ConnectiCare

New Century Health

**Policy #UM ONC_1137**
**PROPRIETARY & CONFIDENTIAL**

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| **POLICY NUMBER**<br>UM ONC_1137 | **SUBJECT**<br>Hypomethylating Agents – Vidaza™, Dacogen™ (azacitidine, decitabine) | | **DEPT/PROGRAM**<br>UM Dept | **PAGE 1 OF 2** |
| **DATES COMMITTEE REVIEWED**<br>07/22/11, 03/13/13, 07/24/14, 04/11/16, 06/01/16, 07/10/19, 12/11/19, 04/08/20 | **APPROVAL DATE**<br>April 8, 2020 | **EFFECTIVE DATE**<br>April 24, 2020 | **COMMITTEE APPROVAL DATES** (latest version listed last)<br>07/22/11, 03/13/13, 07/24/14, 04/11/16, 06/01/16, 07/10/19, 12/11/19, 04/08/20 | |
| **PRIMARY BUSINESS OWNER:** UM<br>**APPROVED BY:** Dr. Andrew Hertler | | **COMMITTEE/BOARD APPROVAL**<br>Utilization Management Committee | | |
| **URAC STANDARDS**<br>HUM 1 | | **NCQA STANDARDS**<br>UM 2 | **ADDITIONAL AREAS OF IMPACT** | |
| **CMS REQUIREMENTS** | **STATE/FEDERAL REQUIREMENTS** | | **APPLICABLE LINES OF BUSINESS**<br>All | |

## I. PURPOSE

To define and describe the accepted indications for Vidaza (azacitidine) or Dacogen (decitabine) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs ( Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs ( Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow** NCH **L1 Pathways** when applicable, otherwise shall follow NCH drug policies: Error! Hyperlink reference not valid. **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Myelodysplastic Syndrome (MDS)**
    a. **NOTE: The preferred hypomethylating agent, per NCH Policy & NCH Pathway is Azacitidine for the treatment of MDS.**
    b. Vidaza (azacitidine) or Dacogen (decitabine) may be used in all subtypes of MDS-Myelodysplastic Syndromes.

2. **Acute Myeloid leukemia (AML)**
    a. **NOTE: The preferred hypomethylating agent, per NCH Policies & NCH Pathway, for the treatment of AML is AZACITIDINE containing regimen.**
    b. Vidaza (azacitidine) or Dacogen (decitabine) is being use for AML as **ONE** of the following:
        i. As a single agent or in combination with venetoclax as induction, post remission consolidation, or salvage therapy
        **NOTE: Azacitidine + Venetoclax regimen is NCH preferred pathway for menbers who are not suitable for intensive therapy.**
        **OR**
        ii. For FLT3-ITD mutation positive AML, Vidaza (azacitidine) or Dacogen (decitabine) is being used as a single agent or in combination with sorafenib for relapsed or refractory disease.

## III. EXCLUSION CRITERIA

1. Member with relapse disease following initial response to Vidaza (azacitidine) or Dacogen (decitabine).
2. Dosing exceeds single dose limit of Vidaza (azacitidine) of 100 mg/$m^2$.
3. Dosing exceeds single dose limit of Dacogen (decitabine) 20 mg/$m^2$.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

## III. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

## IV. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

## V. ATTACHMENTS

1. Attachment A: IPSS scoring system

## VII. REFERENCES

1. Vidaza (azacitidine) prescribing information. Celgene Corporation. Summit, NJ. 2020.
2. Dacogen (decitabine) prescribing information. Otsuka America Pharmaceutical, Inc., Rockville, MD 2020.
3. Clinical Pharmacology Elsevier Gold Standard. 2020.
4. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.