Aukelso™
(denosumab-kyqq)

CODING & BILLING GUIDE

For Aukelso™ (denosumab-kyqq) Injection

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

Aukelso™
(denosumab-kyqq)

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OVERVIEW

PURPOSE OF THIS GUIDE

This Coding and Billing Guide for Aukelso™ (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 AUKELSO at a physician office. AUKELSO is a biosimilar to Xgeva® (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 AUKELSO 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 AUKELSO. 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.

INDICATIONS AND USAGE[1]

- 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.

HOW SUPPLIED[1]

AUKELSO is available as a 120 mg/1.7 mL solution in a single-dose vial.

CODING

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

REPORTING USE OF AUKELSO

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 AUKELSO is:

Table 1. HCPCS Code for AUKELSO[2]

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

Each 1 mg dose of AUKELSO equals 1 billing unit, thus a 120 mg vial of drug represents 120 units of Q5161. 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.

Reporting Discarded Medication (Wastage)

Payers typically cover and pay for both the amount of medication that is administered to a patient and the amount of discarded drug or biologic, called wastage, that is left over from a single-use vial.[3] The amount of medication that was administered to the patient and the amount that was discarded should be documented in the Comment field (Item 19) of the CMS-1500 claim form or Remarks section (Field 80) of the CMS-1450 claim form (or their electronic equivalents). These amounts should also be documented in the patient's medical record. See Table 2 for Medicare Modifiers.

HCPCS Modifiers

CMS has established modifiers that must be reported on claims for drugs and biologics that meet the following criteria[3,4]:

- 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 AUKELSO for certain claims:

Table 2. Modifiers for AUKELSO[3,4]

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
-JW	Drug amount discarded/not administered to any patient	• Physician office • Hospital outpatient
-JZ	Zero drug amount discarded/not administered to any patient	
-JB	Administered subcutaneously	

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.[5] Aukelso™ (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)[5]:

Table 3. NDC for AUKELSO[1]

Product	10-Digit NDC	11-Digit NDC and UoM
AUKELSO (denosumab-kyqq) 120 mg/1.7 mL single-dose vial	83257-030-11	83257-0030-11 eg, N483257003011 ML1.7

The NDC is critical in order for payers to identify AUKELSO 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 AUKELSO.

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

Type of Information	Specifics for AUKELSO
11-digit NDC and UoM	N483257003011 ML1.7
Drug name (brand/generic)	AUKELSO (denosumab-kyqq)
Dose/dosage	XX mg/kg
Amount administered vs discarded	XX mg administered and XX mg discarded from a 120 mg/1.7 mL single-dose vial
Route of administration	Subcutaneous injection

REPORTING DRUG ADMINISTRATION

If a treating healthcare professional decides to administer AUKELSO in a physician's office or hospital outpatient department, the injection is typically reported to a payer using a Current Procedural Terminology (CPT®)[6] or HCPCS code, such as the following:

Table 5. Possible CPT Codes for AUKELSO Subcutaneous Injection[6]

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 AUKELSO.

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 Aukelso™ (denosumab-kyqq) is reported on physician and hospital claims with *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes.[7] 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 AUKELSO[7]

Code		Description
Bone metastases from solid tumors*	C79.51	Secondary malignant neoplasm of bone
Multiple myeloma	C90.00	Multiple myeloma not having achieved remission
	C90.01	Multiple myeloma in remission
	C90.02	Multiple myeloma in relapse
Unresectable giant cell tumor of bone	D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
Hypercalcemia of malignancy refractory to bisphosphonate therapy†	E83.52	Hypercalcemia

*Include both primary solid tumor ICD-10-CM code along with the bone metastatic site code.

†For patients receiving treatment for hypercalcemia of malignancy, payers may also require to document the diagnosis code describing the malignancy; however, specific coding requirements may vary by payer.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

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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 AUKELSO and its administration in hospital outpatient departments.

Table 7. Sample Revenue Codes[8]

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

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

COVERAGE

IMPORTANCE OF BENEFITS VERIFICATION

Verifying a patient's health insurance plan coverage prior to receiving an injection of Aukelso™ (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

AUKELSO is covered under the Part B benefit when it is reasonable and medically necessary for the beneficiary and certain criteria are met.[9] 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[9]:

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.[10] The reference product for Aukelso™ (denosumab-kyqq) is Xgeva.[1] However, because AUKELSO is a newly approved product, its ASP will not be immediately available. Until ASP is established, reimbursement is based on 103% of AUKELSO's wholesale acquisition cost (WAC).[10]

Table 8. Medicare Reimbursement Methodology for a Part B-Covered Biosimilar in the Physician Office Setting[10,11]

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[12]:

- 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[12,13]

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*

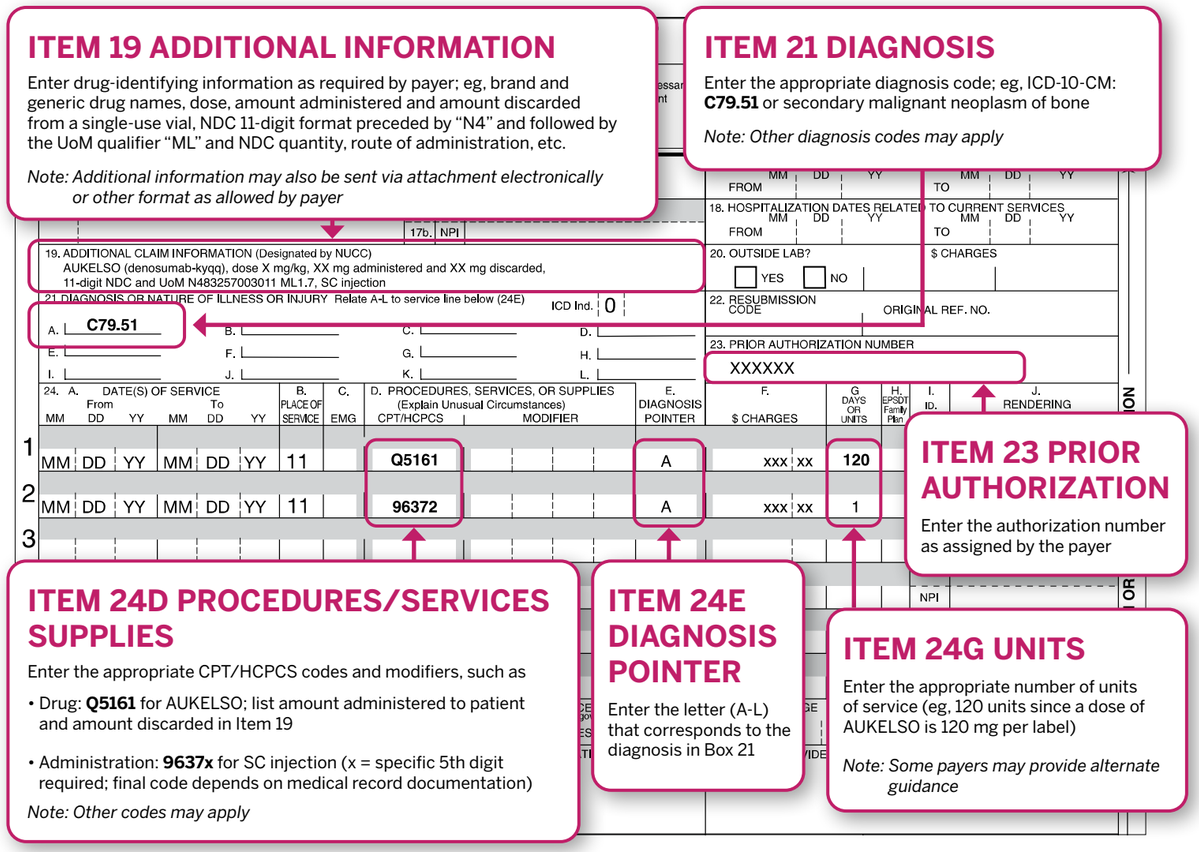
*Applies if product has temporary pass-through status. Medicare payment policies vary based on multiple factors.

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 AUKELSO.

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 Aukelso™ (denosumab-kyqq) is provided below.



ITEM 19 ADDITIONAL INFORMATION

Enter drug-identifying information as required by payer; eg, brand and generic drug names, dose, amount administered and amount discarded from a single-use vial, 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: **C79.51** or secondary malignant neoplasm of bone

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 AUKELSO; list amount administered to patient and amount discarded in Item 19
- 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

Enter the appropriate number of units of service (eg, 120 units since a dose of AUKELSO is 120 mg per label)

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 AUKELSO 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 AUKELSO coverage or reimbursement.

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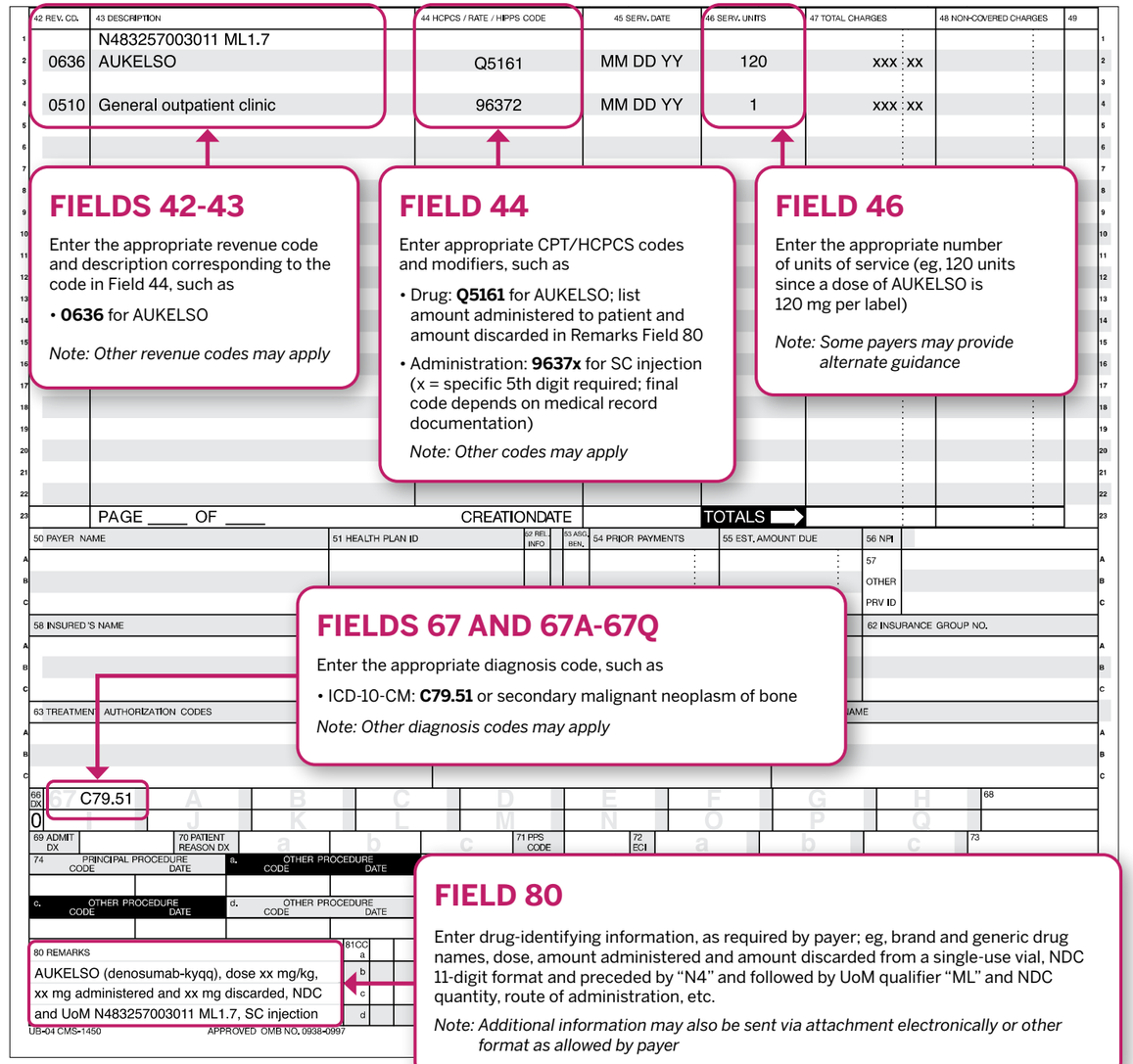
SAMPLE CMS-1450 (UB-04) CLAIM FORM

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 AUKELSO 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 AUKELSO

Note: Other revenue codes may apply

FIELD 44

Enter appropriate CPT/HCPCS codes and modifiers, such as

- Drug: **Q5161** for AUKELSO; list amount administered to patient and amount discarded in Remarks Field 80
- Administration: **9637x** for SC injection (x = specific 5th digit required; final code depends on medical record documentation)

Note: Other codes may apply

FIELD 46

Enter the appropriate number of units of service (eg, 120 units since a dose of AUKELSO is 120 mg per label)

Note: Some payers may provide alternate guidance

FIELDS 67 AND 67A-67Q

Enter the appropriate diagnosis code, such as

- ICD-10-CM: **C79.51** or secondary malignant neoplasm of bone

Note: Other diagnosis codes may apply

FIELD 80

Enter drug-identifying information, as required by payer; eg, brand and generic drug names, dose, amount administered and amount discarded from a single-use vial, 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 Aukelso™ (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 AUKELSO (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 AUKELSO. 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 AUKELSO (denosumab-kyqq), which is biosimilar to reference product Xgeva. AUKELSO 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 AUKELSO 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 Aukelso™ (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 AUKELSO

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 AUKELSO
- Request that an oncology specialist who is familiar with AUKELSO 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 AUKELSO. 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 AUKELSO (denosumab-kyqq), a biosimilar to reference product Xgeva, 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 AUKELSO 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 AUKELSO has resulted in <list documented outcomes> for this patient. AUKELSO is approved by the FDA for <indication relevant to patient's diagnosis>. AUKELSO has been administered to <name of patient> per the FDA-approved prescribing information dosing instructions.

AUKELSO is a medically necessary part of <name of patient>'s treatment. I request that an oncology specialist who is familiar with AUKELSO 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

CONTRAINDICATIONS

Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with AUKELSO.

Hypersensitivity: AUKELSO is contraindicated in patients with known clinically significant hypersensitivity to denosumab products.

WARNINGS AND PRECAUTIONS

Drug Products with Same Active Ingredient
Patients receiving AUKELSO 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 AUKELSO therapy permanently.

Hypocalcemia
Denosumab products can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Correct pre-existing hypocalcemia prior to AUKELSO treatment. Monitor calcium levels, throughout AUKELSO 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 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. Risk factors include a history of tooth extraction, poor oral hygiene, or use of a dental appliance. Other risk factors include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections, and a history of invasive dental procedures for denosumab-treated patients with multiple myeloma.

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

Patients who are suspected of having or who develop ONJ while on AUKELSO should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery 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.

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

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 AUKELSO 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.

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

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥25%) 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 of denosumab were osteonecrosis and hypocalcemia.

The most common adverse reactions in patients receiving denosumab with multiple myeloma (incidence ≥10%) were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction (incidence ≥5%) was pneumonia. The most common adverse reaction resulting in discontinuation of denosumab (≥1.0%) was osteonecrosis of the jaw.

The most common adverse reactions in patients receiving denosumab with giant cell tumor of bone (incidence ≥10%) 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 (3.6%), bone giant cell tumor (1.5%), anemia (1.1%), pneumonia (0.9%), and back pain (0.9%). The most frequent adverse reactions resulting in discontinuation of denosumab was osteonecrosis of the jaw (incidence of 3.6%). The adverse reaction profile appeared similar in skeletally mature adolescents and adults.

Adverse reactions occurring in >20% of patients receiving denosumab 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 (3%) and infection (6%). Grade 3 laboratory abnormalities included hypomagnesemia (3%), hypokalemia (3%), and hypophosphatemia (76%) of patients. No deaths on-study were related to denosumab therapy.

INDICATIONS

AUKELSO (denosumab-kyqq) 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.

My Biocon Biologics™

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

Monday-Friday
8 AM-8 PM ET

Call
1-833-612-4626

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