Medical Policy:

Clolar® (clofarabine) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.138	March 13, 2024	

Definitions

Clolar is a purine nucleoside metabolic inhibitor of the synthesis of DNA by reducing the pools of deoxynucleotide triphosphate. This is attained by inhibiting ribonucleoside reductase, terminating elongation of the DNA chain and inhibiting repair through incorporation into the DNA chain by competitive inhibition of DNA polymerases.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Indication	Dose
Acute lymphoblastic leukemia (ALL)	(≤ 21 years) 52 mg/m^2/day IV over 2 hours for 5 consecutive days; repeat every 2 to 6 weeks, following recovery or return to baseline organ function; subsequent cycles should be initiated no sooner than 14 days from the starting day of the previous cycle provided the absolute neutrophil count is 0.75 x 10^9/L or greater.

Guideline

I. INITIAL APPROVAL CRITERIA

Clolar *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Acute lymphoblastic leukemia (ALL)**
   A. Patient is age 1 to 21 years old; **AND**
   B. Patient has relapsed or refractory acute lymphoblastic leukemia disease after two prior regimens.

Limitations/Exclusions

Clolar is not considered medically necessary for when any of the following selection criteria is met:

1. Disease progression while on Clolar.
2. Age greater than 21 years old
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Tumor response with disease stabilization or reduction of tumor size and spread.

Applicable Procedure Codes

Code	Description
J9027	Injection, clofarabine, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
00024-5860-01	Clolar single use vial; 20 mg intravenous solution

ICD-10 Diagnoses

Code	Description
C91.00-C91.02	Acute lymphoid leukemia

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/13/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	03/22/2024	Annual Review: Removed redundant statement in renewal criteria
EmblemHealth & ConnectiCare	7/20/2023	Annual Review: No criteria changes

EmblemHealth & ConnectiCare	4/07/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/15/2019	Annual review

References

1. Product Information: Clolar® intravenous injection, clofarabine intravenous injection. Genzyme Corporation (per FDA), Cambridge, MA, 2013.