

Example Order Set

FOR

ONPATTRO[®]

(patisiran)



Example order set

Requires review and approval by clinician, pharmacy, and/or any required hospital committees prior to adopting or using any portion of this example order set. Content should be revised to reflect your hospital's treatment protocol and the specifics of the EMR system.

Key

- Required step
- Per clinical judgment

onpattro[®]

(patisiran) lipid complex injection
10 mg/5 mL



Prior authorization^a

- Ensure prior authorization is obtained for infusions, if required

Cycle 1, Day 1 (cycle length – 21 days)

Premedications

(recommended premedications are in **bold**; for premedications not available or not tolerated intravenously, equivalents may be administered orally)

Corticosteroid (select one):

- Dexamethasone 10 mg intravenous (IV) once at least 60 minutes prior to ONPATTRO® (patisiran) administration. NOT FOR IV PUSH. (EPIC: Starting when released)**
- Dexamethasone 10 mg oral once at least 60 minutes prior to ONPATTRO administration. (EPIC: Starting when released)
- Equivalent substitution _____

Analgesic/antipyretic (select one):

- Acetaminophen 500 mg oral once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)**
- Equivalent substitution _____

H1 antagonist (select one):

- Diphenhydramine 50 mg IV once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)**
- Diphenhydramine 50 mg oral once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)
- Equivalent substitution _____

H2 antagonist (select one):

- Ranitidine 50 mg IV once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)**
- Ranitidine 150 mg oral once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)
- Equivalent substitution _____

Hydration^a

- Sodium Chloride 0.9% IV at 100 mL/h. (This is a suggested initial rate and should not supersede any provider order.) (EPIC: Starting when released)
- Dextrose 5% and Sodium Chloride 0.45% IV at 100 mL/h. (This is a suggested initial rate and should not supersede any provider order.) (EPIC: Starting when released)
- No hydration required

Final check prior to ONPATTRO administration^a

- Ensure licensed provider has entered “OK to proceed with treatment” order

^aNot in product label.



Treatment with ONPATTRO®

In the event of an infusion-related reaction (IRR), medical management should be instituted as clinically indicated.

ONPATTRO, total body weight should be used in dosing:

- Patient weight <100 kg:** ONPATTRO 0.3 mg/kg in NS 200 mL administered via IV infusion over approximately 80 minutes, once. Give at initial infusion rate of approximately 1 mL/min for the first 15 minutes, then increase to approximately 3 mL/min for the remainder of the infusion. Use a dedicated line for ONPATTRO treatment with an infusion set containing a 1.2 micron PES in-line infusion filter. Use infusion sets and lines that are DEHP-free. (EPIC: Once, starting 1 hour after treatment start time^a)
- Patient weight ≥100 kg:** ONPATTRO 30 mg in NS 200 mL administered via IV infusion over approximately 80 minutes, once. Give at initial infusion rate of approximately 1 mL/min for the first 15 minutes, then increase to approximately 3 mL/min for the remainder of the infusion. Use a dedicated line for ONPATTRO treatment with an infusion set containing a 1.2 micron PES in-line infusion filter. Use infusion sets and lines that are DEHP-free. (EPIC: Once, starting 1 hour after treatment start time^a)

Nursing orders

ONPATTRO administration instructions:

- The duration of ONPATTRO infusion may be extended in the event of IRRs such as flushing, back pain, nausea, abdominal pain, dyspnea, and headache. If an IRR occurs, consider slowing or interrupting the ONPATTRO infusion and instituting medical management (e.g., corticosteroids or other symptomatic treatment) as clinically indicated. If the infusion is interrupted, consider resuming at a slower infusion rate only if symptoms have resolved
- Administer ONPATTRO only through a free-flowing venous access line. Monitor the infusion site for possible infiltration during drug administration. Suspected extravasation should be managed according to standard practice for nonvesicants
- Observe the patient during the ONPATTRO infusion and, if clinically indicated, following the infusion
- After completion of the ONPATTRO infusion, flush the intravenous administration set with 0.9% Sodium Chloride Injection, USP to ensure that all ONPATTRO has been administered

Clinical monitoring

- Monitor patient for signs of IRRs which include, but are not limited to: arthralgia or pain (including back, neck, or musculoskeletal pain), flushing (including erythema of face or skin warm), nausea, abdominal pain, dyspnea or cough, chest discomfort or chest pain, headache, rash, chills, dizziness, fatigue, increased heart rate or palpitations, hypotension, hypertension, and facial edema. In the case of a serious or life-threatening IRR, the infusion should be discontinued and not resumed

Emergency medications^b

- If an IRR occurs, consider slowing or interrupting the ONPATTRO infusion and instituting medical management (e.g., corticosteroids or other symptomatic treatment) as clinically indicated according to institution-specific guidelines

Patient education^b

- Inform patients about the signs and symptoms of IRRs during ONPATTRO treatment. Advise patients to contact their healthcare provider immediately if they experience signs and symptoms of IRRs
- 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 of vitamin A

^aTreatment start time is the time of first premedication administration.

^bNot in product label.



Cycle 2, Day 1 (cycle length – 21 days)

Premedications

(recommended premedications are in **bold**; for premedications not available or not tolerated intravenously, equivalents may be administered orally)

Corticosteroid (select one):

- Dexamethasone 10 mg IV once at least 60 minutes prior to ONPATTRO® (patisiran) administration. NOT FOR IV PUSH. (EPIC: Starting when released)**
- Dexamethasone 10 mg oral once at least 60 minutes prior to ONPATTRO administration. (EPIC: Starting when released)
- Equivalent substitution _____

For patients who are tolerating their ONPATTRO infusions but experiencing adverse reactions related to dexamethasone, reduce dose by 2.5 mg increments (minimum dose = 5 mg):

- Dexamethasone 7.5 mg IV once at least 60 minutes prior to ONPATTRO administration. NOT FOR IV PUSH. (EPIC: Starting when released)**
- Dexamethasone 7.5 mg oral once at least 60 minutes prior to ONPATTRO administration. (EPIC: Starting when released)
- Dexamethasone 5 mg IV once at least 60 minutes prior to ONPATTRO administration. NOT FOR IV PUSH. (EPIC: Starting when released)**
- Dexamethasone 5 mg oral once at least 60 minutes prior to ONPATTRO administration. (EPIC: Starting when released)
- Equivalent substitution _____

Analgesic/antipyretic (select one):

- Acetaminophen 500 mg oral once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)**
- Equivalent substitution _____

H1 antagonist (select one):

- Diphenhydramine 50 mg IV once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)**
- Diphenhydramine 50 mg oral once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)
- Equivalent substitution _____

H2 antagonist (select one):

- Ranitidine 50 mg IV once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)**
- Ranitidine 150 mg oral once at least 60 minutes prior to ONPATTRO. (EPIC: Starting when released)
- Equivalent substitution _____

Hydration^a

- Sodium Chloride 0.9% IV at 100 mL/h. (This is a suggested initial rate and should not supersede any provider order.) (EPIC: Starting when released)
- Dextrose 5% Sodium Chloride 0.45% IV at 100 mL/h. (This is a suggested initial rate and should not supersede any provider order.) (EPIC: Starting when released)
- No hydration required

Final check prior to ONPATTRO administration^a

- Ensure licensed provider has entered "OK to proceed with treatment" order

^aNot in product label.



Treatment with ONPATTRO®

In the event of an infusion-related reaction (IRR), medical management should be instituted as clinically indicated.

ONPATTRO, total body weight should be used in dosing:

- **Patient weight <100 kg:** ONPATTRO 0.3 mg/kg in NS 200 mL administered via IV infusion over approximately 80 minutes, once. Give at initial infusion rate of approximately 1 mL/min for the first 15 minutes, then increase to approximately 3 mL/min for the remainder of the infusion. Use a dedicated line for ONPATTRO treatment with an infusion set containing a 1.2 micron polyethersulfone (PES) in-line infusion filter. Use infusion sets and lines that are di(2-ethylhexyl)phthalate-free (DEHP-free). (EPIC: Once, starting 1 hour after treatment start time^a)
- **Patient weight ≥100 kg:** ONPATTRO 30 mg in NS 200 mL administered via IV infusion over approximately 80 minutes, once. Give at initial infusion rate of approximately 1 mL/min for the first 15 minutes, then increase to approximately 3 mL/min for the remainder of the infusion. Use a dedicated line for ONPATTRO treatment with an infusion set containing a 1.2 micron PES in-line infusion filter. Use infusion sets and lines that are DEHP-free. (EPIC: Once, starting 1 hour after treatment start time^a)

Nursing orders

ONPATTRO administration instructions:

- ☑ The duration of ONPATTRO infusion may be extended in the event of IRRs such as flushing, back pain, nausea, abdominal pain, dyspnea, and headache. If an IRR occurs, consider slowing or interrupting the ONPATTRO infusion and instituting medical management (e.g., corticosteroids or other symptomatic treatment) as clinically indicated. If the infusion is interrupted, consider resuming at a slower infusion rate only if symptoms have resolved
- ☑ Administer ONPATTRO only through a free-flowing venous access line. Monitor the infusion site for possible infiltration during drug administration. Suspected extravasation should be managed according to standard practice for nonvesicants
- ☑ Observe the patient during the ONPATTRO infusion and, if clinically indicated, following the infusion
- ☑ After completion of the ONPATTRO infusion, flush the IV administration set with 0.9% Sodium Chloride Injection, USP to ensure that all ONPATTRO has been administered

Clinical monitoring

- Monitor patient for signs of infusion reaction which include, but are not limited to: arthralgia or pain (including back, neck, or musculoskeletal pain), flushing (including erythema of face or skin warm), nausea, abdominal pain, dyspnea or cough, chest discomfort or chest pain, headache, rash, chills, dizziness, fatigue, increased heart rate or palpitations, hypotension, hypertension, and facial edema. In the case of a serious or life-threatening IRR, the infusion should be discontinued and not resumed

Emergency medications^b

- ☑ If an IRR occurs, consider slowing or interrupting the ONPATTRO infusion and instituting medical management (e.g., corticosteroids or other symptomatic treatment) as clinically indicated according to institution-specific guidelines

Supportive care (take-home prescription)

- Vitamin A daily while on therapy (recommended daily value is 5,000 IU). Outpatient RX – Dispense 30 with 11 refills

Patient education

- ☑ Inform patients about the signs and symptoms of IRRs during ONPATTRO treatment. Advise patients to contact their healthcare professional immediately if they experience signs and symptoms of IRRs
- ☑ 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 of vitamin A

^aTreatment start time is the time of first premedication administration.

^bNot in product label.



Cycle 3, Day 1 (cycle length – 21 days)

For subsequent cycles repeat Cycle 2.

To learn more about ONPATTRO® (patisiran)
visit www.onpattro.com.