



Original Effective Date: 07/01/2016  
 Current Effective Date: 03/08/2025  
 Last P&T Approval/Version: 01/29/2025  
 Next Review Due By: 01/2026  
 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

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## Drug and Biologic Coverage Criteria

- 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 infection treatment should be a new review

### DURATION OF APPROVAL:

Initial authorization: 1 month, Continuation of therapy: N/A

### 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

## Drug and Biologic Coverage Criteria

### **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.

Dalvance is indicated for the treatment of adult and pediatric patients with 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).

### **COMPENDIAL APPROVED OFF-LABELED USES:**

Osteomyelitis in adults

## APPENDIX

### **APPENDIX:**

None

## BACKGROUND AND OTHER CONSIDERATIONS

### **BACKGROUND:**

Dalvance (dalbavancin) is a IV administered lipoglycopeptide antibiotic approved to treat acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus* (both methicillin-resistant [MRSA] and methicillin-susceptible strains) and *Streptococcus* species.

Dalbavancin inhibits bacterial cell wall synthesis by binding to the *D-alanyl-D-alanine* terminus of peptidoglycan precursors, preventing cross-linking and elongation of the peptidoglycan chains. This disrupts the structural integrity of the bacterial cell wall, leading to cell death. Dalbavancin has an extended half-life that allows for a single or two dose regimen, spaced one week apart.

In 2022, the American Heart Association published guidelines for management of infective endocarditis in people who inject drugs. Recommendation for patients that are stable, but do not agree to complete 6 weeks of IV treatment in hospital or at a skilled nursing facility is to complete the course with oral antibiotics or long-acting lipoglycopeptides. There is evidence that step down from IV to oral antibiotic therapy is superior to incomplete IV antibiotic treatment. Oral antibiotic regimen options for MSSA include dicloxacillin plus rifampin, and ciprofloxacin plus rifampin. Oral antibiotic regimen options for MRSA include linezolid plus rifampin, trimethoprim/sulfamethoxazole, and doxycycline. Considerations for intermittent IV treatment should be made in patients where oral absorption of medication is limited or there are contraindications to oral antibiotics. When considering dalbavancin as an alternate option, one must also consider if IV access can be obtained in the outpatient setting for ongoing infusions.

### **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.

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**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**

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J0875	Injection, dalbavancin, 5 mg

**AVAILABLE DOSAGE FORMS:**  
Dalvance SOLR 500MG

**REFERENCES**

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Drug and Biologic Coverage Criteria

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7. Baddour, L. M., Weimer, M. B., Wurcel, A. G., McElhinney, D. B., Marks, L. R., Fanucchi, L. C., ... DeSimone, D. C. (2022). Management of Infective Endocarditis in People Who Inject Drugs: A Scientific Statement From the American Heart Association. *Circulation*, 146(14). <https://doi.org/10.1161/cir.0000000000001090>

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy FDA-Approved Uses Background	Q1 2025
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