SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Duchenne Muscular Dystrophy (DMD)s Medications (Medical)

Drug Requested: (Check box below that applies)

❑ **Amondys 45** (casimersen) **IV (J1426)**	❑ **Exondys 51** (eteplirsen) **IV (J1428)**
❑ **Viltepso®** (viltolarsen) **IV (J1427)**	❑ **Vyondys 53** (golodirsen) **IV (J1429)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the time frame does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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Recommended Dosing:

Medication	Indication	Dosing Limits
Amondys 45 (casimersen)	DMD with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping	30 mg/kg IV once weekly
Exondys 51 (eteplirsen)	DMD with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping	30 mg/kg IV once weekly
Viltepso® (viltolarsen)	DMD with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping	80 mg/kg IV once weekly
Vyondys 53 (golodirsen)	DMD with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping	30 mg/kg IV once weekly

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Member has been diagnosed with Duchenne Muscular Dystrophy (DMD)
- ❑ Prescriber is or has consulted with a neurologist with expertise in the diagnosis of DMD
- ❑ Provider must submit genetic testing results confirming the mutation of the DMD gene is amenable to **ONE** of the following:
  - ❑ Exon 51 skipping for Exondys 51
  - ❑ Exon 53 skipping for Vyondys 53 or Viltepso 53
  - ❑ Exon 45 skipping for Amondys 45
- ❑ Member must meet **ONE** of the following age requirements before initiation of therapy:
  - ❑ Vyondys 53 or Amondys 45 is initiated before the age of 16
  - ❑ Exondys 51 is initiated before the age of 14
  - ❑ Viltepso is initiated before the age of 10
- ❑ Member is currently stabilized on **ONE** of the following for the past 6 months and will continue to take along with the requested medication **(verified by chart notes and/or pharmacy paid claims)**:

❑ deflazacort (Emflaza)	❑ prednisone	❑ prednisolone

- ❑ Member is able to achieve an average distance of at least 180 meters for Exondys 51 or 250 meters for Vyondys 53, Viltepso, Amondys 45 while walking independently over 6 minutes
- ❑ Provider must submit member's 6-minute walking test baseline value: _____ **(assessment must be attached)**
- ❑ Provider must submit member's baseline dystrophin level: _____ **(current labs must be provided)**

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- ❑ Provider must submit member's current weight: _____ **(chart notes documenting weight must be provided)**
- ❑ For Vyondys 53, Viltepso or Amondys 45 approval, member's baseline renal function must be evaluated **(current labs documenting eGFR must be provided)**
- ❑ Member will **NOT** take the requested medication concomitantly with other exon skipping therapies for DMD
- ❑ For member's previously established on Elevidys therapy, member must meet **BOTH** of the following:
  - ❑ Member is **NOT** on concomitant therapy with Elevidys (delandistrogene moxeparvovec-rokl)
  - ❑ Last administered dose with Elevidys was at least 24 months prior to proposed start date of requested DMD-directed antisense oligonucleotides medication
- ❑ Dosing for requested DMD medication must be in accordance with the United States Food and Drug Administration approved labeling

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has experienced a positive response to therapy as demonstrated by at least **ONE** of the following **(current labs/assessments/chart notes must be submitted)**:
  - ❑ An increase in dystrophin level
  - ❑ Improved 6-minute walk test distance
  - ❑ Member remains ambulatory (e.g., not wheelchair dependent)
- ❑ Provider must submit member's current weight: _____ **(chart notes documenting weight must be provided)**
- ❑ For Vyondys 53, Viltepso or Amondys 45 approval, member's renal function must continue to be evaluated **(current labs documenting eGFR must be provided)**

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____
  NPI or DEA # of administering location: _____
  OR
- ❑ **Specialty Pharmacy – Proprium Rx**

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

**Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by the Pharmacy and Therapeutic Committee:** ~~10/19/2017;~~ **11/16/2023**
REVISED/UPDATED/REFORMATTED: ~~12/18/2017; 3/15/2019; 5/21/2019; 7/11/2019; 9/20/2019; 6/22/20; 7/1/2020; 6/30/2021; 9/14/2021; 10/8/2021.~~ **12/11/2023**