HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Turalio (pexidartinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Turalio, approved by the FDA in 2019, is a kinase inhibitor 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. Turalio is the first FDA-approved systemic treatment for TGCT. It targets colony stimulating factor 1 receptor (CSF1R) and other tyrosine kinases to inhibit cell proliferation and accumulation. Turalio has a REMS program and boxed warning for hepatotoxicity.
TGCT, also known as pigmented villonodular synovitis or giant cell tumor of the tendon, is a rare non-malignant tumor that affects the synovium and tendon sheath. The tumor causes overgrowth and thickening of the tissues which leads to swelling, pain and reduced range of motion. First-line treatment consists of surgery for patients who are considered amendable to improvement.

Turalio (pexidartinib) will be considered for coverage when the following criteria are met:

Tenosynovial Giant Cell Tumor

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an oncologist or orthopedic surgeon; AND
3. Member has a diagnosis of symptomatic benign TGCT confirmed by MRI or histology; AND
4. Disease is associated with severe morbidity or functional limitations; AND
5. Prescriber attests that the member's disease is not amenable to improvement with surgery; AND
6. Chart notes must document that baseline liver tests have been or will be completed prior to starting therapy.
7. **Dosage allowed/Quantity limit:** 250 mg orally twice daily with a low-fat meal.
   Quantity Limit: 120 capsules per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease (such as decreased pain and stiffness, increased range of motion, or reduced tumor volume).

If all the above requirements are met, the medication will be approved for an additional 12 months.

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HAP CareSource considers Turalio (pexidartinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/20/2023	New policy for Turalio created.
04/18/2025	Updated references. Added reduced tumor volume to reauth examples. Removed pregnancy and cancer exclusions.

References:

1. Turalio (pexidartinib) [package insert]. Daiichi Sankyo, Inc.; 2025.
2. Stacchiotti S, Dürr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): A consensus paper from the community of experts. Cancer Treat Rev. 2023;112:102491. doi:10.1016/j.ctrv.2022.102491
3. Healey JH, Bernthal NM, van de Sande M. Management of Tenosynovial Giant Cell Tumor: A Neoplastic and Inflammatory Disease. J Am Acad Orthop Surg Glob Res Rev. 2020;4(11):e20.00028. doi:10.5435/JAAOSGlobal-D-20-00028
4. Tap WD, Gelderblom H, Palmerini E, et al. Pexidartinib versus placebo for advanced tenosynovial giant cell tumour (ENLIVEN): a randomised phase 3 trial. Lancet. 2019;394(10197):478-487. doi:10.1016/S0140-6736(19)30764-0
5. National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 1.2025). https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed April 9, 2025.

Effective date: 10/01/2025
Revised date: 04/18/2025