Medical Policy:

Dacogen® (decitabine) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.140	March 20, 2024	

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

Dacogen undergoes phosphorylation and inhibits DNA methyltransferase. Dacogen causes hypomethylation of DNA and cellular differentiation or apoptosis. Cytotoxicity in rapidly dividing cells is also contributable to covalent adducts between decitabine and DNA methyltransferase incorporated into DNA. Non-proliferating cells are relatively insensitive to decitabine.

Length of Authorization

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

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

20 mg/m^2 per dose

Max Units (per dose and over time) [HCPCS unit]:

MDS 450 billable units (450 mg) per 42 days

Guideline

I. Initial Approval Criteria

Dacogen *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. **Myelodysplastic Syndrome (MDS)**
    A. Dacogen is being used in a member with a diagnosis of myelodysplastic syndrome (MDS) including previously treated and untreated, de novo and secondary MDS of all subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate -1, intermediate -2 and high risk International Prognostic Scoring System groups.

Limitations/Exclusions

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

1. Patients less than 18 years old.

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; **AND**
3. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: serious myelosuppression (e.g., anemia, neutropenia, and thrombocytopenia), etc*.

Dosage/Administration

Indication	Dose
Myelodysplastic Syndrome (MDS)	(3-Day regimen) 15mg/m^2 administered by continuous intravenous infusion over 3 hours repeated every 8 hours for 3 days. Repeat cycle every 6 weeks. (5-Day regimen) 20 mg/m^2/day administered IV over 1 hour for 5 days repeated every 4 weeks upon hematologic recovery (ANC of 1000/mcL or greater and platelets of 50,000/mcL or greater) for a minimum of 4 cycles

Applicable Procedure Codes

Code	Description
J0894	Injection, decitibine, 1 mg, 1 billable unit = 1 mg
J0893	Injection, decitabine, 1 mg - (sun pharma) not therapeutically equivalent to j0894

Applicable NDCs

Code	Description
59148-0046-70	Dacogen single use vial; 50 mg powder for solution

ICD-10 Diagnoses

Code	Description
D46.0-D46.9	Myelodysplastic syndrome (MDS)

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/20/2024	Annual Review: Updated dosing limits, removed redundant statement from renewal criteria and added: "Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious myelosuppression (e.g., anemia, neutropenia, and thrombocytopenia), etc."
EmblemHealth & ConnectiCare	7/17/2023	Annual Review: Updated dosing chart. Myelodysplastic Syndrome (MDS) Initial Criteria: Removed "Physician provided documentation of failure on, intolerance to or contraindication to Vidaza."
EmblemHealth & ConnectiCare	5/30/2023	Added JCODE J0893- Injection, decitabine, 1 mg - (sun pharma) not therapeutically equivalent to j0894
EmblemHealth & ConnectiCare	4/20/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/15/2019	Annual Review

References

1. Dacogen™ [package insert]. Bloomington, MN: MGI Pharma, Inc.; October 2010.
2. National Comprehensive Cancer Network (NCCN). Myelodysplastic Syndromes (MDS). NCCN Clinical Practice Guidelines in Oncology. Version.2.2019. Fort Washington, PA: NCCN; 2019.