Palmetto Infusion Services
COMPLIANCE

Phone: 1-800-809-1265 Fax: 1-866-872-8920

MRN:_____

DOB:_____

STANDARD ONPATTRO™ (patisiran) PLAN OF TREATMENT

(Re) Certification Period From_____to _____

NOTE: Patient ***may be ineligible*** to receive ONPATTRO™ if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, demonstrating signs and symptoms suggestive of vitamin A deficiency, or have had recent surgery.

1. Patient Name: _____ Height (inches): _____ Weight (lbs): _____

2. Allergies: _____

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

☐ E85.1 Neuropathic heredofamilial 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-micro 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: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms and Adverse Drug Reaction Guidelines are available at www.palmettoinfusion.com

Revised 9/26/18, per PI 8/2018

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Guidelines for Prescribing ONPATTRO™ (patisiran)

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:**_____

___ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-7)*
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

___ 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, 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.

Palmetto Infusion Services 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.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.

Revised 9/26/18, per PI 8/2018