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

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.