Conexxence®
denosumab-bnht

CONEXXENCE® (denosumab-bnht)
Injection for subcutaneous use

Billing & Coding Guide

Important Safety Information

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Conexxence in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Conexxence in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Please see additional Important Safety Information throughout this brochure and click to see Full Prescribing Information and Medication Guide, including **Boxed Warning** for CONEXXENCE® (denosumab-bnht).

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CONEXXENCE® (denosumab-bnht) Billing and Coding Guide

The CONEXXENCE® Billing and Coding Guide provides general reimbursement information for healthcare providers.

Topics include billing, coding, coverage, and reimbursement for treatment with CONEXXENCE®.

The content provided in this guide is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure CONEXXENCE® claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee that payers will consider all codes appropriate for all encountered scenarios and Fresenius Kabi does not guarantee CONEXXENCE® coverage or reimbursement.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

Important Safety Information

CONTRAINDICATIONS

Patients with hypocalcemia

Pre-existing hypocalcemia must be corrected prior to initiating therapy with Conexxence.

Pregnant women

Denosumab products may cause fetal harm when administered to a pregnant woman. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Conexxence.

Patients with hypersensitivity to denosumab products

Conexxence is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling, and urticaria.

WARNINGS AND PRECAUTIONS

Severe Hypocalcemia and Mineral Metabolism Changes

Denosumab products can cause severe hypocalcemia and fatal cases have been reported. Preexisting hypocalcemia must be corrected prior to initiating therapy with Conexxence. Adequately supplement all patients with calcium and vitamin D.

In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism, assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Conexxence injection. In some postmarketing cases, hypocalcemia persisted for weeks or months and required frequent monitoring and intravenous and/or oral calcium replacement, with or without vitamin D.

Patients with Advanced Chronic Kidney Disease

Patients with advanced chronic kidney disease [i.e., eGFR < 30 mL/min/1.73 m^2] including dialysis-dependent patients are at greater risk for severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of underlying chronic kidney disease-mineral bone disorder (CKD-MBD, renal osteodystrophy) markedly increases the risk of hypocalcemia. Concomitant use of calcimimetic drugs may also worsen hypocalcemia risk.

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Indications/Formulation

INDICATIONS AND USAGE[1]

CONEXXENCE® (denosumab-bnht) is indicated for treatment:

- of postmenopausal women with osteoporosis at high risk for fracture
- to increase bone mass in men with osteoporosis at high risk for fracture
- of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Available as a single-dose prefilled syringe[1]

60 mg/mL
NDC # 65219-668-01

Important Safety Information (continued)

To minimize the risk of hypocalcemia in patients with advanced chronic kidney disease, evaluate for the presence of chronic kidney disease mineral and bone disorder with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and $1,25(OH)_2$ vitamin D prior to decisions regarding Conexxence treatment. Consider also assessing bone turnover status (serum markers of bone turnover or bone biopsy) to evaluate the underlying bone disease that may be present. Monitor serum calcium weekly for the first month after Conexxence administration and monthly thereafter. Instruct all patients with advanced chronic kidney disease, including those who are dialysis-dependent, about the symptoms of hypocalcemia and the importance of maintaining serum calcium levels with adequate calcium and activated vitamin D supplementation. Treatment with Conexxence in these patients should be supervised by a healthcare provider who is experienced in diagnosis and management of CKD-MBD.

Drug Products with Same Active Ingredient

Patients receiving Conexxence should not receive other denosumab products concomitantly.

Hypersensitivity

Clinically significant hypersensitivity including anaphylaxis has been reported with denosumab products. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Conexxence.

Osteonecrosis of the Jaw (ONJ)

ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing. ONJ has been reported in patients receiving denosumab products. An oral

ICD-10

This coding information may assist you as you complete the payer forms for CONEXXENCE® (denosumab-bnht).

ICD-10-CM Codes[2] for Consideration*	
Osteoporosis	
M80.0	Age-related osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
Cancer Treatment-Induced Bone Loss	
C61.0	Malignant neoplasm of prostate
M85.9	Disorder of bone density and structure, unspecified
M81.0	Age-related osteoporosis without current pathologic fracture
M81.8	Other osteoporosis without pathologic fracture
M80.0	Age-related osteoporosis with current pathologic fracture
M80.8	Other osteoporosis with current pathological fracture

* ICD-10-CM diagnosis codes consist of 3 to 7 alphanumeric characters, providing increasing levels of specificity. A 3-character code is appropriate only when there is no need for additional subdivision. A code is invalid if it has not been coded to the full number of characters required for that code.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Fresenius Kabi does not make any representation or guarantee concerning reimbursement or coverage for any item or service. Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

Important Safety Information

exam should be performed by the prescriber prior to initiation of Conexxence. A dental examination with appropriate preventive dentistry is recommended prior to treatment with Conexxence in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and comorbid disorders. Good oral hygiene practices should be maintained during treatment with Conexxence. Concomitant administration of drugs associated with ONJ may increase the risk of developing ONJ. The risk of ONJ may increase with duration of exposure to denosumab products.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ while on Conexxence should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Conexxence therapy should be considered based on individual benefit-risk assessment.

Atypical Subtrochanteric and Diaphyseal Femoral Fractures

Atypical low energy or low trauma fractures of the shaft have been reported in patients receiving denosumab products. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents. During Conexxence treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Interruption of Conexxence therapy should be considered, pending a benefit-risk assessment, on an individual basis.

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HCPCS

Healthcare Common Procedure Coding System (HCPCS)

HCPCS Code for CONEXXENCE® (denosumab-bnht)[3]

Code	Description	Site of Service	Billing Units
Q5158	Injection, denosumab-bnht (BOMYNTRA/ CONEXXENCE), biosimilar, 1 mg	All	1 mg

Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment.

Important Safety Information

Multiple Vertebral Fractures (MVF) Following Discontinuation of Treatment

Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of denosumab. Prior vertebral fracture was a predictor of multiple vertebral fractures after denosumab discontinuation. Evaluate an individual's benefit-risk before initiating treatment with Conexxence. If Conexxence treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections

In a clinical trial of over 7800 women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the denosumab group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract, and ear, were more frequent in patients treated with denosumab.

Endocarditis was also reported more frequently in denosumab-treated patients. The incidence of opportunistic infections was similar between placebo and denosumab groups, and the overall incidence of infections was similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Conexxence, prescribers should assess the need for continued Conexxence therapy.

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Modifiers

Summary of Code Modifiers				
Modifier	**Description[4]**	**Indication and Placement[5,6]**	**CMS-1500 (Item 24D)**	**CMS-1450 (Box 44)**
JW	Drug amount discarded/ not administered to any patient	Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial.	✓ Required by Medicare	✓ Required by Medicare
JZ	Zero drug amount discarded/not administered to any patient	To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage).	✓ Required by Medicare	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	TB modifier is used to identify drugs or biologicals acquired through the 340B Drug Pricing Program for informational purposes. The TB modifier is required for all 340B covered entities, including hospital-based and non-hospital-based entities, for claims with dates of service beginning on or after January 1, 2025. TB modifier to be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs.	N/A	✓ Required by Medicare

When using miscellaneous code, amount wasted is captured in CMS 1500 Form Block 19 & CMS 1450 Form FL 80, and claim form should not include separate line for JW.

NDC Numbers and CPT Codes

What codes do I use to bill for CONEXXENCE® (denosumab-bnht)?

- A new prescription is required for CONEXXENCE®.
- To ensure your patient will receive CONEXXENCE®, please select the appropriate dosing when prescribing.

National Drug Code (NDC)[1]

Electronic data exchange standards usually require the use of an 11-digit NDC. Check with the payer to confirm the correct code required when billing for CONEXXENCE®.

Dosage Form	Description	10-digit NDC Code	11-digit NDC Code
SC Injection	60 mg/mL	65219-668-01	65219-0668-01

Current Procedural Terminology (CPT) Code[7,8]

CPT codes are the standard coding system for reporting medical procedures and services under both public and private health insurance plans.

Type	Code	Description
CPT Code—SC injection	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.
	96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

Physician's Office Billing Information[9]

CONEXXENCE® (denosumab-bnht) Coding Information*	
Coding Information in **Block 24D:** (Electronic Form: Loop 2400, SV1, 01-2)	Input HCPCS code Q5158 and required modifiers on separate lines.
Number of Units in **Block 24G:** (Electronic Form: Loop 2400, SV1, 04 [03 = UN])	Enter the amount administered. Denosumab-bnht is billed in 1 mg units. Each 60 mg dose of CONEXXENCE is billed as 60 units.
Administration and Professional Service Coding Information*	
Coding Information in Block 24D: (Electronic Form: Loop 2400, SV1, 01-2)	Enter appropriate CPT code and Modifier if applicable.
Diagnosis Code Information*	
ICD-10-CM Code in Block 21: (Electronic Form: Loop 2300, HI, 01-2)	Indicate diagnosis using appropriate ICD-10 CM codes. Use diagnosis codes to highest level of specificity for the date of service, and enter the diagnosis in priority order.

* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for CONEXXENCE®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

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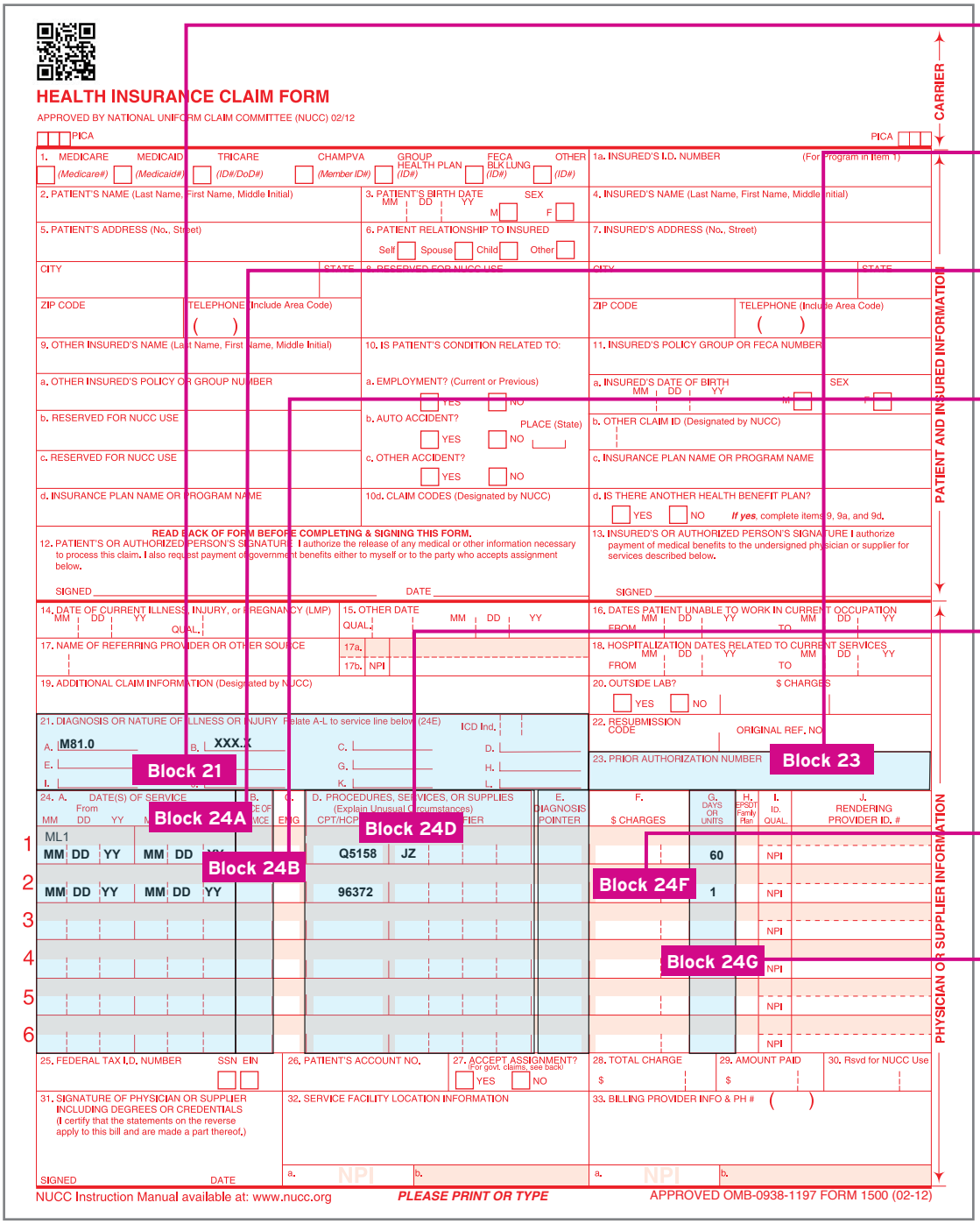
Sample CMS 1500 Claim Form
(physician office site of service)[9]

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure CONEXXENCE® (denosumab-bnht) claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee CONEXXENCE® coverage or reimbursement.



Block 21. Diagnosis

Enter appropriate ICD-10-CM diagnosis code(s).

Block 23. Prior Authorization Number (if applicable)

Add prior authorization number.

Block 24A. Dates of Service:

If line item NDC information is required, enter it in the shaded portion of item 24A.

Block 24B: Place of Service

A place of service code (11-Office, 12-Home, 19-Off Campus-Outpatient Hospital, or 49-Independent Clinic) should be used when billing for office (other than hospital), home infusion, or ambulatory infusion suite (AIS) services.

Block 24D. Drug Code

Enter appropriate HCPCS/ Modifiers and CPT codes.

Block 24F: $ Charges

Indicate total charges.

Block 24G: Units

Enter the amount administered. Denosumab-bnht is billed in 1 mg units. Each 60 mg dose of CONEXXENCE is billed as 60 units.

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Hospital/Institutional Billing[10]

CONEXXENCE® (denosumab-bnht) Coding Information*	
Revenue Code in **Form Location (FL) 42**: (Electronic Form: Loop 2400, SV201)	List revenue codes in ascending order.
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter appropriate HCPCS/Modifiers and CPT codes. Q5158—Injection, denosumab-bnht (BOMYNTRA/CONEXXENCE), biosimilar, 1 mg.
Service Units in **FL 46**: (Electronic Form: Loop 2400, SV205)	Enter the amount administered. Denosumab-bnht is billed in 1 mg units. Each 60 mg dose of CONEXXENCE is billed as 60 units.
Administration and Professional Service Coding Information*	
Revenue Code in **FL 42**: (Electronic Form: Loop 2400, SV201)	Enter appropriate revenue code for the cost center in which the service is performed.
Description in **FL 43**: (Not required by Medicare)	Enter narrative description of corresponding revenue code (e.g., clinic, lab, infusion).
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter appropriate CPT code and Modifier if applicable.
Diagnosis Code Information*	
ICD-10-CM Code in **FL 67**: (Electronic Form: Loop 2300, HI01-2 [HI01-1=BK])	Enter appropriate ICD-10-CM code(s) for patient condition. Sequencing of codes may vary based on patient's condition and payer's policy.

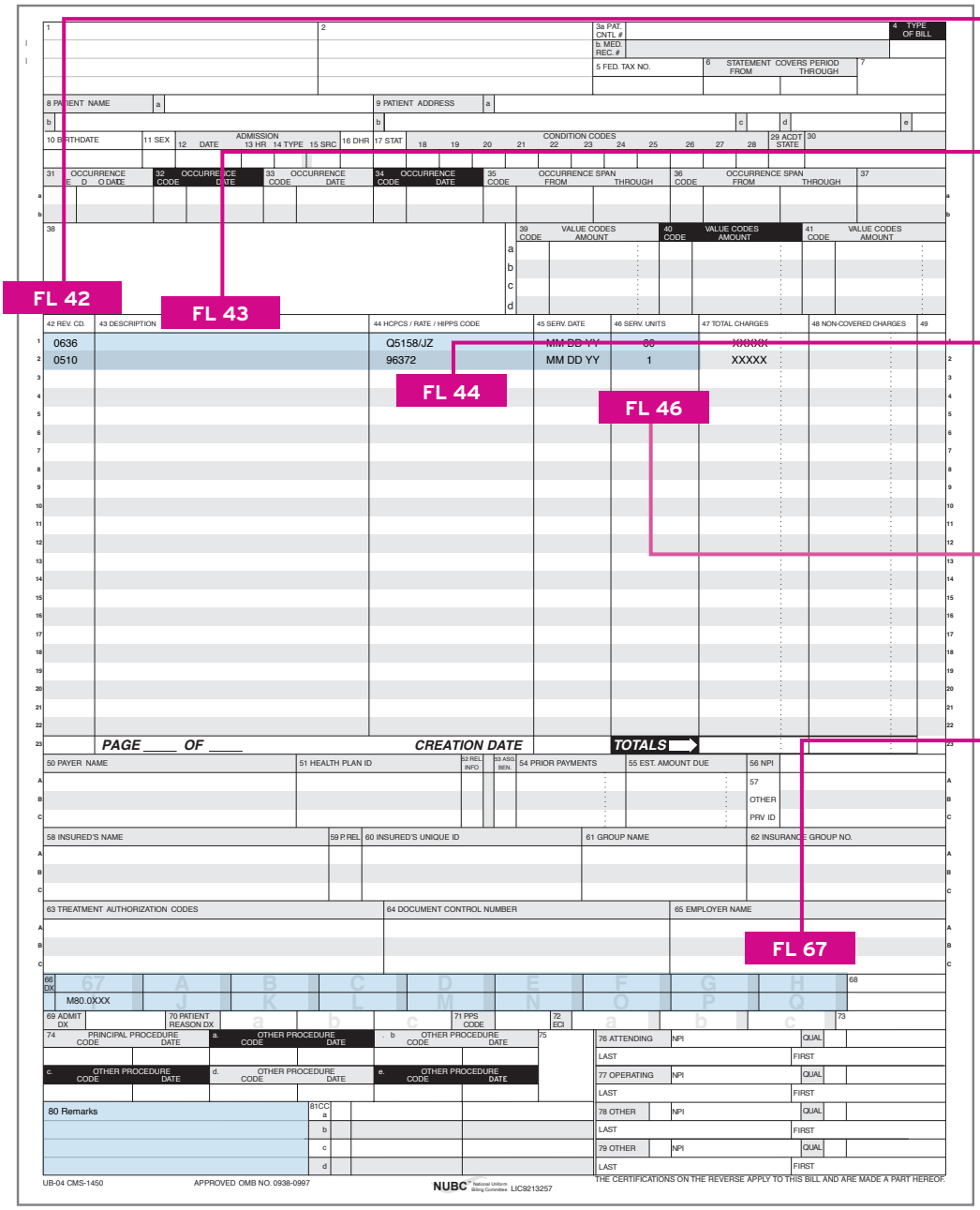
* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for CONEXXENCE®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

The JW and JZ modifier requirement applies to all separately payable drugs from single-dose containers assigned status indicators "G" (pass-through drugs and biologicals) or "K" (non-pass-through drugs) under the OPPS for which there is a discarded amount.

Sample CMS 1450 (UB-04) Claim Form

(hospital outpatient site of service)[10]

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure CONEXXENCE® (denosumab-bnht) claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee CONEXXENCE® coverage or reimbursement.



FL 42

Enter the appropriate revenue code and procedure description.

FL 43

Enter narrative description of corresponding revenue code (e.g., clinic, lab, general). If line item NDC information is required, enter it in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.

FL 44

Enter appropriate HCPCS/Modifiers and CPT codes.

FL 46

Enter the amount administered. Denosumab-bnht is billed in 1 mg units. Each 60 mg dose of CONEXXENCE is billed as 60 units.

FL 67

Enter appropriate ICD-10-CM code(s) for patient condition.

Additional documentation for filing your claim

In addition to the CMS 1500 or CMS 1450 (UB-04) claim form, the payer may request the following:

- Patient medical history
- Physician clinical notes
- PA number
- May require an invoice
- Drug-identifying information (e.g., NDC)
- Letter of medical necessity
- Letter of appeal

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Conexxence®
denosumab-bnht

CONEXXENCE® (denosumab-bnht) offers resources to help your patients start and stay on prescribed therapy

We are dedicated to providing your patients with ongoing support to help them access Fresenius Kabi medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

References: 1. CONEXXENCE®. Prescribing information. Fresenius Kabi, LLC; 2025. **2.** Centers for Medicare & Medicaid Services. ICD Code Lists: Valid ICD-10 List [excel file]. https://www.cms.gov/medicare/coordination-benefits-recovery/overview/icd-code-lists. Page last modified October 29, 2024. Accessed January 10, 2025. **3.** Centers for Medicare & Medicaid Services. HCPCS Application Summaries and Coding Determinations: Second Quarter, 2025 HCPCS Coding Cycle (Drugs and Biologicals). Published July 7, 2025. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-2-2025-drugs-and-biologicals-posted-07/7/2025.pdf. Accessed August 12, 2025. **4.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update: January 2025 Alpha-Numeric HCPCS Files [zip file]. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. Page last modified December 17, 2024. Accessed January 10, 2025. **5.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf. Revised February 15, 2024. Accessed January 10, 2025. **6.** Centers for Medicare & Medicaid Services. Medicare Part B inflation rebate guidance: Use of the 340B Modifier. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf. Accessed January 10, 2025. **7.** American Medical Association. CPT® code 96372: Injection of drug/substance under skin or into muscle. American Medical Association. Published January 1, 2025. https://www.ama-assn.org/practice-management/cpt/cpt-code-96372-injection-drugsubstance-under-skin-or-muscle. Accessed April 28, 2025. **8.** American Academy of Professional Coders. CPT® Code 96401 in section: Chemotherapy and Other Highly Complex Biologic Agent Administration. *AAPC*. https://www.aapc.com/codes/cpt-codes/96401. Accessed May 8, 2025. **9.** Medicare claims processing manual, Chapter 26 - Completing and Processing Form CMS-1500 Data Set. cms.gov. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf. Accessed January 15, 2025. **10.** Medicare claims processing manual, Chapter 25 - Completing and Processing the Form CMS-1450 Data Set. cms.gov. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25pdf.pdf. Accessed January 15, 2025.

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