UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1295-3
Program	Prior Authorization/Notification
Medication	Turalio® (pexidartinib)
P&T Approval Date	10/2019, 10/2020, 10/2021
Effective Date	1/1/2022; Oxford only: 1/1/2022

1. Background:

Turalio (pexidartinib) is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

The National Cancer Comprehensive Network (NCCN) recommends Turalio as single-agent therapy for the treatment of TGCT/ pigmented villonodular synovitis (PVNS) in patients without respect to morbidity and surgery eligibility. NCCN also recommends Turalio for colony stimulating factor 1 receptor (CSF1R) mutation positive histiocytic neoplasms.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

1. Turalio will be approved based on the following criterion:

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Tenosynovial Giant Cell Tumor/Pigmented Villonodular Synovitis</u>

1. <u>Initial Authorization</u>

a. Turalio will be approved based on the following criterion:

(1) Diagnosis of tenosynovial giant cell tumor (TGCT)/ pigmented villonodular synovitis (PVNS)

Authorization will be issued for 12 months.

2. Reauthorization

a. Turalio will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Turalio** therapy.

Authorization will be issued for 12 months.

C. Histiocytic Neoplasms

1. Initial Authorization

a. Turalio will be approved based on **all** the following criteria:

(1) Dignosis of **one** of the following:
(a) Langerhans Cell Histiocytosis
(b) Erdheim-Chester Disease
(c) Rosai-Dorfman Disease

-AND-

(2) Colony stimulating factor 1 receptor (CSF1R) mutation positive

Authorization will be issued for 12 months.

2. Reauthorization

a. Turalio will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Turalio** therapy.

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

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 may be in place.

4. References:

1. Turalio [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.April 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed August 19, 2021.

Program	Prior Authorization/Notification - Turalio
Change Control	
10/2019	New program.
10/2020	Annual review. Added PVNS to TGCT to coincide with NCCN referencing. Updated background. Updated references.
10/2021	Annual review. Clinical coverage criteria added per NCCN recommendations for CSF1R mutation positive histiocytic neoplasms. Background and reference updated.