Mass General Brigham
Health Plan

Amondys 45 (casimersen)
Effective 11/01/2021

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
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 Amondys 45

Coverage Guidelines
Authorization may be granted for new members to the plan who are currently receiving treatment with Amondys 45 excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member has a documented diagnosis of Duchenne muscular dystrophy with a mutation of the DMD gene that is amenable to exon 45 skipping
2. The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy
3. Member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner)
4. Dosing is appropriate (30 mg/kg intravenously every week)
5. ONE of the following:
    a. Member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent

b. Contraindication to corticosteroids

6. Member has at least a baseline measurement for ALL of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    a. Timed ten-meter walk/run (time in seconds)
    b. Timed floor (supine) to stand (time in seconds)
    c. Timed four-step descend (time in seconds)
    d. Timed four-step climb (time in seconds)
    e. Timed sit to stand (time in seconds)

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition and the following:

1. Member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included)
2. Dosing remains appropriate
3. ONE of the following:
    a. Member continues to utilize corticosteroids in combination with the requested agent
    b. Contraindication to corticosteroids
4. Member has a stable or improving pattern of observed performance on at least TWO of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    a. Timed ten-meter walk/run (time in seconds)
    b. Timed floor (supine) to stand (time in seconds)
    c. Timed four-step descend (time in seconds)
    d. Timed four-step climb (time in seconds)
    e. Timed sit to stand (time in seconds)

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months

Appendix

Examples of DMD gene mutations (exon deletions) amenable to exon 45 skipping (not an all-inclusive list):

1. Deletion of exon 44
2. Deletion of exon 46-47
3. Deletion of exon 46-48
4. Deletion of exon 46-49
5. Deletion of exon 46-51
6. Deletion of exon 46-53
7. Deletion of exon 46-55

References

1. Amondys 45 [package insert]. Cambridge, MA: Sarepta Therapeutics; February 2021.
2. ClinicalTrials.gov. Study of SRP-4045 and SRP-4053 in DMD patients (ESSENCE). Available at: https://clinicaltrials.gov/ct2/show/NCT02500381. Accessed March 1, 2021.
3. 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.

4. 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.

Review History
09/22/2021 – Reviewed and Created for Sept P&T. Effective 11/01/2021.