Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 121.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Dalvance (dalbavancin)

I. Policy:
Dalvance (dalbavancin)

II. Purpose/Objective:
To provide a policy of coverage regarding Dalvance (dalbavancin)

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:
Dalvance (dalbavancin), a semisynthetic lipoglycopeptide, interferes with cell wall synthesis by binding to the D-alanyl-D-alanine terminus of the stem pentapeptide in nascent cell wall peptidoglycan, thus preventing cross-linking.

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

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

1. Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutanenous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis (vancomycin susceptible strains) which has been diagnosed and documented with Infectious Disease consultation **AND**
2. Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
3. If Dalvance was initiated during an inpatient stay, medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **AND**
4. Medical record documentation of a prescribed dose of Dalvance (dalbavancin) that is consistent with the Food and Drug Administration (FDA) approved package labeling OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling.

AUTHORIZATION DURATION/QUANTITY LIMIT:
For SINGLE dose regimen: Approval will be for **one (1) week** and will be limited to **one (1) treatment course** (up to 1,500 mg as a single dose) (Facets RX count 300, Darwin RX count 1).

For TWO-dose regimen: Approval will be for **two (2) weeks** and will be limited to **two (2) treatment courses** (up to 1,500 mg divided among two doses) (Facets RX count 300, Darwin RX count 2).

Dalvance (dalbavancin) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutanenous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis (vancomycin susceptible strains) which has been diagnosed and documented with Infectious Disease consultation **AND**
2. Medical record documentation of a prescribed dose of Dalvance (dalbavancin) that is consistent with the Food and Drug Administration (FDA) approved package labeling OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling.

AUTHORIZATION DURATION/QUANTITY LIMIT:
For SINGLE dose regimen: Approval will be for **one (1) week** and will be limited to **one (1) treatment course** (up to 1,500 mg as a single dose) (Facets RX count 300).

For TWO-dose regimen: Approval will be for **two (2) weeks** and will be limited to **two (2) treatment courses** (up to 1,500 mg divided among two doses) (Facets RX count 300).

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: 11/18/14

Revised: 11/2/15, 11/28/16 (updated criteria), 10/27/21, 10/25/22 (Medicaid PARP statement), 10/10/23 (LOB carve out, Medicaid business segment)

Reviewed: 10/26/16, 9/29/17, 8/30/18, 8/29/19, 8/26/20, 8/20/21