

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG	Promacta (eltrombopag)
POLICY #	22146
INDICATIONS	<p>Promacta is indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have an insufficient response to corticosteroids, immunoglobulins, or splenectomy.</p> <p>Promacta is indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.</p> <p>Promacta is indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia.</p> <p>Promacta is indicated for the treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.</p> <p>Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increased the risk of bleeding. Promacta should not be used in an attempt to normalize platelet counts.</p> <p>PROMACTA should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy. Safety and efficacy have not been established in combination with direct acting antiviral agents approved for treatment of chronic hepatitis C genotype 1 infection.</p>
CRITERIA	<p>ConnectiCare considers Promacta to be medically necessary for patients with Chronic ITP who meet all the following criteria:</p> <ul style="list-style-type: none"> • The diagnosis is made by, or in consultation with, a hematologist • Patient has clinically documented chronic (greater than 3 or 4 month) idiopathic thrombocytopenic purpura (ITP) • Patient is at risk of spontaneous bleeding as demonstrated in chart notes by either <ol style="list-style-type: none"> 1. Platelet count less than 20,000/mm³ <p>OR</p> <ol style="list-style-type: none"> 2. Platelet count less than 30,000/ mm³ accompanied by symptoms of bleeding • Patient has a documented intolerance to, or treatment failure of at least one of the following within the past 6 months: <ol style="list-style-type: none"> 1. Systemic corticosteroids (e.g. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days). 2. Immunoglobulin replacement 3. Splenectomy

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	(ITP) in adults: Second-line and subsequent therapies. In: <i>UpToDate</i> . Retrieved from http://www.uptodate.com .
P&T REVIEW HISTORY	12/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 5/17, 5/18, 5/19
REVISION RECORD	11/12, 12/14, 5/16, 5/18, 5/19