JUBEREQ®
(denosumab-desu) injection
120 mg/1.7 mL

JUBEREQ Billing and Coding Guide

HCPCS Code: Q5166

The **interchangeable biosimilar** to XGEVA® (denosumab) from Accord BioPharma

Accord BioPharma, Inc. developed this guide to assist healthcare providers (HCPs) and staff with coding, billing, and reimbursement for JUBEREQ when administered in the HCP's office or hospital outpatient department (HOPD). The details in this guide are for informational purposes only. Accord BioPharma, Inc. does not guarantee reimbursement for JUBEREQ. It is the sole responsibility of the HCPs to ensure the reported codes are accurate, complete, and supported by medical record documentation.

Please see Important Safety Information and Indication on pages 3-5 and for the JUBEREQ full Prescribing Information, visit https://www.accordbiopharma.com/our-therapies/jubereq/jubereq_pi.pdf.

HS-JUB-2600001

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Please see Important Safety Information on pages 3-5 and scan to see the JUBEREQ full Prescribing Information.

INDICATIONS

JUBEREQ is a RANK ligand (RANKL) inhibitor 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: JUBEREQ is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy. JUBEREQ is contraindicated in patients with known clinically significant hypersensitivity to denosumab products.

Same Active Ingredient: Patients receiving JUBEREQ should not receive other denosumab products concomitantly.

Hypersensitivity: Clinically significant hypersensitivity including anaphylaxis has been reported with 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 JUBEREQ therapy permanently.

Hypocalcemia: Severe symptomatic hypocalcemia and fatal cases have been reported. Correct pre-existing hypocalcemia prior to JUBEREQ treatment, and fatal cases have been reported. Monitor calcium levels throughout therapy, especially in the first weeks, 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.

Increased risk of hypocalcemia has been observed in patients with renal dysfunction, most commonly with severe dysfunction CrCl (<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 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 the incidence of ONJ was higher with longer duration of exposure.

Predisposing factors for developing ONJ include a history of tooth extraction, poor oral hygiene, and use of a dental appliance. Other risk factors include immunosuppressive therapy, use of angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.

IMPORTANT SAFETY INFORMATION (cont'd)

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

Patients who are suspected of having or who develop ONJ while on JUBEREQ 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 Fractures: Atypical femoral fractures have 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.

During JUBEREQ treatment, advise patients 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 JUBEREQ therapy should be considered, pending a risk/benefit assessment.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone 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 giant cell tumor of bone and patients with growing skeletons within one year of treatment discontinuation. Monitor for signs and symptoms of hypercalcemia after treatment discontinuation and treat appropriately.

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 JUBEREQ treatment is discontinued, evaluate the patient's risk for vertebral fractures.

Embryo-Fetal Toxicity: JUBEREQ can cause fetal harm when administered to a pregnant woman. Based on data from animal studies and its mechanism of action, JUBEREQ is expected to result in adverse reproductive effects.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

Most Common Adverse Reactions:

- **Bone Metastasis from Solid Tumors:** Greater than or equal to 25%: fatigue/asthenia, hypophosphatemia, and nausea.
- **Multiple Myeloma:** Greater than or equal to 10%: diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- **Giant Cell Tumor of Bone:** Greater than or equal to 10%: arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- **Hypercalcemia of Malignancy:** Greater than 20%: nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

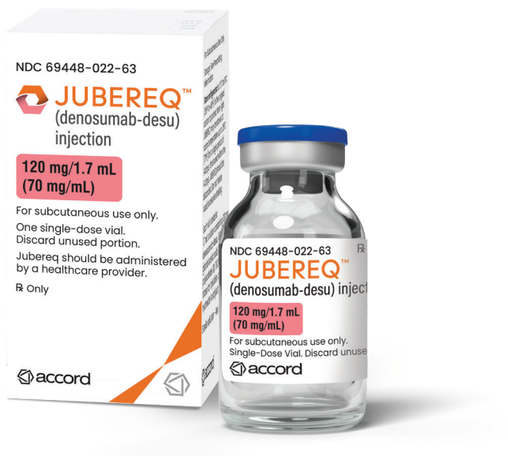
To report SUSPECTED ADVERSE REACTIONS, contact Accord BioPharma Inc at 1-866-941-7875 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

JUBEREQ (denosumab-desu) injection is supplied in a 120 mg/1.7 mL (70 mg/mL) single-dose vial.

XGEVA® (denosumab) is a registered trademark of Amgen Inc.

AVAILABLE FORM OF JUBEREQ[1]

JUBEREQ (denosumab-desu) injection is supplied in a 120 mg/1.7 mL (70 mg/mL) single-dose vial



DOSING AND ADMINISTRATION[1]

JUBEREQ should be administered by an HCP.

JUBEREQ is intended for subcutaneous route only and should not be administered intravenously, intramuscularly, or intradermally. JUBEREQ is typically administered subcutaneously in the upper arm, upper thigh, or abdomen.

Indication	Dose	Dosing Schedule
Multiple Myeloma and Bone Metastasis From Solid Tumors	120 mg	Every 4 weeks as a subcutaneous injection
Giant Cell Tumor of Bone	120 mg	Every 4 weeks with additional 120 mg doses on days 8 and 15 of the first month of therapy
Hypercalcemia of Malignancy	120 mg	Every 4 weeks with additional 120 mg doses on days 8 and 15 of the first month of therapy

Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia.

Please see Important Safety Information on pages 3-5 and scan to see the JUBEREQ full Prescribing Information.

CODING AND BILLING BY SITE OF CARE

The following section provides coding and billing guidance for JUBEREQ administered in an HCP's office or in a hospital outpatient department (HOPD). **Because coding and billing requirements for JUBEREQ may vary, it is important to verify individual payer policy requirements.**

ICD-10-CM CODES[2]

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set should be used, as appropriate, to report the patient-specific diagnosis. Reporting the medical necessity for JUBEREQ may require a primary and secondary diagnosis. HCPs should verify payer-specific coding requirements before submitting a claim, including the order of required codes (eg, primary, secondary), as these may vary by payer. ICD-10-CM codes may include, but are not limited to, the codes listed below:

ICD-10-CM Code*	Description
C90.00, C90.01, C90.02	Multiple myeloma not having achieved remission (00); Multiple myeloma in remission (01); Multiple myeloma in relapse (02)
C79.51	Secondary malignant neoplasm of bone
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
E83.52	Hypercalcemia

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

Please see Important Safety Information on pages 3-5 and scan to see the JUBEREQ full Prescribing Information.

BILLING UNITS AND NDCs

JUBEREQ BILLING UNITS

JUBEREQ HCPCS code Q5166 is described as "injection, denosumab-desu (JUBEREQ), biosimilar, 1 mg"

Billing Units: 1 mg = 1 unit; 120 mg dose = 120 units.

NDCs

For reimbursement purposes, some payers may require the HCP to include NDCs on the claim form. For claims-reporting purposes, some payers may also require HCPs to convert the 10-digit NDC to an 11-digit NDC by adding a "0" (zero) where appropriate to create a 5-4-2 configuration. See placement of the zero in the example below.

NDCs for JUBEREQ		
FDA-Specified 10-Digit NDC (5-3-2 format)[1]	11-Digit NDC (5-4-2 format)[3]	Description[1]
69448-022-63	69448-0022-63	Single-Dose 120 mg Vial

HCPCS CODE[4]

In an HCP's office and HOPD sites of care, Medicare, Medicaid, and private commercial payers typically recognize the following HCPCS codes for reporting JUBEREQ and its administration on claim forms. Effective for dates of service on and after July 1, 2026, HCPCS code Q5166 may be used to report JUBEREQ.

Code	Description
Q5166	Injection, denosumab-desu (JUBEREQ), biosimilar, 1 mg

Modifiers may be included on claims to provide additional information.

JW/JZ Modifiers: For the JUBEREQ single-dose vial, the JW modifier is used to report the drug amount discarded/not administered to any patient. The JZ modifier is used to indicate that no drug was discarded. For Medicare and some payers, the unused amount should be reported on a separate line of the claim form, and the claim should include the drug code, modifier, and number of units discarded.[5] Additional modifiers may also be considered appropriate when submitting claims.

TB Modifiers: Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifier TB (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program.[6]

Modifier Code	Description
JW[5]	Drug amount discarded/not administered to any patient
JZ[5]	Zero drug amount discarded/not administered to any patient
TB[6]	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities

CPT CODES[7]

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by HCPs. The following codes may be considered to report the administration of JUBEREQ.

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

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

REVENUE CODES[8]

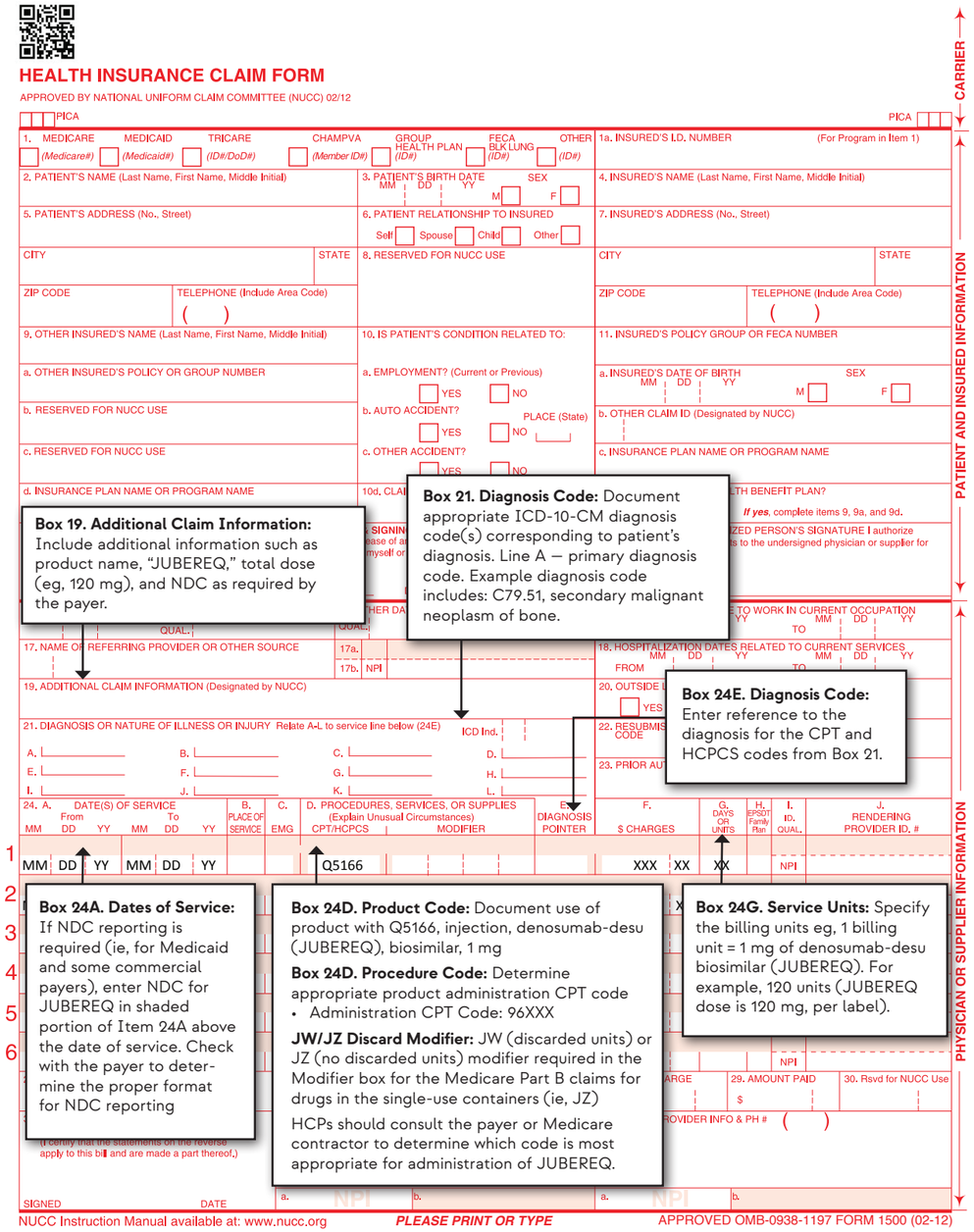
HOPDs use revenue codes to report specific accommodations and/or ancillary charges.

Code	Description
0636	Medicare: Drugs requiring detailed coding
0250	General pharmacy
0510	Clinic—general classification

Please see Important Safety Information on pages 3-5 and scan to see the JUBEREQ full Prescribing Information.

SAMPLE CLAIM FORM

SAMPLE CMS-1500, HCP OFFICE SITE OF SERVICE[9]



Box 19. Additional Claim Information: Include additional information such as product name, "JUBEREQ," total dose (eg, 120 mg), and NDC as required by the payer.

Box 21. Diagnosis Code: Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A – primary diagnosis code. Example diagnosis code includes: C79.51, secondary malignant neoplasm of bone.

Box 24E. Diagnosis Code: Enter reference to the diagnosis for the CPT and HCPCS codes from Box 21.

Box 24A. Dates of Service: If NDC reporting is required (ie, for Medicaid and some commercial payers), enter NDC for JUBEREQ in shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting

Box 24D. Product Code: Document use of product with Q5156, injection, denosumab-desu (JUBEREQ), biosimilar, 1 mg

Box 24D. Procedure Code: Determine appropriate product administration CPT code
- Administration CPT Code: 96XXX

JW/JZ Discard Modifier: JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for the Medicare Part B claims for drugs in the single-use containers (ie, JZ)

HCPs should consult the payer or Medicare contractor to determine which code is most appropriate for administration of JUBEREQ.

Box 24G. Service Units: Specify the billing units eg, 1 billing unit = 1 mg of denosumab-desu biosimilar (JUBEREQ). For example, 120 units (JUBEREQ dose is 120 mg, per label).

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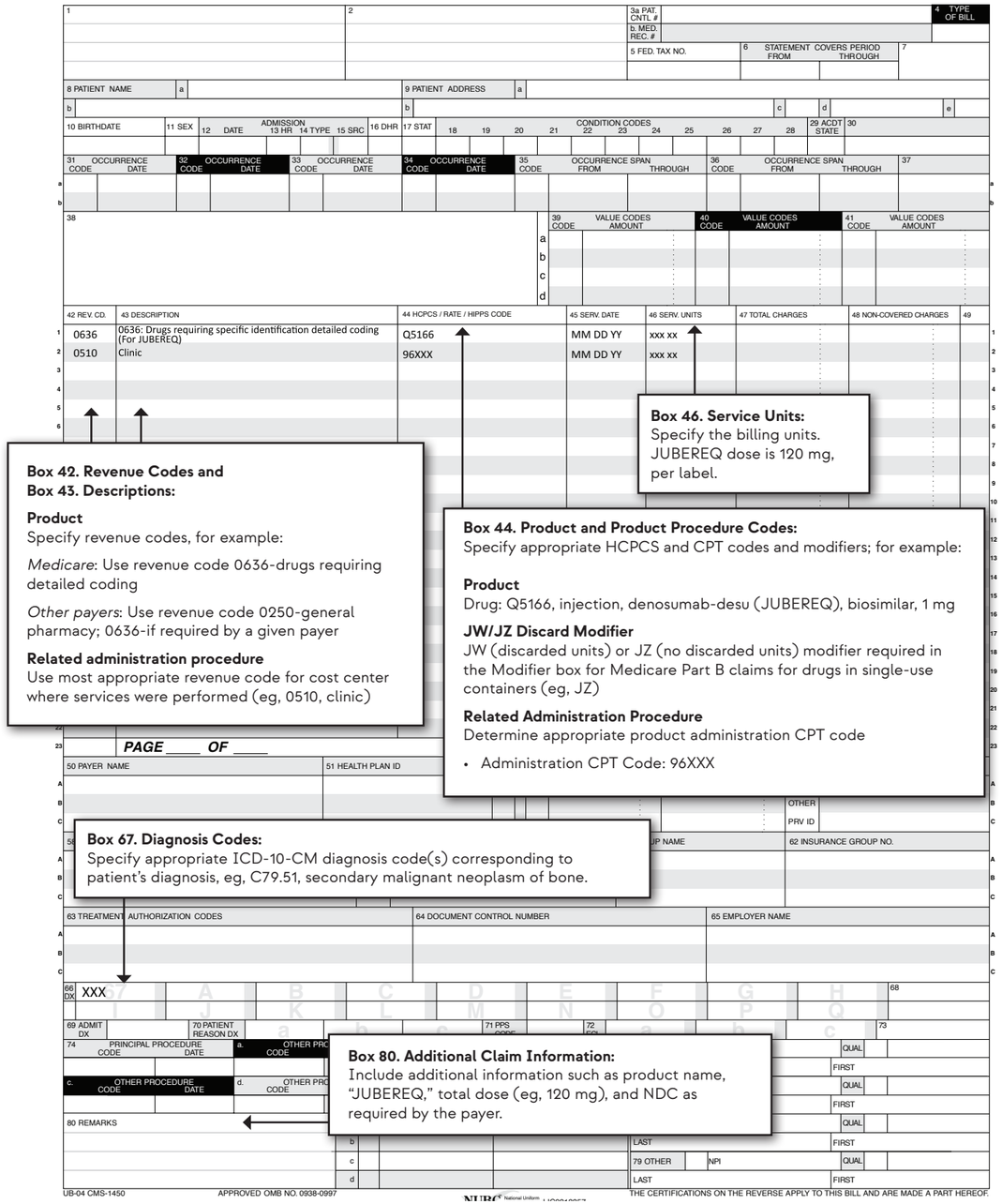
SAMPLE CLAIM FORM

SAMPLE CMS 1450, HOSPITAL OUTPATIENT SITE OF SERVICE[10,11]



Box 42. Revenue Codes and Box 43. Descriptions:

Product
Specify revenue codes, for example:

Medicare: Use revenue code 0636-drugs requiring detailed coding

Other payers: Use revenue code 0250-general pharmacy; 0636-if required by a given payer

Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic)

Box 46. Service Units: Specify the billing units. JUBEREQ dose is 120 mg, per label.

Box 44. Product and Product Procedure Codes: Specify appropriate HCPCS and CPT codes and modifiers; for example:

Product
Drug: Q5166, injection, denosumab-desu (JUBEREQ), biosimilar, 1 mg

JW/JZ Discard Modifier
JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (eg, JZ)

Related Administration Procedure
Determine appropriate product administration CPT code
- Administration CPT Code: 96XXX

Box 67. Diagnosis Codes: Specify appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, C79.51, secondary malignant neoplasm of bone.

Box 80. Additional Claim Information: Include additional information such as product name, "JUBEREQ," total dose (eg, 120 mg), and NDC as required by the payer.

ACCORDCARES® PATIENT SUPPORT SERVICES

Accord BioPharma is committed to helping patients gain access to the medicines they need. Key offerings available for eligible patients through the AccordCares program include:

- **Co-pay Assistance**
- **Patient Assistance**
- **Benefits Investigation**
- **Prior Authorization**
- **Billing and Coding Information**
- **Alternate Coverage Identification**

An AccordCares associate can be reached Monday through Friday, 8 AM to 8 PM ET at:

PHONE: 1-866-258-7151

FAX: 1-855-558-6304

Or by mail at PO Box 4485, Chesterfield, MO 63006

accord Cares®

REFERENCES

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