Bosaya™
(denosumab-kyqq)

Coding & Billing Guide

For Bosaya™ (denosumab-kyqq) Injection

Please see full Indications on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

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OVERVIEW

PURPOSE OF THIS GUIDE

This Coding and Billing Guide for Bosaya™ (denosumab-kyqq) is intended to support medically appropriate patient access by providing general information on coding, coverage, billing, and reimbursement to healthcare professionals and their staff who prescribe and administer BOSAYA at a physician office. BOSAYA is a biosimilar to Prolia® (denosumab) for the indications listed on pages 5 and 23.[1]

DISCLAIMER

The content provided in this guide is for informational purposes only. It 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 BOSAYA claims are accurate, complete, and supported by documentation in the patient's medical record.

Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios, and Biocon Biologics does not guarantee coverage or reimbursement for BOSAYA. Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of April 2026.

HOW SUPPLIED[1]

BOSAYA is available as a 60 mg/mL single-dose prefilled syringe.

Bosaya™
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INDICATIONS AND USAGE[1]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, denosumab reduces the incidence of vertebral, nonvertebral, and hip fractures.
- For treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- For the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer. In these patients denosumab also reduced the incidence of vertebral fractures.
- As a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor (AI) therapy for breast cancer.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

- **Patients with advanced chronic kidney disease (eGFR <30 mL/min/1.73 m^2), including dialysis-dependent patients, 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 in these patients.**
- **Prior to initiating BOSAYA in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with BOSAYA in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.**

Please see Important Safety Information on page 22 and accompanying Full Prescribing Information.

CODING

This section lists some of the billing codes that may be appropriate to report services provided to patients undergoing treatment with Bosaya™ (denosumab-kyqq).

REPORTING USE OF BOSAYA

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

HCPCS Level II product codes are used to report FDA-approved biologic products assigned by the Centers for Medicare and Medicaid Services (CMS). The HCPCS code for BOSAYA is:

Table 1. HCPCS Code for BOSAYA[2]

Code	Description
Q5161*	SC injection, denosumab-kyqq (Bosaya), 1 mg

Each 1 mg dose of BOSAYA equals 1 billing unit, thus a 60 mg prefilled syringe of drug represents 60 units. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment. When coding for Q5161, report the total number of 1 mg increments administered.

*Effective April 1, 2026, CMS has approved pass-through payment for BOSAYA under the Outpatient Prospective Payment System (OPPS), which confers separate payment for 3 years when covered as an administered drug.

HCPCS Modifiers

CMS has established modifiers that must be reported on claims for drugs and biologics that meet the following criteria[3]:

- Furnished to a patient enrolled in fee-for-service (FFS) Medicare Part B
- Administered in the physician and hospital outpatient departments (HOPDs)
- Acquired via the 340B Drug Pricing Program

The following modifiers may be appropriate to bill along with the HCPCS code for BOSAYA for certain claims:

Table 2. Modifiers for BOSAYA[3]

Modifier	Description	Sites of Service
-TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	• Hospital outpatient
-JB	Administered subcutaneously	• Physician office • Hospital outpatient

National Drug Codes (NDCs)

The United States Food and Drug Administration (FDA) assigns approved medications a 3-segment number known as the NDC that is specific to the labeler (manufacturer), product (identifies a specific drug, strength, and dosage formulation), and package size.[4] Bosaya™ (denosumab-kyqq) has been assigned a 10-digit NDC as listed in the Prescribing Information.[1] The 11-digit format is required by HIPAA (the Health Insurance Portability and Accountability Act) for claims submission. It is typically reported on claims without hyphens or other punctuation marks and preceded by the qualifier "N4." Payers may also require the unit of measure (UoM) after the NDC, to include the qualifier "ML" and NDC quantity (eg, N4XXXXXXXXXX MLx)[4]:

Table 3. NDC for BOSAYA[1]

Product	10-Digit NDC	11-Digit NDC and UoM
BOSAYA (denosumab-kyqq) 60 mg/mL single-dose prefilled syringe	83257-029-41	83257-0029-41 eg, N483257002941 ML1

The NDC is critical in order for payers to identify BOSAYA as the medication administered. It should be reported on medical claims along with the most appropriate HCPCS code. The NDC location on the claim form may vary by payer.

Additional Identifying Information on Claims for Biologics

Submitting payer-specific information that is complete and accurate in the Comment or Remarks fields on the claim may facilitate timely coverage and reimbursement.

See Table 4 for the types of drug-identifying information that payers may request on claim forms for BOSAYA.

Table 4. Drug-Identifying Information for BOSAYA[1]

Type of Information	Specifics for BOSAYA
11-digit NDC and UoM	N483257002941 ML1
Drug name (brand/generic)	BOSAYA (denosumab-kyqq)
Dose/dosage	60 mg/mL
Route of administration	Subcutaneous injection

REPORTING DRUG ADMINISTRATION

If a treating healthcare professional decides to administer BOSAYA in a physician's office or hospital outpatient department, the injection is typically reported to a payer using a Current Procedural Terminology (CPT®)[5] or HCPCS code, such as the following:

Table 5. Possible CPT Codes for BOSAYA Subcutaneous Injection[5]

Code	Description	Sites of Service
96372	Therapeutic, prophylatic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	• Physician office • Hospital outpatient
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	

Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of BOSAYA.

Please see full Indications on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

REPORTING DIAGNOSIS

The medical necessity for treatment with Bosaya™ (denosumab-kyqq) is reported on physician and hospital claims with *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes.[6] ICD-10-CM diagnosis codes for cancer indications vary by type and anatomical location. ICD-10-CM codes have 3 to 7 digits and must be reported to the highest level of specificity. This means that if there is a fifth-digit option in the diagnosis category, the code must be reported out to the fifth digit. Allowable ICD-10-CM diagnosis code may vary by payer.

Table 6. Possible ICD-10-CM Diagnosis Codes for BOSAYA[6]

Code		Description
Cancer-Related Diagnosis	C61	Malignant neoplasm of prostate
Aromatase Inhibitor Therapy	Z79.811	Long-term (current) use of aromatase inhibitors
Androgen Deprivation Therapy	Z79.818*	Long-term (current) use or other agents affecting estrogen receptors and estrogen levels
Bone-Related Diagnosis†	M80.0_ _ _	Age-related osteoporosis with current pathologic fracture
	M80.8_ _ _	Other osteoporosis with current pathological fracture
	M81.0	Age-related osteoporosis without current pathologic fracture
	M81.8	Other osteoporosis without pathologic fracture
	M85.9‡	Disorder of bone density and structure, unspecified
	Z87.310	Personal history of healed osteoporosis fracture
	Z79.52	Long-term (current) use of systemic steroids

*Diagnosis code Z79.818 may be used for males receiving androgen deprivation therapy (eg, leuprolide acetate or goserelin acetate) for prostate cancer.
†For postmenopausal women and men with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.
‡Code M85.9 may apply for osteopenia.

These 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 BOSAYA. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

REPORTING REVENUE CODES

Revenue codes categorize hospital services by revenue center to capture cost data. Many payers require claims to include a revenue code for each service provided in the hospital. The following table shows sample revenue codes that may be relevant for BOSAYA and its administration in hospital outpatient departments.

Table 7. Sample Revenue Codes[7]

Code	Description	Appropriate Use
0250	Pharmacy, general	Use in combination with HCPCS drug code
0636	Drugs requiring detailed coding	
0940	Other therapeutic services, general	

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COVERAGE

IMPORTANCE OF BENEFITS VERIFICATION

Verifying a patient's health insurance plan coverage prior to receiving an injection of Bosaya™ (denosumab-kyqq) will identify coding requirements for the product and administration, coverage guidelines, and claims submission criteria.

With a typical response time of 3 business days, My Biocon Biologics:

- Verifies the patient's insurance benefits
- Prepares a detailed Summary of Benefits and shares it with the requester via fax

The Summary of Benefits provides details on:

- The patient's health plan eligibility
- Coverage for the biosimilar and its administration
- Acquisition options
- Prior authorization (PA) requirements
- The patient's out-of-pocket financial responsibility
- The patient's copay support as dictated by coverage and plan

My Biocon Biologics™

Contact My Biocon Biologics for assistance with benefits verification or other coverage and coding-related questions.

Monday-Friday
8 AM-8 PM ET

Call
1-833-612-4626

COVERAGE FOR MEDICARE

Medicare Part B Coverage

BOSAYA is covered under the Part B benefit when it is reasonable and medically necessary for the beneficiary and certain criteria are met.[8] It may be subject to coverage restrictions spelled out in local or national Medicare coverage guidance.

In general, Medicare coverage for drugs and biologics under the Part B benefit includes the following requirements[8]:

The drug or biologic must be furnished "incident to" a physician's service, meaning it must be furnished by a physician and administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. In addition, the charge for the product must be included in the physician's bill, representing an expense to the physician

The product must **meet the definition of a drug or biological**

The treatment must be **reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered**, according to accepted standards of medical practice

The product is **not usually self-administered**

The product must **be safe and effective**

REIMBURSEMENT

MEDICARE

Medicare provides separate payment for Part B-covered drugs and biologics in outpatient settings.

Physician Office

Medicare reimbursement for biosimilars administered in the physician's office is typically based on the average sales price (ASP) of the biosimilar + 6% of the reference product's ASP.[9] The reference product for Bosaya™ (denosumab-kyqq) is Prolia.[1] However, because BOSAYA is a newly approved product, its ASP will not be immediately available. Until ASP is established, reimbursement is based on 103% of BOSAYA's wholesale acquisition cost (WAC).[9]

Table 8. Medicare Reimbursement Methodology for a Part B-Covered Biosimilar in the Physician Office Setting[9,10]

At Launch and Until ASP Is Established	Once ASP Is Established
103% WAC of biosimilar	ASP of biosimilar + 6% of reference product's ASP

Hospital Outpatient Department

Medicare payment for Part B-covered biosimilars administered in hospital outpatient clinics varies based on multiple factors, including whether the biosimilar[11]:

- Has an established ASP
- Has temporary pass-through status
- Is acquired under the 340B Drug Pricing Program

Table 9. Medicare Reimbursement Methodology for a Part B-Covered Biosimilar in the Hospital Outpatient Setting[11,12]

At Launch and Until ASP Is Established	Once ASP Is Established
95% of biosimilar average wholesale price (AWP) or 103% of biosimilar WAC	ASP of biosimilar + 6% of reference product's ASP*

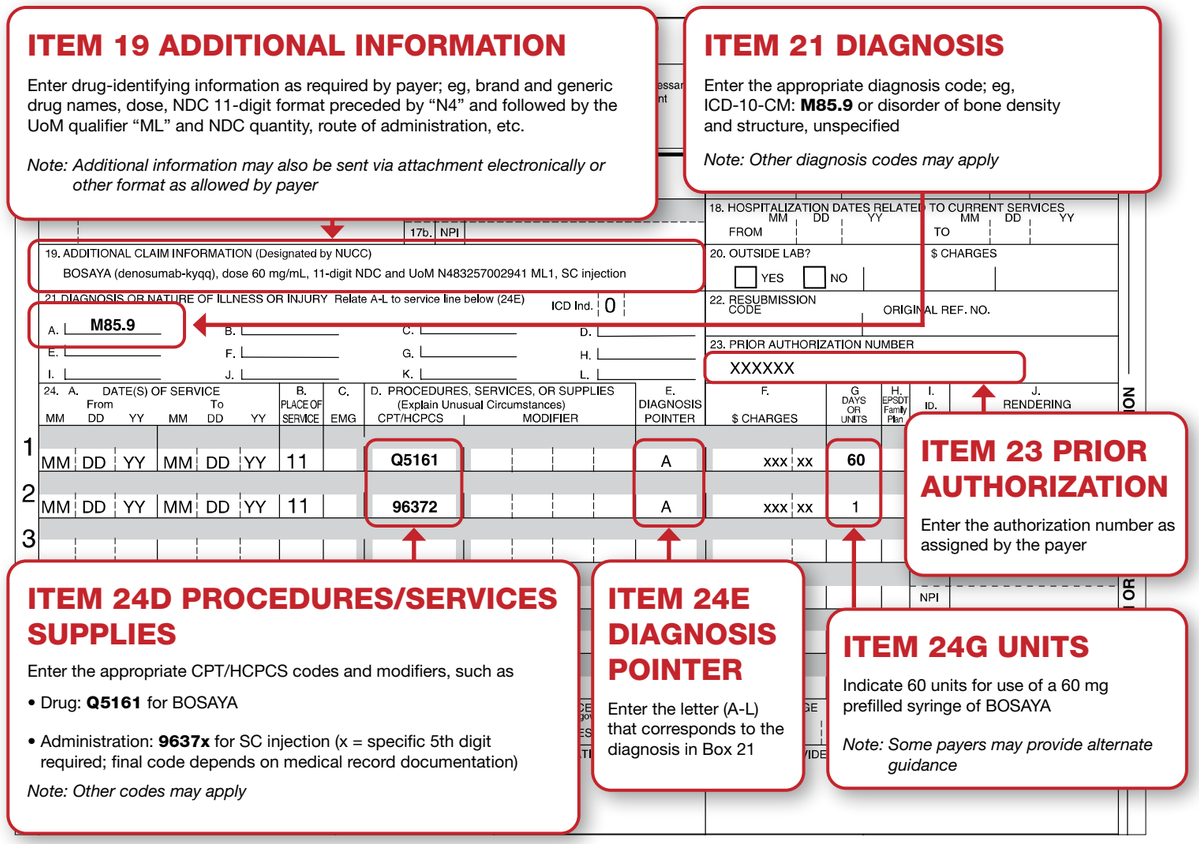
*Applies if product has temporary pass-through status. Medicare payment policies vary based on multiple factors.

For more information, please refer to the flashcard "Medicare Payment for Biosimilars in Outpatient Settings" or contact your My Biocon Biologics Field Reimbursement Specialist. You may also contact your Medicare Administrative Contractor for more information on Medicare policies that may affect reimbursement for BOSAYA.

CLAIMS

SAMPLE CMS-1500 CLAIM FORM

Products and services provided in the physician office setting are billed using the CMS-1500 claim form or the electronic claim file (837P). A sample CMS-1500 claim form for billing Bosaya™ (denosumab-kyqq) is provided below.



ITEM 19 ADDITIONAL INFORMATION

Enter drug-identifying information as required by payer; eg, brand and generic drug names, dose, NDC 11-digit format preceded by "N4" and followed by the UoM qualifier "ML" and NDC quantity, route of administration, etc.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payer

ITEM 21 DIAGNOSIS

Enter the appropriate diagnosis code; eg, ICD-10-CM: **M85.9** or disorder of bone density and structure, unspecified

Note: Other diagnosis codes may apply

ITEM 23 PRIOR AUTHORIZATION

Enter the authorization number as assigned by the payer

ITEM 24D PROCEDURES/SERVICES SUPPLIES

Enter the appropriate CPT/HCPCS codes and modifiers, such as

- Drug: **Q5161** for BOSAYA
- Administration: **9637x** for SC injection (x = specific 5th digit required; final code depends on medical record documentation)

Note: Other codes may apply

ITEM 24E DIAGNOSIS POINTER

Enter the letter (A-L) that corresponds to the diagnosis in Box 21

ITEM 24G UNITS

Indicate 60 units for use of a 60 mg prefilled syringe of BOSAYA

Note: Some payers may provide alternate guidance

The content provided on these sample claim forms 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 BOSAYA injection claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios, and Biocon Biologics does not guarantee BOSAYA coverage or reimbursement.

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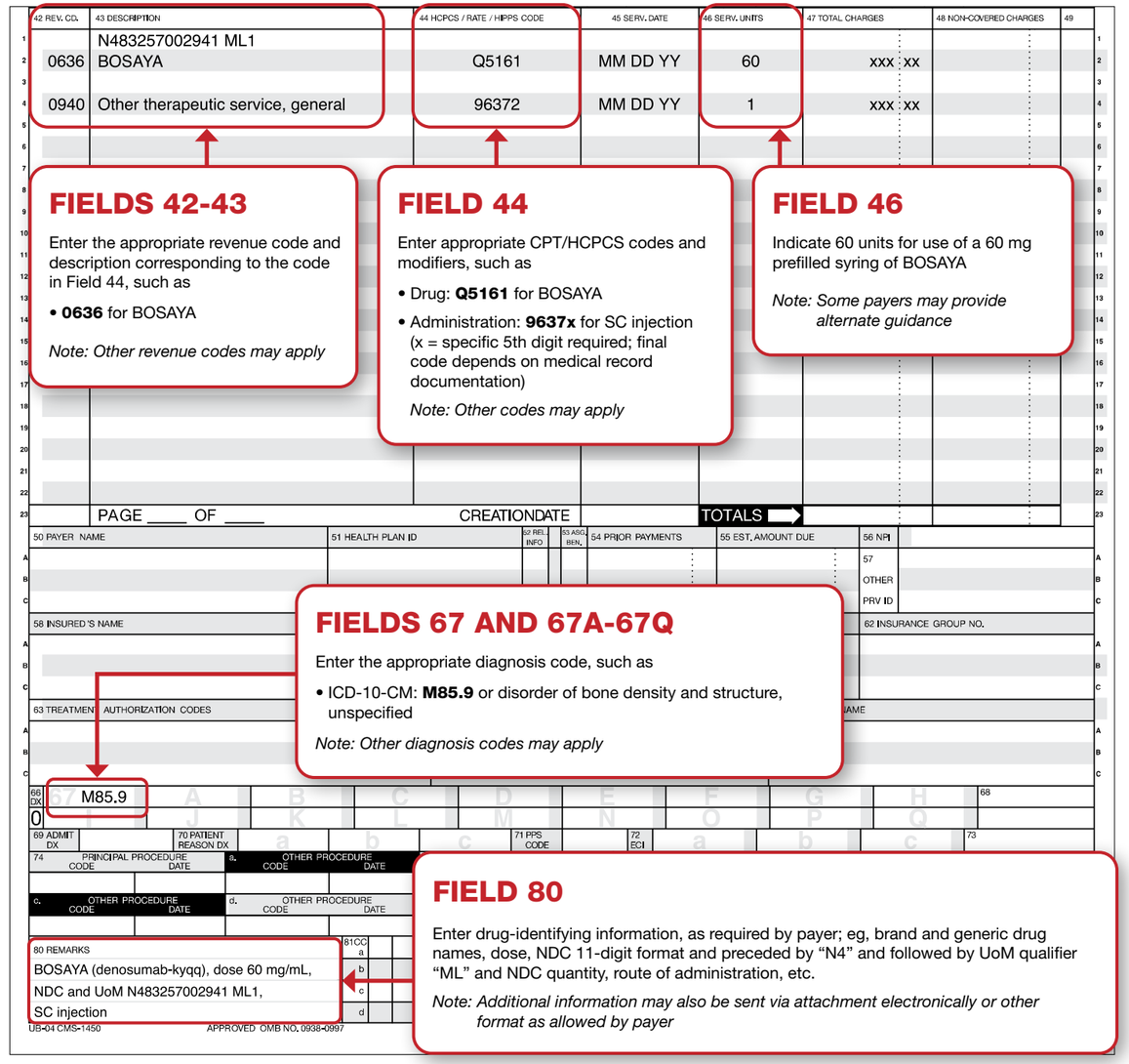
SAMPLE CMS-1450 (UB-04) CLAIM FORM

Products and services provided in the hospital outpatient facility are billed using the CMS-1450 institutional claim form or the electronic claim file (837I). A sample CMS-1450 claim form for billing BOSAYA administered to a Medicare patient is provided.



FIELDS 42-43

Enter the appropriate revenue code and description corresponding to the code in Field 44, such as

- **0636** for BOSAYA

Note: Other revenue codes may apply

FIELD 44

Enter appropriate CPT/HCPCS codes and modifiers, such as

- Drug: **Q5161** for BOSAYA
- Administration: **9637x** for SC injection (x = specific 5th digit required; final code depends on medical record documentation)

Note: Other codes may apply

FIELD 46

Indicate 60 units for use of a 60 mg prefilled syring of BOSAYA

Note: Some payers may provide alternate guidance

FIELDS 67 AND 67A-67Q

Enter the appropriate diagnosis code, such as

- ICD-10-CM: **M85.9** or disorder of bone density and structure, unspecified

Note: Other diagnosis codes may apply

FIELD 80

Enter drug-identifying information, as required by payer; eg, brand and generic drug names, dose, NDC 11-digit format and preceded by "N4" and followed by UoM qualifier "ML" and NDC quantity, route of administration, etc.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payer

Please see full Indications on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

CLEAN CLAIMS SUBMISSION

Submitting an error-free or "clean" claim that has all of the required information necessary may facilitate timely and accurate reimbursement for services rendered. The following are some considerations for preparing and submitting claims for Bosaya™ (denosumab-kyqq):

Include the correct patient/subscriber information Patient—name, date of birth, and member identification number; provider—provider name, identifier (tax identification number, National Provider Identifier, or other payer-specific identifier), clinic demographic information, and required signatures

Report all of the necessary payer-specific, drug-identifying information for BOSAYA (eg, correct codes, modifiers, units, NDC, brand and generic name, and dose)

Report a primary diagnosis code (and secondary code, if applicable) to the highest level of specificity

Include payer-specific required supplemental information (eg, letter of medical necessity, PA number, chart notes, laboratory tests)

When filing a claim electronically, stay within any payer-mandated character limits for completing the sections that correspond to Item 19 (CMS-1500) or Field 80 (CMS-1450)

File the claim within the payer's required time frame for submission

You may contact My Biocon Biologics for additional information about claims submissions.

SAMPLE LETTER OF MEDICAL NECESSITY

Payers may request a letter of medical necessity to support coverage for BOSAYA. The letter explains why the drug was medically necessary for the specific patient and may include supporting documentation. The letter may be submitted as part of a PA request, in tandem with the claim form, or in response to a payer's request for additional documentation.

The following is a sample letter of medical necessity; you may use another form or format. The letter should include patient-specific information, be on your letterhead, and be signed by the prescriber.

<Date>
<Contact Name> <Title>
<Name of Health Insurance Company>
<Address> <City, State Zip>

Insured: <Name>
Policy Number; <Number>
Group Number: <Number>

Dear <Contact's Name>:
I am writing on behalf of my patient, <name of patient>, to request that <name of health insurance company> approve coverage and appropriate reimbursement associated with <name of patient>'s treatment with BOSAYA (denosumab-kyqq), which is biosimilar to reference product Prolia. BOSAYA is approved by the FDA for <indication relevant to patient's diagnosis>.

Patient History and Diagnosis
<Name of patient> is a<n> <age>-year-old <indicate gender> born <MM-DD-YEAR> who was diagnosed on <date> with <patient's diagnosis>. <Provide a brief description of patient's symptoms, diagnostic test results, and therapy to date. Describe any surgical procedures, prior treatments, and underlying medical complications.>

Treatment Rationale and Plan
My planned course of treatment is <include detailed information such as regimen, dose, frequency, and duration of treatment, etc>. Based on the above facts, I am confident you will agree that BOSAYA is medically necessary for this patient. If you have any further questions, please call me at <physician's phone number (XXX) XXX-XXXX> to discuss. Thank you in advance for your prompt attention to this request.

Sincerely,

<Physician's name>
<Physician's practice name>
<Phone number>

Enclosures <supporting documentation, such as FDA approval letter and prescribing information, pathology and surgical reports, clinical notes, computerized tomography scans and other imaging reports, additional supporting documentation, as applicable>

APPEALS FOR DENIED CLAIMS

If a payer improperly reimburses or denies a claim for Bosaya™ (denosumab-kyqq), you may submit an appeal. Many claim denials occur because of incorrect codes, incorrect policy numbers, or missing supplemental documentation, such as a letter of medical necessity.

Many claims issues can be resolved with a single phone call to a payer representative who may be able to reprocess a corrected claim. If not, you may have to carefully craft an appeal letter.

This list offers considerations that may be helpful for appealing denied claims:

Determine the Payer's Process for Filing Appeals

- Use a designated form for the appeal if such a form is required by the payer
- Determine the timely filing limit

Understand the Reason for the Denial

- Read the explanation of benefits (EOB) to find the reason for the claim denial. Payers use remittance advice codes for the service in question. Remittance advice code descriptions are usually included at the bottom of the page
- If the payer needs additional information, compile and submit the necessary documentation as soon as possible
- If you receive a claim denial due to a lack of medical necessity, submit additional documentation that helps to support the physician's clinical decision to prescribe BOSAYA

Draft the Appeal Letter

- Make sure the appeal letter responds to the denial code reason
- Submit a corrected claim if the denial was due to a technical billing error (eg, incorrect patient identifier, missing diagnosis). Write "Corrected Copy" at the top
- Include a copy of the original claim and related denial notification (EOB)
- You may need to include the patient's relevant medical records, prescribing information, FDA approval letter, relevant compendia listings, or journal articles supporting the use of BOSAYA
- Request that an oncology specialist who is familiar with BOSAYA review the appeal letter and additional documentation

Submit and Track Appeal Status

- Submit the appeal as soon as possible and within the required time limits
- Track claims appeal responses to ensure appeals have been processed appropriately
- Document the result (eg, payment made or if further action is required)

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SAMPLE LETTER OF APPEAL

Payers may require a written appeal in cases where they have denied a claim. You may submit an appeal letter in response to a payer's decision for underpayment or nonpayment. Understanding the reason the payer denied the claim is critical for filing a successful appeal; this information can usually be found in the EOB or remittance advice. You may use the sample letter below or another form to appeal a denied claim for BOSAYA. If you use the sample letter here, be sure to customize it with patient-specific details and submit it with additional documentation, as requested by the payer.

<Date>
<Contact Name> <Title>
<Name of Health Insurance Company>
<Address> <City, State Zip>

Insured: <Name>
Policy Number; <Number>
Group Number: <Number>
Claim Control Number: <Number>

Dear <Contact's Name>:

This letter serves as a request for reconsideration for payment of a denied claim representing charges for BOSAYA (denosumab-kyqq), a biosimilar to reference product Prolia, which was administered to <name of patient> on <date(s) of service>. <Name of patient> is a<n> <age>-year-old <indicate gender> born <MM-DD-YEAR> who has been under my care for <his/her/their> diagnosis of <patient's diagnosis>. You have indicated that BOSAYA is not covered by <insurance name> because <reason for denial>.

<Provide a brief description of patient's symptoms and therapy to date, and any other pertinent information.>

Treatment with BOSAYA has resulted in <list documented outcomes> for this patient. BOSAYA is approved by the FDA for <indication relevant to patient's diagnosis>.BOSAYA has been administered to <name of patient> per the FDA-approved prescribing information dosing instructions.

BOSAYA is a medically necessary part of <name of patient>'s treatment. I request that an oncology specialist who is familiar with BOSAYA review this appeal letter with the additional enclosed documentation, as I am confident your reconsideration of this claim will yield appropriate coverage for my patient. Please contact me at <physician's phone number (XXX) XXX-XXXX> if you require additional information. Thank you in advance for your prompt attention to this request.

Sincerely,

<Physician's name>
<Physician's practice name>
<Phone number>

Enclosures <supporting documentation, such as FDA approval letter and prescribing information, pathology and surgical reports, clinical notes, computerized tomography scans and other imaging reports, additional supporting documentation, as applicable>

Please see full Indications on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

- **Patients with advanced chronic kidney disease (eGFR <30 mL/min/1.73 m^2), including dialysis-dependent patients, 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 in these patients.**
- **Prior to initiating BOSAYA in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with BOSAYA in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.**

CONTRAINDICATIONS

- **Patients with hypocalcemia:** pre-existing hypocalcemia must be corrected prior to initiating therapy.
- **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.
- **Patients with hypersensitivity to denosumab products:** BOSAYA 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. Pre-existing hypocalcemia must be corrected prior to initiating therapy with BOSAYA. 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 BOSAYA 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/1.73m^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.
  - 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 BOSAYA 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 BOSAYA 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 BOSAYA 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 BOSAYA 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 BOSAYA.

Osteonecrosis of the Jaw (ONJ)

- ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing and has been reported in patients receiving denosumab products. An oral exam should be performed by the prescriber prior to initiation of BOSAYA. A dental examination with appropriate preventive dentistry is recommended prior to treatment 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 BOSAYA. 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 should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of BOSAYA 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 BOSAYA 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 evaluated to rule out an incomplete femur fracture. Patients presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of BOSAYA therapy should be considered, pending a risk-benefit assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

- 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 BOSAYA. If BOSAYA 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 BOSAYA, prescribers should assess the need for continued therapy with BOSAYA.

Dermatologic Adverse Reactions

- In a clinical trial of over 7800 women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema, and rashes occurred at a significantly higher rate in the denosumab group compared to the placebo group. Most of these events were not specific to the injection site. Consider discontinuing BOSAYA if severe symptoms develop.

Musculoskeletal Pain

- Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking denosumab products. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover

- In clinical trials in women with postmenopausal osteoporosis, treatment with denosumab resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment with denosumab products are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta

- BOSAYA is not approved for use in pediatric patients. Hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated with denosumab products. Some cases required hospitalization.

ADVERSE REACTIONS

- The most common adverse reactions (>5% and more common than placebo) reported with denosumab products in patients with postmenopausal osteoporosis were back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. The most common adverse reactions (>5% and more common than placebo) reported with denosumab products in men with osteoporosis were back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with denosumab. The most common adverse reactions leading to discontinuation of denosumab products in patients with postmenopausal osteoporosis were back pain and constipation.
- The overall incidence of new malignancies in postmenopausal women with osteoporosis was 4.3% in the placebo group and 4.8% in the denosumab group, and in men with osteoporosis, no patients in the placebo group and 3.3% in the denosumab group. A causal relationship to drug exposure has not been established.
- The most common adverse reactions (>3% and more common than active control) reported with denosumab products in patients with glucocorticoid-induced osteoporosis were back pain, hypertension, bronchitis, and headache. The most common adverse reactions (≥10% and more common than placebo) reported with denosumab products in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer were arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in denosumab-treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

INDICATIONS

BOSAYA (denosumab-kyqq) is indicated:

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, denosumab reduces the incidence of vertebral, nonvertebral, and hip fractures.
- For treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- For the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer. In these patients denosumab also reduced the incidence of vertebral fractures.
- As a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor (AI) therapy for breast cancer.

My Biocon Biologics™

My Biocon Biologics™ provides patient access support and can assist with patient-specific verification of benefits for Bosaya™ (denosumab-kyqq). For assistance:

Monday-Friday
8 AM-8 PM ET

Call
1-833-612-4626

REFERENCES

1. BOSAYA. Prescribing information. Biocon Biologics Inc; 2025. **2.** American Medical Association. *HCPCS Level II: Professional 2025*. American Medical Association; 2025. **3.** Centers for Medicare & Medicaid Services. Part B hospital (including inpatient hospital Part B and OPPS). In: *Medicare Claims Processing Manual*. Chapter 4. Revised November 14, 2024. Accessed November 12, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf **4.** Rahjou-Esfandiary L; US Food and Drug Administration. Future format of the National Drug Code. September 12, 2024. Accessed December 2, 2025. https://www.fda.gov/media/184345/download **5.** American Medical Association. *CPT® 2025: Professional Edition*. American Medical Association; 2024. **6.** US Centers for Disease Control and Prevention. ICD-10-CM tabular list of diseases and injuries. April 1, 2022. Accessed November 12, 2025. https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf **7.** Noridian Healthcare Solutions. Revenue codes. Updated March 18, 2024. Accessed November 12, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **8.** Centers for Medicare and Medicaid Services. Covered medical and other health services. In: *Medicare Benefit Policy Manual*. Chapter 15: section 50.0, section 60.1. Revised October 4, 2024. Accessed November 12, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf **9.** Health and Human Services; Centers for Medicare & Medicaid Services. Medicare program; CY 2021 payment policies under the physician fee schedule and other changes to Part B payment policies; Medicare shared savings program requirements. *Fed Regist*. 2020;85(248):84688-84689. December 28, 2020. Accessed November 12, 2025. https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf **10.** Health and Human Services; Centers for Medicare & Medicaid Services. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2018; Medicare shared savings program requirements; Medicare diabetes prevention program. *Fed Regist*. 2017;82(219):53182-53187. November 15, 2017. Accessed November 12, 2025. https://www.gpo.gov/fdsys/pkg/FR-2017-11-15/pdf/2017-23953.pdf **11.** Health and Human Services; Centers for Medicare & Medicaid Services. Medicare program: hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. CMS-1736-FC. *Fed Regist*. 2020;85(249):85866. December 29, 2020. Accessed November 12, 2025. https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf **12.** Centers for Medicare & Medicaid Services. MLN Matters. January 2021 update of the hospital outpatient prospective payment system (OPPS): drugs and biologicals with payments based on average sales price (ASP). Publication MM12120. January 2021:11. Accessed November 12, 2025. https://www.cms.gov/files/document/mm12120.pdf

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