

MRN: \_\_\_\_\_

DOB: \_\_\_\_\_

## STANDARD ONPATTRO™ (patisiran) PLAN OF TREATMENT

(Re) Certification Period From \_\_\_\_\_ to \_\_\_\_\_

NOTE: Patient *may be ineligible* to receive ONPATTRO™ if demonstrating signs and symptoms suggestive of vitamin A deficiency.

1. Patient Name: \_\_\_\_\_ Height (inches): \_\_\_\_\_ Weight (lbs): \_\_\_\_\_

2. Allergies: \_\_\_\_\_

3. Diagnosis: \* Please complete the 2<sup>nd</sup> and 3<sup>rd</sup> digits to complete the ICD-10 code for billing

E85.1 Neuropathic hereditary amyloidosis

Other ICD-10 Code: \_\_\_\_\_ Diagnosis description: \_\_\_\_\_

4. Pre-medications:  None OR **Administered 60 minutes prior to infusion as selected:**

*\*Product Information suggests that all patients are premedicated with IV corticosteroid, acetaminophen 500mg PO, and both H1 and H2 antihistamine blocker IV 60 minutes prior to Infusion as per selected by referring physician below.*

### Acetaminophen:

- 650 mg PO
- 500 mg PO
- 325 mg PO
- 1000 mg PO

**Diphenhydramine:**  50 mg IVP,  25 mg IVP,  25 mg PO,  50 mg PO or

**Ranitidine:**  50 mg IVP **Dexamethasone:**  10 mg IVP or other \_\_\_\_\_mg IVP

Methylprednisolone:  125 mg IVP  40 mg IVP or other \_\_\_\_\_mg IVP

Other: Fexofenadine  60mgs or  180mgs  Cetirizine 10 mg  Loratadine 10 mg

Famotidine:  20mgs IV,  40mgs IV,  20mgs PO,  40mgs PO

Pre-medicate with other: \_\_\_\_\_

## 5. ORDERS:

ONPATTRO™ (patisiran) IV infused in Sodium Chloride 0.9% for a total volume of 200 ml via pump with infusion set containing 1.2-micron filter as per ramping protocol. Prepared using 0.45-micron (PES) syringe filter; utilizing infusion set and line that are DEHP-free.

Patient less than < 100 kg: 0.3 mg/kg IV every 3 weeks OR

Patient 100 kg or more: 30 mg IV every 3 weeks

\* If dose is missed and received within 3 days of missed dose, then continue dosing according to original schedule. If greater than 3 days after missed dose, then continue dosing every 3 weeks thereafter.

Special orders: \_\_\_\_\_

**If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES**

6. Physician's Signature: \_\_\_\_\_ / \_\_\_\_\_ Date: \_\_\_\_\_  
No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: \_\_\_\_\_ NPI: \_\_\_\_\_

MRN: \_\_\_\_\_

DOB: \_\_\_\_\_

## Guidelines for Prescribing ONPATTRO™ (patisiran) (Required documentation with all initial referrals)

Patient Name: \_\_\_\_\_

Referral Date: \_\_\_\_\_

\_\_\_ Include signed and completed **Plan of Treatment**.

\_\_\_ Include patient demographic information and insurance information. (Copy of insurance cards if available)

\_\_\_ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results, serum TTR, PND Scores, FAP Stage, or modified Neuropathy Impairment Scores and/or tests to support diagnosis.**

• ONPATTRO™ contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

\_\_\_ Inform patients that ONPATTRO™ treatment leads to a decrease in vitamin A levels measured in the serum. Instruct patients to take the recommended daily allowance (RDA) of vitamin A. Higher doses than the RDA should not be given to try to achieve normal serum vitamin A levels during treatment, as serum levels do not reflect the total vitamin A in the body.

\_\_\_ Other as requested: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

\*\* Warnings/Precautions: • **Infusion-related reactions (IRR):** In clinical studies, all patients received premedication with a corticosteroid, acetaminophen, and antihistamines (H1 and H2 blockers) to reduce the risk of IRRs. In a controlled clinical study, 19% of ONPATTRO-treated patients experienced IRRs. Among ONPATTRO-treated patients who experienced an IRR, 79% experienced the first IRR within the first 2 infusions. The frequency of IRRs decreased over time. Slow or interrupt the infusion if clinically indicated. Discontinue the infusion if a serious or life-threatening infusion-related reaction occurs. • **Adverse Reactions:** The most frequently reported adverse reactions (that occurred in at least 10% of ONPATTRO-treated patients and at least 3% more frequently than on placebo) were upper respiratory tract infections and infusion-related reactions • **Reduced serum vitamin A levels and recommended supplementation:** Supplement with the recommended daily allowance of vitamin A. Refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur (e.g., night blindness). Pregnancy: Instruct patients that if they are pregnant or plan to become pregnant while taking ONPATTRO they should inform their healthcare provider. Advise female patients of childbearing potential of the potential risk to the fetus. See full prescribing information.



Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.