BlueCross BlueShield
Federal Employee Program

IBTROZI
(taletrectinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ibtrozi (taletrectinib) is an inhibitor of tyrosine-protein kinase ROS1, including ROS1 resistance mutations. Ibtrozi also showed inhibitory effects on tropomyosin receptor kinases (TRKs) TRKA, TRKB, and TRKC. Fusion proteins that include ROS1 domains can drive tumorigenic potential through hyperactivation of downstream signaling pathways leading to unconstrained cell proliferation. Ibtrozi inhibited growth of cancer cells expressing *ROS1* fusion genes and mutations (1).

Regulatory Status

FDA-approved indications: Ibtrozi is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC).

Select patients for treatment with Ibtrozi based on the presence of *ROS1* rearrangement(s) in tumor specimens (1).

Ibtrozi has been associated with hepatotoxicity, interstitial lung disease/pneumonitis, QTc interval prolongation, hyperuricemia, myalgia with creatine phosphokinase elevations, and skeletal fractures. If needed, Ibtrozi may be withheld and resumed at the same or reduced dose upon improvement, or permanently discontinued based on severity (1).

Ibtrozi can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Ibtrozi and for 3 weeks after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Ibtrozi and for 3 weeks after the last dose (1).

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

Summary

Ibtrozi (taletrectinib) is a kinase inhibitor indicated for the treatment of *ROS1*-positive non-small cell lung cancer (NSCLC). Ibtrozi has been associated with hepatotoxicity, interstitial lung

disease/pneumonitis, QTc interval prolongation, hyperuricemia, myalgia with creatine phosphokinase elevations, skeletal fractures, and embryo-fetal toxicity. The safety and effectiveness of Ibtrozi in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Ibtrozi [package insert]. Burlington, MA: Nuvation Bio Inc.; June 2025.
2. NCCN Drugs & Biologics Compendium® Taletrectinib 2025. National Comprehensive Cancer Network, Inc. Accessed on June 12, 2025.