

Clinical Policy Title:	Antimetabolites – Anaplastic Lymphoma Kinase (ALK)/ Tropomyosin Receptor Kinase (TRK) Inhibitors
Policy Number:	RxA.582
Drug(s) Applied:	Alecensa (brigatinib), Alunbrig (alectinib), Zykadia (ceritinib), Xalkori (crizotinib), Lorbrena (lorlatinib), Rozlytrek (Entrectinib), Vitrakvi (Larotrectinib)
Original Policy Date:	03/06/2020
Last Review Date:	6/14/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (Alecensa, Alunbrig, Zykadia, Xalkori, Lorbrena):

1. Diagnosis of recurrent or metastatic NSCLC;
2. Meets one of the following (a or b):
 - a. Disease is anaplastic lymphoma kinase (ALK) positive tumor and request is for Alecensa, Alunbrig, Zykadia, Xalkori, or Lorbrena;
 - i. Patient has had disease progression on, contraindication or intolerance to, or is not a candidate to one of the following (a or b):
 - a) Alecensa (alectinib);
 - b) Alunbrig (brugatinib);
 - b. Disease is ROS1 or MET rearrangement-positive tumor, and request is for Xalkori;
 - c. Disease is ROS1 positive, and request is for Rozlytrek.

Approval Duration

All lines of business (except Medicare): 12 months, Split-fill

B. Anaplastic Large Cell Lymphoma (Xalkori):

1. Diagnosis relapsed or refractory anaplastic large cell lymphoma;
2. Disease is ALK positive tumor.

Approval Duration

All lines of business (except Medicare): 12 months, Split-fill

C. Inflammatory Myofibroblastic Tumor (Xalkori):

1. Diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor;
2. Disease is ALK positive tumor.

Approval Duration

All lines of business (except Medicare): 12 months, Split-fill

D. NTRK Fusion-Positive Cancer (Rozlytrek, Vitrakvi):

1. Solid tumor which is metastatic or unresectable;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

2. Tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.);
3. Documentation of no known acquired tropomyosin receptor kinase resistance mutation (e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations);
4. One of the following (a or b):
 - a. Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy);
 - b. Disease has no satisfactory alternative treatments.

Approval Duration:

All Lines of Business (except Medicare) 12 months, Split-fill

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 5.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed June 14, 2024.
2. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 14, 2024.
3. National Comprehensive Cancer Network Guidelines. T-Cell Lymphomas Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed June 14, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 3. References were updated. 	09/04/2020	12/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval criteria I.C added to include off label indication criteria for “Central Nervous System Cancers”. 2. References were reviewed and updated. 	10/09/2021	12/07/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4, I.B.5, I.C.4: Updated to include new prescribing criteria 	07/29/2022	10/19/2022

Prescribed as a single agent. 2. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Approval Duration Updated. 2. Continuation Criteria Updated. 3. Reference were reviewed and updated.	6/14/2024	6/14/2024