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).

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 for patients 18 years of age and older for the treatment of symptomatic tenosynovial giant cell tumor (TGCT) and if the conditions indicated below are met.

Turalio is considered investigational in patients who are less than 18 years of age and 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)
  - Disease is associated with severe morbidity or functional limitations
  - Patient has had prior surgical treatment or patient is not a candidate for surgery

  AND ALL of the following:
  - Prescriber agrees to monitor liver tests for hepatotoxicity during therapy and discontinue if necessary
  - Patient and prescriber are enrolled in the TURALIO REMS program
  - Prescriber agrees to advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after
the last dose
d. Prescriber agrees to advise males with female partners of reproductive potential 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. Prescriber agrees to advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose
d. Prescriber agrees to advise males with female partners of reproductive potential 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**

**Policy History**

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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.