Onpattro (patisiran)
Tegsedi (inotersen)
Effective June 19, 2019

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<th>Benefit</th>
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<th>Speciality Limitations</th>
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<tr>
<td>MassHealth</td>
<td>Pharmacy Benefit</td>
<td>☒ Prior Authorization</td>
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<tr>
<td>Commercial/Exchange</td>
<td>Medical Benefit (NLX)</td>
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**Specialty Medications**
All Plans
Phone: 866-814-5506
Fax: 866-249-6155

**Non-Specialty Medications**

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<tr>
<th>MassHealth</th>
<th>Phone: 877-433-7643</th>
<th>Fax: 866-255-7569</th>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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**Medical Specialty Medications (NLX)**
All Plans
Phone: 844-345-2803
Fax: 844-851-0882

**Exceptions**
Onpattro is covered through the medical benefit while Tegsedi is covered on the pharmacy benefit.

**Overview**
The indications below including FDA-approved indication is considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indication**
Treatment of the polyneuropathy of hereditary transthyretin mediated amyloidosis in adults

**Coverage Guidelines**
Authorization of 12 months 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.

**Continuation of Therapy**
Reauthorizations will be granted with 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
2. The following quantity limits apply:

   | Tegsedi inj 284/1.5 | 4 inj per 28 days |

**References**
1. Onpattro (patisiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; August 2018.
2. Tegsedi (inotersen) [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc; October 2018
5. Benson MD, Dasgupta NR, Monia BP. Inotersen (transthyretin-specific antisense oligonucleotide) for treatment of transthyretin amyloidosis. Neurodegener Dis Manag 2019

**Review History**
06/19/19 – Reviewed

**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.