therapy for DMD(see Appendix 1)

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 20 years of age or younger

Diagnosis

Patient must have the following:

Duchenne muscular dystrophy (DMD)

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AND ALL of the following:

1. Prescriber agrees to monitor for renal toxicity during treatment
2. Patient will be advised to monitor for hypersensitivity reactions
3. Patient has had an improvement from baseline in **ONE** of the following:
 - a. 6-minute walk test (6MWT)
 - b. North Star ambulatory assessment (NSAA)
 - c. Motor Function Measure (MFM)
4. **NO** concurrent therapy with another exon skipping therapy for DMD (see Appendix 1)

Prior - Approval *Renewal* Limits

Duration 24 months

**Appendix 1 - List of Exon Skipping Therapies for Duchenne
Muscular Dystrophy (DMD)**

Generic Name	Brand Name
casimersen	Amondys 45
eteplirsen	Exondys 51
golodirsen	Vyondys 53
viltolarsen	Viltepso