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DRUG POLICY

Turalio (pexidartinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Turalio (pexidartinib) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Turalio (pexidartinib) is 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.

Compendial Uses

1. Pigmented Villonodular Synovitis (PVNS)
2. Histiocytic Neoplasms:
 - a. Erdheim-Chester Disease (ECD)
 - b. Langerhans Cell Histiocytosis (LCH)
 - c. Rosai-Dorfman Disease (RDD)

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Required Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of colony stimulating factor 1 receptor (CSF1R) mutation (where applicable).

Criteria for Initial Approval

A. Symptomatic Tenosynovial Giant Cell Tumor

Authorization of 12 months may be granted for the treatment of Tenosynovial Giant Cell Tumor (TGCT) as a single agent

B. Pigmented Villonodular Synovitis

Authorization of 12 months may be granted for the treatment of Pigmented Villonodular Synovitis (PVNS) as a single agent.

C. Histiocytic Neoplasms

Authorization of 6 months will be granted for any of the following histiocytic neoplasm subtypes as a single agent in members with a CSF1R mutation:

1. Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
2. Symptomatic or relapsed/refractory Rosai-Dorfman Disease (RDD)
3. Langerhans Cell Histiocytosis (LCH)

Continuation of Therapy

A. Symptomatic Tenosynovial Giant Cell Tumor (TGCT)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen..

B. Pigmented Villonodular Synovitis (PVNS)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

C. Histiocytic Neoplasms

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other

Turalio (peixidartinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Standard Limit	FDA-Recommended dosing
Turalio 200 mg capsules	120 per 30 days	Initial dose: 400mg (two 200 mg capsules) twice daily Dose adjustments due to adverse reactions: <ul style="list-style-type: none">• First reduction: 200 mg in the morning and 400 mg in the evening• Second reduction: 200 mg twice daily
Turalio 125 mg capsules	120 per 30 days	Initial dose: 250mg (two 125 mg capsules) twice daily Dose adjustments due to adverse reactions: <ul style="list-style-type: none">• First reduction: 125 mg in the morning and 250 mg in the evening• Second reduction: 125 mg twice daily

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Turalio [package insert]. Rasking Ridge, NJ: Daiichi Sankyo, Inc.; November 2023.
- The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 28, 2025.
- Pigmented Villonodular Synovitis. American Academy of Orthopaedic Surgeons. Available at: [https://orthoinfo.aaos.org/en/diseases--conditions/pigmented-villonodular-synovitis#:~:text=Pigmented%20villonodular%20synovitis%20\(PVNS\)%20is,other%20areas%20of%20the%20body](https://orthoinfo.aaos.org/en/diseases--conditions/pigmented-villonodular-synovitis#:~:text=Pigmented%20villonodular%20synovitis%20(PVNS)%20is,other%20areas%20of%20the%20body). Accessed October 1, 2021.

*Some content reprinted from CVS Health

POLICY HISTORY

Policy #: 05.02.81

Original Effective Date: January 17, 2020

Reviewed: August 2025

Revised: August 2025

Current Effective Date: September 25, 2025