Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 53.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Eraxis (anidulafungin)

I. Policy:
Eraxis (anidulafungin)

II. Purpose/Objective:
To provide a policy of coverage regarding Eraxis (anidulafungin)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Eraxis (anidulafungin) is an echinocandin antifungal agent that results in the inhibition of β-1,3-D-glucan synthase, an essential component of fungal cell walls.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Eraxis (anidulafungin) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when all of the following criteria are met:

- The insured individual is at least 1 month of age and non-neutropenic; **AND**
- There is physician provided documentation of a diagnosis of candidemia or other *Candida* infection as determined by an infectious disease specialist; **OR**
- There is physician provided documentation of a diagnosis of esophageal candidiasis with failure on, intolerance to, or contraindication to fluconazole therapy as determined by an infectious disease specialist.

AUTHORIZATION DURATION: Prior Authorization will be limited to a period of 6 weeks (one course of therapy). Re-authorization for an extended treatment period (beyond the initial 6 weeks) will require documentation of a continued positive culture or documentation of a positive culture within the previous 14 days of the request. Duration of treatment should be based on the patient's clinical response. Therapy should continue for at least 14 days after the last positive culture. Requests for re-authorization will be limited to a duration of 2 weeks for each re-authorization request.

LIMITATIONS:
Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate causative organism(s). Therapy may be instituted before the results of cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.

Eraxis (anidulafungin) will be considered medically necessary for the Medicare lines of business when all of the following criteria are met:

- The insured individual is at least 1 month of age and non-neutropenic; **AND**
- There is physician provided documentation of a diagnosis of candidemia or other *Candida* infection as determined by an infectious disease specialist; **OR**
- There is physician provided documentation of a diagnosis of esophageal candidiasis as determined by an infectious disease specialist.

AUTHORIZATION DURATION: Prior Authorization will be limited to a period of 6 weeks (one course of therapy). Re-authorization for an extended treatment period (beyond the initial 6 weeks) will require documentation of a continued positive culture or documentation of a positive culture within the previous 14 days of the request. Duration of treatment should be based on the patient's clinical response. Therapy should continue for at least 14 days after the last positive culture. Requests for re-authorization will be limited to a duration of 2 weeks for each re-authorization request.

LIMITATIONS:
Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate causative organism(s). Therapy may be instituted before the results of cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 4/27/07

Revised: 2/12 (PA timeframe), 1/20/15 (formatting changes), 9/12/18 (duration per DHS), 7/9/19 (per DHS), 3/16/21 (age), 1/27/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment)

Reviewed: 7/08; 11/09, 12/10, 2/14, 1/20/2015, 11/2/2015, 9/20/16, 7/31/17, 7/10/18, 5/31/19, 2/1/20, 1/28/21, 2/7/22