UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|---|---|
| Program Number | 2020 P 3116-3 |
| Program | Step Therapy |
| Medication | Tavalisse™ (fostamatinib) |
| P&T Approval Date | 10/2018, 11/2019, 11/2020 |
| Effective Date | 2/1/2021;<br>Oxford only: 2/1/2021 |

## 1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires members to use guideline recommended first-line therapies and try Promacta before providing coverage for Tavalisse.[3]

Tavalisse (fostamatinib) is a 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.[1]

Promacta (eltrombopag) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.[2]

Members currently on Tavalisse therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

## 2. Coverage Criteria[a]:

**A. Chronic immune thrombocytopenia (ITP)**

1. **Tavalisse** will be approved based on the following criteria:

   a. **One** of the following:

      (1) **Both** of the following:

         (a) History of failure, contraindication, or intolerance to at least one of the following:

            - Corticosteroids
            - Immunoglobulins

         **-AND-**

         (b) History of failure, contraindication, or intolerance to Promacta

(eltrombopag)

**-OR-**

(2) **Both** of the following:

(a) Patient is currently on Tavalisse therapy

**-AND-**

(b) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Rigel ONECARE Co-Pay Savings Program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Tavalisse

**Authorization will be issued for 12 months**

**B. Other Diagnoses**

1. **Tavalisse** will be approved.

**Authorization will be issued for 12 months**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits and/or Notification may be in place.

**4. References**:


1. Tavalisse [package insert]. South San Francisco, CA: Rigel Pharmaceuticals; April 2018.
2. Promacta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
3. Neunert et al. The American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019; 3(23): 3829-3866.

| Program | Step Therapy – Tavalisse (fostamatinib) |
|---|---|
| **Change Control** | |
| 10/2018 | New program |
| 11/2019 | Removed splenectomy requirement to align with other programs. Added manufacturer sample language. Updated background and references. |
| 11/2020 | Annual review. Updated references. |