

Drug Therapy Guidelines

Dacogen® (decitabine)

Applicable

Medical Benefit

x

Effective: 5/1/18

Pharmacy- Formulary 1

Next Review: 3/19

Pharmacy- Formulary 2

Date of Origin: 6/09

Pharmacy- Formulary 3/Exclusive

Review Dates: 6/17/09, 12/09, 12/10, 12/11, 12/12, 12/13, 12/14, 3/15, 3/16, 3/17, 12/17, 3/18

Pharmacy- Formulary 4/AON

I. Medication Description

Decitabine is believed to exert its antineoplastic effects after phosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation or apoptosis. Decitabine-induced hypomethylation in neoplastic cells may restore normal function to genes that are critical for the control of cellular differentiation and proliferation. In rapidly dividing cells, the cytotoxicity of decitabine may also be attributed to the formation of covalent adducts between DNA methyltransferase and decitabine incorporated into DNA. Non-proliferating cells are relatively insensitive to decitabine.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Dacogen is available when the following criteria have been met:

- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available:

- For total of 135 mg/m² per every 6 week cycle **OR**
- For total of 100 mg/m² per every 4 week cycle

Other dosages may be considered when supported by current NCCN guidelines.

V. Coverage Duration

Coverage is granted for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- J0894; 1 billable unit = 1 mg of decitabine
- Pertinent indications:
 - AML: C92.A0, C92.A1, C92.A2, C92.00, C92.01, C92.02, C92.50, C92.51, C92.52, C92.60, C92.61, C92.62, C93.00, C93.01, C93.02, C94.00, C94.01, C94.02, C94.20, C94.21, C94.22
 - MDS: C93.10, D46.A, D46.B, D46.C, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.Z, D46.9
 - Myeloproliferative Neoplasms - Primary Myelofibrosis and Post-PV or Post-ET MF: C94.40 – 94.42, C94.6, D47.1, D47.4, D75.81

VIII. Summary of Policy Changes

- 3/1/11: no changes
- 6/15/12: no changes
- 3/15/13: no changes
- 3/15/14: moved to own policy, quantity limits expanded, ICD10 codes added to policy for use starting 10/1/14.
- 3/15/15: clarification of MDS approval criteria
- 6/15/15: criteria for coverage in AML updated in accordance with current NCCN treatment guidelines
- 7/1/15: formulary distinctions made
- 10/1/15: ICD9 references omitted
- 6/15/16: no policy changes
- 4/5/17: updated policy in accordance with current NCCN treatment guidelines, ICD10 codes updated
- 1/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines; requests for all diagnostic codes will require prior authorization; addendum with diagnostic codes exceptions removed
- 5/1/18: no policy changes

IX. References

1. Product Information: Dacogen® (decitabine) Otsuka America Pharmaceutical, Inc. Revised 10/2014.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes, Version 1.2018. Available at http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf. Accessed 1/2018.
3. Gold Standard, Inc. Decitabine. Clinical Pharmacology. [database online]. Available at: <http://www.clinicalpharmacology.com>. Accessed 1/2018.
4. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium – decitabine. Accessed 1/2018.
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia, Version 3/2017. Available at http://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed 1/2018.
6. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms, Version 2.2018. Available at http://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed 1/2018.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies. .

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.