Bomyntra®
denosumab-bnht

BOMYNTRA® (denosumab-bnht)
Injection for subcutaneous use

Billing & Coding Guide

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

FRESENIUS KABI

BOMYNTRA® (denosumab-bnht) Billing and Coding Guide

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

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

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 BOMYNTRA® 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 BOMYNTRA® coverage or reimbursement.

INDICATIONS AND USAGE[1]

BOMYNTRA® (denosumab-bnht) is indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Important Safety Information

CONTRAINDICATIONS

Hypocalcemia

Pre-existing hypocalcemia must be corrected prior to initiating therapy with Bomyntra (denosumab-bnht).

Hypersensitivity

Bomyntra is contraindicated in patients with known clinically significant hypersensitivity to denosumab products.

WARNINGS AND PRECAUTIONS

Drug Products with Same Active Ingredient

Patients receiving Bomyntra should not receive other denosumab products concomitantly.

Hypersensitivity

Clinically significant hypersensitivity including anaphylaxis has been reported with use of denosumab products. Reactions may include hypotension, dyspnea, upper airway edema, lip swelling, rash, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue Bomyntra therapy permanently.

Hypocalcemia

Denosumab products can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Correct pre-existing hypocalcemia prior to Bomyntra treatment. Monitor calcium levels, throughout Bomyntra therapy, especially in the first weeks of initiating therapy, and administer calcium, magnesium, and vitamin D as necessary. Concomitant use of calcimimetics and other drugs

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

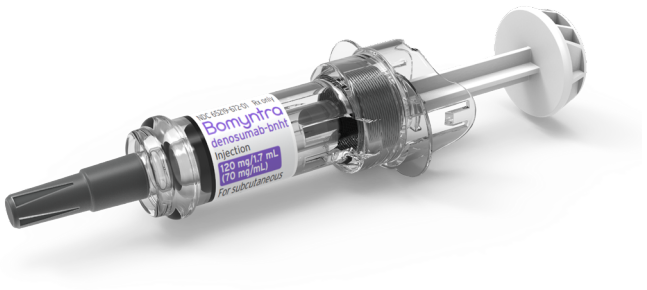
AVAILABLE BOMYNTRA® (denosumab-bnht) FORMULATIONS

BOMYNTRA® is available as a vial or prefilled syringe[1]

Single-dose vial for subcutaneous injection

120 mg/1.7 mL (70 mg/mL)
(NDC# 65219-670-01)

Single-dose prefilled syringe for subcutaneous injection



120 mg/1.7 mL (70 mg/mL)
(NDC# 65219-672-01)

Important Safety Information (continued)

that can lower calcium levels may worsen hypocalcemia risk and serum calcium should be closely monitored. Advise patients to contact a healthcare provider for symptoms of hypocalcemia.

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/min and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

Osteonecrosis of the Jaw (ONJ)

ONJ has been reported in patients receiving denosumab products, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ. In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure.

Patients with a history of tooth extraction, poor oral hygiene, or use of a dental appliance are at a greater risk to develop ONJ. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.

Perform an oral examination and appropriate preventive dentistry prior to the initiation of Bomyntra and periodically during Bomyntra therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with Bomyntra. Consider temporary discontinuation of Bomyntra therapy if an invasive dental procedure must be performed.

ICD-10 CODES

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

ICD-10-CM Codes[2] for Consideration*	
Multiple Myeloma or Bone Metastases from Solid Tumors	
C79.51	Secondary malignant neoplasm of bone
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
Giant Cell Tumor of Bone	
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
Hypercalcemia	
E83.52	Hypercalcemia

*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.

Healthcare Common Procedure Coding System (HCPCS)

HCPCS Code for BOMYNTRA (denosumab-bnht)®3*			
Code	**Description**	**Site of Service**	**Billing Units**
J3490	Unclassified drugs	All	1
J3590	Unclassified biologics	All	1
C9399	Unclassified drugs or biologics (applies only to CMS Form 1450 - Medicare Hospital Outpatient Prospective Payment System (OPPS))	Hospital outpatient	1

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

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 (continued)

Patients who are suspected of having or who develop ONJ while on Bomyntra should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture

Atypical femoral fracture has been reported with denosumab products. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution.

Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture.

During Bomyntra 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. Patient presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of Bomyntra therapy should be considered, pending a risk/benefit assessment, on an individual basis.

MODIFIERS

Summary of Code Modifiers				
Modifier	**Description[3]**	**Indication and Placement[4,5]**	**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.

Important Safety Information (continued)

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone (GCTB) and in Patients with Growing Skeletons

Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in denosumab product-treated patients with GCTB and patients with growing skeletons within the first year after treatment discontinuation. After treatment is discontinued, monitor patients for signs and symptoms of hypercalcemia and manage patients as clinically appropriate.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

MVF have been reported following discontinuation of treatment with denosumab products. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures. When Bomyntra treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.

Embryo-Fetal Toxicity

Based on data from animal studies and its mechanism of action, denosumab products can cause fetal harm when administered to a pregnant woman.

NDC Numbers and CPT Codes

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

- A new prescription is required for BOMYNTRA®.
- To ensure your patient will receive BOMYNTRA®, 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 BOMYNTRA®.

Dosage Form	Description	10-digit NDC Code	11-digit NDC Code
SC Injection	120 mg/1.7 mL (70 mg/mL), single-dose prefilled syringe	65219-672-01	65219-0672-01
	120 mg/1.7 mL (70 mg/mL), single-dose vial	65219-670-01	65219-0670-01

Current Procedural Terminology (CPT) Code[6,7]

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.

Important Safety Information (continued)

Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of Bomyntra. Advise pregnant women and females of reproductive potential that exposure to Bomyntra during pregnancy or within 5 months prior to conception can result in fetal harm.

ADVERSE REACTIONS

The most common adverse reactions in patients receiving denosumab with bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction was dyspnea. The most common adverse reactions resulting in discontinuation were osteonecrosis and hypocalcemia.

The most common adverse reactions in patients receiving denosumab with multiple myeloma were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia. The most common adverse reaction resulting in discontinuation of denosumab was osteonecrosis of the jaw.

The most common adverse reactions in patients with giant cell tumor of bone were arthralgia, back pain, pain in extremity, fatigue, headache, nausea, nasopharyngitis, musculoskeletal pain, toothache, vomiting, hypophosphatemia, constipation, diarrhea, and cough. The most frequent serious adverse reactions were osteonecrosis of the jaw, bone giant cell tumor, anemia, pneumonia,

Physician's Office Billing Information[8]

BOMYNTRA® (denosumab-bnht) Coding Information*	
Coding information in **Block 19**: (Electronic Form: Loop 2400)	Enter drug name, drug strength, unit of measure, number of units administered/discarded, route of administration, 11-digit NDC, and date administered.
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Enter appropriate HCPCS/Modifiers and CPT codes. Enter the code without a narrative description (enter narrative description in Block 19).
Number of Units in **Block 24G**: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Providers should enter "1" in the quantity billed/number of services field, and enter the total amount of the drug or biological actually administered (in mg) in Block 19 or the electronic equivalent field. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided.
Administration and Professional Service Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Indicate appropriate CPT codes and modifier.
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 BOMYNTRA®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Important Safety Information (continued)

and back pain. The most frequent adverse reactions resulting in discontinuation of denosumab was osteonecrosis of the jaw.

The most common adverse reactions in patients with hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea. The following adverse reactions of Grade 3 or greater severity related to study therapy were reported on-study: fatigue and infection. Grade 3 laboratory abnormalities included hypomagnesemia, hypokalemia, and hypophosphatemia. No deaths on-study were related to denosumab therapy

INDICATIONS

Bomyntra (denosumab-bnht) is indicated for:

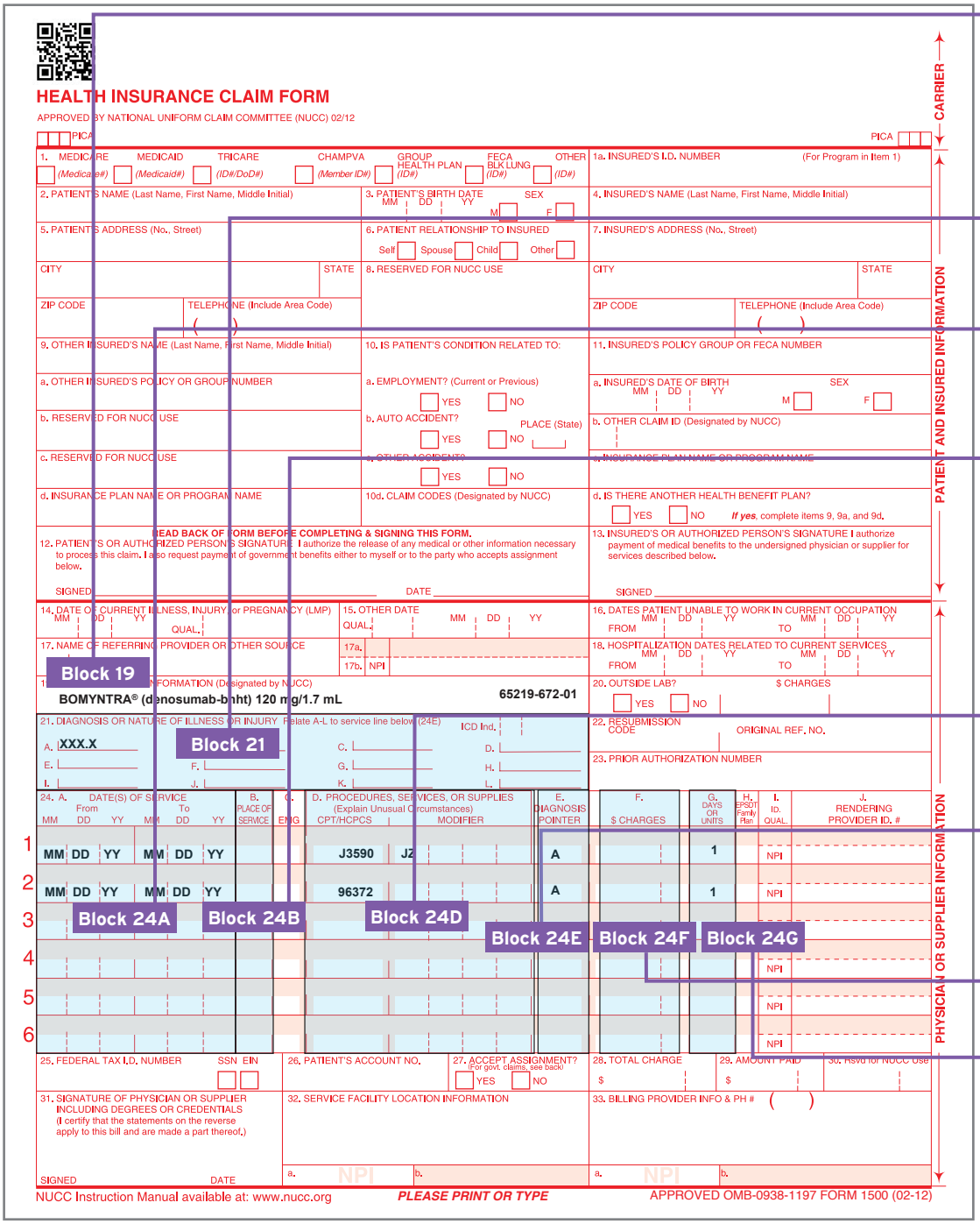
- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Please see **Bomyntra full Prescribing Information**.

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

Sample CMS 1500 Claim Form
(physician office site of service)[8]

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 BOMYNTRA® (denosumab-bnht) claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee BOMYNTRA® coverage or reimbursement.



Block 19: Additional Information

Enter drug name, drug strength, unit of measure, number of units administered/discarded, route of administration, 11-digit NDC, and date administered.

Block 21: Diagnosis

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

Block 24A: Date(s) 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 24E: Diagnosis Pointer

Refer to the diagnosis for this service from line 21 and enter only 1 diagnosis pointer per line.

Block 24F: $ Charges

Indicate total charges.

Block 24G: Units

Enter the billing units. The number of units for BOMYNTRA® will always be 1 unit since it uses a miscellaneous code.

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

Hospital/Institutional Billing[9]

BOMYNTRA® (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. The C code only applies to Medicare OPPS, and use miscellaneous J code for commercial claims. Enter the code without a narrative description (enter narrative description in FL 80).
Service Units in **FL 46**: (Electronic Form: Loop 2400, SV205)	Providers should enter "1" in the quantity billed/number of services field, and enter the total amount of the drug or biological actually administered (in mg) in FL 80 or the electronic equivalent field.
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.
Additional remarks in **FL 80**: (Electronic Form: Loop 2400)	Enter drug name, drug strength, unit of measure, number of units administered/discarded, route of administration, 11-digit NDC, and date administered.

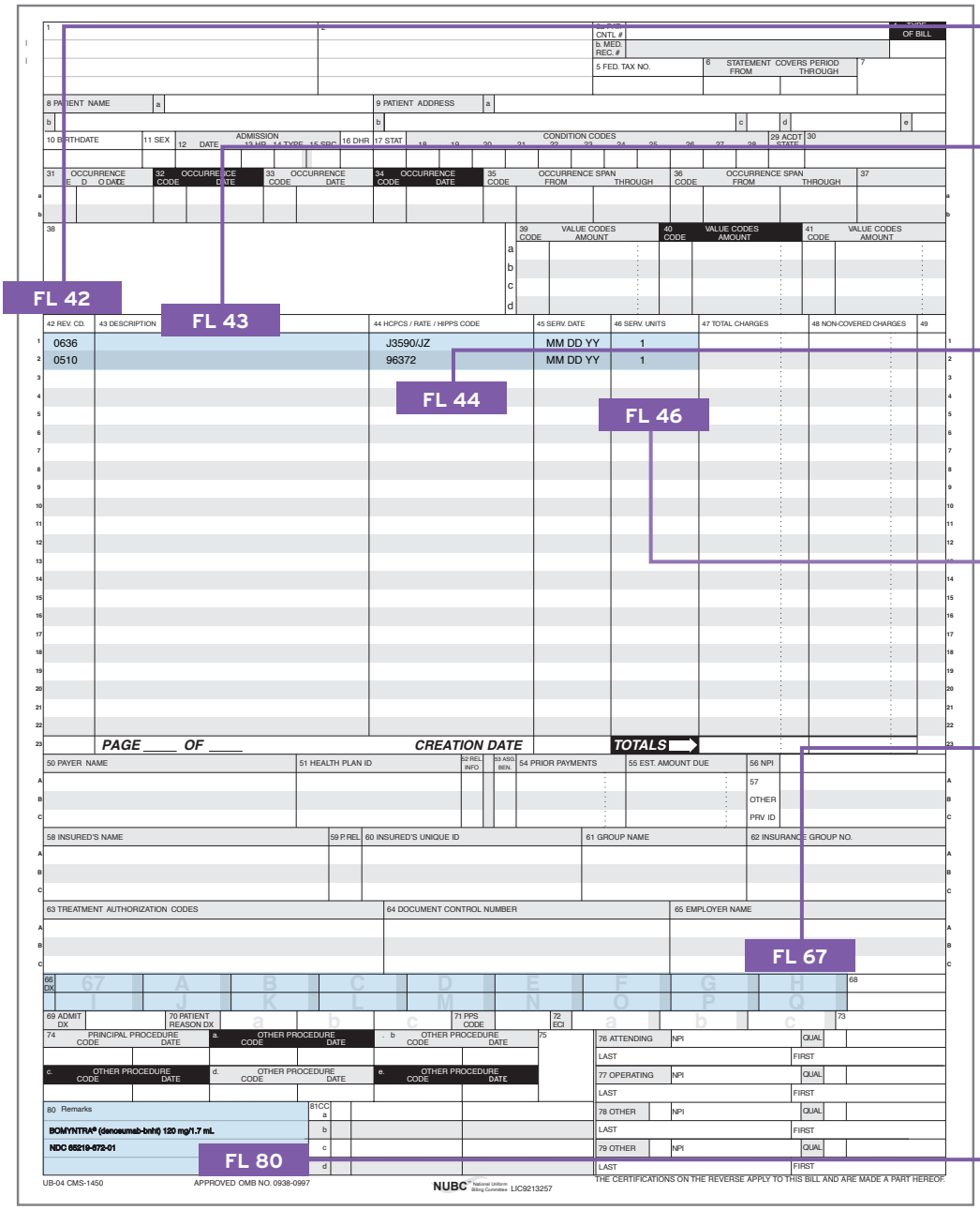
*The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for BOMYNTRA®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and 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)[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 BOMYNTRA® (denosumab-bnht) claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee BOMYNTRA® 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 billing units. The number of units for BOMYNTRA® will always be 1 unit since it uses a miscellaneous code.

FL 67

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

FL 80

Enter drug name, drug strength, unit of measure, number of units administered/discarded, route of administration, 11-digit NDC, and date administered.

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

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

Bomyntra®
denosumab-bnht

BOMYNTRA® (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. BOMYNTRA®. 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 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. **4.** 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. **5.** 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. **6.** 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. **7.** 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. **8.** 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. **9.** 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.

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

5942-BOM-09-04/25 v1.0

FRESENIUS KABI