

Coding & Billing Reference Guide

DALVANCE CONNECTS[®]

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8 AM-8 PM ET, Monday-Friday, excludes 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 and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of 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).

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 or prevent 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 throughout. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/dalvance_pi.pdf

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. 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 CONNECTS®, 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 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.

JW Modifier

Effective January 1, 2017, Medicare required providers to use the JW modifier (drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single-use vials that are appropriately discarded and to document the discarded drug or biological in the patient's medical record.

Code Set	Long Descriptor
JW	Drug amount discarded/not administered to any patient

JZ Modifier

Beginning July 1, 2023, CMS requires the use of the JZ modifier to indicate there were no units of a drug discarded.

Code Set	Long Descriptor
JZ	Zero drug amount discarded/not administered to any patient

Code Set	Setting of Care	Code and Description
HCPCS codes used to report DALVANCE	<ul style="list-style-type: none"> Hospital outpatient department Free-standing infusion center Hospital outpatient provider-based clinic Hospital inpatient Physician office Emergency department Observation department 	<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 permanent J-code for DALVANCE (dalbavancin) for Injection:</p> <p>J0875 Injection, dalbavancin, 5 mg</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
3	1500	300

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

Code Set	Setting of Care	Code and Description
CPT codes used to report IV infusion	<ul style="list-style-type: none"> • Hospital outpatient department • Free-standing infusion center • Hospital outpatient provider-based clinic • Hospital inpatient • Physician office • Emergency department • Observation department 	<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[®] (dalbavancin) 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	Code and Description
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 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	Code and Description
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
<p>Call DALVANCE CONNECTS[®] toll-free at 1.855.387.2824 for more information on ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification codes.</p> <p>THIS IS NOT AN ALL-INCLUSIVE LIST; CONSULT WITH PAYOR TO OBTAIN SPECIFIC COVERAGE POLICIES AND REQUIREMENTS FOR COVERED INDICATIONS.</p>	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	Services		
		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>				

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[®] 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).

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

1	2	3a PAT. CNTRL #	4 TYPE OF BILL
b. MED. REC. #	5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	7 THROUGH
8 PATIENT NAME	a	9 PATIENT ADDRESS	a
b	c	d	e
10 BIRTHDATE	11 SEX	12 DATE	13 HR
14 TYPE	15 SRC	16 DHR	17 STAT
18	19	20	21
22	23	24	25
26	27	28	29 ACDT STATE
30	31 OCCURRENCE DATE	32 OCCURRENCE DATE	33 OCCURRENCE DATE
34 OCCURRENCE DATE	35 CODE	OCCURRENCE SPAN FROM	THROUGH
36 CODE	OCCURRENCE SPAN FROM	THROUGH	37
38	c	d	e
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE
46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1 0636	Drugs requiring detailed information (DALVANCE)	J0875	MM DD YY
2	3 0510	J0875	MM DD YY
4	Clinic visit (IV infusion in clinic)		
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PAGE	OF	CREATION DATE	TOTALS
50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASIG BEN.
54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57 OTHER PRV ID
59 P.REL.	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
63	64	65	66
67	68	69	70
71	72	73	74
75	76	77	78
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91	92	93	94
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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 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 CONNECTS[®], 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 obtain accurate 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 AbbVie Inc. 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 AbbVie Inc., that these codes will be appropriate or that reimbursement will be made.

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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.

***Clostridioides difficile*-associated Diarrhea**

Clostridioides 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 or a prophylactic indication 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 adult patients treated with DALVANCE in Phase 2/3 trials were nausea (5.5%), headache (4.7%), and diarrhea (4.4%). The most common adverse reaction that occurred in more than 1% of pediatric patients was pyrexia (1.2%).

Use in Specific Populations

- There are no adequate and well-controlled studies with DALVANCE use in pregnant or nursing women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DALVANCE and any adverse effects on the breast-fed child from DALVANCE or from the underlying maternal condition.
- In patients with renal impairment whose known creatinine clearance (CL_{cr}) 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. There is insufficient information to recommend dosage adjustment for pediatric patients younger than 18 years of age with CL_{cr} less than 30 mL/min/1.73m².
- 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 additional Important Safety Information throughout. Please see full **Prescribing Information** or visit https://www.rxabbvie.com/pdf/dalvance_pi.pdf