Generic Name: Pexidartinib

Therapeutic Class or Brand Name: Turalio

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/8/2025

Date Last Reviewed / Revised: 9/8/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Tenosynovial giant cell tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS)

i. Documentation that surgical resection will cause worsening functional limitation or severe morbidity

ii. Diagnosis of symptomatic disease associated with severe morbidity or functional limitations.

II. Minimum age requirement: 18 years old

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Available in 125 mg capsules
- Maximum dose: 250 mg orally twice daily

- Maximum quantity allowed: 120 capsules / 30-day supply

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 1.2025. Updated May 2, 2025. Accessed June 19, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
2. Turalio. Prescribing Information. Daiichi Sankyo, Inc. January 2025. Accessed June 19, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2025/211810s013lbl.pdf