BlueCross BlueShield Federal Employee Program

CAPRELSA
(vandetanib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Caprelsa (vandetanib) is a kinase inhibitor approved for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Caprelsa inhibits endothelial cell migration, proliferation, survival and new blood vessel formation in *in vitro* models of angiogenesis. Caprelsa inhibits EGFR-dependent cell survival *in vitro*. In addition, Caprelsa inhibits epidermal growth factor (EGF)–stimulated receptor tyrosine kinase phosphorylation in tumor cells and endothelial cells and VEGF-stimulated tyrosine kinase phosphorylation in endothelial cells (1).

Regulatory Status

FDA-approved indication: Caprelsa is a kinase inhibitor indicated for symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease (1).

Use Caprelsa in patients with indolent, asymptomatic, or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa (1).

Caprelsa carries a boxed warning of QT prolongation and torsades de pointes. Caprelsa can prolong the QT interval. Torsades de pointes and sudden death have been reported in patients receiving Caprelsa. Caprelsa should not be used in patients with hypocalcemia, hypokalemia, hypomagnesemia, or congenital long QT syndrome. Hypocalcemia, hypokalemia, and/or hypomagnesemia must be corrected prior to Caprelsa administration and should be periodically monitored. Drugs known to prolong the QT interval should be avoided. Given the half-life of 19 days, ECGs should be obtained to monitor the QT interval at baseline, at 2 to 4 weeks and 8 to 12 weeks after starting treatment with Caprelsa, and every 3 months thereafter. Following any dose reduction for QT prolongation or any dose interruptions of more than 2 weeks, QT assessment should be conducted as previously described. Because of the 19-day half-life, adverse reactions, including a prolonged QT interval, may not resolve quickly (1).

Caprelsa is available only through a restricted distribution program called Caprelsa REMS. Only prescribers and pharmacies certified by the program may prescribe and dispense Caprelsa. The Risk Evaluation and Mitigation Strategy (REMS) program for Caprelsa is required by the FDA and is intended to help manage known and potential serious risks associated with Vandetanib as well

to ensure the benefits outweigh the risks for each patient (1).

Safety and effectiveness of Caprelsa in pediatric patients have not been established (1).

Summary

Caprelsa is a kinase inhibitor indicated for symptomatic or progressive medullary thyroid cancer in patients 18 years of age or older, with unresectable locally advanced or metastatic disease. Caprelsa should not be used in patients with hypocalcemia, hypokalemia, hypomagnesemia, or congenital long QT syndrome. Hypocalcemia, hypokalemia, and/or hypomagnesemia must be corrected prior to Caprelsa administration and should be periodically monitored. The Risk Evaluation and Mitigation Strategy (REMS) program for Caprelsa is required by the FDA (1).

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

References

1. Caprelsa [package insert]. Cambridge, MA: Genzyme Corporation; April 2024.
2. NCCN Drugs & Biologics Compendium® Vandetanib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.