FOSTAMATINIB

Generic	Brand	HICL	GCN	Exception/Other
FOSTAMATINIB DISODIUM	TAVALISSE	44895		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is prescribed by or in consultation with a hematologist or immunologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient received splenectomy?

   If yes, **approve for 3 months by HICL with a quantity limit of #2 tablets per day.**
   APPROVAL TEXT: Renewal requires physician attestation of clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10(9)/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

   If no, continue to #3.

3. Has the patient had a previous trial of or contraindication to at least **TWO** of the following treatments?
   - Corticosteroids
   - IVIG (intravenous immunoglobulin)
   - Rhogam
   - Rituxan (rituximab)
   - Thrombopoietin receptor agonist (i.e., Promacta (eltrombopag), Nplate (romiplostim))

   If yes, **approve for 3 months by HICL with a quantity limit of #2 tablets per day.**
   APPROVAL TEXT: Renewal requires physician attestation of clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10(9)/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FOSTAMATINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **FOSTAMATINIB (Tavalisse)** requires a diagnosis of chronic immune thrombocytopenia (cITP). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a hematologist or immunologist
- The patient has had a splenectomy **OR** a previous trial of or contraindication to at least **TWO** of the following treatments:
  - Corticosteroids
  - IVIG (intravenous immunoglobulin)
  - Rhogam
  - Rituxan (rituximab)
  - Thrombopoietin receptor agonist (i.e., Promacta (eltrombopag), Nplate (romiplostim))

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - Physician attestation of clinically significant prevention of bleeds while on therapy
   - The patient's AST and ALT levels have remained under 3 times the upper limits of normal per reference range
   - The patient's total bilirubin level has remained under 2 times the upper limits of normal per reference range
   - The patient's ANC has remained within normal limits per reference range
   - The patient's platelets have attained a level between 50 and 450 x 10^9/L

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **FOSTAMATINIB (Tavalisse)** requires a diagnosis of chronic immune thrombocytopenia (cITP). In addition, the following criteria must be met:
   - The patient has prevented clinically significant bleeds, per physician attestation
   - The patient's AST (aspartate aminotransferase) and ALT (alanine aminotransferase) levels have remained under 3 times the upper limits of normal per reference range
   - The patient's total bilirubin level has remained under 2 times the upper limits of normal per reference range
   - The patient's ANC (absolute neutrophil count) has remained within normal limits per reference range
   - The patient's platelets have attained a level between 50 and 450 x 10(9)/L

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FOSTAMATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavalisse.

REFERENCES

- Tavalisse [Prescribing Information]. South San Francisco, CA. Rigel Pharmaceuticals, Inc. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/19
Created: 08/18
Client Approval: 08/19
P&T Approval: 07/19