Reference number(s)
4938-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Health Exchange (AHE)	☐
IVL	☐
Value (VF)	☑
New to Market (NTM)	☐

Formulary	Applies
ACSF Chart (ACSFC)	☐
SF Chart (SFC)	☐
VF Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Biosimilars First	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid	☐
Medical Benefit: Add-on	☐
Medicare Part B	☐
Medicare Part B: Biosimilars First	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
ALK/ROS1 Inhibitors

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), and Value Formulary (VF).

Plan Design Summary

This program applies to the ALK/ROS1 inhibitor products specified in this document. Coverage for the targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. ALK/ROS1 Inhibitors

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Alecensa (alectinib) • Alunbrig (brigatinib) • Augtyro (repotrectinib) • Zykadia (ceritinib)
Target	• Xalkori (crizotinib) capsule

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for the targeted product is provided when any of the following criteria is met:

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member is requesting Xalkori for the treatment of ALK-positive non-small cell lung cancer (NSCLC) and has had a documented intolerable adverse event with Alecensa, Alunbrig, and Zykadia.
- Member is requesting Xalkori for the treatment of ROS1-positive non-small cell lung cancer (NSCLC) and has had a documented intolerable adverse event with Augtyro.

References

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; April 2024.
2. Alunbrig [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2023.
3. Augtyro [package insert]. Princeton, NJ. Bristol-Myers Squibb Company; June 2024.
4. Xalkori [package insert]. New York, NY: Pfizer Laboratories Div Pfizer Inc.; July 2024.
5. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021.