

Idhifa® (enasidenib) (Oral)

Document Number: IC-0313

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Idhifa 50 mg tablets: 1 per day
- Idhifa 100 mg tablets: 1 per day

B. Max Units (per dose and over time) [Medical Benefit]:

- 100 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Acute Myeloid Leukemia (AML) †

- Patient has an isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved test (e.g., RealTime™ IDH2 Assay); **AND**
- Must be used as single agent therapy; **AND**
 - Patient has relapsed or refractory disease ‡; **OR**
 - Patient who is ≥ 60 years old and used in place of or is not a candidate for intensive therapy **OR** will undergo post-remission therapy following response to a previous lower intensity therapy ‡

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

IV. Renewal Criteria

Authorizations may be renewed based on the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of differentiation syndrome (e.g., fever, dyspnea, acute respiratory distress, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction), noninfectious leukocytosis, elevated bilirubin, tumor lysis syndrome, etc.; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration

| Indication | Dose |
|------------|---|
| AML | 100 mg orally once daily; may reduce to 50 mg daily in order to manage toxicity |

VI. Billing Code/Availability Information

Jcode:

- J8999: Prescription drug, oral, chemotherapeutic, nos
- C9399 Unclassified drugs or biologicals, (Hospital Outpatient Use ONLY)

NDC:

- Idhifa 50 mg tablets: 59572-0705-xx
- Idhifa 100 mg tablets: 59572-0710-xx

VII. References

1. Idhifa [package insert]. Summit, NJ; Celgene Corporation, August 2017. Accessed June 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Acute Myeloid Leukemia. Version 1.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2018.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for enasidenib. 2018 National Comprehensive Cancer Network. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2018.
4. Stein EM, DiNardo CD, Pollyea DA, et al. Enasidenib in mutant-IDH2 relapsed or refractory acute myeloid leukemia. *Blood*. 2017 Jun 6. pii: blood-2017-04-779405.
5. Amatangelo MD, Quek L, Shih A, et al. Enasidenib induces acute myeloid leukemia cell differentiation to promote clinical response. *Blood*. 2017 Jun 6. pii: blood-2017-04-779447.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--|
| C92.00 | Acute myeloblastic leukemia not having achieved remission |
| C92.01 | Acute myeloblastic leukemia in remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia not having achieved remission |
| C92.51 | Acute myelomonocytic leukemia in remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.61 | Acute myeloid leukemia with 11q23-abnormality in remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia not having achieved remission |
| C92.A1 | Acute myeloid leukemia with multilineage dysplasia in remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C93.00 | Acute monoblastic/monocytic leukemia not having achieved remission |
| C93.01 | Acute monoblastic/monocytic leukemia in remission |
| C93.02 | Acute monoblastic/monocytic leukemia, in relapse |
| C94.00 | Acute erythroid leukemia not having achieved remission |
| C94.01 | Acute erythroid leukemia in remission |
| C94.02 | Acute erythroid leukemia, in relapse |
| C94.20 | Acute megakaryoblastic leukemia not having achieved remission |
| C94.21 | Acute megakaryoblastic leukemia in remission |
| C94.22 | Acute megakaryoblastic leukemia, in relapse |

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>. 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

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|--|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |