BlueCross BlueShield Federal Employee Program

LORBRENA (lorlatinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lorbrena (lorlatinib) is a kinase inhibitor with in vitro activity against anaplastic lymphoma kinase (ALK) and ROS1 as well as other kinases. Lorbrena demonstrated in vitro activity against multiple mutant forms of the ALK enzyme, including some mutations detected in tumors at the time of disease progression on crizotinib and other ALK inhibitors (1).

Regulatory Status

FDA-approved indication: Lorbrena is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (1).

Lorbrena has warnings for risk of serious hepatotoxicity with concomitant use of strong CYP3A4 inducers, central nervous system effects (including seizures, hallucinations, and changes in cognitive function, mood, speech, mental status, and sleep), hyperlipidemia, atrioventricular block, interstitial lung disease/pneumonitis, hypertension, hyperglycemia and embryo-fetal toxicity (1).

Serum cholesterol and triglycerides should be monitored before initiating Lorbrena, 1 and 2 months after initiating Lorbrena, and periodically thereafter. ECG should be monitored prior to initiating Lorbrena and periodically thereafter (1).

Lorbrena can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use an effective non-hormonal method of contraception, since Lorbrena can render hormonal contraceptives ineffective, during treatment with Lorbrena and for at least 6 months after the final dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Lorbrena and for 3 months after the final dose (1).

The safety and effectiveness of Lorbrena in pediatric patients have not been established (1).

Summary

Lorbrena (lorlatinib) is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive.

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Lorbrena has warnings for risk of serious hepatotoxicity with concomitant use of strong CYP3A4 inducers, central nervous system effects, hyperlipidemia, atrioventricular block, interstitial lung disease/pneumonitis, hypertension, hyperglycemia and embryo-fetal toxicity. The safety and effectiveness of Lorbrena in pediatric patients have not been established (1).

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

References

1. Lorbrena [package insert]. New York, NY: Pfizer Inc.; August 2024.
2. NCCN Drugs & Biologics Compendium® Lorlatinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.