

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Turalio Prior Authorization Policy

- Turalio® (pexidartinib capsules – Daiichi Sankyo)

REVIEW DATE: 06/19/2024

OVERVIEW

Turalio, a kinase inhibitor, is indicated for the treatment of **symptomatic tenosynovial giant cell tumor** associated with severe morbidity or functional limitations and not amenable to improvement with surgery in adults.¹

Guidelines

Turalio is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Histiocytic Neoplasms:** NCCN guidelines (version 1.2024 – March 15, 2024) recommend Turalio as first-line or subsequent therapy for colony stimulating factor 1 receptor *CSF1R* mutation target as “Useful in Certain Circumstances,” for Langerhans cell histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman disease in various settings (category 2A).²⁻³
- **Soft Tissue Sarcoma:** NCCN guidelines (version 1.2024 – April 26, 2024), indicate that Turalio is the “preferred” single-agent therapy for the treatment of pigmented villonodular synovitis/tenosynovial giant cell tumor (category 1).³⁻⁴

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Turalio. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Turalio is recommended in those who meet one of the following criteria:

FDA-Approved Indication

- 1) **Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis).** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) According to the prescriber, the tumor is not amenable to improvement with surgery.

Other Uses with Supportive Evidence

- 2) **Histiocytic Neoplasms.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has a colony stimulating factor 1 receptor (*CSF1R*) mutation; AND
 - C) Patient has ONE of the following (i, ii, or iii):
 - i. Langerhans cell histiocytosis; OR
 - ii. Erdheim-Chester disease; OR

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- iii. Rosai-Dorfman disease.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Turalio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Turalio® capsules [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; November 2023.
2. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – March 15, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 13, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 13, 2024. Search term: pexidartinib.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 13, 2024.