



Original Effective Date: 07/22/2021  
 Current Effective Date: 09/21/2025  
 Last P&T Approval/Version: 07/30/2025  
 Next Review Due By: 07/2026  
 Policy Number: C17894-A

## Onpattro (patisiran), Tegsedi (inotersen)

### PRODUCTS AFFECTED

Onpattro (patisiran), Tegsedi (inotersen)

### COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

#### Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

#### DIAGNOSIS:

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR)

#### REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

#### A. HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS ASSOCIATED POLYNEUROPATHY (hATTR-PN):

1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis associated polyneuropathy (hATTR-PN)  
AND
2. Documentation of BOTH of the following [DOCUMENTATION REQUIRED]:

## Drug and Biologic Coverage Criteria

(a) Pathogenic transthyretin (TTR) mutation verified by genetic testing

*Note: More than 120 different transthyretin (TTR) gene mutations have been identified, with predominant symptom presentation varying by genotype. The most common mutations in the US are V122I, T60A, and V30M.*

AND

(b) ONE of the following: Polyneuropathy disability (PND) score  $\leq$  IIIb, Familial amyloidotic polyneuropathy (FAP) stage 1 or 2, OR Neuropathy impairment score (NIS) between 10 and 130

AND

3. Documentation of presence of clinical signs and symptoms of the disease such as: Peripheral sensory-motor neuropathy (e.g., neuropathic pain, paresthesia, weakness, bilateral carpal tunnel syndrome, difficulty walking), Autonomic neuropathy (e.g., hypotension, recurrent urinary tract infections, sexual dysfunction, sweating abnormalities, urinary retention), Gastrointestinal manifestations (e.g., diarrhea, nausea, vomiting, unintentional weight loss), Cardiovascular manifestations (e.g., arrhythmias, conduction abnormalities, heart failure)

AND

4. Documentation the member has tried or is currently receiving at least one systemic agent for symptoms of polyneuropathy from one of the following pharmacologic classes: a gabapentin-type product (e.g., gabapentin, pregabalin) or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline), or Serotonin/Norepinephrine Reuptake Inhibitors (e.g., duloxetine)

AND

5. For Tegsedi (inotersen):

a. Documentation of baseline renal function status (serum creatinine, urinary protein to creatinine ratio (UPCR)  $\leq$  1000 mg/g, urinalysis), AND baseline liver function tests (ALT, AST, bilirubin). Refer to "Other Special Considerations" section.

AND

b. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Tegsedi (inotersen) include: platelet count  $<100 \times 10^9/L$ , a history of acute glomerulonephritis caused by Tegsedi, and a history of hypersensitivity reaction to Tegsedi.]

## CONTINUATION OF THERAPY:

### A. HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS ASSOCIATED POLYNEUROPATHY (hATTR-PN):

1. Documentation of a positive response to therapy (e.g., improved neurologic impairment, motor function, slowing of disease progression, cardiac parameters, improvement in baseline scores: Polyneuropathy disability (PND) score  $\leq$  IIIb OR FAP Stage 1 or 2, neuropathy impairment score) [DOCUMENTATION REQUIRED]

AND

2. Prescriber attests to or clinical review has found no evidence of intolerable adverse effects or drug toxicity (i.e., thrombocytopenia, renal dysfunction, liver injury)

## DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

## PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

## AGE RESTRICTIONS:

18 years of age and older

## Drug and Biologic Coverage Criteria

### QUANTITY:

Onpattro (patisiran): For patients weighing less than 100 kg, the recommended dosage of Onpattro is 0.3 mg/kg once every 3 weeks. For patients weighing 100 kg or more, the recommended dosage of Onpattro is 30 mg once every 3 weeks.

Tegsedi (inotersen): 284 mg/1.5mL per week

### PLACE OF ADMINISTRATION:

Onpattro (patisiran): The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility- based location as per the Molina Health Care Site of Care program.

**Note:** Site of Care Utilization Management Policy applies for Onpattro (patisiran). For information on site of care, see [Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](https://www.molinamarketplace.com)

Tegsedi (inotersen): The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Onpattro (patisiran): Intravenous

Tegsedi (inotersen): Subcutaneous injection

### DRUG CLASS:

Onpattro (patisiran): Small interfering ribonucleic acid (siRNA)

Tegsedi (inotersen): Antisense Oligonucleotide (ASO) Inhibitor Agent

### FDA-APPROVED USES:

Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

### COMPENDIAL APPROVED OFF-LABELED USES:

None

## APPENDIX

### APPENDIX:

The polyneuropathy disability score is an additional assessment tool with ranking based on different classes I-IV. Higher scores are indicative of more impaired walking ability. The varying 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

Familial Amyloid Polyneuropathy (FAP) clinical staging:

Stage 0: no symptoms

Stage 1: unimpaired ambulation; mostly mild sensory, motor, and autonomic neuropathy in the lower limbs

Stage 2: assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs, and trunk

Stage 3: wheelchair-bound or bedridden; severe sensory, motor, and autonomic involvement of all Limbs

Drug and Biologic Coverage Criteria

A. Scoring Scale of Mnis+7 (the higher the score, the less function)

<b>A) mNIS+7</b>			
<b>Test</b>	<b>Component</b>	<b>Minimum Score</b>	<b>Maximum Score</b>
NIS	Cranial Nerves	0	40
	Muscle Weakness	0	152
	Reflexes	0	20
	Sensation	0	32
Modified +7	Heart Rate Deep Breathing†	-3.72	3.72
	Nerve Conduction†	-18.6	18.6
	Touch Pressure	0	40
	Heat-Pain	0	40
<b>mNIS+7*</b>	<b>Composite</b>	<b>-22.3</b>	<b>346.3</b>

B. Scoring Scale of Norfolk QoL-DN (the higher the score, the poorer the quality of life)

<b>B) Norfolk QoL-DN</b>			
<b>Domain</b>	<b>Items<sup>1,2</sup></b>	<b>Minimum Score</b>	<b>Maximum Score</b>
Symptoms	Σ (1-7, 9)	0	32
Physical Functioning/Large Fiber Neuropathy	Σ (8, 11, 13-15, 24, 27-35)	-4	56
Small Fiber Neuropathy	Σ (10, 16-18)	0	16
Large Fiber Neuropathy	Σ (19-21)	0	12
Activities of Daily Living	Σ (12, 22, 23, 25, 26)	0	20
<b>Norfolk QoL-DN*</b>	<b>Total</b>	<b>-4</b>	<b>136</b>

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

Hereditary transthyretin-mediated amyloidosis (hATTR) is a rare condition affecting about 50,000 people worldwide caused by a genetic mutation in the transthyretin (TTR) gene. Mutations in the TTR gene lead to de-stabilization, misfolding and aggregation into insoluble amyloid fibrils which deposit into multiple sites such as the nervous system, heart, kidneys, and eyes. There are multiple TTR mutations, the most prevalent being TTR V30M. Common symptoms of hATTR amyloidosis include peripheral sensory or autonomic neuropathy, cardiomyopathy, and GI dysfunction. As the disease progresses, symptoms can worsen and lead to life-threatening multiorgan dysfunction.

Hereditary transthyretin-mediated amyloidosis manifests as abnormal buildup of amyloids which are protein fibers that deposit in organs and tissues in consequence interfering with normal functioning. The amyloid deposits usually occur in the peripheral nervous system, which can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet. They can also deposit in the heart, kidneys, eyes and gastrointestinal tract and affect their functioning. The focus of the hATTR treatment is generally symptom management.

Given the magnitude of non-specific symptoms, diagnosis of hATTR is often challenging and is commonly confused with other conditions. Treatment options include liver transplantation and a limited number of pharmacologic therapies. While liver transplantation has been shown to eliminate the production of variant TTR protein and slow disease progression, it does not prevent cardiomyopathy as amyloids can continue to deposit in the heart. One treatment option is Vyndaqel (tafamidis), a transthyretin stabilizer, which stabilizes the tetramer of the TTR transport protein to slow the dissociation into monomers that drives TTR amyloidosis. Vyndaqel is indicated for the treatment of cardiomyopathy of wild type or hATTR amyloidosis. Recently approved treatment options for polyneuropathy of hATTR amyloidosis involve inhibition of hepatic production of TTR using a gene silencing RNA molecule, Onpattro (patisiran), and an antisense oligonucleotide, Tegsedi (inotersen).

Patisiran is a small interfering ribonucleic acid (siRNA) which works by silencing a portion of RNA involved in causing polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. More specifically, patisiran prevents production of transthyretin (TTR) which leads to reduction in accumulation of amyloid deposits in peripheral nerves, improving symptoms and helping patients better manage the condition.<sup>3</sup> The FDA approved Onpattro in August 2018 based on data from “Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis” study. It was multicenter, international, randomized, double-blind, placebo-controlled, phase 3 trial of patisiran in patients with hATTR polyneuropathy. The primary end point was the change from baseline in the modified Neuropathy Impairment Score+7 (mNIS+7) at 18 months.

Participants were adult patients (aged 18 to 85 years) with a documented pathogenic variant in TTR; a diagnosis of hereditary transthyretin amyloidosis with peripheral neuropathy, with a NIS of 5 to 130 and a polyneuropathy disability score of IIIb or lower. A total of 225 patients underwent randomization (148 to the patisiran group and 77 to the placebo group). The mean ( $\pm$ SD) mNIS+7 at baseline was 80.9 $\pm$ 41.5 in the patisiran group and 74.6 $\pm$ 37.0 in the placebo group; the least-squares mean ( $\pm$ SE) change from baseline was -6.0 $\pm$ 1.7 versus 28.0 $\pm$ 2.6 (difference, -34.0 points; P<0.001) at 18 months. The effect on gait speed and modified BMI was also observed at 18 months. The least-squares mean change from baseline in gait speed was 0.08 $\pm$ 0.02 m per second with patisiran versus -0.24 $\pm$ 0.04 m per second with placebo (difference, 0.31 m per second; P<0.001). The least-squares mean change from baseline in the modified BMI was -3.7 $\pm$ 9.6 versus -119.4 $\pm$ 14.5 (difference, 115.7; P<0.001). Patisiran improved multiple clinical manifestations of hereditary transthyretin amyloidosis in this trial.<sup>4</sup>

Tegsedi (inotersen) binds to and degrades the mutant and wild-type TTR mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. The FDA approved Tegsedi in October 2018 based on data from the NEURO-TRR study, a 66-week placebo-controlled, phase 3 trial with primary efficacy endpoints being mean change in baseline of the Modified Neuropathy Impairment

## Drug and Biologic Coverage Criteria

Score+7 (mNIS+7) and the Norfolk Quality of Life-Diabetic Neuropathy (QOL-DN) score (see Appendix A and B). Participants of this study were between the ages of 18-82 years old with a diagnosis of stage 1 or 2 hATTR amyloidosis, a Neuropathy Impairment Score (NIS) between 10 – 130, a TTR mutation, and amyloid deposits confirmed through biopsy. Key exclusion criteria included NYHA Class III or higher, previous liver transplant, presence of DM associated neuropathy, and chronic kidney disease. The NEURO-TRR study showed Tegsedi to improve the course of neurologic disease in the quality of life in members with hATTR amyloidosis. Both primary endpoints showed significant benefits with Tegsedi treatment when compared to placebo.

### Tegsedi REMS Program

TEGSEDI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TEGSEDI REMS Program, because of risks of serious bleeding caused by severe thrombocytopenia and because of glomerulonephritis.

Important requirements of the TEGSEDI Prescribing Program include:

- Prescribers must be certified within the program by enrolling and completing training.
- Patients must enroll in the program and comply with ongoing monitoring requirements. Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive TEGSEDI.

Further information, including a list of qualified pharmacies/distributors, is available at [www.TEGSEDIREMS.com](http://www.TEGSEDIREMS.com) or 1-844-483-4736.

### **CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Onpattro (patisiran) and Tegsedi (inotersen) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

Contraindications to Onpattro (patisiran) include: No labeled contraindications.

Contraindications to Tegsedi (inotersen) include: platelet count  $<100 \times 10^9/L$ , a history of acute glomerulonephritis caused by Tegsedi, and a history of hypersensitivity reaction to Tegsedi.

### **Exclusions/Discontinuation:**

Onpattro has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Coverage is not recommended for the following circumstances: Cardiomyopathy associated with hATTR amyloidosis, Primary or leptomeningeal amyloidosis, Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis or Concurrent use with Tegsedi (inotersen) injections.

Discontinue Onpattro if a serious or life-threatening infusion-related reaction occurs.

Tegsedi should not be given to patients who develop a UPCR of 1,000 mg/g or higher, or eGFR below 45 mL/minute/1.73 m<sup>2</sup>.

Do not use in combination with another TTR- lowering agent, including Amvuttra, Tegsedi, Onpattro, Wainua OR TTR-stabilizing agent, including diflunisal, Vyndaqel, Vyndamax.

### **OTHER SPECIAL CONSIDERATIONS:**

Onpattro (patisiran):

A. Infusion-related reactions:

- a. Monitor for signs and symptoms during infusion
- b. Slow or interrupt the infusion if clinically indicated
- c. Discontinue if a serious or life-threatening infusion-related reaction occurs

B. Patisiran can lead to reduced serum vitamin A levels, vitamin A supplementation is advised if patient is taking patisiran.

- a. Refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur

C. Patisiran has not been studied in patients with severe renal or hepatic impairment

Tegsedi (inotersen):

Tegsedi (inotersen) has a Black Box Warning for thrombocytopenia and glomerulonephritis.

Monitoring:

Molina Healthcare, Inc. confidential and proprietary © 2025

*This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.*

## Drug and Biologic Coverage Criteria

Platelets: At baseline, as necessary throughout treatment and for 8 weeks (or longer if platelet counts remain  $<100,000/\text{mm}^3$ ) following the discontinuation of treatment. Inotersen is contraindicated in patients with a platelet count below  $100,000/\text{mm}^3$

Serum creatinine, eGFR, urine protein to creatinine ratio, urinalysis: Inotersen should not be given to patients who develop a UPCR of 1,000 mg/g or higher, or eGFR below  $45 \text{ mL/minute}/1.73 \text{ m}^2$ , pending further evaluation of the cause AST, ALT, total bilirubin: Monitor at baseline, every 4 months during treatment, and for 8 weeks following the discontinuation of treatment. In liver transplant patients, monitor at baseline, monthly during treatment, and for 8 weeks following the discontinuation of treatment.

Onpattro and Tegsedi can lead to reduced serum vitamin A levels, vitamin A supplementation is advised if patient is taking either. Vitamin A is essential for normal embryofetal development; however, excessive levels of vitamin A are associated with adverse developmental effects. The effects on the fetus of a reduction in maternal serum TTR caused by Onpattro and Tegsedi and of vitamin A supplementation are unknown. Refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur.

If a dose of Onpattro is missed, administer as soon as possible. If Onpattro is administered within 3 days of the missed dose, continue dosing according to the patient's original schedule. If Onpattro is administered more than 3 days after the missed dose, continue dosing every 3 weeks thereafter.

## CODING/BILLING INFORMATION

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J0222	Injection, patisiran, 0.1mg

## AVAILABLE DOSAGE FORMS:

Onpattro SOLN 10MG/5ML single-dose vial  
Tegsedi SOSY 284MG/1.5ML prefilled syringe

## REFERENCES

1. Onpattro (patisiran) lipid complex injection, for intravenous use [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals. January 2023.
2. Tegsedi (inotersen) injection, for subcutaneous use [prescribing information]. Waltham, MA: Sobi Inc; January 2024.
3. Rowczenio DM, Noor I, Gillmore JD, et al. Human Mutat. 2014;35(9):E2403-E2412.
4. Commissioner, Office of the. FDA Approves First-of-Its Kind Targeted RNA-Based Therapy to Treat a Rare Disease. U.S. Food and Drug Administration, FDA [online].
5. Adams D, Gonzalez-Duarte A, O' Riordan W, et al., Patisiran, an RNAi Therapeutic, for Hereditary

## Drug and Biologic Coverage Criteria

Transthyretin Amyloidosis: NEJM. New England Journal of Medicine, doi: 10.1056/NEJMoa1716153

6. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. *BMCNeurol*. 2017 Sep 11;17(1):181.
7. Adams D. Recent advances in the treatment of familial amyloid polyneuropathy. *Ther Adv NeurolDisord*. 2013 Mar; 6(2): 129–139
8. Alnylam Pharmaceuticals. The Study of an Investigational Drug, Patisiran (ALN-TTR02), for the Treatment of Transthyretin (TTR)-Mediated Amyloidosis in Patients Who Have Already Been Treated With ALN-TTR02 (Patisiran). In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2018 April 12]. Available from: <https://clinicaltrials.gov/show/NCT02510261>. NLM Identifier: NCT02510261.
9. Institute for Clinical and Economic Review: Draft Evidence Report – Inotersen and Patisiran for Hereditary Transthyretin Amyloidosis: Effectiveness and Value. July 20, 2018.
10. Minamisawa M, Claggett B, Adams D, et al. Association of Patisiran, an RNA Interference Therapeutic, With Regional Left Ventricular Myocardial Strain in Hereditary Transthyretin Amyloidosis: The APOLLO Study. *JAMA Cardiol*. 2019 Mar 16.
11. Solomon SD, Adams D, Kristen A, et al. Effects of Patisiran, an RNA Interference Therapeutic, on Cardiac Parameters in Patients With Hereditary Transthyretin-Mediated Amyloidosis. *Circulation*. 2019Jan 22;139(4):431-443.
12. Koike H, Tanaka F, Hashimoto R, et al. Natural history of transthyretin Val30Met familial amyloid polyneuropathy: analysis of late-onset cases from non-endemic areas. *J Neurol Neurosurg Psychiatry*. 2012 Feb;83(2):152-8.
13. Ando, Y., Coelho, T., Berk, J. L., Cruz, M. W., Ericzon, B. G., Ikeda, S., N Salvi, F. (2013). Guideline of transthyretin-related hereditary amyloidosis for clinicians. *Orphanet journal of rare diseases*, 8, 31. Doi:10.1186/1750-1172-8-31
14. Gales, L. (2019). Tegsedi (Inotersen): An Antisense Oligonucleotide Approved for the Treatment of Adult Members with Hereditary Transthyretin Amyloidosis. *Pharmaceuticals*, 12(2), 78. Doi:10.3390/ph12020078
15. Inotersen and Patisiran for Hereditary Transthyretin Amyloidosis: Effectiveness and Value. Institute for Clinical and Economic Review. August 29, 2018
16. Alcantara, M., Mezei, M. M., Baker, S. K., Breiner, A., Dhawan, P., Fiander, A., ... Bril, V. (2022). Canadian Guidelines for Hereditary Transthyretin Amyloidosis Polyneuropathy Management. *Canadian Journal of Neurological Sciences*, 49(1), 7–18. <https://doi.org/10.1017/cjn.2021.34>

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Quantity Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q3 2025
REVISION- Notable revisions: Required Medical Information References	Q3 2024



## Drug and Biologic Coverage Criteria

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q3 2023
Q2 2022 Established tracking in new format	Historical changes on file

HIGH RISK ALERT