Medical Policy

Dalvance (dalbavancin)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-114
ORIGINAL EFFECTIVE DATE	5/24/2022
CURRENT VERSION NUMBER	2
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Dalvance (dalbavancin) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Dalvance will be provided for 1 month and may be renewed.

- Max Units (per dose and over time): 1500 mg, administered either as a single dose, -OR- 1000 mg followed one week later by 500 mg

Initial

A. Patient has a documented diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (including S. anginosus, S. intermedius, S. constellatus) and Enterococcus faecalis (vancomycin susceptible isolates); **AND**
B. Documentation of a recent culture and sensitivity showing the patient's infection is susceptible to Dalvance; **AND**
C. Documentation of inadequate treatment response, intolerance, or non-susceptibility report for the current infection to alternative antibiotic treatments including, but not limited to vancomycin; **OR**
D. Request is for a continuation of therapy that was started at an in-patient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER, DURATION OF THERAPY; START AND END DATE].

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; AND
B. Absence of unacceptable toxicity from the drug.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. DALVANCE (dalbavancin) for injection, for intravenous use. Initial U.S. Approval: 2014

CODING

Applicable NDC Codes	
57970-0100-01	Dalvance 500 mg/vial

Applicable Procedure Code	
J0875	Injection, dalbavancin, 5 mg

Applicable ICD-10 Codes	
L03.011-L03.019	Cellulitis of finger
L03.031-L03.039	Cellulitis of toe
L03.111-L03.119	Cellulitis of other parts of limb
L03.211	Cellulitis of face
L03.221	Cellulitis of neck
L03.311-L03.319	Cellulitis of trunk
L03.811-L03.818	Cellulitis of other sites
L03.90	Cellulitis, unspecified
A49.02	Methicillin-resistant Staphylococcus aureus infection, unspecified site
B95.62	Methicillin-resistant Staphylococcus aureus infection as the cause of diseases classified elsewhere
A41.01-A41.2	Sepsis due to Staphylococcus
A49.01	Methicillin-susceptible Staphylococcus aureus infection, unspecified site
A49.02	Methicillin-resistant Staphylococcus aureus infection, unspecified site
B95.61-B95.8	Staphylococcus aureus as the cause of diseases classified elsewhere
A40.0-A40.9	Streptococcal sepsis
A49.1	Streptococcal infection, unspecified site
B95.01-B95.1, B95.3-B95.8	Streptococcus

EVIDENCE BASED REFERENCES

1. Product Information: DALVANCE(R) intravenous injection, dalbavancin intravenous injection. Allergan USA Inc (per FDA), Madison, NJ, 2021.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	
P&T Committee Endorsement	5/24/2022
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024

Approved by Pharmacy and Therapeutics Committee