JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP103
		Effective Date	01/15/2025
		Approval Date	07/17/2024
	Subject **Amondys 45**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Amondys 45

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I. POLICY

A. Amondys 45 (casimersen) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Amondys 45 may be approved for patients who meet the following:
   1. Documentation has been submitted showing the following:
      a. Diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing with identification of the specific type of DMD gene mutation
      b. The DMD gene mutation is amenable to exon 45 skipping. Examples include the following (not all-inclusive lists):
         I. Deletion of exon 44 2
         II. Deletion of exon 46-47
         III. Deletion of exon 46-48
         IV. Deletion of exon 46-49
         V. Deletion of exon 46-51
         VI. Deletion of exon 46-53
         VII. Deletion of exon 46-55
      c. Treatment with Amondys 45 is initiated before the age of 14.
      d. Patient is able to achieve an average distance of at least 300 meters while walking independently over 6 minutes
      e. Patient meets one of the following scenarios:
         I. Patient has not previously received gene replacement therapy for DMD (e.g., Elevidys)
         II. Patient has previously received gene replacement therapy for DMD (e.g., Elevidys) and has experienced a worsening in clinical status since receiving gene replacement therapy (e.g., decline in ambulatory function)
      f. Patient will not exceed a dose of 30 mg/kg once weekly

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the following:
   1. The patient has had a beneficial response to therapy, evidenced by remaining ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent)
   2. Patient will not exceed a dose of 30 mg/kg once weekly
C. Limitation: Patient that were previously established on Amondys 45 and subsequently administered gene replacement therapy (e.g., Elevidys) must meet all the initial criteria prior to re-starting Amondys 45 therapy.

IV. EXCLUSIONS

A. Amondys 45 will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, casimersen, 10 mg	J1426

VII. REFERENCES

1. Amondys 45 [prescribing information]. Cambridge, MA: Sarepta Therapeutics; February 2021.
2. 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.
3. 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

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation

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01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

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