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Current Effective Date: 01/31/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
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), Osteomyelitis

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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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
AND
2. (a) Documentation of FDA labeled contraindication to Vancomycin

OR

(b) Documentation of inadequate treatment response, serious side effects, 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 continuation of therapy that was started at an inpatient 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 CONSULT, DURATION OF THERAPY, START AND END DATE]

B. OSTEOMYELITIS:

1. Documented diagnosis of osteomyelitis with suspected gram-positive source of infection AND
2. (a) Documentation of inadequate treatment response, serious side effects, non-susceptibility report for current infection, or FDA labeled contraindication to ALL of the following: i. For MSSA - nafcillin, cefazolin, oxacillin, OR ii. For MRSA - vancomycin, daptomycin

   OR

   (b) Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with i. For MSSA - nafcillin, cefazolin, oxacillin, OR ii. For MRSA - vancomycin, daptomycin

CONTINUATION OF THERAPY:

N/A, each new occurrence requires a new authorization

DURATION OF APPROVAL:

Initial authorization: 1 month, Continuation of therapy: N/A; 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 with initial request]

AGE RESTRICTIONS:

ABSSSI: No restriction
Osteomyelitis: 18 years of age and older

QUANTITY:

ABSSSI:
Adults: 1500 mg, administered either as a single dose, OR 1000 mg followed one week later by 500 mg
Pediatrics:
<6 years of age: 22.5 mg/kg (maximum 1500 mg) single dose regimen
6 years of age to less than 18 years of age: 18 mg/kg (maximum 1500 mg) single dose regimen

Osteomyelitis: 1500 mg x 2 doses, 1 week apart

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:
Glycopeptide

FDA-APPROVED USES:
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.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dalvance and other antibacterial drugs, Dalvance should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

COMPENDIAL APPROVED OFF-LABELED USES:
Osteomyelitis in adults

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

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

OTHER SPECIAL CONSIDERATIONS:
Clostridioides difficile-associated diarrhea (CDAD) has been reported in users of nearly all systemic antibacterial drugs, including DALVANCE, with severity ranging from mild diarrhea to fatal colitis. Treatment with antibacterial agents can alter the normal flora of the colon, and may permit overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antibacterial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

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, 5 mg

AVAILABLE DOSAGE FORMS:
Dalvance SOLR 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.
6. Bury, D., Rogers, T., & Dickman, M. (2021). Osteomyelitis: Diagnosis and Treatment. American Family Physician, 104(4), 395–402. Retrieved from https://www.aafp.org/pubs/afp/issues/2021/1000/p395.pdf

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Age Restrictions Quantity Drug Class Other Special Considerations References	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Age Restrictions Quantity FDA-Approved Uses	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file