PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Turalio Prior Authorization Policy
- Turalio® (pexidartinib capsules – Daiichi Sankyo)

REVIEW DATE: 07/29/2020

OVERVIEW

Turalio, a kinase inhibitor, 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.[1] Turalio targets the colony stimulating factor 1 (CSF1) receptor; it also inhibits KIT proto-oncogene receptor tyrosine kinase, as well as FMS-like tyrosine kinase 3 with an internal tandem duplication mutation. Due to the risk of hepatotoxicity, Turalio is only available through a restricted Risk Evaluation and Mitigation Strategy (REMS) program.

Disease Overview

TGCTs are rare, benign tumors of the synovium (joint lining), bursae, and tendon sheath.[2] Tumors cause thickening and overgrowth of the affected tissues, leading to pain, swelling, and reduced mobility. Disease is caused by a chromosomal translocation resulting in CSF1 overexpression, leading to macrophage recruitment and inflammation. The exact incidence is unknown but is estimated at approximately 43 cases per 1 million in the general population, of which approximately 10% are the diffuse subtype (also known as pigmented villonodular synovitis).[2,3] Diffuse TGCTs have a high recurrence rate after surgery of up to 50%, often with multiple recurrences.[4] Untreated or recurrent disease can lead to damage and degeneration of the affected joint. Disease typically affects a single joint, most commonly the knee or hip.

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines for soft tissue sarcoma (version 2.2020 – May 28, 2020), Turalio (category 1) and imatinib (category 2A) are preferred regimens for systemic therapy in TGCT.[5]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Turalio. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Turalio is recommended in those who meet the following criteria:

FDA-Approved Indications

1) **Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis).** Approve for 3 years if, according to the prescriber, the tumor is not amenable to improvement with surgery.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Turalio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Turalio® [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; April 2020.
2. Tenosynovial giant cell tumor. National Organization for Rare Disorders. Updated 2017. Available at: https://rarediseases.org/rare-diseases/tenosynovial-giant-cell-tumor/. Accessed on July 21, 2020.
3. 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.
4. Lucas DR. Tenosynovial giant cell tumor: case report and review. *Arch Pathol Lab Med*. 2012;136(8):901-906.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 2.2020 – May 28, 2020). © 2020 National Comprehensive Cancer Network Inc. Available at: http://www.nccn.org. Accessed July 21, 2020.