BlueCross BlueShield Federal Employee Program

TURALIO (pexidartinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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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 October 7, 2024.