

J0875, the permanent J-code for DALVANCE
effective January 1, 2016

DALVANCE[®]
(dalbavancin) for injection

CODING & BILLING REFERENCE GUIDE

**For more information: Call the DALVANCE CONNECTSSM program
toll-free 1.855.387.2824**



Program Coordinators are available 8:00 AM to 8:00 PM ET,
Monday through Friday, excluding holidays.

**What is the relevant billing and claims information for DALVANCE
in my setting of care?**

INDICATION AND USAGE

DALVANCE[®] (dalbavancin) for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (including *S. anginosus*, *S. intermedius*, *S. constellatus*) and *Enterococcus faecalis* (vancomycin-susceptible strains).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DALVANCE and other antibacterial agents, DALVANCE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Contraindications

DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

Please see additional Important Safety Information on page 12.

Please also see enclosed full Prescribing Information.



INTRODUCTION

The DALVANCE[®] (dalbavancin) for injection CODING AND BILLING REFERENCE GUIDE has been developed to help healthcare providers and billing staff understand third-party reimbursement for DALVANCE (dalbavancin). Specifically, this guide presents general information on coverage, coding, payment and claims submission for DALVANCE to third-party payors. As such, the information contained in this guide is intended to provide a general understanding of the reimbursement process and is not intended to assist healthcare providers in obtaining reimbursement for any specific claim. Additional information about coding, billing, and coverage of DALVANCE can be obtained through DALVANCE CONNECTSSM, a single source of services designed to simplify access to therapy with DALVANCE, at: **1.855.387.2824**, Monday through Friday excluding holidays, 8 AM to 8 PM ET, or visit the website: **www.DALVANCE.com** for additional support, including prescribing information.

COVERAGE for DALVANCE

Third-party payors (eg, commercial insurers, Medicare, Medicaid, etc.) cover DALVANCE (dalbavancin) for its approved U.S. Food and Drug Administration indications (see Indication on front cover of this guide). Coverage and benefits, however, may vary depending upon a patient's insurer or specific insurance plan or "product" (ie, HMO, PPO, Indemnity, other) offered by a payor.

When reviewing claims for DALVANCE, third-party payors will first determine if the reported service is covered under their coverage policies or contract. Most payors cover drug infusions as part of their core medical benefits according to indications. In some cases, payors will look for evidence supporting the medical necessity of therapy. This evidence may sometimes include:

- Prescribing information
- A physician's statement or letter of medical necessity
- Information about the patient's medical condition and history

There are other general administrative policies that may also affect coverage of therapy with DALVANCE. For example, payors may consider the following:

A Prior Authorization may be required by the patient's insurance plan

Many commercial plans and Medicaid require that non-emergency services be preapproved through a Prior Authorization process prior to the administration of DALVANCE. Failure to obtain appropriate Prior Authorization can result in nonpayment by the plan. Medicare does not require a Prior Authorization for services, regardless of setting.

The patient's health plan may restrict coverage of the therapy when provided in certain settings

Payors may have site-specific coverage rules that restrict provision of infused antibiotics. For example, Medicare may restrict coverage for infused therapies in the home setting under Medicare Part B.

Payors contract with providers to deliver services to the plan's members

Contracted healthcare providers are thus "participating" or within that plan's network ("in-network"), requiring the billing healthcare provider to abide by the contract charge structure when providing care for that plan's members.

CODING for DALVANCE

It is important to accurately and fully complete claim forms for the therapy, whether the claim is submitted by physician offices or infusion centers using the CMS-1500 claim form or by hospital outpatient departments using the UB-04 claim form. This section identifies procedure and supply codes that are likely to be most relevant to healthcare provider claims for therapy with DALVANCE. Please note that healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition and the items and services that are furnished. Contact your local payor with regard to local payment and policies. The Table on the following page summarizes the relevant codes for DALVANCE claims.

Code Set	Setting of Care	Code and Description
HCPCS codes used to report DALVANCE	<ul style="list-style-type: none"> • Physician office • Free-standing infusion center • Hospital outpatient department • Hospital outpatient provider-based clinic • Hospital inpatient 	<p>Medicare, most commercial insurers, and most Medicaid agencies require healthcare providers to use Healthcare Common Procedure Coding System (HCPCS) codes (known as "J-Codes") to identify infused drugs on claims forms. HCPCS codes have a 5-character alphanumeric format.</p> <p>A new and permanent J-code has been issued for DALVANCE (dalbavancin) for injection effective January 1, 2016:</p> <p>J0875 Injection, dalbavancin, 5 mg</p> <p>The J0875 permanent J-code replaces Miscellaneous J-codes (J3490 or J3590) and C-9443 that have been used to bill for DALVANCE prior to 2016.</p>

DALVANCE Billing Units

When coding and billing for DALVANCE (dalbavancin) and drug administration services, providers may also need to accurately calculate billing units for the dosage amount used.

The HCPCS code for DALVANCE (dalbavancin) is **J0875**, described as: "Injection, dalbavancin, 5 mg." Thus, each 5 mg dose of dalbavancin equals one billing unit. It is important to understand that when billing for DALVANCE, each 500 mg vial of drug represents 100 units of J0875.

Number of 500 mg vials of DALVANCE	Number of mg	Number of billing units based on J0875 (5 mg dalbavancin per unit)
1	500	100
2	1000	200

Code Set	Setting of Care	Code and Description
NDCs used to report DALVANCE	<ul style="list-style-type: none"> • Varies 	<p>Some commercial payors and the majority of Medicaid fee-for-service programs require a National Drug Code (NDC) for billing in addition to, or instead of, an HCPCS code, for physicians and other service providers as well.</p> <p>Although the FDA uses a 10-digit format when registering NDCs, payors usually recognize and often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payor which NDC format they require. Guidelines for reporting the NDC in the appropriate format, quantity, and unit of measure vary by state and by payor, and should be reviewed prior to submitting the claim.</p> <p>The 10-digit NDC and 11-digit alternative NDC formats for DALVANCE 500 mg dalbavancin, single-use vial are:</p> <ul style="list-style-type: none"> • 10-digit NDC format: 57970-100-01 • 11-digit NDC format: 57970-0100-01

Please see Important Safety Information on page 12.

Please also see enclosed full Prescribing Information.

Code Set	Setting of Care	Description and Code
CPT codes used to report IV infusion	<ul style="list-style-type: none"> Physician office Free-standing infusion center Hospital outpatient department Hospital outpatient provider-based clinic Hospital inpatient 	<p>Services in physician offices, infusion centers, and hospital departments are reported on claims forms using the Current Procedural Terminology (CPT), 4th Edition, coding system. The CPT code most commonly associated with the administration of DALVANCE[®] is:</p> <p>96365 Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour</p> <p>NOTE: The medical record documented start and stop time of IV infusion must be >15 minutes.</p>
Code Set	Setting of Care	Description and Code
Revenue Codes	<ul style="list-style-type: none"> Varies 	<p>Many payors require use of American Hospital Association (AHA) revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by three other digits and are used on claim forms to assign costs to broad categories of hospital revenue centers.</p> <p>The revenue codes that are commonly used with DALVANCE (dalbavancin) are:</p> <ul style="list-style-type: none"> 0250 Pharmacy, drugs not requiring detailed coding (used for claims to many non-Medicare payors) 0510 Clinic 0636 Pharmacy, drugs requiring detailed coding with HCPCS code (suggested for Medicare and sometimes required for other payors to obtain pass-through payment for drugs) <p>When AHA revenue code 0636 is used to identify DALVANCE, hospital outpatient departments should also record HCPCS code J0875.</p> <p>It is important to review your major payor contracts and their billing manuals to determine the appropriate revenue codes to link to the HCPCS and CPT codes that represent the outpatient hospital services, procedures, and products.</p>
Code Set	Setting of Care	Description and Code
ICD-10-CM Codes	<ul style="list-style-type: none"> All healthcare settings 	<p>International Classification of Diseases, 10th edition, Clinical Modification (ICD-10-CM) is a detailed and specific diagnosis coding system developed by the Centers for Disease Control and Prevention (CDC) for use in all U.S. healthcare treatment settings. More detailed than ICD-9-CM, ICD-10 has been in use in a number of other countries for over a decade. It is intended to enhance accurate payment for services and assist with evaluating medical processes and outcomes. Diagnosis coding under ICD-10-CM uses 3-7 alpha and numeric digits and full code titles, but the format is very much the same as ICD-9. ICD-10 does not impact outpatient hospital or physician practice coding for supplies and services using HCPCS and CPT codes.</p> <p>The compliance date for implementation of ICD-10-CM is October 1, 2015, for all Health Insurance Portability and Accountability Act (HIPAA)-covered entities. ICD-10-CM will replace International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) Diagnosis Codes in all healthcare settings for diagnosis reporting with dates of service, or dates of discharge for inpatients, that occur on or after October 1, 2015.</p>

DALVANCE (dalbavancin) Coding Summary				Physician Office/Infusion Centers	Hospital Outpatient Department
Type of Claim Information	Type of Code	Code	Description	Location on CMS-1500 Form	Location on UB-04 Form
Call DALVANCE CONNECTS SM toll-free at 1.855.387.2824 for more information on ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification codes. THIS IS NOT AN ALL-INCLUSIVE LIST; CONSULT WITH PAYOR TO OBTAIN SPECIFIC COVERAGE POLICIES AND REQUIREMENTS FOR COVERED INDICATIONS.	ICD-10-CM Diagnosis	Cellulitis		Item 21	Form Locator 67
		L03.011-L03.019	Cellulitis of finger		
		L03.031-L03.039	Cellulitis of toe		
		L03.111-L03.119	Cellulitis of other parts of limb		
		L03.211	Cellulitis of face		
		L03.221	Cellulitis of neck		
		L03.311-L03.319	Cellulitis of trunk		
		L03.811-L03.818	Cellulitis of other sites		
		L03.90	Cellulitis, unspecified		
		Methicillin-resistant <i>Staphylococcus aureus</i>			
		A49.02	Methicillin-resistant <i>Staphylococcus aureus</i> infection, unspecified site		
		B95.62	Methicillin-resistant <i>Staphylococcus aureus</i> infection as the cause of diseases classified elsewhere		
		<i>Staphylococcus</i>			
		A41.01-A41.2	Sepsis due to <i>Staphylococcus</i>		
		A49.01	Methicillin-susceptible <i>Staphylococcus aureus</i> infection, unspecified site		
		A49.02	Methicillin-resistant <i>Staphylococcus aureus</i> infection, unspecified site		
		B95.61-B95.8	<i>Staphylococcus aureus</i> as the cause of diseases classified elsewhere		
		<i>Streptococcus</i>			
		A40.0-A40.9	Streptococcal sepsis		
		A49.1	Streptococcal infection, unspecified site		
B95.01-B95.1, B95.3-B95.8	<i>Streptococcus</i>				

Please see Important Safety Information on page 12.
 Please also see enclosed full Prescribing Information.

DALVANCE [®] (dalbavancin) Coding Summary				Physician Office/Infusion Centers	Hospital Outpatient Department
Type of Claim Information	Type of Code	Code	Description	Location on CMS-1500 Form	Location on UB-04 Form
Procedures, Services and Supplies	CPT	96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	Item 24D	Form Locator 44
	AHA Revenue Codes	0250	Pharmacy, drugs not requiring detailed coding (used for claims to many non-Medicare payors)	N/A	Form Locator 42 and 43
		0510	Clinic visit		
		0636	Pharmacy, with detailed coding (requires HCPCS code)		
DALVANCE	Medicare HCPCS	J0875	Injection, dalbavancin, 5 mg	Item 24/D	Form Locator 44 or Electronic Comment Field
	NDC (11 digit)	57970-0100-01	500 mg dalbavancin, single-use vial	Shaded area above 24D or Item 24A or Item 19	

2016 Physician Office Sample Claim Form: CMS-1500

1	Item 19—Some payors may ask providers to specify DALVANCE (dalbavancin) dosage and NDC code while others may require alternative product codes (eg, Medicaid claims). Please consult with your local payors or contact DALVANCE CONNECTS SM toll-free at 1.855.387.2824 to confirm payor-specific coding requirements.
2	Item 21—Indicate diagnosis/diagnoses using appropriate ICD-10-CM codes effective October 1, 2015.
3	Item 24D—Indicate appropriate CPT and HCPCS codes as required.
4	Use of evaluation and management codes requires documentation of medically appropriate services performed on the same day as the infusion. Medicare requires the use of modifier 25 when reporting a significant, separately identifiable E/M service by the same physician, on the same day of the infusion procedure.
5	Item 24E—Refer to the diagnosis for this service (see box 21). Enter only one diagnosis pointer per line.
6	Item 24G—5-mg units (100 units of J0875 = a single 500-mg vial of dalbavancin).

CMS-1500 FOR SERVICES PERFORMED IN THE PHYSICIAN OFFICE
Sample CMS-1500 02/12 (ICD-10-CM) DALVANCE[®] (dalbavancin) IV Injection

HEALTH INSURANCE CLAIM FORM
 APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02-12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA OTHER 1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE MM DD YY SEX M F 4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED 7. INSURED'S ADDRESS (No., Street)

CITY STATE ZIP CODE TELEPHONE (Include Area Code)

8. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10. IS PATIENT'S CONDITION RELATED TO: a. INSURED'S DATE OF BIRTH MM DD YY SEX M F b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME

9. OTHER INSURED'S POLICY OR GROUP NUMBER? b. RESERVED FOR NUCC USE b. AUTO ACCIDENT? PLACE (State) c. OTHER ACCIDENT?

11. INSURED'S POLICY GROUP OR FECA NUMBER a. INSURED'S DATE OF BIRTH MM DD YY SEX M F b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME

12. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 8, 9a, and 9d.

13. SIGNATURE OF AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. SIGNATURE OF PHYSICIAN OR SUPPLIER I certify that the statements on the reverse apply to this bill and are made a part thereof.

15. DATE OF SERVICE FROM MM DD YY TO MM DD YY 16. PLACE OF SERVICE EMG CPT/HCPCS MODIFIER DIAGNOSIS POINTER \$ CHARGES DATE OF BILLING OR UNIT

17a. INPATIENT 17b. OUTPATIENT 17c. HOME HEALTH CARE 17d. NURSING HOME 17e. OTHER

19. ADDITIONAL CLAIM INFORMATION (Explained by NUCC) DALVANCE (dalbavancin), Dose 500 mg, NDC 57970010001, IV Infusion over 30 minutes

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24C)) ICD Ind. 9

A. 041.12 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE 23. PRIOR AUTHORIZATION XXXXXX

24. A. DATE(S) OF SERVICE FROM MM DD YY TO MM DD YY B. PLACE OF SERVICE EMG C. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER D. DIAGNOSIS POINTER E. \$ CHARGES F. DATE OF BILLING OR UNIT G. UNITS

1 MM DD YY MM DD YY 11 J0875 A XXX,XX 1 NPI

2 MM DD YY MM DD YY 11 96365 A XXX,XX 1 NPI

3

4

5

6

25. FEDERAL ASSIGNMENT? YES NO 26. TOTAL CHARGE \$ 27. AMOUNT PAID \$ 28. BILLING PROVIDER INFO & PH # ()

29. SIGNATURE OF PHYSICIAN OR SUPPLIER 30. SERVICE FACILITY LOCATION INFORMATION 31. BILLING PROVIDER INFO & PH # ()

SIGNED DATE a. NPI b. NPI a. NPI b. NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Box 19 Additional Information: Enter the appropriate drug-identifying information as required by payor; eg, brand and generic drug name, National Drug Code (NDC) 11-digit format, dosage, method of administration, etc
 Note: Additional information may also be sent via attachment electronically or other format as allowed by payor

Box 21 Diagnosis: Enter the appropriate diagnosis code; eg, ICD-10-CM: 041.12 for MRSA
 Final code depends on medical record documentation
 Note: Other diagnosis codes may apply

Box 21 ICD Indicator: Identify the type of ICD diagnosis code used; eg, enter a "0" for ICD-10-CM

Box 23 Prior Authorization: Enter the payor authorization number as obtained prior to services rendered

Box 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
 - Drug: J0875 for DALVANCE
 - Administration: 96365 for IV infusion

Box 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Box 21

Box 24G Units: Enter the appropriate number of units of service.
 Note: Some payors may provide alternative guidance

2015 HOPD Sample Claim Form: UB-04

1	Locator Box 42—List revenue codes in ascending order.
2	Locator Box 43—Describe procedure (eg, IV therapy, clinic visit).
3	Use of E/M codes requires documentation of medically appropriate services performed on the same day as the infusion.
4	Locator Box 44—Indicate appropriate CPT and HCPCS codes and modifiers if required.
5	Locator Box 46—5 mg units (100 units of J0875 = a single 500 mg vial of dalbavancin).
6	Locator Box 47—Indicate total charges.
7	Locator Box 67—Indicate diagnosis using appropriate ICD-10-CM codes effective October 1, 2015.

CMS-1450 FOR SERVICES PERFORMED IN THE HOSPITAL
Sample CMS-1450 (UB-04) ICD-10-CM DALVANCE[®] (dalbavancin) IV Injection

This document is provided for your guidance only. Please call DALVANCE CONNECTSSM at 1.855.387.2824 to verify coding and claim information for specific payors

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	Drugs requiring detailed information (DALVANCE)	J0875	MM DD YY	1	XXX.XX		
0510	Clinic visit (IV infusion in clinic)	J0875	MM DD YY	1	XXX.XX		

Fields 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44; eg, - 0636 for DALVANCE - 0510 for IV infusion administered in the clinic
Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers; eg, - Drug: J0875 for DALVANCE (for Medicare) - Administration: 96365 for drug administration

Field 46: Enter appropriate number of units of service; eg, J0875 1 unit equals 5 mg. Therefore a 500 mg injection would be 100 units (500 mg/5 mg = 100 units)
Note: Some payors may provide alternative guidance

Field 66: Identify the type of ICD diagnosis code used; eg, enter a "0" for ICD-10-CM

Fields 67 and 67A-67Q: Enter the appropriate diagnosis code. Final code may depend on medical record documentation
Note: Other diagnosis codes may apply

Field 74: Enter principal ICD-10-CM procedure code; eg, 99.29 for IV infusion

Field 80: Enter the appropriate drug-identifying information as required by payor; eg, brand and generic drug name, National Drug Code (NDC) 11-digit format, dosage, method of administration, etc; when using J0875, Medicare will no longer require this information
Note: Additional information may also be sent via attachment electronically or other format as allowed by payor

Please see Important Safety Information on page 12.
Please also see enclosed full Prescribing Information.

Checklist for Accurate Billing

To proactively prevent denials and underpayments, it may be helpful to perform a prebilling review prior to submitting any claim to a payor. The following may be considered:

- ✓ Has insurance been verified?
- ✓ Is this a covered service?
- ✓ Were the specific payor requirements followed?
- ✓ Was a Prior Authorization needed and obtained?
- ✓ If applicable, is the referral authorized?
- ✓ Is medical necessity documented?
- ✓ Is all of the required information included on the claim?
- ✓ Are the correct codes (diagnosis, CPT, and HCPCS) reported?
- ✓ Are the billed units accurate and consistent with the J code descriptor?
- ✓ If a separate and distinct E/M service was provided, is it identified with modifier 25?

Appeals

The most common reasons for denials or underpayment of claims include:

- Omission of any information that clarifies medical necessity (eg, relevant diagnosis codes)
- Inaccurately reporting the billable units of drug; note that DALVANCE[®] (dalbavancin) is reported in 5 mg units
- Use of incorrect CPT or HCPCS codes; note that DALVANCE has a new and permanent HCPCS code: J0875, effective January 1, 2016
- Failure to follow payor-specific requirements for providing this therapy, including referrals and Prior Authorization
- Lack of proper and complete documentation
- Omission of special coding requirements (eg, the NDC number or required modifiers)
- In certain cases, omission of a physician letter/statement of medical necessity

Different payors provide different appeals rights depending upon the level of appeal for the denied claim (eg, first appeal, second appeal). In the event of a claim denial, be sure to resubmit your claim. Most well-documented follow-up submissions are successful.

For additional information regarding coding, coverage, and reimbursement policies or claim denials for DALVANCE (dalbavancin), call DALVANCE CONNECTSSM, a single source of services designed to simplify access to therapy with DALVANCE, at: **1.855.387.2824**, Monday through Friday excluding holidays, 8 AM to 8 PM ET.

The information in this guide is provided to assist you in understanding the reimbursement process. It is intended to help providers in accurately obtaining reimbursement for healthcare services. It is not intended to increase or maximize reimbursement by any payor. We strongly suggest that you consult your payor organization with regard to local reimbursement policies. This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and updated frequently. While Allergan plc has made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Please consult with your reimbursement specialist for any reimbursement or billing questions. Similarly, all Current Procedural Terminology (CPT[®]) & Healthcare Common Procedure Coding System (HCPCS) billing codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Allergan plc that these codes will be appropriate or that reimbursement will be made.

CPT © 2016 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for the data contained or not contained herein.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Hypersensitivity Reactions

Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE[®]. Exercise caution in patients with known hypersensitivity to glycopeptides due to the possibility of cross-sensitivity. If an allergic reaction occurs, treatment with DALVANCE should be discontinued.

Infusion-related Reactions

Rapid intravenous infusion of DALVANCE can cause reactions, including flushing of the upper body, urticaria, pruritus, rash, and/or back pain.

Hepatic Effects

ALT elevations with DALVANCE treatment were reported in clinical trials.

Clostridium difficile-associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Development of Drug-resistant Bacteria

Prescribing DALVANCE in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%).

Use in Specific Populations

- There have been no adequate and well-controlled studies with DALVANCE in pregnant or nursing women. DALVANCE should only be used if the potential benefit justifies the potential risk in these populations.
- In patients with renal impairment whose known creatinine clearance is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis, the recommended regimen of DALVANCE is 1125 mg, administered as a single dose, or 750 mg followed one week later by 375 mg. No dosage adjustment is recommended for patients receiving regularly scheduled hemodialysis, and DALVANCE can be administered without regard to the timing of hemodialysis.
- Caution should be exercised when prescribing DALVANCE to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) as no data are available to determine the appropriate dosing in these patients.

Please see full Indication and additional Important Safety Information on front cover.

Please see enclosed full Prescribing Information.

