Doptelet (avatrombopag)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD)
   Doptelet is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
2. Treatment of Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP)
   Doptelet is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Thrombocytopenia in chronic liver disease: pretreatment platelet count
B. Immune thrombocytopenia: pretreatment and current platelet counts

Criteria for Initial Approval

A. Thrombocytopenia in chronic liver disease

Authorization of 30 days may be granted for treatment of thrombocytopenia in members with chronic liver disease when both of the following criteria are met:

1. Member has an untransfused platelet count of less than $50x10^9$/L taken within 14 days of the request.
2. Member is scheduled to undergo a procedure.

B. Chronic immune thrombocytopenia (ITP)

Authorization of 6 months may be granted for treatment of chronic ITP when both of the following criteria are met:

1. Inadequate response or intolerance to prior therapy (for example, corticosteroids or immunoglobulins).
2. Untransfused platelet count at any point prior to the initiation of the requested medication is less than $30x10^9$/L OR $30x10^9$/L to $50x10^9$/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Section VI).

Continuation of Therapy

A. Thrombocytopenia in chronic liver disease

Continuation of therapy, defined as use beyond the initial approval for same procedure, is not approvable. All members (including new members) requesting authorization due to newly scheduled procedure must meet all initial authorization criteria.

B. Chronic ITP

1. Authorization of 3 months may be granted to members with current platelet count less than $50x10^9$/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal Doptelet dose for at least 4 weeks.
2. Authorization of 12 months may be granted to members with current platelet count less than $50x10^9$/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
3. Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.
4. Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/L for whom Doptelet dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

Exclusions

Coverage will not be provided for members with the following exclusion: concomitant use of Doptelet with other thrombopoietin receptor agonists (e.g., Mulpleta, Promacta, Nplate) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

Appendix

Examples of risk factors for bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes patient to trauma

Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

- 3 tablets/day

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Not applicable

REFERENCES

- Doptelet [package insert]. Durham, NC: AkaRx, Inc.; October 2020.
- Jurczak W, Chojnowski K, et al. Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. *Br J Haematol.* 2018;183(3):479-490.
- Nuenert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv* 2019;3(23):3829–3866.
- Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv* 2019;3(22): 3780–3817.
- Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group. *Blood*. 2009;113(11):2386-2393.

POLICY HISTORY

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