Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Amondys 45™ (casimersen)

Effective: January 14, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Amondys 45 (casimersen) is an antisense oligonucleotide 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.

This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Amondys45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Clinical Guideline Coverage Criteria

The plan may authorize Amondys 45 for Members when the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the Duchenne muscular dystrophy gene that is amenable to exon 45 skipping

   Note: Common Duchenne muscular dystrophy deletions that are theoretically amenable to exon 45 skipping include: 7-44,12-44, 18-44, 44, 46, 46-47, 46-48, 46-49, 46-51, 46-53, 46-55, 46-57, 46-59, 46-60, 46-67, 46-69, 46-75, 46-78

AND

2. The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy

AND

3. Documentation of **one (1)** of the following:
   a. Member has been receiving a stable dose of corticosteroids for a period of at least 6 months and will continue to utilize corticosteroids in combination with Amondys 45

b. Member has a contraindication to corticosteroid

AND

4. Amondys 45 will not be used concomitantly with any other disease-modifying therapies for Duchenne muscular dystrophy

Reauthorization Criteria

1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the Duchenne muscular dystrophy gene that is amenable to exon45 skipping

   Note: Common Duchenne muscular dystrophy deletions that are theoretically amenable to exon 45 skipping include: 7-44,12-44, 18-44, 44, 46, 46-47, 46-48, 46-49, 46-51, 46-53, 46-55, 46-57, 46-59, 46-60, 46-67, 46-69, 46-75, 46-78

AND

2. The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy

AND

3. Documentation of **one (1)** of the following:
   a. Member continues to utilize corticosteroids in combination with Amondys 45
   b. Member has a contraindication to corticosteroids

AND

4. Documentation that based on the prescriber's assessment, the Member continues to benefit from Amondys 45 documented by a standardized assessment of motor function or respiratory function

AND

5. Amondys 45 will not be used concomitantly with any other disease-modifying therapies for Duchenne muscular dystrophy

Limitations

- Initial Authorizations will be provided for 6 months. Reauthorizations will be provided for 12 months.
- Members new to the plan stable on Amondys 45 should be reviewed against Reauthorization Criteria.
- The plan will not authorize the use of Amondys 45 in members with Duchenne muscular dystrophy who do not have a confirmed mutation of the Duchenne muscular dystrophy gene that is amenable to exon 45 skipping.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HPCPS Codes	Description
J1426	Injection, casimersen, 10 mg

References

1. Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. The Lancet Neurology. 2018 March;17(3):251-267.
2. Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: respiratory, cardiac, bone health, and orthopaedic management. The Lancet Neurology. 2018 April;17(4):347-361.
3. Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 3: primary care, emergency management, psychosocial care, and transitions of care across the lifespan. The Lancet Neurology. 2018 May; 17(5):445-455.
4. Gloss D, Moxley RT, Ashwal S, et al. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy. Neurology. 2016;86:465-72.
5. Eser G, et al. Current outline of exon skipping trials in Duchenne muscular dystrophy. Genes (Basel). 2022;13(7):1241.
6. Fletcher, S., et. al. Dystrophin Isoform Induction In Vivo by Antisense-mediated Alternative Splicing. The American Society of Gene & Cell Therapy. 2010;18(6):1218-1223.
7. Gloss D, et al. 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.

8. Polavarapu K, Preethish-Kumar V, Sekar D, et al. Mutation pattern in 606 Duchenne muscular dystrophy children with a comparison between familial and non-familial forms: a study in an Indian large single-center cohort. J Neurol. 2019;266(9):2177-2185.
9. Kang PB, et al. Evidence-based guideline summary: Evaluation, diagnosis, and management of congenital muscular dystrophy. Neurology. 2015 March. 84 (13) 1369-1378. Reaffirmed on September 18, 2021.
10. Amondys 45 (casimersen) [prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc; July 2024.

Approval And Revision History

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- April 19, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939, and added a reauthorization duration clarification
- May 2023 Annual Review No Change effective July 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- March 12, 2024: Updated prerequisite language to state “Member has been receiving a stable dose of corticosteroids for a period of at least 6 months and will continue to utilize corticosteroids in combination with Amondys 45” Added Amondys 45 will not be used concomitantly with any other disease-modifying therapies for Duchenne muscular dystrophy. Removed the Limitation The plan will not authorize the use of Amondys 45 in combination with other disease modifying therapies for Duchenne muscular dystrophy as there no evidence to suggest combination therapy is safe or effective (effective 6/1/24).
- January 14, 2025: No changes (eff 1/14/25)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.