Original Effective Date: 05/01/2019
Current Effective Date: 09/15/2024
Last P&T Approval/Version: 7/31/2024
Next Review Due By: 07/2025
Policy Number: C16449-A

Tavalisse (fostamatinib)

PRODUCTS AFFECTED

Tavalisse (fostamatinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic primary immune thrombocytopenia

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CHRONIC PRIMARY IMMUNE THROMBOCYTOPENIA (ITP):
1. Documented diagnosis of chronic immune thrombocytopenia (ITP)
   AND
2. Documentation of ONE of the following [DOCUMENTATION REQUIRED]:
   i. Platelet count less than 20 x 10^9/L (20,000/mm3)

OR

ii. Platelet count less than 30 x 10^9/L with ITP whose degree of thrombocytopenia and clinical condition(s) increase the risk of bleeding (e.g., hypertension, renal insufficiency, concomitant antiplatelet agents or anticoagulant medications, alcoholism, infections, undergoing a medical or dental procedure with blood loss anticipation, recent surgery, head trauma)

AND

3. Documented failure, serious side effects, or contraindication to at least ONE of the following ITP treatments:
   i. Corticosteroids (i.e., prednisone, methylprednisolone, dexamethasone) at immunosuppressive doses (See Appendix)
   OR
   ii. Intravenous immune globulin (IVIG)
   OR
   iii. Immunosuppressive therapy (i.e., cyclosporine, mycophenolate mofetil, sirolimus)
   OR
   iv. Has had splenectomy or is not a surgery candidate

   AND
4. Prescriber attests to monitoring CBCs including neutrophils, ALT, AST, and bilirubin) and blood pressure prior to initiation of Tavalisse (fostamatinib) and during therapy per labeled recommendations
   AND
5. Prescriber attests or the clinical reviewer has found the medication is NOT being used to normalize platelet counts
   AND
6. Prescriber attests the medication is NOT being used concurrently with another thrombopoietic agent or Spleen Tyrosine Kinase Inhibitor [e.g., Doptelet (avatrombopag), Promacta (eltrombopag), Nplate (romiplostim), or Mulpleta (lusutrombopag)]
   AND
7. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. CHRONIC PRIMARY IMMUNE THROMBOCYTOPENIA (ITP):

1. Documentation of positive clinical response to therapy as evidenced by increase in platelet count to a level sufficient to avoid clinically important bleeding, OR increase or achievement of platelet count to at least ≥ 50 x 10^9/L [DOCUMENTATION REQUIRED]
   NOTE: If the member's platelets do NOT increase enough to avoid clinically significant bleeding after 12 weeks on the maximum dose [300mg daily], Tavalisse will be recommended for denial
   AND
2. Prescriber attests member still requires fostamatinib (Tavalisse) to maintain a platelet count sufficient to avoid clinically important bleeding
   AND
3. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
5. Prescriber attests to monitoring CBC including neutrophils, ALT, AST, and bilirubin, and blood pressure per labeled recommendations

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified hematologist or physician specializing in the treatment of thrombocytopenia in patients with chronic ITP [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
150 mg twice daily

Maximum Quantity Limits – 300 mg/day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Spleen Tyrosine Kinase (SYK) inhibitor

FDA-APPROVED USES:
Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenic purpura (ITP) who have had an insufficient response to a previous treatment

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and

(B) must have specific provider assessment; or

(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

APPENDIX 1:

Systemic corticosteroid immunosuppressive doses include:
≥ 14 days therapy with doses ≥ 80 mg per day of prednisone.
Equivalent doses include:

- ≥ 400mg/day cortisone
- 320mg/day hydrocortisone
- 80mg/day prednisolone
- 64mg/day methylprednisolone
- 12mg/day dexamethasone

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Immune thrombocytopenia (ITP) is a hematological disease in which the body's immune system produces antibodies that destroy its functioning platelets. Primary ITP is when the etiology of disease is unknown. Secondary causes of ITP include H. pylori infection, certain drugs, bone marrow transplantation, vaccinations, HIV, Hepatitis C, cytomegalovirus, and more. ITP is characterized as chronic when an individual has the disease for more than 12 months. Treatment is not recommended to be initiated for individuals with a platelet count above 30,000/mm3, if no complications related to bleeding are present. The treatment goal for ITP consists of increasing platelets to a safe level (commonly 50,000/mm33) in order to prevent major bleeding events. First line treatment consists of corticosteroids and IVIG treatments. If failure occurs, 2nd line treatment options include splenectomy, rituximab, and TPO-receptor agonists eltrombopag and romiplostim. The response rate for all current individual therapies is greater than 70%. In clinical efficacy studies, Tavalisse was initiated in treatment-experienced patients who had tried and failed 1st line therapies, 2nd line therapies, or both. While it can be used earlier in the treatment algorithm, clinicians recommend using Tavalisse as last line therapy due to its lower response rate of 44% and its adverse effect profile (diarrhea, hypertension, elevated LFTs, neutropenia). Two identical trials were conducted to evaluate the efficacy and safety of Tavalisse: FIT-1 and FIT-2. The primary efficacy endpoint was stable response defined as platelet count of 50,000/mm3 or greater demonstrated from at least 4 of 6 biweekly check-ups between weeks 14-24, without rescue therapy. The FIT-1 trial showed a significantly higher stable response rate of 18% for primary efficacy endpoint (stable platelet response > 50,000/mm3 for 24 weeks) versus the placebo 0% response rate. While FIT-2 trial data was nonsignificant, pooled analysis of both trials showed a significant response rate of 43% versus 14% for placebo in overall response (at least 1 platelet count of 50,000/mm3 within first12 weeks of treatment) and 18% versus 2% for the primary endpoint. Pooled analysis of member population for both FIT-1 and FIT-2 showed a median baseline platelet count of 16,000/mm3 and median duration of primary ITP diagnosis of 8.5 years. The most common adverse events were diarrhea, hypertension, nausea, dizziness, and ALT increase. Serious adverse events also included neutropenia and infection.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Tavalisse (fostamatinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tavalisse (fostamatinib) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

Based on adverse effect profile, use of this drug may carry risk for patients with uncontrolled hypertension, severe liver or pancreatic disease, or neutropenia. Discontinue treatment if dose falls below 100 mg daily OR if AST/ALT are 3 times above normal limit with bilirubin 2 times above normal limit OR if platelet count does not increase to level sufficient to avoid clinically important bleeding within 12 weeks. Monitor the ANC monthly, and for infection during treatment. Manage toxicity with TAVALISSE interruption, reduction or

discontinuation Monitor patients for the development of diarrhea. Manage diarrhea using supportive care measures, including dietary changes, hydration and/or antidiarrheal medication, early after the onset of symptoms. Interrupt, dose reduce, or discontinue TAVALISSE if diarrhea becomes severe (Grade 3 or above).

Based on findings from animal studies and its mechanism of action, Tavalisse can cause fetal harm when administered to a pregnant woman. For females of reproductive potential, verify pregnancy status prior to initiating Tavalisse.

Metabolism via CYP3A4 enzymes: Concomitant use with strong CYP3A4 inducers is not recommended.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Tavalisse TABS 100MG
Tavalisse TABS 150MG

REFERENCES

1. Tavalisse (fostamatinib disodium hexahydrate) tablets, for oral use [prescribing information]. South San Francisco, CA: Rigel Pharmaceuticals, INC; November 2020.
2. Primary immune thrombocytopenia. In: Murphy, JE, Lee MW, eds. Pharmacotherapy and Self-Assessment program, 2018 Book 2. Hematology, Immunology, Oncology, Lenexa, KS: American College of Clinical Pharmacy, 2018: 29-36.
3. Zheng, X. L., Vesely, S. K., Cataland, S. R., Coppo, P., Geldziler, B., Iorio, A., … Peyvandi, F. (2020). ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. Journal of Thrombosis and Haemostasis, 18(10), 2496–2502. doi:10.1111/jth.15010
4. Neunert, C., Terrell, D. R., Arnold, D. M., Buchanan, G., Cines, D. B., Cooper, N., … Vesely, S. K. (2019). American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Advances, 3(23), 3829–3866. https://doi.org/10.1182/bloodadvances.2019000966

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Duration of Approval References	Q3 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Quantity Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Contraindications/Exclusions/Discontinuation Other Special Considerations	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file