DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Pulmonary Arterial Hypertension – Orenitram Drug Quantity Management Policy – Per Rx

- Orenitram® (treprostinil extended-release tablets – United Therapeutics)

REVIEW DATE: 08/10/2022

OVERVIEW

Orenitram, a prostacyclin mimetic, is indicated for the treatment of **pulmonary arterial hypertension** (PAH) World Health Organization (WHO) Group 1 to delay disease progression and to improve exercise capacity.[1]

Dosing

The recommended starting dose of Orenitram is 0.125 mg three times daily (TID) with food, taken approximately 8 hours apart or 0.25 mg twice daily (BID) with food, taken approximately 12 hours apart.[1] The dose should be titrated by 0.125 mg TID or 0.25 mg or 0.5 mg BID not more frequently than every 3 or 4 days. The maximum dose is determined by tolerability. The mean dose in a controlled clinical trial at Week 12 was 3.4 mg BID. In another investigation, at Week 60, the median dose of Orenitram was approximately 5 mg TID. Maximum doses investigated were 12 mg BID in a 12-week blinded trial and up to 21 mg BID in an open-label long-term investigation.

Consider a slower titration if dose increments are not tolerated.[1] If the patient experiences intolerable adverse events (AEs), reduce the dose in increments of 0.125 mg TID or 0.25 BID. Avoid abrupt discontinuation. Orenitram tablets should be swallowed whole; do not crush, split, or chew.

If the patient is transitioning from subcutaneous (SC) or intravenous (IV) treprostinil, decrease the dose of SC or IV remodulin, while simultaneously increasing the dose of Orenitram up to 6 mg per day (2 mg TID) if tolerated.[1] The Pprescribing Iinformation provides an equation to estimate the target total daily dose of Orenitram in mg using a patient's dose of IV or SC treprostinil and weight.

If the patient has mild hepatic impairment, the recommended initial Orenitram dose is 0.125 mg BID with 0.125 mg BID dose increases not more frequently than every 3 to 4 days.[1] The use of Orenitram is not recommended in patients with moderate hepatic impairment and is contraindicated in patients with severe hepatic impairment.

If Orenitram is co-administered with strong cytochrome P450 (CYP)2C8 inhibitors (e.g., gemfibrozil), the recommended initial dose is 0.125 mg BID with 0.125 mg BID dose increases not more frequently than every 3 to 4 days.[1]

Any missed doses of Orenitram should be taken as soon as possible.[1] If a patient misses two or more doses, restart at a lower dose and re-titrate. In the event of a planned, short-term Orenitram treatment interruption, consider a temporary infusion of SC or IV treprostinil.

Availability

Orenitram is available as 0.125 mg, 0.25 mg, 1 mg, 2.5 mg, and 5 mg extended-release tablets in bottles of 10 and 100 tablets.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Orenitram. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals will be provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Orenitram® (treprostinil extended-release tablets)	0.125 mg extended-release tablets	90 tablets per Rx	270 tablets per Rx
	0.25 mg extended-release tablets	90 tablets per Rx	270 tablets per Rx
	1 mg extended-release tablets	90 tablets per Rx	270 tablets per Rx
	2.5 mg extended-release tablets	90 tablets per Rx	270 tablets per Rx
	5 mg extended-release tablets	90 tablets per Rx	270 tablets per Rx

CRITERIA

Orenitram 0.125 mg extended-release tablets

1. If the patient's dose is being titrated using the requested product, approve the quantity requested, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
2. If the patient requires a dose of more than 0.375 mg per day approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Orenitram 0.25 mg extended-release tablets

1. If the patient's dose is being titrated using the requested product, approve the quantity requested, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
2. If the patient requires a dose of more than 0.75 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Orenitram 1 mg extended-release tablets

1. If the patient's dose is being titrated using the requested product, approve the quantity requested, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
2. If the patient requires a dose of more than 3 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Orenitram 2.5 mg extended-release tablets

1. If the patient's dose is being titrated using the requested product, approve the quantity requested, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
2. If the patient requires a dose of more than 7.5 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Orenitram 5 mg extended-release tablets

1. If the patient's dose is being titrated using the requested product, approve the quantity requested, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
2. If the patient requires a dose of more than 15 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

REFERENCES

1. Orenitram® extended-release tablets [prescribing information]. Research Triangle Park, NC: United Therapeutics; May 2021.