 Draft Revision Policy: Do Not Implement

Nelarabine (Arranon®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of T-cell acute lymphoblastic leukemia (T-ALL); **AND**
  - This is an initial request for therapy; **AND**
    - The patient is at least one year of age; **AND**
    - The patient has relapsed or refractory disease; **AND**
    - The patient failed at least two prior chemotherapy regimens; **OR**
  - This is an initial request for therapy; **AND**
    - The patient is at least one year of age; **AND**
    - The patient has newly diagnosed or intermediate to high-risk disease; **AND**
    - The patient will receive the requested medication as post-induction therapy in combination with the augmented Berlin-Frankfurt-Muenster (ABFM) regimen; **OR**
  - The patient is already receiving treatment with the requested medication; **AND**
    - The patient has experienced disease stabilization or improvement; **AND**
    - The patient has NOT experienced unacceptable toxicity from treatment with the requested medication; **OR**
- The patient has a diagnosis of T-cell lymphoblastic lymphoma (T-LBL); **AND**
  - This is an initial request for therapy; **AND**
    - The patient is at least one year of age; **AND**
    - The patient has relapsed or refractory disease; **AND**
    - The patient failed at least two prior chemotherapy regimens; **OR**
  - The patient is already receiving treatment with the requested medication; **AND**
    - The patient has experienced disease stabilization or improvement; **AND**
    - The patient has NOT experienced unacceptable toxicity from treatment with the requested medication

*The NCCN Drugs & Biologics Compendium recognizes additional uses for Nelarabine beyond the FDA-approved labeling (Refer to the NCCN Drugs & Biologics Compendium or NCCN Clinical Practice Guidelines for detailed recommendations)

LENGTH OF AUTHORIZATION

Approval may be provided for six (6) months and may be renewed.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Arranon [package insert]. East Hanover, NJ; Novartis Pharmaceuticals; March 2025. Accessed July 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 28, 2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): NCCN Guidelines Version 2.2025 Acute Lymphoblastic Leukemia Accessed August 14, 2025. ~~https://www.nccn.org/professionals/physician_gls/pdf/AcuteLymphoblastic Leukemia.pdf~~ https://www.nccn.org/professionals/physician_gls/pdf/all.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): NCCN Guidelines Version 1.2026 Pediatric Acute Lymphoblastic Leukemia Accessed August 14, 2025. ~~https://www.nccn.org/professionals/physician_gls/pdf/PediatricAcuteLymphoblastic Leukemia.pdf~~ https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf
5. Lexi-comp Online. (2025, February). AHFS DI. Nelarabine. Retrieved July 2025. from Lexi-comp Online with AHFS.
6. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2024, April). Nelarabine. Retrieved July 2025. from MICROMEDEX Healthcare Series.
7. Nelarabine. In: Clinical Pharmacology. Tampa (FL): Elsevier. Revised April 2025. Accessed July 2025.

EFFECTIVE DATE

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