PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Xalkori (crizotinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Xalkori, originally approved by the FDA in 2011, is a small molecule tyrosine kinase inhibitor (TKI). As of 2022, it is indicated for adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive. It is also indicated to treat specific types of non-small cell lung cancer (NSCLC) and anaplastic large cell lymphoma (ALCL).
IMTs are a rare but usually benign type of mesenchymal neoplasm that can be found in any age, although they most often develop in children or young adults. While these tumors typically affect the abdominal cavity, any area of the body can be affected. Surgery is the initial standard of care treatment, but surgery may not be possible in some cases, and tumors may recur after surgery. Malignant IMTs are uncommon, especially when ALK-positive.
ALK rearrangements have been implicated in giving rise to oncogenic fusion proteins in at least 50% of IMTs. Expression of ALK fusion proteins contributes to cell proliferation and tumor survival. ALK is a type of tyrosine kinase and has proven to be a suitable target for systemic therapy with high response rates.

Xalkori (crizotinib) will be considered for coverage when the following criteria are met:

Inflammatory Myofibroblastic Tumor (IMT)

For **initial** authorization:
1. Member is at least 1 year of age; AND
2. Medication must be prescribed by or in consultation with a hematologist/oncologist; AND
3. Member has a documented diagnosis of unresectable, recurrent, or refractory IMT; AND
4. Test results show the member's tumor is ALK-positive.
5. **Dosage allowed/Quantity limit:**
   Adult: 250 mg orally twice daily
   Pediatric: 280 mg/m^2 orally twice daily (refer to body surface area table in prescribing information)

   Capsule QL: 120 per 30 days
   Pellet QL: 240 per 30 days

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must show a positive clinical response to treatment such as tumor shrinkage and/or symptomatic improvement.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Lung Cancer or Lymphoma

Any request for cancer must be submitted through NantHealth/Eviti portal.

CareSource considers Xalkori (crizotinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/28/2023	New policy for Xalkori created.

References:

1. Xalkori [prescribing information]. Pfizer Inc.; 2023.
2. Schöffski P, Kubickova M, Wozniak A, et al. Long-term efficacy update of crizotinib in patients with advanced, inoperable inflammatory myofibroblastic tumour from EORTC trial 90101 CREATE. *Eur J Cancer*. 2021;156:12-23. doi:10.1016/j.ejca.2021.07.016
3. Butrynski JE, D'Adamo DR, Hornick JL, et al. Crizotinib in ALK-rearranged inflammatory myofibroblastic tumor. *N Engl J Med*. 2010;363(18):1727-1733. doi:10.1056/NEJMoa1007056
4. Mossé YP, Voss SD, Lim MS, et al. Targeting ALK With Crizotinib in Pediatric Anaplastic Large Cell Lymphoma and Inflammatory Myofibroblastic Tumor: A Children's Oncology Group Study. *J Clin Oncol*. 2017;35(28):3215-3221. doi:10.1200/JCO.2017.73.4830
5. Siemion K, Reszec-Gielazyn J, Kisluk J, Roszkowiak L, Zak J, Korzynska A. What do we know about inflammatory myofibroblastic tumors? - A systematic review. *Adv Med Sci*. 2022;67(1):129-138. doi:10.1016/j.advms.2022.02.002
6. Trahair T, Gifford AJ, Fordham A, et al. Crizotinib and Surgery for Long-Term Disease Control in Children and Adolescents With ALK-Positive Inflammatory Myofibroblastic Tumors. *JCO Precis Oncol*. 2019;3:PO.18.00297. Published 2019 May 16. doi:10.1200/PO.18.00297
7. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 2.2023 – April 25, 2023. Accessed September 28, 2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.

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Revised date: 09/28/2023