Dalvance (dalbavancin)
Policy Number: C9351-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
7/1/2016	11/18/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J0875-injection, dalbavancin, 5mg C9443-injection, dalbavancin, 10mg	RxPA	Q1 2021 20210127C9351-A

PRODUCTS AFFECTED:
Dalvance (dalbavancin)

DRUG CLASS:
Anti-Infective Agents - Misc.

ROUTE OF ADMINISTRATION:
Intravenous Infusion

PLACE OF SERVICE:
Buy and Bill

AVAILABLE DOSAGE FORMS:
Dalvance Sol 500MG

FDA-APPROVED USES:
indicated for acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms

COMPENDIAL APPROVED OFF-LABELED USES:
osteomyelitis in adults

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Acute bacterial skin and skin structure infections (ABSSSI)

REQUIRED MEDICAL INFORMATION:
A. ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI):
1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported
AND
2. (a) Documentation of FDA labeled contraindication to Vancomycin
OR

(b) Documentation of inadequate treatment response, intolerance, or non-susceptibility report for the current infection to Vancomycin
OR
(c) Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with 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]

B. OSTEOMYELITIS:
1. Documented diagnosis of osteomyelitis or suspected gram-positive source of infection AND
2. Documentation of inadequate treatment response, intolerance, non-susceptibility report, for current infection, FDA labeled contraindication to the following [(MSSA-nafcillin, cefazolin, oxacillin), (MRSA- vancomycin, daptomycin)] OR prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with vancomycin

DURATION OF APPROVAL:
Initial authorization: 1 month, Continuation of therapy: NA; Members must meet the initial approval criteria.

QUANTITY:
1500 mg, administered either as a single dose, -OR- 1000 mg followed one week later by 500 mg

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
NA, each new occurrence requires a new authorization

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of dalbavancin are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Dalvance (dalbavancin) include a hypersensitivity to dalbavancin.

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:
None

APPENDIX:
None

Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:

1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary, or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at a non-hospital facility-based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

Note: a hospital outpatient setting or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Dalvance® [package insert]. Chicago, IL: Durata Therapeutics Inc; July2018
2. Boucher HW, Wilcox M, Talbot GH et al. Once-weekly dalbavancin versus daily conventional therapy for skin infection. N Engl J Med. 2014 Jun 5; 370(23): 2169-79
3. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clin Infect Dis. 2014;59 (2): 147-159
4. Liu C, Bayer A, Cosgrove S, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant Staphylococcus Aureus Infections in Adults and Children. CID. 2011; 52: 1 – 38
5. Rappo U, Puttagunta S, Shevchenko V, Shevchenko A, Jandourek A, Gonzalez PL, Suen A, Mas Casullo V, Melnick D, Miceli R, Kovacevic M, De Bock G, Dunne MW. Dalbavancin for the Treatment of Osteomyelitis in Adult Patients: A Randomized Clinical Trial of Efficacy and Safety. Open Forum Infect Dis. 2018 Dec 10;6(1):ofy331. doi: 10.1093/ofid/ofy331. PMID: 30648126; PMCID: PMC6326511.