DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 07/09/2025; selected revision 08/13/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.
- **ITP**, persistent or chronic, for treatment in pediatric patients ≥ 1 year of age 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

Doptelet tablets and Doptelet Sprinkle are not substitutable on a mg per mg basis.[1] The Doptelet Sprinkle mixture prepared from the granules is more bioavailable than

the Doptelet tablets. There is no clinical trial experience in switching between the dose forms to guide dosing. If the formulation is switched, platelet counts should be monitored weekly until stable platelet counts are obtained and adjusted as needed before resuming monthly monitoring.

Doptelet Tablets for 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.

Doptelet Tablets for Immune Thrombocytopenia (Adults and Pediatric Patients ≥ 6 years of age)

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.[1] 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. Immune Thrombocytopenia Doptelet Tablet Dose Adjustments (Patients ≥ 6 years of age).[1]

Platelet Count	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 regimen 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 (2 tablets) QD	Discontinue Doptelet.
> 400 x 10^9/L after 2 weeks of Doptelet 20 mg (1 tablet) weekly	Discontinue Doptelet.

QD – Once daily.

Table 2. Doptelet Tablet Dose Levels for Titration in Immune Thrombocytopenia (Patients ≥ 6 years of age).[1]

Dose	Dose Level
40 mg (2 tablets) QD	6
40 mg (2 tablets) three times per week AND 20 mg (1 tablet) four times per week (remaining days)	5
20 mg (1 tablet) QD	4

20 mg (1 tablet) three times per week	3
20 mg (1 tablet) two times per week OR 40 mg (2 tablets) once weekly	2
20 mg (1 tablet) 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.

Doptelet Sprinkle for Immune Thrombocytopenia (Patients 1 year to < 6 years of age)

Doptelet Sprinkle capsules should be opened and the granules mixed into a small amount of soft food or liquid in a spoon or cup. The capsules should not be swallowed whole and the granules should not be chewed or crushed. The mixture should be consumed immediately after preparation.

The recommended dose of Doptelet Sprinkle 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.[1] Initiate Doptelet Sprinkle at a dose of 10 mg (content of 1 capsule) 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 3). Do not exceed a dose of 20 mg (content of 2 capsules) QD. Doptelet should not be used to normalize platelet counts.

Table 3. Immune Thrombocytopenia Doptelet Sprinkle Dose Adjustments (Patients 1 to < 6 years).[1]

Platelet Count	Dose Adjustment or Action
< 50 x 10^9/L after at least 2 weeks of Doptelet Sprinkle	Increase One Dose Level per Table 4. 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 4. Wait 2 weeks to assess the effects of this regimen and any subsequent dose adjustments.
> 400 x 10^9/L	Stop Doptelet Sprinkle. Increase platelet monitoring to twice weekly. When platelet count is < 150 x 10^9/L, decrease One Dose Level per Table 4 and reinitiate therapy.
< 50 x 10^9/L after 4 weeks of Doptelet Sprinkle 20 mg (content of 2 capsules) QD	Discontinue Doptelet.
> 400 x 10^9/L after 2 weeks of Doptelet Sprinkle 10 mg (content of 1 capsule) weekly	Discontinue Doptelet.

QD – Once daily.

Table 4. Doptelet Sprinkle Dose Levels for Titration in Immune Thrombocytopenia (Patients 1 year to < 6 years).[1]

Dose	Dose Level
20 mg (content of 2 capsules) QD	6
20 mg (content of 2 capsules) three times per week AND 10 mg (content of 1 capsule) four times per week (remaining days)	5
10 mg (content of 1 capsule) QD	4
10 mg (content of 1 capsule) three times per week	3
10 mg (content of 1 capsule) two times per week OR 20 mg (content of 2 capsules) once weekly	2
10 mg (content of 1 capsule) once weekly	1

QD – Once daily.

The recommended starting dose for a patient taking Doptelet Sprinkle with a moderate or strong dual inhibitor of cytochrome P450 (CYP)2C9 and CYP3A4 is 10 mg (content of 1 capsule) 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 20 mg (content of 2 capsules) 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)

Doptelet Sprinkle is available as 10 mg capsules filled with granules supplied in bottles of 30 capsules each.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Doptelet and Doptelet Sprinkle. 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	60 tablets	180 tablets
Doptelet® Sprinkle (avatrombopag oral granules)	10 mg capsules	60 capsules	180 capsules

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

No overrides recommended.

REFERENCES

1. Doptelet® tablets/Doptelet® Sprinkle oral granules [prescribing information]. Morrisville, NC: AkaRx; July 2025.

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
Annual Revision	**Doptelet 20mg tablets:** The quantity limit was updated to 60 tablets per dispensing at retail and 180 tablets per dispensing at home delivery. Previously, the quantity limits were 15 tablets per dispensing at retail and 15 tablets per dispensing at home delivery. Override criteria were removed. No overrides apply to the updated quantity limits.	07/09/2025
Selected Revision	**Doptelet Sprinkle 10 mg capsules:** New quantity limits of 60 capsules per dispensing at retail and 180 capsules per dispensing at home delivery were added to the policy. No overrides apply.	08/13/2025