OVERVIEW
Myelodysplastic syndromes (MDS) are a group of diseases in which the bone marrow does not function normally. The bone marrow begins to produce malformed or immature blood cells. MDS are classified into 5 subcategories: Refractory Anemia (RA), Refractory Anemia with Ringed Sideroblasts (RARS), Refractory Anemia with Excess Blasts (RAEB), Refractory Anemia with Excess Blasts in Transformation (RAEB-T), and Chronic Myelomonocytic Leukemia (CMMoL). Dacogen is an analogue of deoxycytidine, and Vidaza is a nucleoside analog of cytidine. Both drugs exert their effect by causing hypomethylation of DNA and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow. Hypomethylation may restore normal production of blood cells in the bone marrow.

Medications
Dacogen® (decitabine) and generics for intravenous [IV] injection
Vidaza® (azacitidine) and generics for subcutaneous [SC] or intravenous [IV] injection

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Dacogen and Vidaza. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist.

Prior Authorization Criteria:
Coverage of Dacogen, Vidaza and generic formulations are recommended in those who meeting the following criteria:

1. **Refractory anemia (RA)**. Approve if accompanied by neutropenia, thrombocytopenia or requiring transfusions

2. **Refractory anemia with ringed sideroblasts (RARS)**. Approve if accompanied by neutropenia, thrombocytopenia or requiring transfusions

3. **Refractory anemia with excess blasts (RAEB)**. Approve.

4. **Refractory anemia in transformation (RAEB-T)**. Approve.

5. **Chronic myelomonocytic leukemia (CMMoL)**. Approve.

6. **Acute Myeloid Leukemia (AML)**. Approve.

7. **Myelodysplastic Syndromes (MDS)**. Approve.

8. **Primary Myelofibrosis and Post-PV or Post-ET MF**. Approve.
9. Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber will provide specific diagnosis for documentation. Approve.

10. Patient has been started on Dacogen, Vidaza or generic formulations. Approve for an indication or condition addressed as an approval in this document.

Approval Duration
Approval = 365 days (1 year)

References