

Clinical Pharmacy Program Guidelines for Turalio

Program	Prior Authorization
Medications	Turalio™ (pexidartinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2019
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Turalio 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) also recommends Turalio as single-agent therapy for the treatment of TGCT/ pigmented villonodular synovitis (PVNS) in patients without respect to morbidity and surgery eligibility.

2. Coverage Criteria:

<p>A. <u>Tenosynovial Giant Cell Tumor/Pigmented Villonodular Synovitis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Turalio will be approved based on the following:</p> <p>(1) Diagnosis of tenosynovial giant cell tumor (TGCT) / pigmented villonodular synovitis (PVNS)</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Turalio will be approved based on the following criterion:</p> <p>(1) Patient does not show evidence of progressive disease while on Turalio therapy</p> <p>Authorization will be issued for 12 months.</p>

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Turalio** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Turalio therapy.

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 http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 26, 2020.

Program	Prior Authorization - Turalio
Change Control	
10/2019	New program.
10/2020	Annual review. Added PVNS to TGCT to coincide with NCCN referencing. Updated background. Updated references. Added Additional Clinical Rules section.