

Medical Policy:

Clolar® (clofarabine) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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.