

SPECIALTY GUIDELINE MANAGEMENT

TURALIO (pexidartinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Turalio 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.

B. 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)

All other indications are considered experimental/investigational and not medically necessary.

II. 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).

III. CRITERIA FOR INITIAL APPROVAL

A. **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT)**

Authorization of 12 months may be granted for the treatment of pigmented villonodular synovitis (PVNS)/tenosynovial giant cell tumor (TGCT) as a single agent.

B. **Histiocytic Neoplasms**

Authorization of 12 months may 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)

IV. CONTINUATION OF THERAPY

Reference number(s)
3151-A

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

V. REFERENCES

1. Turalio [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; November 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 8, 2024.