Turalio (pexidartinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Turalio (pexidartinib) capsules	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Turalio (pexidartinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of tenosynovial giant cell tumor [(TGCT), also known as GCT-TS or PVNS]; **AND**
II. Disease is not amenable to surgical resection; **AND**
III. Individual has symptomatic disease with severe morbidity or functional limitations at the time of request;

OR

IV. Individual has a diagnosis of symptomatic, relapsed or refractory Erdheim-Chester disease (NCCN 2A); **AND**
V. Individual has colony stimulating factor 1 receptor (CSF1R) mutation target;

OR

VI. Individual has a diagnosis of Langerhans Cell Histiocytosis (LCH) (NCCN 2A); **AND**
VII. One of the following:
    1. Individual has symptomatic or impending organ dysfunction; **OR**
    2. Individual has single-system lung LCH; **OR**
    3. Individual has single system bone disease with at least 2 lesions and not responsive to bisphosphonate treatment; **OR**
    4. Individual has lesions in central nervous system; **OR**
    5. Individual has relapsed or refractory disease;

OR

VIII. Individual has a diagnosis of Rosai-Dorfman disease (NCCN 2A); AND
IX. One of the following:
    1. Individual has colony stimulating factor 1 receptor (CSF1R) mutation target; OR
    2. Individual has symptomatic unresectable unifocal disease; OR
    3. Individual has symptomatic multifocal disease; OR
    4. Individual has relapsed or refractory disease.

Turalio (pexidartinib) may not be approved for the following:

I. When the above criteria are not met; **OR**
II. Individual has active or chronic infection with hepatitis C or hepatitis B virus, or known active or chronic infection with HIV (human immunodeficiency virus).

Notes:
Turalio has a black box warning for causing serious and potentially fatal liver injury. Liver tests should be completed prior to starting Turalio and during treatment. Withhold and reduce dose, or permanently discontinue Turalio based on severity of hepatotoxicity. Turalio is only available through a REMS (Risk Evaluation and Mitigation Strategy) program.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 6, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCT02371369. ClinicalTrials.gov. U.S. National Library of Medicine. Available at https://clinicaltrials.gov/ct2/show/NCT02371369?term=nct02371369&draw=2&rank=1.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 6, 2023.
    a. Histolytic Neoplasms. V1.2022. Revised May 20, 2022.
    b. Soft Tissue Sarcoma. V1.2023. Revised March 13, 2023.