

Pharmacy Policy

Promacta

Policy Number: 9.107

Version Number: 2

Version Effective Date: 1/1/2022

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth- MCO

MassHealth- ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Promacta (eltrombopag)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved and medically accepted indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	<ol style="list-style-type: none"> 1. Diagnosis of one of the following: <ol style="list-style-type: none"> a. Chronic immune thrombocytopenia (ITP); AND <ol style="list-style-type: none"> i. One of the following; <ol style="list-style-type: none"> 1. Chronic, relapsed or refractory ITP and platelet count is less than 20,000/microL with documented bleeding symptoms present OR 2. Medical necessity for platelet elevation (e.g. upcoming

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	<p>surgery, peptic ulcer disease or condition that may predispose member to bleeding); AND</p> <p>ii. An inadequate response or intolerance to a trial of corticosteroids, immune globulin, rituximab or splenectomy</p> <p>b. Chronic Hepatitis-C associated ITP; AND</p> <p>i. One of the following;</p> <p>1. Diagnosis of ITP associated with chronic hepatitis C and plan to start interferon therapy, and platelet count is < 75,000/microL OR</p> <p>2. Interferon regimen cannot be continued due to low platelets and there is an active authorization for Hep-C regimen</p> <p>c. Severe aplastic anemia; AND</p> <p>i. Platelet count <50,000 cell/mcl; AND</p> <p>ii. Promacta will be used in combination with immunosuppressive therapy such as cyclosporine or Atgam (antithymocyte globulin) which is given intravenously or there has been an inadequate response, adverse reaction, or contraindication to immunosuppressive therapy; AND</p> <p>2. Baseline serum ALT, AST, and bilirubin levels have been obtained prior to initiation of therapy</p>
Age Restrictions	<p>Chronic ITP: Patients 1 year of age or older</p> <p>HepC associated ITP: Patients 18 years of age or older</p> <p>Severe aplastic anemia: Patients 2 years of age or older</p>
Prescriber Restriction	Prescribed by a specialist in this condition
Coverage Duration	<p>ITP: Initial 6 months</p> <p>Reauthorization: 12 months</p> <p>Chronic Hepatitis C: 3 months intervals or less based on interferon regimen</p>
Other criteria	<p>Reauthorization:</p> <p>Documentation of the following:</p> <p>1. Initial criteria has been met; AND</p> <p>2. Platelet levels have improved and stabilized.</p>

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Clinical Background Information and References

1. Promacta (eltrombopag) Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC 27709. February 2021.
2. George, JN. Treatment and prognosis of immune (idiopathic) thrombocytopenia purpura in adults. In UpToDate. Accessed June 2017.
3. George, JN. Immune thrombocytopenia (ITP) in adults: Treatment of chronic refractory disease. In UpToDate. Accessed June 2017.
4. Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions, and outcome criteria in immune thrombocytopenia purpura of adults and children: a report from an international working group. Blood 2009;113(11):2386-2393. Available at: <http://bloodjournal.hematologylibrary.org/content/113/11/2386.full.pdf+html>
5. Crowther MA, et al. The American Society of Hematology 2011 Evidence-Based Practice Guideline For Immune Thrombocytopenia. Blood 2011; 117(16):4190-4207.
6. Schrier, S. Treatment of aplastic anemia in adults. In UpToDate. Topic last updated May 16, 2017. Accessed June 2017.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.102 Promacta Policy retired, new policy created, reflecting changes from June 2020 P&T	1/1/2021	P&T Committee
8/12/2021	Annual P&T Review: changed initial approval duration for ITP to 6 months, reauthorization to 12 months. Updated reauthorization criteria to include 'initial criteria has been met'	1/1/2022	P&T Committee

Next Review Date

8/2022

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Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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