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CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Cresemba® - isavuconazonium sulfate	
MEDICAL POLICY NUMBER	MED_Clin_Ops_049
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Cresemba® (isavuconazonium sulfate) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Cresemba will be provided for 3 months.

1. Member has a diagnosis of invasive Apergillosis OR invasive Mucomycosis; **AND**
2. Member must be 18 years of age and older; **AND**
3. Fungal culture report shows causative organism(s) are sensitive to isavuconazonium only; **AND**
4. Cresemba is prescribed by a provider specializing in the patient's diagnosis or is in consultation with an Infectious Disease Specialist, Transplant Physician, or Oncologist.

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LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Coadministration of strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir (400 mg every 12 hours)
3. Coadministration of strong CYP3A4 inducers, such as rifampin, carbamazepine, St. John's wort, or long-acting barbiturates
4. Patients with familial short QT syndrome

BACKGROUND

Cresemba (isavuconazonium sulfate) is the prodrug of isavuconazole, an azole antifungal. Isavuconazole weakens the fungal cell membrane structure and function by inhibiting lanosterol 14-alpha-demethylase which prevents the conversion to ergosterol, part of the fungal cell membrane. Mammalian cells are less sensitive to isavuconazole inhibition of demethylation.

DEFINITIONS

1. CRESEMBA (isavuconazonium sulfate) for injection, for intravenous use. Initial U.S. Approval: 2015
    a. CRESEMBA (isavuconazonium sulfate) for injection is supplied in a single-dose vial as white to yellow sterile lyophilized powder containing 372 mg isavuconazonium sulfate (equivalent to 200 mg isavuconazole).

CODING

Applicable NDC Codes	
00469-0420-99	Cresemba (isavuconazonium sulfate) injection, powder, lyophilized, for solution

Applicable Procedure Code	
J1833	Injection, isavuconazonium sulfate, 1 mg

Applicable ICD-10 Codes	
B44.0	Invasive pulmonary aspergillosis
B44.1	Other pulmonary aspergillosis
B44.2	Tonsillar aspergillosis
B44.7	Disseminated aspergillosis
B44.89	Other forms of aspergillosis
B44.9	Aspergillosis, unspecified
B46.0	Pulmonary mucormycosis
B46.1	Rhinocerebral mucormycosis
B46.2	Gastrointestinal mucormycosis
B46.3	Cutaneous mucormycosis
B46.4	Disseminated mucormycosis
B46.5	Mucormycosis, unspecified
B46.8	Other zygomycoses
B46.9	Zygomycosis, unspecified

EVIDENCE BASED REFERENCES

1. Product Information: CRESEMBA(R) oral capsules, intravenous injection, isavuconazonium sulfate oral capsules, intravenous injection. Astellas Pharma US (per FDA), Northbrook, IL, 2019.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021 – no changes made. November 8, 2022 – Annual review – no changes made March 01, 2023 – Adopted by MA UMC – no changes made January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics 11/8/2022