PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Turalio Prior Authorization Policy
- Turalio® (pexidartinib capsules – Daiichi Sankyo)

REVIEW DATE: 08/17/2022

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

Guidelines
Turalio is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):
- **Histiocytic Neoplasms**: NCCN guidelines (version 1.2022 – May 20, 2022) recommend Turalio as first-line or subsequent therapy for CSF1R mutation target as a single agent, 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 2.2022 – May 17, 2022), indicate that Turalio (category 1) is the preferred regimen for systemic therapy in pigmented villonodular synovitis/tenosynovial giant cell tumor.[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 Indications

1) **Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis).** Approve for 1 year if the patient meets the following criteria (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 the following criteria (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 conditions (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; July 2022.
2. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 10, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 10, 2022. Search term: pexidartinib.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 10, 2022.