



Effective Date: 07/01/2016
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C9351-A

Dalvance (dalbavancin)

PRODUCTS AFFECTED

Dalvance (dalbavancin)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

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

DIAGNOSIS:

Acute bacterial skin and skin structure infections (ABSSSI)

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

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

Drug and Biologic Coverage Criteria

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. a. documentation of inadequate treatment response, intolerance, non-susceptibility report, for current infection, FDA labeled contraindication to ALL of the following: i. [(MSSA-nafcillin, cefazolin, oxacillin), OR ii. (MRSA- vancomycin, daptomycin)]
OR
b. prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with-i. [(MSSA-nafcillin, cefazolin, oxacillin), OR ii. (MRSA- vancomycin, daptomycin)]

CONTINUATION OF THERAPY:

NA, each new occurrence requires a new authorization

DURATION OF APPROVAL:

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

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

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

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous Infusion

DRUG CLASS:

Anti-Infective Agents - Misc.

FDA-APPROVED USES:

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

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COMPENDIAL APPROVED OFF-LABELED USES:

osteomyelitis in adults

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

| HCPCS CODE | DESCRIPTION |
|------------|-----------------------------|
| J0875 | Injection, dalbavancin, 5mg |

AVAILABLE DOSAGE FORMS:

Dalvance Sol 500MG

REFERENCES

1. Dalvance (dalbavancin) [prescribing information]. Madison, NJ: Allergan USA; July 2021
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.