

PHARMACY POLICY STATEMENT

North Carolina Marketplace

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

Turalio (pexidartinib) 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. Initially approved in 2019, Turalio is the first FDA-approved systemic treatment for TGCT. Turalio targets colony stimulating factor 1 receptor (CSF1R) and other tyrosine kinases to inhibit cell proliferation and accumulation. 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;
2. Medication must be prescribed by a physician in consultation with an oncologist or orthopedic surgeon; AND
3. Member has a diagnosis of symptomatic high TGCT confirmed by MRI or histology; AND
4. Disease is associated with severe morbidity or functional limitations; AND
- 5.
6. Chart notes must document that baseline liver tests have been or will be completed prior to starting therapy; AND
7. Member does not have ANY of the following:
 - a) Pregnancy or plan to become pregnant during treatment;
 - b) Active cancer
8. **Dosage allowed/Quantity limit:** 250 mg orally twice daily with a low-fat meal. Quantity Limit: 120 capsules per 30 days.

