



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Pulmonary Arterial Hypertension – Uptravi Drug Quantity Management Policy – Per Days
- Uptravi® (selexipag tablets – Actelion)

REVIEW DATE: 04/24/2024; selected revision 06/19/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Uptravi, a prostacyclin receptor agonist, is indicated for the treatment of **pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1** to delay disease progression and reduce the risk of hospitalization for PAH.¹

Dosing

The recommended initial dose of Uptravi is 200 mcg twice daily (BID).¹ Tolerability may be improved if Uptravi is taken with food. The dose should be increased in increments of 200 mcg BID, usually at weekly intervals, to the highest tolerated dose, up to 1,600 mcg BID. Table 1 represents a standard titration schedule and one possible tablet combination to achieve the appropriate dosing. If a patient reaches a dose that cannot be tolerated, reduce the dose to the last tolerated dose. Do not split, crush, or chew tablets. If a dose of Uptravi is missed, patients should take the missed dose as soon as possible, unless the next dose is due within the next 6 hours. If the patient misses 3 or more days of therapy, Uptravi should be restarted at a lower dose and then retitrated.

Table 1. Uptravi Titration Dosing.^{1*}

Month	Titration schedule	# of tablets per day	# of tablets per 7 days	200 mcg tablets total	800 mcg tablets total	Product
Month 1 (Days 1-28)	200 mcg BID x 7 days	2 x 200 mcg	14 x 200 mcg	140	0	#140 bottle of 200 mcg tablets
	400 mcg BID x 7 days	4 x 200 mcg	28 x 200 mcg			
	600 mcg BID x 7 days	6 x 200 mcg	42 x 200 mcg			
	800 mcg BID x 7 days	8 x 200 mcg	56 x 200 mcg			
Month 2 (Days 29-56)	1000 mcg BID x 7 days	2 x 800 mcg + 2 x 200 mcg	14 x 800 mcg + 14 x 200 mcg	140	56	Uptravi Titration Pack (#140 x 200 mcg tablets and #60 x 800 mcg tablets)
	1200 mcg BID x 7 days	2 x 800 mcg + 4 x 200 mcg	14 x 800 mcg + 28 x 200 mcg			
	1400 mcg BID x 7 days	2 x 800 mcg + 6 x 200 mcg	14 x 800 mcg + 42 x 200 mcg			
	1600 mcg BID x 7 days	2 x 800 mcg + 8 x 200 mcg	14 x 800 mcg + 56 x 200 mcg			

* This table represents one possible option using the 200 mcg and 800 mcg tablets. Other tablet combinations could be used. BID – Twice daily.

Availability

Uptravi is available as 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg tablets.¹ Tablets are supplied in bottles of 60 or 140 tablets (200 mcg strength only) and also in a titration pack. The Uptravi titration pack includes a bottle of 140 x 200 mcg tablets and a bottle of 60 x 800 mcg tablets.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Uptravi. 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 are provided for the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Uptravi® (selexipag tablets)	200 mcg tablets	60 tablets per Rx	180 tablets per Rx
	400 mcg tablets	60 tablets per Rx	180 tablets per Rx
	600 mcg tablets	60 tablets per Rx	180 tablets per Rx
	800 mcg tablets	60 tablets per Rx	180 tablets per Rx
	1,000 mcg tablets	60 tablets per Rx	180 tablets per Rx
	1,200 mcg tablets	60 tablets per Rx	180 tablets per Rx
	1,400 mcg tablets	60 tablets per Rx	180 tablets per Rx
	1,600 mcg tablets	60 tablets per Rx	180 tablets per Rx
	Titration Pack (140 x 200 mcg tablets and 60 x 800 mcg tablets)	200 tablets (1 pack) per 365 days	200 tablets (1 pack) per 365 days

Pulmonary Arterial Hypertension – Uptravi Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Uptravi Titration Pack

1. If the patient is reinitiating therapy with Uptravi, approve a one-time override for 200 tablets (1 titration pack) at retail or home delivery.
2. If, according to the prescriber, the patient requires a prolonged dose-titration period, approve a one-time override for 200 tablets (1 titration pack) at retail or home delivery.

Uptravi 200 mcg tablets

1. If the patient is initiating therapy with Uptravi, approve a one-time override for 140 tablets at retail or home delivery.
2. If, according to the prescriber, the patient requires a prolonged dose-titration period, approve a one-time override for 140 tablets at retail or home delivery.

Uptravi 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg tablets

No overrides recommended.

REFERENCES

1. Uptravi® tablets [prescribing information]. South San Francisco, CA: Actelion; October 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Uptravi Titration Pack: Quantity limits for Uptravi tablets were previously approved. Policy was created to change the quantity limit for the Uptravi Titration Pack from 200 tablets (1 titration pack) per dispensing at retail or home delivery to 200 tablets (1 titration pack) per 365 days. Override criteria were added to provide a one-time approval of 200 tablets (1 titration pack), if the patient is reinitiating therapy with Uptravi or if the patient requires a prolonged dose-titration period.	04/24/2024
Selected Revision	Uptravi 200 mcg tablets: New override criteria were added to approve a one-time override for 140 tablets at retail or home delivery if the patient is initiating therapy with Uptravi or if, according to the prescriber, the patient requires a prolonged dose-titration period.	06/19/2024

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