Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

DALVANCE® (*dalbavancin*) PA CRITERIA:

DALVANCE® (*dalbavancin*) is a lipoglycopeptide antibacterial indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms.

Prior authorization is required for DALVANCE® (*dalbavancin*). Prior authorization approval will be considered when the following criteria are met.

When submitting a PA request, please include any supporting clinical documentation along with relevant culture and sensitivity reports.

Initial Authorization: 1 month

1. Diagnosis of acute bacterial skin and skin structure infection (ABSSSI) due to a gram-positive organism outlined in the FDA-labeling; **AND**

2. Patient has one of the following:
    a) Documented contraindication or intolerance to ceftaroline, daptomycin, linezolid, and vancomycin
    b) Inadequate treatment response to one of the following treatments for the current active infection: ceftaroline, daptomycin, linezolid, or vancomycin
    c) Culture and sensitivity report indicating ceftaroline, daptomycin, linezolid, and vancomycin resistance; **OR**

3. Prescriber provides detailed rationale against prolonged outpatient parenteral antibiotic therapy **AND** patient has documented age limitation, contraindication, intolerance, or inadequate response to Orbactiv® (oritavancin); **OR**

4. Request is for a continuation of therapy that was started at an inpatient setting (within the last 14 days) and the member is transitioning to an outpatient site of care at the time of PA request

DALVANCE® Dosing:

Dosage in Adult Patients		
Estimated Creatinine Clearance	**Single Dose Regimen**	**Two-Dose Regimen**
30 mL/min and above or on regular hemodialysis	1,500 mg	1,000 mg followed one week later by 500 mg
Less than 30 mL/min and not on regular hemodialysis	1,125 mg	750 mg followed one week later by 375 mg

Dosage in Pediatric Patients with Creatinine Clearance 30 mL/min/1.73 m^2 and above	
Age Range	**Dosage (Single Dose Regimen)**
Birth to less than 6 years	22.5 mg/kg (maximum of 1,500 mg)
6 to less than 18 years	18 mg/kg (maximum of 1,500 mg)

Formulation:

- Available as 500 mg of lyophilized powder in a vial for reconstitution