THROMBOPOIETIN RECEPTOR AGONISTS
Pharmacy Coverage Policy

P&T Review Date: 3/26/2014
UMC Revision Date: 02/27/2014
Reviewer Initials: AS
Effective Date: 06/15/2014

Policy type: PA with QL, QL only
Program type: Standard
Specialty: Yes
Line of Business: Commercial

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>GPI</th>
<th>Drug Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPLATE</td>
<td>romiplostim</td>
<td>8240506000****</td>
<td>Thrombopoietin receptor agonist</td>
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<tr>
<td>PROMACTA</td>
<td>eltrombopag</td>
<td>824050301003**</td>
<td>Thrombopoietin receptor agonist</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE/NONCOVERAGE

PROMACTA® (eltrombopag) and NPLATE™ (romiplostim) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) for greater than 6 months AND
- Patient’s baseline platelet count is <50,000/mcL AND
- Patient’s degree of thrombocytopenia and clinical condition increase the risk of bleeding AND
- Patient had an insufficient response, intolerance, or contraindication to corticosteroids or immune globulin OR
- Patient had an inadequate response or contraindication to a splenectomy

PROMACTA (eltrombopag) will additionally be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of chronic hepatitis C
- Patient has thrombocytopenia defined as platelets <90,000/mcL for initiation (pre-treatment) of interferon-based therapy
- Patients has thrombocytopenia defined as platelets <75,000/mcL for maintenance of optimal interferon-based therapy

PROMACTA (eltrombopag) is subject to the following quantity limits:

- 12.5 mg and 25 mg: 3 tabs/day
- 50 mg, 75 mg, 100 mg: 1 tab/day

Authorization for continued use shall be reviewed at least every 12 months for ITP to confirm the following: patient’s platelet count has increased (to a level sufficient to avoid clinically important bleeding) after at least 4 weeks of therapy at the maximum weekly dose (75 mg for eltrombopag; 10 mcg/kg for romiplostim). Initial authorizations for Hepatitis C will be granted for 9 weeks. Reauthorizations shall be granted for 24 weeks when the current coverage criteria are met.

Off label uses for oncology diagnoses are approvable if considered medically acceptable as described in the Supporting Information section.

PROMACTA (eltrombopag) and NPLATE (romiplostim) are considered experimental/investigational for conditions not listed in this coverage policy section.