Onpattro (patisiran) IV Solution  
Tegsedi (inotersen) Subcutaneous Injection  
Effective June 19, 2019

<table>
<thead>
<tr>
<th>Plan</th>
<th>☒ MassHealth</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☐ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<tbody>
<tr>
<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
<td>☒ Medical Benefit (NLX)</td>
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**Specialty Limitations**
These medications have been designated specialty and must be filled at a contracted specialty pharmacy.

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<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
<th>All Plans</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
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<tr>
<td>Exchange</td>
<td>☒ Commercial</td>
<td>☒ Exchange</td>
<td>Medicine Specialty Medications (NLX)</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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| Exceptions        | Onpattro is covered through the medical benefit while Tegsedi is covered on the pharmacy benefit. |

**Overview**
Patisiran and inotersen are interfering ribonucleic acids (siRNA) which cause degradation of mutant and wild-type transthyretin (TTR) mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Serum TTR is a carrier of retinol binding protein, which is involved in the transport of vitamin A in the blood. Patisiran and inotersen are indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

**Coverage Guidelines**
Authorization may be granted for members who are currently receiving treatment with Onpattro or Tegsedi excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**
AllWays Health Partners may authorize Onpattro when the following criteria have been met and documentation has been provided:

1. Member has documented diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) through genetic testing confirming a pathogenic variant in TTR
2. Member has peripheral neuropathy associated with hATTR with a baseline polyneuropathy disability score of IIIb or lower †
3. Member is at least 18 years of age
4. Prescriber is a specialist in rheumatology or neurology OR specialist consult is provided
5. For Tegsedi only: Member has had an inadequate response, adverse reaction or a contraindication to Onpattro.

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AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
Continuation of Therapy
Reauthorizations will be granted when documentation of positive clinical response has been submitted as evidenced by improved neurological impairment, motor function, quality of life or ambulation

† The polyneuropathy disability score is an additional assessment tool with ranking based on classes I-IV. Higher scores are indicative of more impaired walking ability. The classes are defined as follows:
   I: preserved walking, sensory disturbances
   II: impaired walking without need for a stick or crutches
   IIIa: walking with one stick or crutch
   IIIb: walking with two sticks or crutches
   IV: confined to wheelchair or bedridden

Limitations
1. Approvals will be granted for 12 months

Dosing

| Tegsedi injection 284/1.5 | 4 injections per month |

References
1. Onpattro (patisiran) [prescribing information], Cambridge, MA: Alnylam Pharmaceuticals Inc; February 2020
2. Tegsedi (inotersen) [prescribing information], Boston, MA: Akcea Therapeutics Inc; October 2019
5. Benson MD, Dasgupta NR, Monia BP. Inotersen (transthyretin-specific antisense oligonucleotide) for treatment of transthyretin amyloidosis. Neurodegener Dis Manag 2019

Review History
06/19/2019 – Reviewed
05/20/2020 – Reviewed May P&T Mtg; included different formulation into criteria; updated references

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.