BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/02/18
LAST REVIEW DATE: 8/02/18
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ARCHIVE DATE:

TAVALISSE™ (fostamatinib disodium hexahydrate) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

TAVALISSE™ (fostamatinib disodium hexahydrate) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Tavalisse (fostamatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of chronic immune thrombocytopenia (ITP) as defined by either of the following:
     - Platelet count of $< 30 \times 10^9$/L
     - Platelet count of $< 30 \times 10^9$/L to $< 50 \times 10^9$/L with evidence of significant bleeding or a high risk for bleeding

  3. Individual has failure, contraindication or intolerance to **ALL** the following preferred step therapy agents:
     - Corticosteroids [**EITHER** dexamethasone, methylprednisolone, or prednisone]
     - Immunoglobulin [**EITHER** IVIG **or** Anti-D (Rho)]
     - Thrombopoietic agent Promacta (eltrombopag)
     - Splenectomy **or** is not a candidate for splenectomy
     - Azathioprine
     - Danazol

  4. Woman patient of child bearing potential should use effective contraception during and for 1 months after therapy

  5. Woman patient who is breast feeding an infant or child should stop breast feeding during and 1 month after therapy

  6. Will not be used with a thrombopoietic agent e.g., Promacta (eltrombopag), Doptelet (avatrombopag) or Nplate (romiplostim)

  Initial approval duration: 3 months

- **Criteria for continuation of coverage (renewal request):** Tavalisse (fostamatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded or has worsened while on therapy
     - Response is defined as:
       - Achieved and maintains a platelet count of 50×10^9/L
       - Has not had any platelet transfusions
       - Has not had any serious or severe bleeding events
       - Has not had any hospitalizations for severe thrombocytopenia
       - Dose is at least 100 mg daily
     - Worsening is defined as:
       - After 12 weeks, platelet count did not increase to a level sufficient to avoid clinically important bleeding

TAVALISSE™ (fostamatinib disodium hexahydrate) oral tablet (cont.)

2. Individual has been adherent with the medication

3. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Hepatotoxicity – AST/ALT is ≥ 3x ULN and total bilirubin is > 2x ULN or AST/ALT persists at ≥ 5x ULN for 2 weeks after dose adjustment
     - Severe hypertension despite 4 weeks of aggressive antihypertensive therapy
     - Hypertensive crisis (SBP > 180 and/or DBP > 120 mmHg)
     - Severe diarrhea despite use of antidiarrheal agents
     - Neutropenia (neutrophil count < 1 x 10^9/L)

4. Will not be used with a thrombopoietic agent e.g., Promacta (eltrombopag), Doptelet (avatrombopag) or Nplate (romiplostim)

5. There are no significant interacting drugs

Renewal duration: 6 months

Description:

Tavalisse (fostamatinib) is a tyrosine kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. Tavalisse (fostamatinib) should be discontinued after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding.

Fostamatinib is a phosphate pro-drug that is converted in the gut by alkaline phosphatase into an active metabolite that is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase (SYK). The metabolite reduces antibody mediated destruction of platelets.

Thrombocytopenia is one of the most common hematologic disorders, characterized by an abnormally low number of platelets from multiple causes. Thrombocytopenia is defined as a platelet count of less than 150,000 per microliter. A normal count of thrombocytes (or platelets) is between 150,000 and 450,000 per microliter. The clinical expression of thrombocytopenia ranges from asymptomatic to life-threatening bleeding.

Patients with platelet counts greater than 50,000 per microliter rarely have symptoms. A platelet count from 30,000 to 50,000 per microliter may manifests as purpura. A count from 10,000 to 30,000 per microliter may cause bleeding with minimal trauma. A platelet count less than 5,000 per microliter may cause spontaneous bleeding and constitutes a hematologic emergency. Various syndromes and diseases are associated with thrombocytopenia.

ITP is characterized by isolated thrombocytopenia often occurring in the absence of an identifiable cause. It is an autoimmune disorder with immunologic destruction of otherwise normal platelets. ITP has variably been called immune thrombocytopenic purpura, idiopathic thrombocytopenic purpura, and immune thrombocytopenia.

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Controlled studies on the treatment of ITP are lacking. The goal of therapy, when needed, is to raise the platelet count high enough to prevent major bleeding.

First-line treatment is usually use of a corticosteroid, such as prednisone or dexamethasone. Intravenous immunoglobulin (IVIG) or intravenous anti-D (Rho[D] immune globulin) can also be used as initial treatment with or without steroids. The most effective second-line treatment option is splenectomy. Splenectomy offers the best chance for cure but patients may not be good surgical candidates. Other second-line treatment options that may postpone the need of splenectomy include: azathioprine, cyclosporine, cyclophosphamide, danazol, vinca alkaloids, mycophenolate mofetil, rituximab, and thrombopoietin-receptor agonists.

Resources:

Tavalisse (fostamatinib) product information accessed 07-25-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=21149cc3-049b-43e2-b141-c9499160556c

UpToDate: Immune thrombocytopenia (ITP) in adults: Initial management and prognosis. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/immune-thrombocytopenia-itp-in-adults-initial-treatment-and-prognosis?topicRef=6676&source=see_link

UpToDate: Immune thrombocytopenia (ITP in adults: Second line and subsequent therapies. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/immune-thrombocytopenia-itp-in-adults-second-line-and-subsequent-therapies?topicRef=6676&source=see_link

UpToDate: Extrahepatic manifestations of hepatitis C virus infection. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/extrahepatic-manifestations-of-hepatitis-c-virus-infection?sectionName=Immune%20thrombocytopenia%20(ITP)%20and%20autoimmune%20hemolytic%20anemia&topicRef=6677&anchor=H11&source=see_link#H11

UpToDate: Approach to the adult with unexplained thrombocytopenia. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/approach-to-the-adult-with-unexplained-thrombocytopenia?search=thrombocytopenia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Clinical and laboratory aspects of platelet transfusion therapy. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/clinical-and-laboratory-aspects-of-platelet-transfusion-therapy?search=thrombocytopenia%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.