

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## 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.

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

- I. When the above criteria are not met; **OR**
- II. Individual has a diagnosis of metastatic TGCT/GCT-TS/PVNS (NCT02371369); **OR**
- III. 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.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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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 15, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 15, 2020.
  - a. Soft Tissue Sarcoma. V6.2019. Revised February 10, 2020.
6. NCT02371369. ClinicalTrials.gov. U.S. National Library of Medicine. Available at <https://clinicaltrials.gov/ct2/show/NCT02371369?term=nct02371369&draw=2&rank=1>. Accessed on April 15, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.