Introduction

Thrombocytopenia means that a person has lower number of platelets than normal. Platelets are the cells in the blood that help blood to clot. Having a low number of platelets can cause bruises and increase the risk of bleeding. A number of disorders can cause low platelets, but one common cause occurs when the immune system attacks and destroys platelets. This is called Immune thrombocytopenia (ITP). Both adults and children can get an immune based thrombocytopenia. The treatment for ITP depends on a person’s age, symptoms and how low the platelets are. This policy discusses the different types of treatment for thrombocytopenia with medications, and which medications need to be pre-approved by the health plan.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs providers about when a service may be covered.

Policy Coverage Criteria

Note: Quantity limits for individual agents can be found in Dosage and Quantity Limits section below.
Click on the links below to be directed to the related medical necessity criteria:

- Chronic Immune (Idiopathic) Thrombocytopenia
- Immune Thrombocytopenic Purpura (ITP)
- Hepatitis C-induced Thrombocytopenia
- Severe Aplastic Anemia
- Patients with Chronic Liver Disease scheduled to undergo a procedure

<table>
<thead>
<tr>
<th>Agent</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hepatitis C-induced Thrombocytopenia</strong></td>
<td>Eltrombopag may be considered medically necessary as the first-line agent in the treatment of hepatitis C-induced thrombocytopenia when the patient requires initiation and maintenance of interferon-based therapy.</td>
</tr>
</tbody>
</table>
| **Chronic Immune (Idiopathic) Thrombocytopenia** | Eltrombopag may be considered medically necessary as the first-line agent in the treatment of chronic immune (idiopathic) thrombocytopenia when:  
  - The patient has a platelet count of <30,000 μL  
  AND  
  - The patient has had an insufficient response to corticosteroids  
  AND  
  - The patient has had an insufficient response to an immune globulin (IVIg) or splenectomy |
| **Chronic Liver Disease (use prior to scheduled procedure)** | Avatrombopag or lusutrombopag may be considered medically necessary as prophylactic treatment of chronic liver disease patients when:  
  - The patient has a platelet count of <50,000 μL  
  AND  
  - The patient is scheduled to undergo an invasive procedure |
<table>
<thead>
<tr>
<th>Agent</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Severe Aplastic Anemia</td>
<td></td>
</tr>
<tr>
<td>Thrombopoietic Agents</td>
<td>Eltrombopag may be considered medically necessary as the first-line agent in the treatment of severe aplastic anemia when the patient has had insufficient response to immunosuppressive therapy.</td>
</tr>
<tr>
<td>Promacta® (eltrombopag)</td>
<td></td>
</tr>
<tr>
<td>Immune Thrombocytopenic Purpura (ITP)</td>
<td></td>
</tr>
<tr>
<td>Thrombopoietic Agents</td>
<td>Romiplostim may be considered medically necessary as the first-line agent in the treatment of chronic immune thrombocytopenic purpura (ITP) when:</td>
</tr>
<tr>
<td>Nplate® (romiplostim)</td>
<td>• The patient has a platelet count of &lt;30,000 μL</td>
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<tr>
<td></td>
<td>AND</td>
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<td></td>
<td>• The patient has had an insufficient response to corticosteroids</td>
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<tr>
<td></td>
<td>AND</td>
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<tr>
<td></td>
<td>• The patient has had an insufficient response to an immune globulin (IVIg) or splenectomy</td>
</tr>
<tr>
<td>Kinase Inhibitor</td>
<td>Fostamatinib may be considered medically necessary for treatment of chronic immune thrombocytopenic purpura (ITP) in adults when all of the following criteria are met:</td>
</tr>
<tr>
<td>Tavalisse™ (fostamatinib disodium hexahydrate)</td>
<td>• The patient has a platelet count of &lt;30,000 μL</td>
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<tr>
<td></td>
<td>AND</td>
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<tr>
<td></td>
<td>• The patient has had an insufficient response to corticosteroids</td>
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<td></td>
<td>AND</td>
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<tr>
<td></td>
<td>• The patient has had an insufficient response to an immune globulin (IVIg) or splenectomy</td>
</tr>
<tr>
<td></td>
<td>AND</td>
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</tbody>
</table>
### Agent | Medical Necessity
--- | ---
|  | • The patient has had an insufficient response to Thrombopoietin Receptor Agonist (TPO-RA) such as romiplostim or eltrombopag

*Note: Discontinue Tavalisse if platelet response is insufficient to prevent clinically important bleeding after 12 weeks.

### Anti-CD20
- **Rituxan® (rituximab)** | **Rituximab is subject to review for site of service administration.**

*See policy 5.01.556 Rituximab: Non-oncologic and Miscellaneous Uses

### Dosage and Quantity Limits

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dosage and Quantity Limit</th>
</tr>
</thead>
</table>
| **Promacta® (eltrombopag)** | **Hepatitis C-induced Thrombocytopenia**
- The initial dose is 25 mg once daily for all patients. Do not exceed 100mg per day.

**Chronic Immune (Idiopathic) Thrombocytopenia**
- The initial dose is 50 mg once daily for most adults and pediatric patients 6 years and older and 25mg once daily for pediatric patients aged 1 to 5 years. Adjust to maintain platelet count greater than or equal to 50,000 μL. Do not exceed 75mg per day.

**Severe Aplastic Anemia**
- The initial dose is 50 mg once daily for most patients. Reduce the initial dose in patients with hepatic impairment or patients of East Asian ancestry. Adjust to maintain platelet count greater than or equal to 50,000 μL. Do not exceed 150mg per day.

| **Nplate® (romiplostim)** | **Immune Thrombocytopenic Purpura (ITP)**
- The initial dose is 1 mcg / kg once weekly. Adjust weekly dose by increments of 1 mcg / kg to achieve and maintain a platelet count of ≥ 50 x 10^9/L as necessary to reduce the risk of bleeding.
- Do not exceed the maximum weekly dose of 10 mcg / kg.

| **Tavalisse™ (fostamatinib)** | **Chronic Immune Thrombocytopenic Purpura (ITP)**

Dosage and Quantity Limits

<table>
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<th>Dosage and Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>disodium hexahydrate)</td>
<td>• The initial dose is 100 mg taken orally twice daily. After a month, if platelet count has not increased to at least 50 x 10^9/L, increase TAVALISSE dose to 150 mg twice daily.</td>
</tr>
<tr>
<td></td>
<td>• Use the lowest dose of TAVALISSE to achieve and maintain a platelet count at least 50 x 10^9/L as necessary to reduce the risk of bleeding</td>
</tr>
</tbody>
</table>

Length of Approval

<table>
<thead>
<tr>
<th>Approval</th>
<th>Criteria</th>
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</thead>
<tbody>
<tr>
<td>Initial Approval</td>
<td>Initial duration may be approved for three months when medical necessity criteria specified above are met.</td>
</tr>
<tr>
<td>Reauthorization</td>
<td>Continued therapy may be approved for periods of six months as long as the drug-specific conditions are met, the patient has shown and continues to show clinical benefit (e.g., platelet count meets goal), and patient has not had any clinically significant bleeds while on therapy.</td>
</tr>
</tbody>
</table>

Documentation

<table>
<thead>
<tr>
<th>Documentation</th>
<th>Initial:</th>
<th>Reauthorization:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Chart notes demonstrating that the patient meets the stated criteria for medical necessity.</td>
<td>• Chart notes demonstrating that the patient continues to show clinical benefit.</td>
</tr>
</tbody>
</table>

Coding

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

Related Information
Consideration of Age

The age described in this policy for medical necessity of select intravenous and injectable therapy services is 13 years of age or older. The age criterion is based on the following: Pediatric patients are not small adults. Pediatric patients differ physiologically, developmentally, cognitively, and emotionally from adult patients, and vary by age groups from infancy to teen. Children often require smaller doses than adults, lower infusion rates, appropriately sized equipment, the right venipuncture site determined by therapy and age, and behavioral management during administration of care. Specialty infusion training is therefore necessary for pediatric IV insertions and therapy. Due to pediatrics unique physiology and psychology, this policy is limited to patients above the age of 13.

Evidence Review

The term “autoimmune disorders” covers a wide range of syndromes often involving damage to multiple organ systems. Since the advent of biologics and small molecule targeted therapies, a variety of pathways and specific points of intervention have been identified and drugs developed to modify the pathology that is damaging the patient. Since multiple diseases share common signaling pathways, it is not surprising that drugs and diseases often overlap, leading to the complex web of alternative therapies that are now available to physicians.

Idiopathic Thrombocytopenic Purpura (ITP) is an autoimmune disorder characterized by destruction of normal platelets due to unknown stimulus and a resulting risk of severe bleeding complications. Recent update by International Working Group (IWG) consensus panel set the platelet count threshold as less than 100,000 per µL. The initiating event of ITP is unclear and various mechanisms of platelet destruction may be important. IgG autoantibodies on the platelet surface can cause platelet uptake and destruction by reticuloendothelial phagocytes. T-cell mediated cytotoxicity against megakaryocytes and platelets may cause thrombocytopenia. In addition to increased platelet destruction, the production of platelets is often decreased in ITP.

Adult ITP has an annual incidence of approximately two cases per 100,000. It is estimated in the United States there are 100 patients with ITP per one million people or approximately 30,000 total and 15,000 with a chronic form of ITP assuming the population is 300 million. Adult ITP is more likely than childhood ITP to be chronic. Spontaneous remission occurs in more than 80%
of cases in children but is uncommon in adults. As a result, evidence based treatment guidelines differ between adult and children. For specific treatment recommendations in children with ITP, please refer to the ASH 2011 guideline “Section 1: ITP in children”. The incidence rate appears to increase with age, with the highest age-specific incidence in patients older than 60 years of age. The female-to-male ratio of ITP patients is bimodal, being 1.9 women for each man in ages less than 50 and 1.2:1 in ages 65 and older. There is no apparent prevalence difference between African Americans and whites. Intracranial hemorrhage represents the most serious complication of ITP. The mortality rate from hemorrhage is approximately 1% in children and 5% in adults. In patients with severe thrombocytopenia, predicted five-year mortality rates from bleeding are significantly raised in patients older than 60 years versus patients younger than 40 years, 47.8% versus 2.2%, respectively.

Longer courses of corticosteroids may be preferred over shorter courses of corticosteroids or IVIG as first-line treatment. IVIG may be used in addition to corticosteroids when a more rapid increase in platelet count is required. Either IVIG or anti-D (in appropriate patients) may be used as a first-line treatment if corticosteroid are contraindicated. The criteria for using Intravenous Immune Globulin (IVIG) to treat ITP are addressed separately in another medical policy (see Related Policies). The use of rituximab and human thrombopoietin (TPO) agents are not recommended in the initial treatment of ITP. Rituximab may be considered for treatment of chronic adult ITP or in those who are unresponsive to or relapse after initial corticosteroid therapy or have failed splenectomy. FDA-approved agents are romiplostim (Nplate®), a subcutaneously injected thrombopoietic agent that increases platelet production in a dose-dependent manner by binding to and activating the human thrombopoietin (TPO) receptor, and eltrombopag (Promacta®), an oral, small-molecule TPO-receptor agonist that binds to the transmembrane domain of the human TPO-receptor to initiate signaling cascades to induce proliferation and differentiation of megakaryocytes from bone marrow progenitor cells. The optimal treatment for patients requiring second-line therapy is uncertain. Guidelines and expert opinions have not reached consensus due to the lack of comparative clinical and economical data. This policy is based on ASH 2011, which is a well-established evidence-based guideline. Selection of a treatment option should take into consideration the individual patient’s bleeding risk, activity level, likely side effects of treatment and patient preferences. This guideline and several other expert reviews support the use of rituximab as a second line treatment option for patients with ITP who have failed at least one other therapy such as corticosteroids, IVIG, or splenectomy.
Efficacy of Promacta® (eltrombopag)

There are three published clinical trials evaluating the efficacy and safety of Promacta® (eltrombopag) in chronic idiopathic thrombocytopenic purpura (ITP). A Phase II pivotal study showed that significantly more subjects treated with eltrombopag 50 mg (70%) and 75 mg (81%) responded to therapy compared to placebo (11%) (P < 0.001). About one third of the subjects used concomitant ITP medications during the study, and one half of the subjects were splenectomized. Although it was noted that response was higher in those treated with concomitant medications, stratified results for these subgroups were not presented. Bleeding events were only considered as secondary endpoints, and the results showed that subjects treated with eltrombopag 30 mg and 50 mg showed fewer signs of bleeding than placebo, but subjects treated with eltrombopag 75 mg showed increased signs of bleeding.

Another Phase III pivotal trial showed that the primary endpoint of response, defined as subjects who had an increase in platelet counts to ≥ 50,000/µL at week six, was reached in 58.9% of those treated with eltrombopag versus 16.2% of those receiving placebo (P <0.001). Additionally this study showed that the odds of responding were significantly higher in the eltrombopag group versus the placebo group (P <0.001). Response to eltrombopag was not statistically significantly affected by concomitant treatment (P = 0.766), prior splenectomy (P = 0.747) or having baseline platelet counts below 15,000/µL (P = 0.453). Bleeding events were considered as a secondary endpoint and significantly fewer events took place in the eltrombopag group versus placebo (39% and 60%, respectively; P = 0.029), however the trial was not powered to detect such differences.

An ongoing, Phase III extension trial (EXTEND) evaluating the long-term efficacy of eltrombopag showed that 50% of enrolled subjects had a continuous response (platelet count ≥ 50,000) for more than four weeks, 35% for at least 10 weeks, and 24% for more than six months. At the one-year time point, only 7% of patients still showed response. A summary of this study in the manufacturer’s dossier states that 48% of patients were able to discontinue or reduce concomitant ITP medications, and that bleeding events were significantly reduced for eltrombopag-treated patients. Since data from this study is only available in post-hoc reviews, it is not yet possible to evaluate the validity or usefulness of these results.

Efficacy of Nplate® (romiplostim)

In the published RCT of Nplate® (romiplostim) for the treatment of chronic ITP, a statistically significant response was achieved by subjects treated with romiplostim (49%) compared to placebo (2%) (P < 0.0001). Romiplostim also showed a statistically significant reduction in the
dependence on rescue medication (21.7%) compared to placebo (59.5%) (P < 0.0001).

Limitations of this study include that all participants were allowed use of concurrent ITP medications, and the results were not stratified to demonstrate the effect of these medications on the results. Additionally, the primary endpoint of this study was to determine the platelet response of patients to romiplostim, whereas bleeding events were a secondary endpoint. It would have been more clinically relevant if the study would have been specifically powered to determine the difference in bleeding events between romiplostim and placebo-treated subjects.

There is an ongoing, open-label extension study to evaluate the long-term safety and efficacy of romiplostim in subjects who had previously completed a romiplostim trial. The primary endpoint is platelet response, defined as a platelet count of ≥ 50,000/µL. Throughout the study, 18 subjects never met the primary endpoint, but 10 of those still continued with the treatment. After a sharp increase in platelet counts during the first four weeks, platelet counts generally remained stable or gradually increased through week 144. The study reported platelet responses of 30% after the first dose and 51% after the third dose. Subjects that responded had a response during 67% of the weeks enrolled in the study. The results reported do not include any raw numbers, but are reported solely as percentages, except for the instance of those that showed a response at least once. This study lacks definitive information to demonstrate that a response to romiplostim once or continually will result in prevention of adverse events or improve mortality and morbidity.

No head-to-head trials have been conducted between eltrombopag or romiplostim and other agents used to treat chronic ITP, such as IVIg, anti-D, or rituximab. Five small uncontrolled studies were found reporting response rates generally in the 30-40% range. These are classified as case series and are considered Level C evidence. No head to head studies versus romiplostim, eltrombopag or IVIG were found.

**Efficacy of Doptelet® (avatrombopag)**

Avatrombopag was shown to be efficacious based on ADAPT-1 and -2 trials. Patients were separated into high (40-50,000/µL) or low (<40,000/µL) baseline platelet count cohorts. In both cohort groups, avatrombopag was more effective in preventing use of platelet transfusions or rescue therapies for bleeding. The high baseline cohort (received avatrombopag 40 mg) in ADAPT-1 had 88.1% vs 38.2% when comparing efficacy of study drug versus placebo, and in ADAPT-2, 87.9% vs 33.3%, respectively. In the low baseline cohort (received avatrombopag 60 mg), the primary endpoint was reached in 65.6% vs 22.9% of patients when comparing study drug and placebo in ADAPT-1, and in ADAPT-2, 68.6% vs 34.9%, respectively. Evidence was
limited due to smaller sample sizes and no direct comparison to standard of therapy (platelet transfusions).

Evidence for lusutrombopag efficacy is limited due to only two phase III trial, in which only abstracts were available at the time of review; complete results are not yet available. Nonetheless, 64.8% of patients on lusutrombopag compared to 29.0% on placebo did not need platelet transfusions or rescue therapies for bleeding.

Safety of Promacta® (eltrombopag), Doptelet® (avatrombopag), Mulpleta® (lusutrombopag) and Nplate® (romiplostim)

The evidence for the safety of eltrombopag and romiplostim is based on clinical studies, which are considered to be Level B evidence. Although eltrombopag and romiplostim have shown to have mostly mild side effects, rare but serious adverse reactions have been reported. The safety of eltrombopag and romiplostim seem to be similar, however some additional adverse events have occurred in patients treated with one or the other medication.

Bone marrow reticulin formation and risk for bone marrow fibrosis have been associated with the use of eltrombopag and romiplostim. TPO-receptor agonists increase the risk for formation or progression of reticulin fiber deposition within bone marrow. Peripheral blood smears have confirmed the presence of bone marrow reticulin formation in both the eltrombopag and romiplostim clinical trials. Prior to the initiation of these medications, peripheral blood smears must be obtained and examined to establish a baseline level of cellular abnormalities, and obtained along with complete blood counts (CBCs) monthly after the initiation of either.

Worsened thrombocytopenia and increased risk of bleeding has been associated with the cessation of eltrombopag and romiplostim. Thrombocytopenia may be of greater severity than prior to initiation of either agent, which can increase the risk of bleeding. The increased risk of bleeding may be particularly apparent in patients on anticoagulants or antiplatelet agents. Follow-up studies of both medications have indicated that the rebound effect is transient, but CBCs with platelets should be obtained weekly for at least two weeks following discontinuation.

Thrombotic/thromboembolic events may occur from excessive increases in platelet counts, associated with excessive doses of eltrombopag and romiplostim. To minimize this risk, these medications should not be administered to normalize platelet counts. Caution should be used when administering either medication to patients with known risks for thromboembolism.

Development and progression of hematological malignancies have been observed in patients treated with eltrombopag or romiplostim, due to the stimulation of the TPO-receptor on the
surface of hematopoietic cells. This risk may be particularly important in myelodisplastic syndrome. These agents should not be used to treat any thrombocytopenia other than ITP.

Eltrombopag carries a Black Boxed Warning for hepatotoxicity. Hepatotoxicity was one of the most commonly reported severe adverse events in patients treated with eltrombopag. Hepatotoxicity has not been reported in patients treated with romiplostim, likely due to the lack of first pass metabolism because it is administered IV. Grade 4 liver abnormalities were reported in patients treated with eltrombopag in randomized controlled trials (RCTs), whereas none were reported in patients treated with placebo. ALT, AST, and bilirubin should be measured prior to the initiation of eltrombopag, every two weeks during dose titration, and monthly after a stable dose has been established. Abnormal tests should be repeated within three to five days, and if confirmed, serum liver tests should be monitored weekly until they resolve. Eltrombopag should be discontinued if ALT levels reach ≥ three times baseline and are progressive, persistent for ≥ four weeks, or are accompanied by increased direct bilirubin, clinical symptoms of liver injury or evidence for hepatic decompensation.

Cataracts have developed or worsened in some patients treated with eltrombopag. Eltrombopag was shown to cause cataracts in pre-clinical trials of rodents. Ocular examinations should be performed prior to the initiation of eltrombopag, and patients should be regularly monitored for signs and symptoms of cataracts during treatment.

A lack or loss of platelet response has been demonstrated in patients treated with romiplostim. Patients who are hyporesponsive or fail to respond should be evaluated for causative factors, including formation of neutralizing antibodies or bone marrow fibrosis. Blood samples should be submitted to Amgen for assay to determine antibody formation against romiplostim or TPO. Romiplostim should be stopped after four weeks on the highest dose (10µg/kg) if sufficient platelet levels have not been achieved to avoid clinically important bleeding.

Eltrombopag and romiplostim are only available through restricted distribution programs, Promacta CARES and NEXUS, respectively. Only prescribers and patients who enroll in these programs and understand the risks of therapy are eligible to prescribe, obtain, administer, and receive these medications. Prescribers are required to understand the information in the prescribing information and be able to educate patients on the risks and benefits, provide the medication guide, and encourage questions regarding the use of the medication. Adverse events must be actively solicited every six months, and be reported to the drugs’ respective program.

Adverse effects in avatrombopag appear to be pretty similar to placebo based on both ADAPT trials. Most side effects were mild to moderate in severity and consisted of pyrexia, abdominal
pain, nausea, headache, fatigue, and peripheral edema. Lusutrombopag adverse effects included procedural pain and hypertension.

ADAPT trials and package insert provided a good idea of safety for avatrombopag, but data for safety was limited by availability of studies for lusutrombopag.

**2017 Update**

Dosage and quantity limits with specific age range of eltrombopag is updated.

**2018 Update**

Tavalisse™ (fostamatinib) criteria, dosage, and quantity limits were added to policy. Length of approval table was also added to policy which encompasses all drugs listed within this medical policy.

**References**

9. Eltrombopag (Promacta®) prescribing information, 2008. GSK, Research Triangle Park, NC.


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### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/16</td>
<td>New policy approved June 14, 2016. Add to Prescription Drug section. Policy information on drug treatment for miscellaneous autoimmune diseases extracted from 5.01.550. Medical necessity review criteria for site of service IV therapy added.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>Interim Review, approved October 11, 2016. Clarified age criteria language indicating that site of service review is applicable to only those age 13 and older; drug criteria review applies to all ages.</td>
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<tr>
<td>07/01/17</td>
<td>Formatting update; added hyperlinks to Medical Necessity Criteria sections.</td>
</tr>
<tr>
<td>10/01/17</td>
<td>Annual Review, approved September 21, 2017. Updated dosage and quantity limits</td>
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<tr>
<td>Date</td>
<td>Comments</td>
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<td>-----------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 13, 2018. Tavalisse™ (fostamatinib) criteria and dosage and quantity limits were added to policy. Length of approval table was also added to policy which encompasses all drugs listed within this medical policy. Removed HCPCS code J8499.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  • Qualified interpreters
  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5992. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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Oromo (Cushite):

Deutsche (German):

Italiano (Italian):