Tavalisse (fostamatinib disodium hexahydrate)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 6 months
Quantity Limit	Continuation requests: 1 year

Medications	Quantity Limit
Tavalisse (fostamatinib disodium hexahydrate)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Tavalisse (fostamatinib disodium hexahydrate) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is diagnosed with chronic immune thrombocytopenia; AND
- III. Documentation is provided that individual has a platelet count of less than 50 X 10⁹/L;
- IV. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and insufficient response to **one** of the following:
 - A. Corticosteroids; OR
 - B. Immunoglobulins (for example IVIg, anti-D); OR
 - C. Splenectomy.

Continuation requests for Tavalisse (fostamatinib disodium hexahydrate) may be approved if the following criteria is met:

- I. Documentation is provided that individual has demonstrated a response to therapy as evidenced by increased platelet counts; **AND**
- II. Continuation of treatment is to maintain an adequate platelet count $(50 100 \text{ X } 10^9/\text{L})$ to decrease the risk of bleeding.

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.

- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Hicks LK, Bering H, Carson KR, et al. Five hematologic tests and treatments to question. *Blood*. 2014; 124(24):3524-3528. Available from: http://www.bloodjournal.org/content/bloodjournal/124/24/3524.full.pdf?sso-checked=true. Accessed on: March 21, 2019.
- 5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
- Neunert C, Terrell DR, Arnold DM, et al. The American Society of Hematology (ASH) 2019 evidence-based practice guideline for immune thrombocytopenia. *Blood Adv.* 2019; 3(23):3829-3866. Available from: <a href="https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed on: April 13, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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