MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy

Antisense Oligonucleotide Medications

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Policy Number: 027

BCBSA Reference Number: None

Related Policies

- N/A

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Standard Formulary	
Drug	**Formulary Status**
Amondys 45 ™(casimersen)	PA Required
Exondys 51 ™(eteplirsen)	PA Required
Givlaari ™(givosiran)	PA Required
Viltepso ®(viltolarsen)	PA Required
Vyondys 53 ™(golodirsen)	PA Required

We may cover Amondys 45 ™ **(**casimersen**)** for the treatment Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping when **all** of the following criteria are met:

- Confirmed diagnosis of Duchenne muscular dystrophy (DMD) which will benefit from Exon 45 skipping.

AND

- Documentation of ambulation without assistance or devices.

AND

- Concurrent use of glucocorticoids, unless clinically contraindicated.

AND

- The prescription is written by a board certified / board eligible Neurologist.

AND

- Dose is limited to FDA approved dosing of 30 mg/kg administered once weekly (weight and calculated dose required)

Reauthorization will require the same criteria above.

If approved the Prior Authorization will be granted for up to six months.

We may cover Exondys 51™ **(**eteplirsen**)** for the treatment Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping when **all** of the following criteria are met:

- Confirmed diagnosis of Duchenne muscular dystrophy (DMD) which will benefit from Exon 51 skipping.

AND

- Documentation of ambulation without assistance or devices.

AND

- Concurrent use of glucocorticoids, unless clinically contraindicated.

AND

- The prescription is written by a board certified / board eligible Neurologist.

AND

- Dose is limited to FDA approved dosing of 30 mg/kg administered once weekly (weight and calculated dose required)

Reauthorization will require the same criteria above.

If approved the Prior Authorization will be granted for up to six months.

We may cover Givlaari ™ **(**givosiran**)** for the treatment of adults with acute hepatic porphyria (AHP) when **all** of the following criteria are met:

- Confirmed diagnosis of acute hepatic porphyria (AHP) [including acute intermittent porphyria (AIP), variegate porphyria (VP), aminolevulinic acid dehydratase deficiency porphyria (ALAD), and hereditary coproporphyria (HCP)].

AND

- Patient is ≥ 12 years of age.

AND

- Elevated urinary or plasma porphobilinogen (PBG) or ALA values within the past year.

AND

- Patient has active disease, with at least 4 documented porphyria attacks within the last 12 months.

AND

- Patient is not anticipating a liver transplantation

Reauthorization will require the same criteria above.

If approved the first Prior Authorization will be granted for up to six months and continuation approvals will be granted for up to one(1) year.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We may cover Vyondys 53 ™ **(**golodirsen**) or** Viltepso ® (viltolarsen) for the treatment Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping when **all** of the following criteria are met:

- Confirmed diagnosis of Duchenne muscular dystrophy (DMD) which will benefit from Exon 53 skipping.

AND

- Documentation of ambulation without assistance or devices

AND

- Documentation of a recent (within four weeks of request) pre-treatment 6-Minute Walk Time of at least 300 meters while walking independently (e.g., without assist, cane, walker, wheelchair)

AND

- Concurrent use of glucocorticoids, unless clinically contraindicated

AND

- Member has stable pulmonary and Cardiac function

AND

- The prescription is written by a board certified / board eligible Neurologist

AND

- Member is not concurrently enrolled in a clinical trial to receive an experimental therapy for DMD

AND

- Dose is limited to FDA approved dosing of 30 mg/kg administered once weekly (weight and calculated dose required)

Reauthorization will require the same criteria above.

If approved the Prior Authorization will be granted for up to six months.

We do not cover the medications listed above for other conditions not listed above.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	**Code Description**
C9071	Injection, viltolarsen (Viltepso), 10 mg
J1428	Injection, eteplirsen, 10 mg (Exondys 51)
J1429	Injection, golodirsen, 10 mg (Vyondys 53)
J0223	Injection, givosiran, 0.5 mg (Givlaari)
C9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J3490	Unclassified drugs
J3590	Unclassified biologics

Other Information
Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network, see link below:
Link to Specialty Pharmacy List

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Prior Authorization Information

Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO	Prior authorization is **required**.

Policy History

Date	Action
7/2021	Updated to add Amondys 45 to the policy.
1/2021	Updated to add Viltepso to the policy
4/2020	Updated to add Vyondys-53 to the Policy.
2/2020	Updated to change the name of the policy and to add Givlaari to the policy.
2/2019	BCBSA National medical policy review. No changes to policy statements. New references added.
10/2018	Clarified coding information.
1/2018	Clarified coding information.
10/2017	Updated to change Walgreens Specialty Name.
7/2017	Updated to add AllCare to Pharmacy Specialty list.
5/2017	Implementation of a new policy including the medication Exondys -51 ™.

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To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf