Hematopoietic Agents:
Thrombopoiesis (TPO) Stimulating Proteins

WA.PHAR.73 Hematopoietic Agents: Thrombopoiesis (TPO) Stimulating Proteins
Effective Date: July 1, 2019

Note:
- For non-preferred agents in this class/category, patients must have had an inadequate response or have had a 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/category documentation of inadequate response to ONE preferred agent is needed
- If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria

Background:
Thrombopoietin (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:

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

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:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Clinical Criteria (Initial Approval)</th>
</tr>
</thead>
</table>
| 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/mm³); **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. |
| **Preferred drugs:**  
  - fostamatinib disodium (Tavalisse)  
  - romiplostim (Nplate)  
  - eltrombopag olamine (Promacta) | **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. |

<table>
<thead>
<tr>
<th>Indication</th>
<th>Clinical Criteria (Initial Approval)</th>
</tr>
</thead>
</table>
| 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. |
| **Preferred drugs:**  
  - eltrombopag olamine (Promacta) | **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. |

<table>
<thead>
<tr>
<th>Indication</th>
<th>Clinical Criteria (Initial Approval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Hepatitis C-associated Thrombocytopenia</td>
<td>1. Patient has diagnosis of chronic hepatitis C-associated thrombocytopenia; <strong>AND</strong></td>
</tr>
</tbody>
</table>

Policy: TPO Stimulating Proteins  
Last Updated 06/12/2019
Preferred drugs:
eltrombopag olamine (Promacta)

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.

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.

Indication
Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure

Preferred drugs:
avatrombopag (Doptelet)
lusutrombopag (Mulpleta)

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

Dosage and quantity limits:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose and Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>avatrombopag (Doptelet)</td>
<td>#3 tablets per day for 5-days</td>
</tr>
<tr>
<td>eltrombopag olamine</td>
<td></td>
</tr>
<tr>
<td>12.5mg tablet: #1 per day</td>
<td></td>
</tr>
<tr>
<td>25mg tablet: #1 per day</td>
<td></td>
</tr>
<tr>
<td>50mg tablet: #2 per day</td>
<td></td>
</tr>
<tr>
<td>75mg tablet: #2 per day</td>
<td></td>
</tr>
<tr>
<td>25mg oral suspension</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ITP: 75 mg per day</td>
</tr>
<tr>
<td></td>
<td>o #1 75mg tablet per day</td>
</tr>
<tr>
<td></td>
<td>Aplastic Anemia: 150 mg per day</td>
</tr>
<tr>
<td></td>
<td>o #2 75mg tablets per day</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C: 100 mg per day</td>
</tr>
<tr>
<td></td>
<td>o #2 50mg tablets per day</td>
</tr>
<tr>
<td>fostamatinib disodium</td>
<td>100 mg tablets</td>
</tr>
<tr>
<td></td>
<td>#2 tablets per day</td>
</tr>
<tr>
<td></td>
<td>150 mg tablets</td>
</tr>
<tr>
<td></td>
<td>#2 tablets per day</td>
</tr>
<tr>
<td>lusutrombopag (Mulpleta)</td>
<td>#1 tablet per day for 7 days</td>
</tr>
</tbody>
</table>

Policy: TPO Stimulating Proteins

Last Updated 06/12/2019
romiplostim (Nplate) | 10 mg/kg per week
---|---
- Subcutaneous injection

**Coding:**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J2796</td>
<td>Injection, romiplostim 10 mcg</td>
</tr>
</tbody>
</table>

**References**


---

*Policy: TPO Stimulating Proteins*  |  *Last Updated 06/12/2019*


<table>
<thead>
<tr>
<th>Date</th>
<th>Action and Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>06.12.2019</td>
<td>Updated dosage and quantity limits section</td>
</tr>
<tr>
<td>05.06.2019</td>
<td>New Policy</td>
</tr>
</tbody>
</table>