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.

Prior Authorization Information

| ☒ Prior Authorization | Pharmacy Operations: |
| ☐ Step Therapy | Tel: 1-800-366-7778 |
| ☒ Quality Care Dosing | Fax: 1-800-583-6289 |

Policy applies to Commercial Members:
- Managed Care (HMO and POS), PPO and Indemnity
- MEDEX with Rx plan
- Managed Major Medical with Custom BCBSMA Formulary
- Comprehensive Managed Major Medical with Custom BCBSMA Formulary
- Managed Blue for Seniors with Custom BCBSMA Formulary

To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration.
Please refer to the chart below for the formulary and step status of the medications affected by this policy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amondys 45™ (casimersen)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Exondys 51™ (eteplirsen)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Givlaari™ (givosiran)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Qalsody™ (tofersen)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Viltens® (viltolarsen)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Vyondys 53™ (golodirsen)</td>
<td>PA Required</td>
</tr>
</tbody>
</table>

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** Qalsody ™ (tofersen) for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene when all of the following criteria are met:

- Confirmed diagnosis of amyotrophic lateral sclerosis (ALS) in adults with a mutation in the superoxide dismutase 1 (SOD1) gene **AND**
- The previous or concurrent use of any form of Riluzole or Radicava (edaravone), **AND**
- Patient is ≥ 18 years of age.

Reauthorization will require the same criteria above.

If approved the Prior Authorization 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 medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9071</td>
<td>Injection, viltolarsen (Viltespo), 10 mg</td>
</tr>
<tr>
<td>J1428</td>
<td>Injection, eteplirsen, 10 mg (Exondys 51)</td>
</tr>
<tr>
<td>J1429</td>
<td>Injection, golodirsen, 10 mg (Vyondys 53)</td>
</tr>
<tr>
<td>J0223</td>
<td>Injection, givosiran, 0.5 mg (Givlaari)</td>
</tr>
<tr>
<td>C9399</td>
<td>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)</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
</tbody>
</table>

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
Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual’s unique clinical circumstances. This is also referred to as “individual consideration” or an “exception request.”

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:
We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/2023</td>
<td>Updated to include Qalsody™ to the policy and updated IC to align with 118E MGL § 51A.</td>
</tr>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>7/2021</td>
<td>Updated to add Amondys 45 to the policy.</td>
</tr>
<tr>
<td>1/2021</td>
<td>Updated to add Viltepso to the policy.</td>
</tr>
<tr>
<td>4/2020</td>
<td>Updated to add Vyondys-53 to the Policy.</td>
</tr>
<tr>
<td>2/2020</td>
<td>Updated to change the name of the policy and to add Givlaari to the policy.</td>
</tr>
<tr>
<td>2/2019</td>
<td>BCBSA National medical policy review. No changes to policy statements. New references added.</td>
</tr>
<tr>
<td>10/2018</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>1/2018</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>10/2017</td>
<td>Updated to change Walgreens Specialty Name.</td>
</tr>
<tr>
<td>7/2017</td>
<td>Updated to add AllCare to Pharmacy Specialty list.</td>
</tr>
<tr>
<td>5/2017</td>
<td>Implementation of a new policy including the medication Exondys -51™.</td>
</tr>
</tbody>
</table>

References

9. Ruff S. Sarepta Presentations for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee 2016;


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