Drug Therapy Guidelines

<table>
<thead>
<tr>
<th>Drug Therapy Guidelines</th>
<th>Vidaza® (azacitidine)</th>
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<tbody>
<tr>
<td><strong>Medical Benefit</strong></td>
<td>x</td>
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<td><strong>Effective:</strong> 1/1/18</td>
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<tr>
<td><strong>Pharmacy- Formulary 1</strong></td>
<td>Next Review: 12/18</td>
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<tr>
<td><strong>Date of Origin:</strong> 6/17/09</td>
<td>Review Dates: 6/17/09, 12/09, 12/10, 12/11, 12/12, 12/13, 12/14, 12/15, 12/16, 12/17</td>
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<td><strong>Pharmacy- Formulary 2</strong></td>
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<td><strong>Pharmacy- Formulary 3/Exclusive</strong></td>
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<td><strong>Pharmacy- Formulary 4/AON</strong></td>
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I. Medication Description

Azacitidine is a pyrimidine nucleoside analog of cytidine. Azacitidine is believed to exert its antineoplastic effects by causing hypomethylation of DNA and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow. Hypomethylation may restore normal function to genes that are critical for differentiation and proliferation. The cytotoxic effects of azacitidine cause the death of rapidly dividing cells, including cancer cells that are no longer responsive to normal growth control mechanisms. Non-proliferating cells are relatively insensitive to azacitidine.

II. Position Statement

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

III. Policy

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

- Member is at least 18 years of age AND
- 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

- Up to 98 vials every 6 months are covered (to allow for up to 14 vials every 4 weeks).
- Additional quantities may be considered if BSA exceeds 2m²

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

- Available as: 100mg single-dose vial
- J9025; 1 billable unit = 1mg azacitidine
- Pertinent indications:
  - AML: C92.00, C92.01, C92.02, C92.50, C92.51, C92.52, C92.60, C92.61, C92.62, C92.A0, C92.A1, C92.A2, C93.00-C93.02, C94.00-C94.02, C94.20-C94.22
  - MDS: C92.10, C92.12, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.Z, D46.9, D46.4
  - Myeloproliferative Neoplasms: C94.40-C94.42, 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: addition of autopay code for AML for Vidaza only
- 3/15/14: moved to own policy, quantity limits expanded, ICD10 codes added to policy for use starting 10/1/14.
- 3/15/15: addition of AML diagnosis codes for which coverage may be reviewed; updated MDS coverage to coincide with current NCCN guidelines
- 7/1/15: formulary distinctions made
- 10/1/15: omission of ICD9 references
- 3/15/16: policy updated to correspond with current NCCN treatment guidelines
- 1/1/17: policy updated to correspond with current NCCN treatment guidelines
- 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

IX. References


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.