Dacogen® (decitabine)

Medical Guideline Disclaimer

All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. 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. 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 Services Company LLC, (“EmblemHealth”) has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

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

Max Units (per dose and over time) [Medical Benefit]:
- 20 mg/m² per dose

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; AND
   b. Physician provided documentation of failure on, intolerance to or contraindication to Vidaza.
Limitations/Exclusions

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

1. Patients less then 18 years old.

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Tumor response with disease stabilization or reduction of tumor size and spread.
- Same as initial approval criteria.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
</table>
| Myelodysplastic Syndrome (MDS) | (3-Day regimen) 15mg/m2 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/m2/day administered IV over 1 hour for 5 days repeated every 6 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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0894</td>
<td>Injection, decitibine, 1 mg, 1 billable unit = 1 mg</td>
</tr>
</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>59148-0046-70</td>
<td>Dacogen single use vial; 50 mg powder for solution</td>
</tr>
</tbody>
</table>

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D46.0-D46.9</td>
<td>Myelodysplastic syndrome (MDS)</td>
</tr>
</tbody>
</table>

References