Clofarabine (Clolar®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration Home Infusion HCPCS: J9027 per 1 mg

Condition(s) listed in policy (*see criteria for details*)

- Acute lymphoblastic leukemia
- Acute myelogenous leukemia
- Langerhans cell histiocytosis

AHFS therapeutic class: Antineoplastic

Mechanism of action: antimetabolite, synthetic purine nucleoside

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for clofarabine (Clolar®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute lymphoblastic leukemia (ALL)

Relapsed or refractory disease

Covered Doses
Up to 70 mg/m^2 IV infusion daily for 5 consecutive days repeated every 2 to 6 weeks

Coverage Period
Yearly

ICD-10:
C90.00-C91.02

Acute myelogenous leukemia (AML)

Covered Doses
Up to 120 mg (120 billable units) once daily for 5 days, no more often than every 3 weeks

ICD-10:
C92.00, C92.02, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C93.00, C93.02, C94.00, C94.02, C94.20, C94.22

Langerhans cell histiocytosis

Covered Doses
Up to 25 mg/m^2 IV infusion daily for 5 consecutive days of a 28-day cycle

Coverage Period
Indefinite

ICD-10:
C96.0, C96.2, C96.5-C96.7, C96.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for clofarabine (Clolar®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Solid tumors
- Non-Hodgkin's Lymphoma Chronic Lymphocytic Leukemia Myelodysplastic syndrome

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
20 mg (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Clolar® (clofarabine) [Prescribing information]. Cambridge, MA: Genzyme, Inc., 12/2019.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- National Comprehensive Cancer Network Drugs and Compendium (2023). Available at: www.nccn.org
- National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 4.2021). Available at: www.nccn.org
- National Comprehensive Cancer Network. Acute Myeloid Leukemia (Version 1.2022). Available at: www.nccn.org
- National Comprehensive Cancer Network. Histiocytic Neoplasms (Version 2.2021). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia (Version 1.2022). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee