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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 16, 2019
Subject:	Turalio	**Page:**	1 of 5

Last Review Date: September 6, 2024

Turalio

Description

Turalio (pexidartinib)

Background
Turalio (pexidartinib) is a tyrosine kinase inhibitor that targets colony stimulating factor 1 receptor (CSF1R), KIT proto-oncogene receptor tyrosine kinase (KIT), and FMS-like tyrosine kinase 3 (FLT3) harboring an internal tandem duplication (ITD) mutation. Overexpression of the CSF1R ligand promotes cell proliferation and accumulation in the synovium (1).

Regulatory Status
FDA-approved indication: Turalio 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 amendable to improvement with surgery (1).

Turalio can cause serious and potentially fatal liver injury and is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Patient's liver tests must be monitored prior to initiation of Turalio and at specified intervals during treatment (including every week for the first 8 weeks of treatment, every 2 weeks for the next month, and every 3 months thereafter). Consider withholding, dose reducing, or permanently discontinuing Turalio based on severity of hepatotoxicity (1).

Turalio should be given twice daily with a low-fat meal (approximately 11 to 14 grams of total fat). Taking Turalio with a high-fat meal (approximately 55 to 65 grams of total fat) increases Turalio concentrations and may increase the risk of adverse reactions, including hepatotoxicity (1).

Females of reproductive potential should be advised to avoid becoming pregnant while being treated, as Turalio may cause fetal harm. Females of reproductive potential should be advised to use effective contraception during treatment with Turalio and for 1 month after the last dose. Males with a female partner of reproductive potential should be advised to use effective contraception during treatment with Turalio and for 1 week after the last dose (1).

The safety and effectiveness of Turalio in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Turalio may be considered **medically necessary** if the conditions indicated below are met.

Turalio may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Symptomatic tenosynovial giant cell tumor (TGCT)

a. Disease is associated with severe morbidity or functional limitations
b. Patient has had prior surgical treatment or patient is not a candidate for surgery

AND ALL of the following:

a. Prescriber agrees to monitor liver tests for hepatotoxicity during therapy and discontinue if necessary
b. Patient and prescriber are enrolled in the TURALIO REMS program

c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 1 month after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Symptomatic tenosynovial giant cell tumor (TGCT)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor liver tests for hepatotoxicity during therapy and discontinue if necessary
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 1 month after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 360 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Turalio (pexidartinib) is a tyrosine kinase inhibitor that targets colony stimulating factor 1 receptor (CSF1R), KIT proto-oncogene receptor tyrosine kinase (KIT), and FMS-like tyrosine kinase 3 (FLT3) harboring an internal tandem duplication (ITD) mutation. Overexpression of the CSF1R ligand promotes cell proliferation and accumulation in the synovium. The safety and effectiveness of Turalio in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Turalio while maintaining optimal therapeutic outcomes.

References

1. Turalio [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; November 2023.
2. NCCN Drugs & Biologics Compendium ® Pexidartinib 2024. National Comprehensive Cancer Network, Inc. Accessed on July 19, 2024.

Policy History

Date	Action
August 2019	New Addition
September 2019	Annual review
December 2019	Annual review
June 2020	Annual review and reference update
December 2021	Annual review and reference update
December 2022	Annual editorial review and reference update. Reworded contraception requirements for consistency
September 2023	Annual review and reference update
March 2024	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.