I. Length of Authorization

Coverage will be provided for a maximum of 2 cycles of induction (5 doses total) and 2 cycles of consolidation (4 doses total) within 6 months. Coverage may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Vyxeos single-dose vial: 23 vials total

B. Max Units (per dose and over time) [Medical Benefit]:
   - Induction: 132 billable units per dose (3 vials per dose; 5 doses total)
   - Consolidation: 88 billable units per dose (2 vials per dose; 4 doses total)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Therapy-related Acute Myeloid Leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)

- Patient is at least 18 years old; AND
- Baseline left ventricular ejection fraction (LVEF) within normal limits; AND
- Cumulative lifetime anthracycline (e.g., daunorubicin, etc.) dose does not exceed 550 mg/m² (or 400 mg/m² in patients who received radiation to the mediastinum); AND
- Patient has newly diagnosed disease; AND
- Will not be used in combination with other chemotherapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Authorizations may not be renewed.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
First Induction
- daunorubicin 44 mg/m² and cytarabine 100 mg/m² liposome intravenously days 1, 3 and 5

Second induction
- daunorubicin 44 mg/m² and cytarabine 100 mg/m² liposome intravenously days 1 and 3
  - Only for patients who fail to respond to the first induction cycle
  - May be administered 2 to 5 weeks after the first induction cycle if there was no unacceptable toxicity

Consolidation
- daunorubicin 29 mg/m² and cytarabine 65 mg/m² liposome intravenously days 1 and 3
  - Administer the first consolidation cycle 5 to 8 weeks after the start of the last induction cycle
  - Administer the second consolidation cycle 5 to 8 weeks after the start of the first consolidation cycle if there was not unacceptable toxicity of disease progression

VI. Billing Code/Availability Information

Jcode:
- J9999: Not otherwise classified antineoplastic drugs
- C9024 – Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine; 1 billable unit = 1mg/2.27 mg as daunorubicin/cytarabine, respectively (Effective 1/1/2018)

NDC:
Vyxeos (44 mg daunorubicin and 100 mg cytarabine) liposome, single-dose vial: 68727-0745-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C92.00</td>
<td>Acute myeloblastic leukemia not having achieved remission</td>
</tr>
<tr>
<td>C92.01</td>
<td>Acute myeloblastic leukemia in remission</td>
</tr>
</tbody>
</table>
ICD-10 | ICD-10 Description
---|---
C92.50 | Acute myelomonocytic leukemia not having achieved remission
C92.51 | Acute myelomonocytic leukemia in remission
C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61 | Acute myeloid leukemia with 11q23-abnormality in remission
C92.A0 | Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A1 | Acute myeloid leukemia with multilineage dysplasia in remission
C93.00 | Acute monoblastic/monocytic leukemia not having achieved remission
C93.01 | Acute monoblastic/monocytic leukemia in remission
C94.00 | Acute erythroid leukemia not having achieved remission
C94.01 | Acute erythroid leukemia in remission
C94.20 | Acute megakaryoblastic leukemia not having achieved remission
C94.21 | Acute megakaryoblastic leukemia in remission

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
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</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
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<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
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<tr>
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<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<td>First Coast Service Options, Inc.</td>
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<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
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<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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