Clinical Edit Criteria

Drug/Drug Class:	**Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR) Clinical Edit**
Date:	**May 16, 2019**
Prepared for:	
Prepared by:	**MO HealthNet**

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Onpattro™ (patisiran) and Tegsedi™ (inotersen).

Why was this Issue Selected: Onpattro and Tegsedi are indicated for the treatment of the polyneuropathy caused by hereditary transthyretin-mediated amyloidosis (hATTR) in adults. hATTR is a rapidly progressing, life-threatening disease caused by a mutation of the transthyretin gene that results in misfolded protein accumulation as amyloid fibrils in the nerves, heart or gastrointestinal tract. Onpattro and Tegsedi work by targeting RNA to reduce the production of the transthyretin protein thus reducing the accumulation of amyloid deposits in the peripheral nerves, improving symptoms and helping patients better manage the condition. Polyneuropathy caused by hATTR affects approximately 3,200 people in the United States. The use of Tegsedi requires prescribers and patients to enroll in a Risk Evaluation and Mitigation Strategies (REMS) program due to its potential to cause thrombocytopenia and glomerulonephritis that may require immunosuppressive treatment and may result in dialysis. Due to the highly specific patient population that would benefit from treatment with Onpattro and Tegsedi, high cost, and the risk of thrombocytopenia and glomerulonephritis with Tegsedi, MO HealthNet recommends adding a clinical edit to ensure appropriate patient selection.

Program-Specific Information:	Date Range FFS 1/1/2018 – 4/1/2019		
	Drug	**Claims**	**MAC**
	Onpattro™	0	$9595.00 per 5 ml vial ($38,380 per month)
	Tegsedi™	0	$8736.50 per 1.5ml syringe ($34,946 per month)

Type of Criteria:	☒ **Increased risk of ADE** ☒ **Appropriate Indications**	☒ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Onpattro™ (patisiran) and Tegsedi™ (inotersen)
- Age range: all appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

- 18 years of age or older
- Appropriate diagnosis of peripheral nerve disease caused by hATTR (ICD10 E85.1)
    - Documented transthyretin variant by genotyping **AND**
    - Documented amyloid deposit by biopsy
- For Tegsedi:
    - Documentation of laboratory tests prior to treatment, including platelet count, serum creatinine, estimated glomerular filtration rate (eGFR), urine protein to creatinine ratio (UPCR), and urinalysis
    - Initial approval duration of 6 months in order to reevaluate therapy and ensure proper monitoring has occurred with regards to platelet count, serum creatinine, eGFR, UPCR, and urinalysis. If criteria is met to continue therapy, 6 month renewal PA can be given with re-review required again in 6 months.

Denial Criteria

- Therapy with be denied if approval criteria not met

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.

3. Onpattro (patisiran)
   https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Recent/NovelBrandApprovals
4. Tegsedi (inotersen)
   https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Recent/NovelBrandApprovals