RX.PA.009.CCH AMONDYS 45 (CASIMERSEN) & VYONDYS 53 (GOLODIRSEN)

The purpose of this policy is to define the prior authorization process for Amondys 45 (casimersen) and Vyondys 53 (golodirsen).

Amondys 45 (casimersen) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.

Vyondys 53 (golodirsen) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

For Exondys 51 (eteplirsen) – refer to the HFS criteria at https://hfs.illinois.gov/content/dam/soi/en/web/hfs/sitecollectiondocuments/exondys51webcriteria.pdf

DEFINITIONS

Duchenne muscular dystrophy (DMD) - is a rare, X-linked, recessive, life-threatening, degenerative neuromuscular disease affecting males. It is attributed to mutations in the DMD gene (chromosome Xp21), which is responsible for producing the protein dystrophin. Dystrophin is needed for proper muscle functioning and provides mechanical stability to muscle fibers during muscle contraction. The absence of or defect in this protein, leads to progressive muscle degeneration with loss of independent ambulation, as well as respiratory and cardiac complications.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drugs, Amondys 45 and Vyondys 53, are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must have a diagnosis of Duchenne Muscular Dystrophy (DMD) with a confirmed mutation of a DMD gene that is amenable to:
  - Exon 45 skipping (Amondys 45)
  - Exon 53 skipping (Vyondys 53)
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must be prescribed by, or in consultation with, a provider board certified in ONE of the following specialties:
  - Neurology
  - Orthopedics
  - Physical medicine and rehabilitation
  - Neuromuscular medicine
  - Neurodevelopmental disabilities
- Must have documentation of ALL the following:
  - Current weight
  - 6-Minute Walk Test (6MWT) if ambulatory
  - Brooke Upper Extremity (BUE) Function score of ≤5
  - Stable pulmonary function with Forced Vital Capacity (FVC) ≥30% predicted
  - Urinalysis showing absence of proteinuria
  - Blood Urea Nitrogen (BUN)
  - Serum Creatinine (SCr)
- Must have tried (and been adherent) to standard corticosteroid therapy for a minimum of 6 months OR must have justification for discontinuation of standard therapy
- Must have documentation of the goals of therapy

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation of the following:

- Must continue to be adherent to the requested medication – infusion records are

required to support adherence
- Must have a clinical response to therapy, based upon the prescriber's assessment while on therapy
- Must submit current:
  - Weight
  - 6MWT if ambulatory
  - BUE Function score of ≤5
  - FVC ≥30% predicted
  - Urinalysis showing absence of proteinuria
  - BUN
  - SCr
- Must have continued standard therapy previously initiated (if appropriate/tolerated)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1426	Amondys 45	Injection, casimersen, 10mg
J1429	Vyondys 53	Injection, golodirsen, 10mg

References:

1. Vyondys 53 [prescribing information]. Sarepta Therapeutics, Cambridge, MA, December 2019.
2. Amondys 45 [prescribing information]. Sarepta Therapeutics, Cambridge, MA, March 2023.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	01/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

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