

Fostamatinib (Tavalisse™) for Chronic Immune Thrombocytopenia (ITP) Criteria for Use February 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive fostamatinib.

- Care not provided by a VA or VA purchased care (e.g. Choice Program, Fee Basis) hematology provider
- Patient with history of non-adherence with oral medication, follow-up appointments or laboratory visits
- Patient is unable to comply with dosing instructions
- Chronic therapy with a strong CYP3A4 inducer that cannot be interrupted, as the inducer will reduce exposure to the active metabolite of fostamatinib
- Patient has not received prior therapy to increase platelet counts
- Thrombocytopenia is secondary to bone marrow suppressive anti-cancer therapy, antibiotics or other medication
- Thrombocytopenia is secondary to chronic liver disease
- Pregnancy and/or breastfeeding

Inclusion Criteria

All of the following must be fulfilled in order to meet criteria.

- Documented diagnosis of chronic ITP per American Society of Hematology (ASH) guidelines: diagnosis based upon history, PE, CBC and exam of peripheral smear.
- Platelet count < 30,000 mm³
- Patient had an inadequate response or contraindication to at least 2 prior treatment categories:
 - Splenectomy
 - Rituximab
 - Thrombopoietin agonists (i.e. eltrombopag or romiplostim)
 - Danazol or immune suppressants (i.e. azathioprine, cyclosporine or mycophenolate mofetil)

For women of childbearing potential

- Pregnancy should be excluded prior to receiving fostamatinib and the patient provided contraceptive counseling on potential risks vs. benefits of taking fostamatinib if patient were to become pregnant.
- Fostamatinib may affect female fertility.

Dosage and Administration

- Refer to Prescribing Information for details
- Fostamatinib 100 mg should be taken orally twice daily with or without food. After 4 weeks, if platelet count has not increased to at least $50 \times 10^9/L$, increase dose to 150 mg twice daily.
- Dosing regimen, if needed, should be interrupted, reduced or discontinued to manage adverse effect profile that may include HTN, hepatotoxicity, diarrhea and neutropenia
- Concomitant use with a strong CYP3A4 inhibitor increases exposure to the active metabolite; monitor for toxicity as doses may need to be adjusted

Monitoring

Baseline labs, prior to initiation of treatment

- CBC with differential (ANC, platelets)
- LFTs (AST, ALT, bilirubin)
- Baseline stable BP

During treatment

- CBC with differential (ANC, platelets) monthly
- LFTs (AST, ALT, bilirubin) monthly
- BP every 2 weeks until stabilized dose, then monthly thereafter
- Severity and duration of diarrhea
- Fever and signs/symptoms of infection
- Unusual bleeding and/or bruising

Issues for Consideration

- Hypertension (all grades 28%; \geq grade 3: 2%) Monitor, Management of hypertension may require addition and/or adjustment of antihypertensive therapies
- Hepatotoxicity. Monitor. Manage by fostamatinib dose adjustment or discontinuation
- Diarrhea. Monitor. Manage with supportive measures and dose adjustment
- Neutropenia. Monitor for infection. Manage with supportive measures and dose adjustment

Discontinuation Recommendations

- Non-compliance with therapy, laboratory or follow-up requests
- Discontinue fostamatinib after 12 weeks of therapy if platelets have not yet increased to a level sufficient to avoid clinically important bleeding

Prepared: February 2019. Contact person: Berni Heron, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services
