HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Amondys 45 (casimersen)
BILLING CODE	J1426
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Amondys 45 (casimersen) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of DMD gene that is amenable to exon 45 skipping. This is the first FDA-approved treatment for patients with this specific type of mutation. This indication was approved based on an increase in dystrophin production in skeletal muscle observed in patients treated with Amondys 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Amondys 45 (casimersen) will be considered for coverage when the following criteria are met:

DUCHENNE MUSCULAR DYSTROPHY (DMD)

For **initial** authorization:

1. Member has a diagnosis of DMD with confirmed mutation of DMD gene that is amenable to exon 45 skipping (genetic testing results required); AND
2. Medication is being prescribed by or in consultation with a DMD specialist (i.e., neurologist); AND
3. Member is currently stable on corticosteroid for at least 6 months prior to starting therapy with Amondys 45, unless not tolerated or contraindicated.
4. **Dosage allowed/Quantity limit:** 30 mg/kg IV once weekly.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show stability or slowed rate of decline of the member's motor function compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 6 months.

HAP CareSource considers Amondys 45 (casimersen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/17/2021	New policy for Amondys 45 (casimersen) created.
03/04/2022	Removed ambulatory requirement for reauthorization criteria. Added J code.
3/31/2023	Removed ambulatory requirement from initial criteria.

References:

1. Amondys 45 [package insert]. Cambridge, MA; Sarepta Therapeutics, Inc. February 2021.
2. ClinicalTrials.gov. Study of SRP-4045 and SRP-4053 in DMD Patients (ESSENCE). NCT02500381. Available at https://clinicaltrials.gov/ct2/show/NCT02500381.
3. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267.
4. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-472.

Effective date: 01/01/2025
Revised date: 03/31/2023