Washington State Health Care Authority

Hematopoietic Agents : Thrombopoiesis (TPO) Stimulating Proteins

Medical policy no. 82.40.50-2 Effective Date: July 1, 2019

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

Thrombopoeitin (TPO) is a protein which plays a role in the regulation of platelet production. TPO and its receptor act in several different ways to increase platelet count. Reduced TPO production and function may lead to thrombocytopenia and anemia. TPO stimulating proteins have demonstrated efficacy in several conditions.

Medical necessity:

Drug	Medical Necessity
avatrombopag (**Doptelet**)	Avatrombopag may be considered medically necessary for the following conditions: 1. Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
eltrombopag olamine (**Promacta**)	Eltrombopag olamine may be considered medically necessary for the following conditions: 1. Thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. 2. Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. 3. Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
fostamatinib disodium (**Tavalisse**)	Fostamatinib disodium may be considered medically necessary for the following conditions: 1. Thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
lusutrombopag (**Mulpleta**)	Lustrombopag may be considered medically necessary for the following conditions:

	1. Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
romiplostim (**Nplate**)	Romiplostim may be considered medically necessary for the following conditions: 1. Thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Clinical policy:

Indication	Clinical Criteria (Initial Approval)
Chronic Immune (Idiopathic) Thrombocytopenic Purpura (ITP)	1. Patient has diagnosis of chronic immune thrombocytopenic purpura (ITP); **AND** 2. Documentation of platelet count of less than $30x10^9$/L (30,000/mm^3); **AND** 3. Patient has a history of failure, contraindication, or intolerance to at least ONE of the following: a. corticosteroids; **OR** b. immunoglobulins; **OR** c. rituximab; **OR** d. previous history of splenectomy If ALL criteria are met, the request will be approved for 12 months. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization)
	Documentation of positive clinical response (e.g., increase in platelet count) If ALL criteria are met, the request will be approved for 12 months. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Indication	**Clinical Criteria (Initial Approval)**
Aplastic Anemia	1. Patient has diagnosis of aplastic anemia; **AND** 2. Patient has a history of failure, contraindication, or intolerance to at least ONE course of immunosuppressive therapy. Appropriate immunosuppressive therapy include but are not limited to: a. antithymocyte globulin equine (Atgam); **OR** b. antithymocyte globulin rabbit (Thymoglobulin); **OR** c. cyclosporine

	If ALL criteria are met, the request will be approved for 6 months. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. **Criteria (Reauthorization)** Documentation of positive clinical response (e.g., increase in platelet count) If ALL criteria are met, the request will be approved for 12 months. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Indication	**Clinical Criteria (Initial Approval)**
Chronic Hepatitis C-associated Thrombocytopenia	1. Patient has diagnosis of chronic hepatitis C-associated thrombocytopenia; **AND** 2. Thrombocytopenia is preventing the initiation of interferon-based therapy or limiting the ability to maintain interferon-based therapy; **AND** 3. Patient has **ONE** of the following: a. a reason why cannot use direct acting antivirals for hepatitis C; **OR** b. planning to initiate and maintain interferon-based treatment; **OR** c. currently receiving interferon-based treatment If ALL criteria are met, the request will be approved for 6 months. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. **Criteria (Reauthorization)** 1. Documentation of positive clinical response (e.g., increase in platelet count); **AND** 2. Patient is currently on interferon-based therapy for treatment of chronic hepatitis C If ALL criteria are met, the request will be approved for 6 months. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the

	clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Indication	**Clinical Criteria (Initial Approval)**
Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	1. Age 18 and older; **AND** 2. Used for the treatment of thrombocytopenia in a patient with chronic liver disease who is scheduled to undergo a procedure; a. Patient should undergo their procedure within 8 days after the last dose If ALL criteria are met, the request will be approved for 5-to-7 days supply for **each** of the approved procedures. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.

Dosage and quantity limits:

Drug Name	Dose and Quantity Limits
avatrombopag (**Doptelet**)	#3 tablets per day for 5-days
eltrombopag olamine (**Promacta**) • **12.5mg tablet: #1 per day** • **25mg tablet: #1 per day** • **50mg tablet: #2 per day** • **75mg tablet: #2 per day** • **25mg oral suspension**	• **ITP:** 75 mg per day ○ #1 75mg tablet per day • **Aplastic Anemia**: 150 mg per day ○ #2 75mg tablets per day • **Hepatitis C:** 100 mg per day ○ #2 50mg tablets per day
fostamatinib disodium (**Tavalisse**)	100 mg tablets • #2 tablets per day 150 mg tablets • #2 tablets per day
lusutrombopag (**Mulpleta**)	#1 tablet per day for 7 days
romiplostim (**Nplate**) • **Subcutaneous injection**	10 mcg/kg per week

Coding:

HCPCS Code	Description
J2796	Injection, romiplostim 10 mcg

References

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3. **Mulpleta (lusutrombopag)** [prescribing information]. Florham Park, NJ: Shionogi Inc; July 2018.
4. **Nplate (romiplostim)** [prescribing information]. Thousand Oaks, CA: Amgen; October 2017.
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History

Date	Action and Summary of Changes
03.04.2021	Updated note, added link to AHPDL publication, removed Preferred product listings
04.29.2020	Dosage and quantity limits corrected for romiplostim (Nplate)
06.12.2019	Updated dosage and quantity limits section
05.06.2019	New Policy