DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Thrombocytopenia – Doptelet Drug Quantity Management Policy – Per Rx
- Doptelet® (avatrombopag tablets – AkaRx)

REVIEW DATE: 07/01/2024

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

Doptelet, a thrombopoietin receptor agonist, is indicated for the following uses:[1]
- **Immune thrombocytopenia (ITP)**, chronic for treatment in adults who have had an insufficient response to a previous treatment.
- **Thrombocytopenia,** as treatment in adults with **chronic liver disease** who are scheduled to undergo a procedure.

Dosing

Chronic Liver Disease

Doptelet therapy should be initiated 10 to 13 days prior to the patient's scheduled procedure and administered orally once daily (QD) for 5 consecutive days with food.[1] The procedure should then take place 5 to 8 days after the final dose of Doptelet. The recommended dose of Doptelet is dependent on the patient's platelet count:
- Platelet count < 40 x 10^9/L: 60 mg (3 tablets) QD x 5 days.
- Platelet count 40 to < 50 x 10^9/L: 40 mg (2 tablets) QD x 5 days.

Chronic Immune Thrombocytopenia

The recommended dose of Doptelet is the lowest dose needed to achieve and maintain a platelet count ≥ 50 x 10^9/L as needed to reduce the patient's risk for bleeding. Initiate Doptelet therapy at a dose of 20 mg (1 tablet) QD administered with food. After initial therapy, assess platelet counts weekly until a stable count ≥ 50 x 10^9/L is achieved. Then, obtain platelet counts monthly thereafter. Dose adjustments should be made based on the patient's platelet count response (Table 1). Do not exceed a dose of 40 mg (2 tablets) QD. Doptelet should not be used to normalize platelet counts.

Table 1. Chronic Immune Thrombocytopenia Doptelet Dose Adjustments.[1]

Platelet Count (x 10^9/L)	Dose Adjustment or Action
< 50 x 10^9/L after at least 2 weeks of Doptelet	Increase One Dose Level per Table 2. Wait 2 weeks to assess the effects of this regimen and any subsequent dose adjustments.
Between 200 and 400 x 10^9/L	Decrease One Dose Level per Table 2. Wait 2 weeks to assess the effects of this regime and any subsequent dose adjustments.
> 400 x 10^9/L	Stop Doptelet. Increase platelet monitoring to twice weekly. When platelet count is < 150 x 10^9/L, decrease One Dose Level per Table 2 and reinitiate therapy.
< 50 x 10^9/L after 4 weeks of Doptelet 40 mg QD	Discontinue Doptelet.
> 400 x 10^9/L after 2 weeks of Doptelet 20 mg weekly	Discontinue Doptelet.

QD – Once daily.

Table 2. Doptelet Dose Levels for Titration in Patients with Chronic Immune Thrombocytopenia.[1]

Dose	Dose Level
40 mg QD	6
40 mg three times per week AND 20 mg four times per week (remaining days)	5
20 mg QD	4
20 mg three time per week	3
20 mg two time per week OR 40 mg once weekly	2
20 mg once weekly	1

QD – Once daily.

The recommended starting dose for a patient taking Doptelet with a moderate or strong dual inhibitor of cytochrome P450 (CYP)2C9 and CYP3A4 is 20 mg (1 tablet) three times per week.[1] If the patient is taking Doptelet with a moderate or strong dual inducer of CYP2C9 and CYP3A4, the initial recommended dose is 40 mg (2 tablets) QD.

Availability

Doptelet is available as 20 mg tablets supplied in the following:[1]

- Carton of one blister card with 10 tablets
- Carton of one blister card with 15 tablets
- Carton of two blister cards, each with 15 tablets (30 tablets total)

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Doptelet. 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 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Doptelet® (avatrombopag tablets)	20 mg tablets	15 tablets*	15 tablets*

* This is a quantity sufficient for the treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a procedure.

Thrombocytopenia – Doptelet Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient requires treatment for chronic immune thrombocytopenia, approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing.

REFERENCES

1. Doptelet® tablets [prescribing information]. Durham, NC: AkaRx; June 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	06/15/2023
Annual Revision	No criteria changes.	07/01/2024