OSVYRTI®
(denosumab-desu) injection
60 mg/mL

OSVYRTI Billing and Coding Guide

HCPCS Code: Q5166

Accord BioPharma, Inc. developed this guide to assist healthcare providers (HCPs) and staff with coding, billing, and reimbursement for OSVYRTI 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 OSVYRTI. 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 OSVYRTI full Prescribing Information including Boxed Warning, visit https://www.accordbiopharma.com/our-therapies/osvyrti/osvyrti_pi.pdf.

HS-OSV-2600001

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INDICATIONS

OSVYRTI is a RANK ligand (RANKL) inhibitor indicated for treatment:

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

BOXED WARNING AND ADDITIONAL IMPORTANT SAFETY INFORMATION

BOXED WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

See full prescribing information for complete boxed warning.

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

Contraindications: OSVYRTI is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating OSVYRTI. OSVYRTI is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment. OSVYRTI is contraindicated in patients with hypersensitivity to denosumab products. Reactions have included anaphylaxis, facial swelling and urticaria.

Severe Hypocalcemia and Mineral Metabolism Changes: Pre-existing hypocalcemia must be corrected prior to initiating therapy; severe hypocalcemia and fatal cases have been reported with denosumab products. Adequately supplement all patients with calcium and vitamin D.

In patients without advanced CKD who are predisposed to hypocalcemia and disturbances of mineral metabolism, assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after OSVYRTI 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 (eGFR <30 mL/min/1.73 m^2), including dialysis-dependent patients, are at high risk for severe hypocalcemia after denosumab products administration, which can lead to hospitalization, life-threatening events, or death. CKD-MBD and concomitant calcimimetic use further increase risk.

IMPORTANT SAFETY INFORMATION (cont'd)

Assess for mineral bone disorder before OSVYRTI treatment, monitor serum calcium weekly for the first month, then monthly, and educate patients on hypocalcemia symptoms and the need for adequate calcium and activated vitamin D supplementation.

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

Hypersensitivity: Clinically significant hypersensitivity including anaphylaxis has been reported with denosumab products. Symptoms 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 OSVYRTI.

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 prior to initiation of OSVYRTI. 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 based on individual benefit-risk assessment.

Patients 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 OSVYRTI 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 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. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents.

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

During OSVYRTI 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 OSVYRTI therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Multiple Vertebral Fractures Following Discontinuation of Treatment: Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures.

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

IMPORTANT SAFETY INFORMATION (cont'd)

Serious Infections: Serious infections leading to hospitalization were reported more frequently in patients taking denosumab. Serious skin infections, and 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. 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 OSVYRTI, prescribers should assess the need for continued therapy.

Dermatologic Adverse Reactions: Epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate in patients taking denosumab. Most of these events were not specific to the injection site. Consider discontinuing OSVYRTI if severe symptoms develop.

Musculoskeletal Pain: Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported with denosumab products. Consider discontinuing OSVYRTI use if severe symptoms develop.

Suppression of Bone Turnover: Treatment with denosumab resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance and effect of long-term treatment with denosumab products are unknown. Monitor patients for the consequences, including ONJ, atypical fractures, and delayed fracture healing.

Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta: OSVYRTI 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.

Most Common Adverse Reactions:

- **Postmenopausal osteoporosis:** Greater than 5% and more common than placebo: back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis. Pancreatitis has been reported in clinical trials.
- **Male osteoporosis:** Greater than 5% and more common than placebo: back pain, arthralgia, and nasopharyngitis.
- **Glucocorticoid-induced osteoporosis:** Greater than 3% and more common than active-control group were: back pain, hypertension, bronchitis, and headache.
- **Bone loss due to hormone ablation for cancer:** Greater than or equal to 10% and more common than placebo: arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

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

OSVYRTI (denosumab-desu) injection is supplied in a 60 mg/mL single-dose prefilled syringe.

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

AVAILABLE FORM OF OSVYRTI[1]

OSVYRTI injection is supplied in a single-dose 60 mg/mL prefilled syringe

DOSING AND ADMINISTRATION[1]

- Pre-existing hypocalcemia must be corrected and pregnancy must be ruled out prior to initiating therapy with OSVYRTI.
- OSVYRTI should be administered by an HCP.
- Administer OSVYRTI 60 mg every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen.
- Instruct patients to take calcium 1000 mg daily and at least 400 IU vitamin D daily.

CODING AND BILLING BY SITE OF CARE

The following section provides coding and billing guidance for OSVYRTI administered in an HCP's office or in a hospital outpatient department (HOPD). **Because coding and billing requirements for OSVYRTI 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 OSVYRTI 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:

Indication	ICD-10-CM Code*	Description
Osteoporosis	M80.0_ _ _	Age-related osteoporosis with current pathological fracture 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type to ensure specificity *Refer to page 8 for coding details for patients with current osteoporotic fracture*
	M81.0	Age-related osteoporosis without current pathological fracture
	M81.8	Other osteoporosis without current pathological fracture
	Z87.310	Personal history of healed osteoporosis fracture
	Z79.52	Long-term (current) use of systemic steroids
Cancer Treatment-Induced Bone Loss‡	C61	Malignant neoplasm of prostate or Provider to determine appropriate site and laterality for breast cancer diagnosis ICD-10 code
	Z79.818	Long-term (current) use of other agents affecting estrogen receptors and estrogen levels†
	Z79.811	Long-term (current) use of aromatase inhibitors
	M85.9	Disorder of bone density and structure, unspecified
	M81.0	Age-related osteoporosis without current pathologic fracture
	M81.8	Other osteoporosis without current pathologic fracture
	M80.0_ _ _	Age-related osteoporosis with current pathologic fracture
	M80.8_ _ _	Other osteoporosis with current pathological fracture

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

†Diagnosis code Z79.818 may be used for males receiving androgen deprivation therapy (eg, leuprolide acetate or goserelin acetate).

‡Coding requirements may vary by payer for men receiving androgen deprivation therapy for nonmetastatic prostate cancer and for women undergoing adjuvant aromatase inhibitor therapy for breast cancer, including the sequence in which codes should be reported.

Please see Important Safety Information on pages 3-5 and scan to see the OSVYRTI full Prescribing Information, including Boxed Warning.

EXAMPLES OF ICD-10-CM CODES RELEVANT FOR PATIENTS WITH CURRENT OSTEOPOROTIC FRACTURE[2*]

Anatomic Site and Laterality	ENCOUNTER TYPE[†]					
	Initial Encounter for Fracture	Subsequent Encounter for Fracture With Routine Healing	Subsequent Encounter for Fracture With Delayed Healing	Subsequent Encounter for Fracture With Nonunion	Subsequent Encounter for Fracture With Malunion	Sequela
Unspecified Site	M80.00XA	M80.00XD	M80.00XG	M80.00XK	M80.00XP	M80.00XS
SHOULDER						
Right	M80.011A	M80.011D	M80.011G	M80.011K	M80.011P	M80.011S
Left	M80.012A	M80.012D	M80.012G	M80.012K	M80.012P	M80.012S
Unspecified	M80.019A	M80.019D	M80.019G	M80.019K	M80.019P	M80.019S
HUMERUS						
Right	M80.021A	M80.021D	M80.021G	M80.021K	M80.021P	M80.021S
Left	M80.022A	M80.022D	M80.022G	M80.022K	M80.022P	M80.022S
Unspecified	M80.029A	M80.029D	M80.029G	M80.029K	M80.029P	M80.029S
FOREARM						
Right	M80.031A	M80.031D	M80.031G	M80.031K	M80.031P	M80.031S
Left	M80.032A	M80.032D	M80.032G	M80.032K	M80.032P	M80.032S
Unspecified	M80.039A	M80.039D	M80.039G	M80.039K	M80.039P	M80.039S
HAND						
Right	M80.041A	M80.041D	M80.041G	M80.041K	M80.041P	M80.041S
Left	M80.042A	M80.042D	M80.042G	M80.042K	M80.042P	M80.042S
Unspecified	M80.049A	M80.049D	M80.049G	M80.049K	M80.049P	M80.049S
FEMUR[‡]						
Right	M80.051A	M80.051D	M80.051G	M80.051K	M80.051P	M80.051S
Left	M80.052A	M80.052D	M80.052G	M80.052K	M80.052P	M80.052S
Unspecified	M80.059A	M80.059D	M80.059G	M80.059K	M80.059P	M80.059S
LOWER LEG						
Right	M80.061A	M80.061D	M80.061G	M80.061K	M80.061P	M80.061S
Left	M80.062A	M80.062D	M80.062G	M80.062K	M80.062P	M80.062S
Unspecified	M80.069A	M80.069D	M80.069G	M80.069K	M80.069P	M80.069S
ANKLE AND FOOT						
Right	M80.071A	M80.071D	M80.071G	M80.071K	M80.071P	M80.071S
Left	M80.072A	M80.072D	M80.072G	M80.072K	M80.072P	M80.072S
Unspecified	M80.079A	M80.079D	M80.079G	M80.079K	M80.079P	M80.079S
PELVIS						
Right	M80.0B1A	M80.0B1D	M80.0B1G	M90.0B1K	M80.0B1P	M80.0B1S
Left	M80.0B2A	M80.0B2D	M80.0B2G	M80.0B2K	M80.0B2P	M80.0B2S
Unspecified	M80.0B9A	M80.0B9D	M80.0B9G	M80.0B9K	M80.0B9P	M80.0B9S
VERTEBRA(E)	M80.88XA	M80.88XD	M80.88XG	M80.88XK	M80.88XP	M80.88XS
OTHER SITE	M80.8AXA	M80.8AXD	M80.8AXG	M80.8AXK	M80.8AXP	M80.8AXS

For other osteoporosis with or without current pathological fracture, refer to ICD-10-CM for reference.

*According to the ICD-10-CM Official Guidelines for Coding and Reporting, M80.0 codes are for patients who have a current pathologic fracture at the time of an encounter. The codes under M80 identify the site of the fracture. A code from category M80, not a traumatic fracture code, should be used for any patient with known osteoporosis who suffers a fracture, even if the patient had a minor fall or trauma, if that fall or trauma would not usually break a normal, healthy bone.[3]

†According to the ICD-10-CM Official Guidelines for Coding and Reporting, seventh character A is for use as long as the patient is receiving active treatment for the fracture. Assignment of the seventh character is based on whether the patient is undergoing active treatment and not whether the provider is seeing the patient for the first time. Seventh character D is to be used for encounters after the patient has completed active treatment. The other seventh characters, listed under each subcategory in the Tabular List, are to be used for subsequent encounters for treatment of problems associated with healing, such as malunions, nonunions, and sequelae.[3]

‡Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

Please see Important Safety Information on pages 3-5 and scan to see the OSVYRTI full Prescribing Information, including Boxed Warning.

BILLING UNITS AND NDCs

OSVYRTI BILLING UNITS

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

Billing Units: 1 mg = 1 unit; 60 mg dose = 60 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 OSVYRTI		
FDA-Specified 10-Digit NDC (5-3-2 format)[1]	11-Digit NDC (5-4-2 format)[4]	Description[1]
69448-021-63	69448-0021-63	60 mg prefilled syringe

HCPCS CODE[5]

In an HCP's office and HOPD sites of care, Medicare, Medicaid, and private commercial payers typically recognize the following codes for reporting OSVYRTI 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 OSVYRTI.

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

Modifiers may be included on claims to provide additional information.

JW/JZ Modifiers: For the OSVYRTI prefilled syringe, 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.[6] 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.[7]

Modifier Code	Description
JW[6]	Drug amount discarded/not administered to any patient
JZ[6]	Zero drug amount discarded/not administered to any patient
TB[7]	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities

CPT CODES[8]

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

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

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

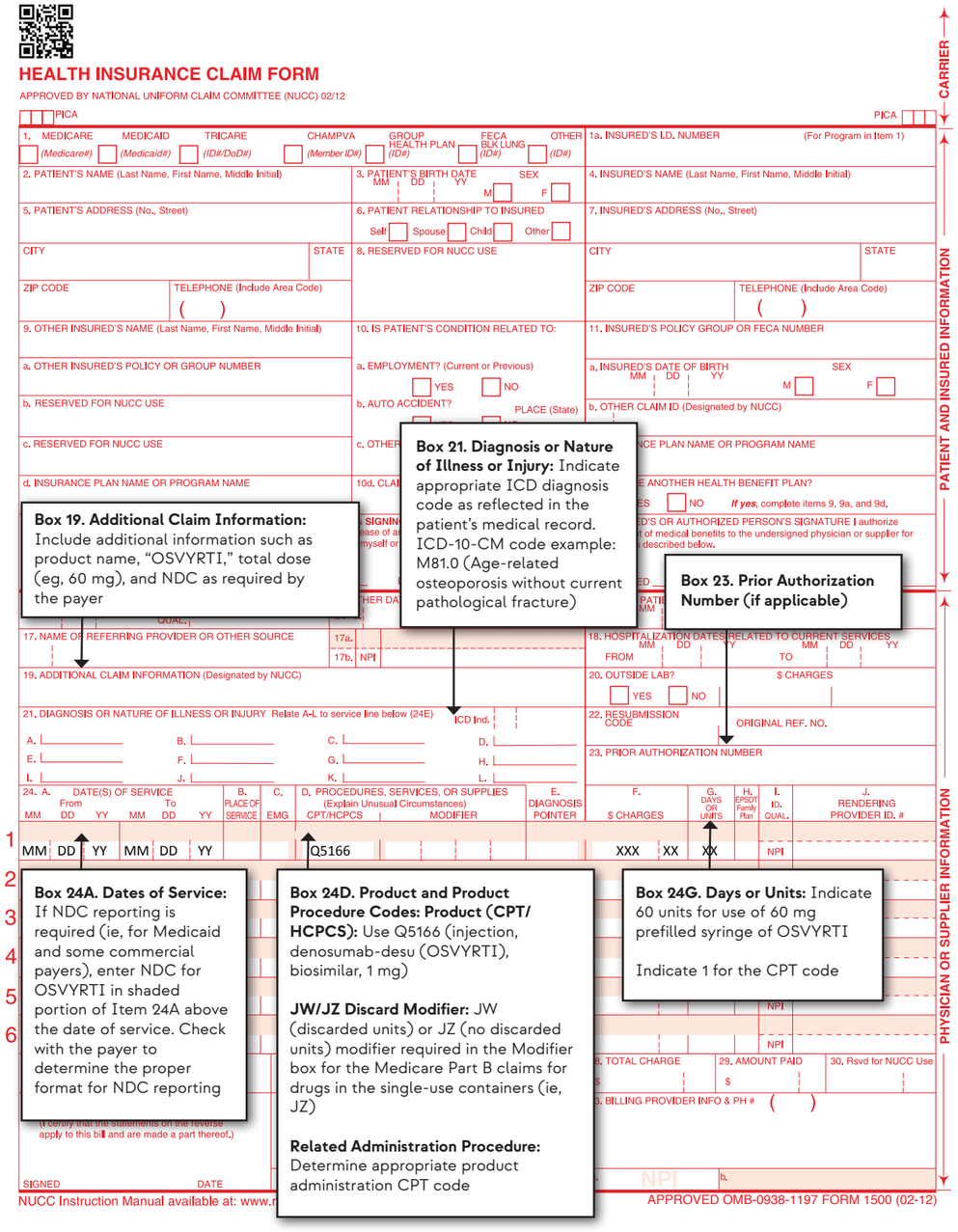
REVENUE CODES[9]

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

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

SAMPLE CLAIM FORM

SAMPLE CMS-1500, HCP OFFICE SITE OF SERVICE[10]



Box 19. Additional Claim Information: Include additional information such as product name, "OSVYRTI," total dose (eg, 60 mg), and NDC as required by the payer

Box 21. Diagnosis or Nature of Illness or Injury: Indicate appropriate ICD diagnosis code as reflected in the patient's medical record. ICD-10-CM code example: M81.0 (Age-related osteoporosis without current pathological fracture)

Box 23. Prior Authorization Number (if applicable)

Box 24A. Dates of Service: If NDC reporting is required (ie, for Medicaid and some commercial payers), enter NDC for OSVYRTI 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 and Product Procedure Codes: Product (CPT/HCPCS): Use Q5166 (injection, denosumab-desu (OSVYRTI), biosimilar, 1 mg)

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)

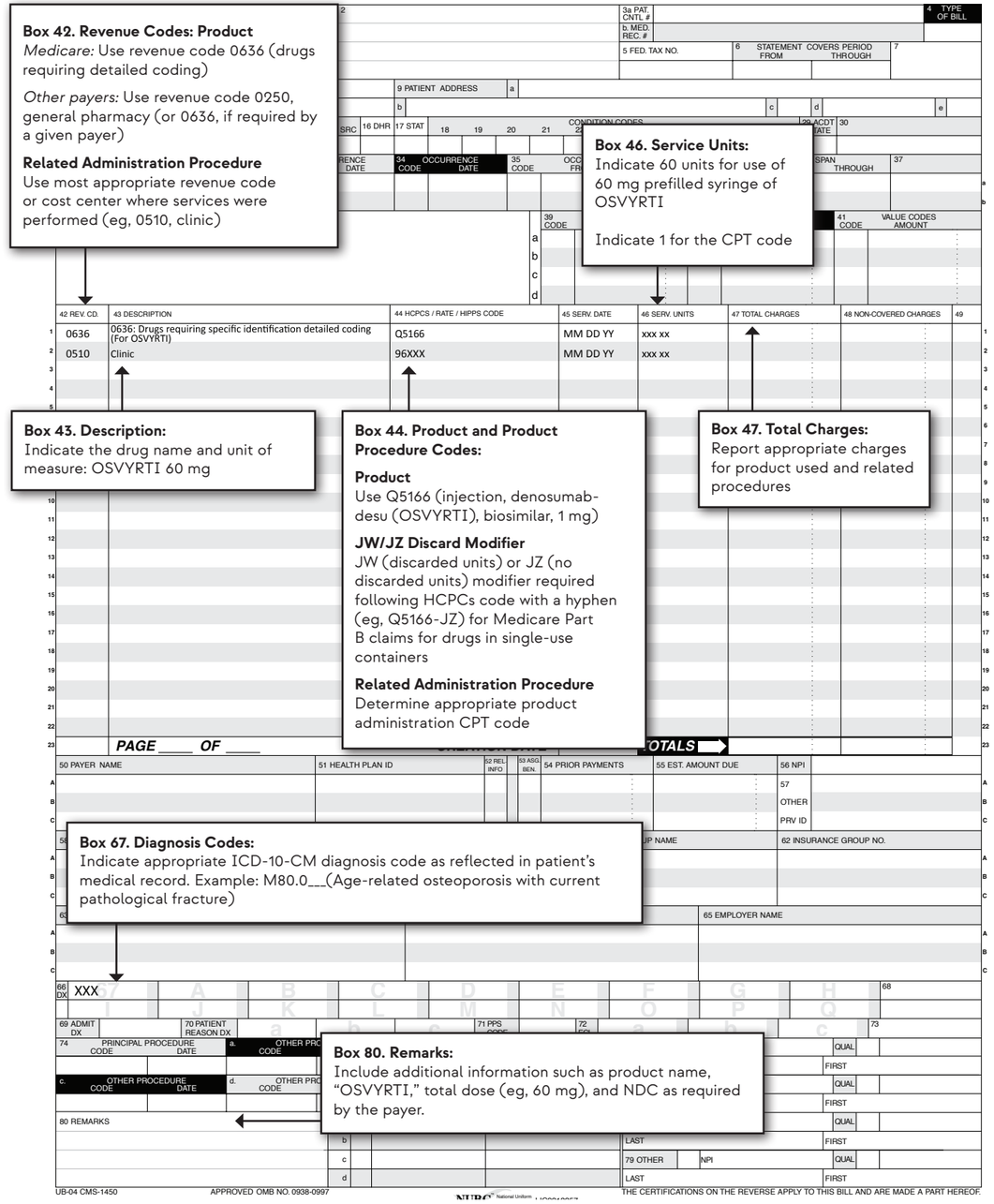
Related Administration Procedure: Determine appropriate product administration CPT code

Box 24G. Days or Units: Indicate 60 units for use of 60 mg prefilled syringe of OSVYRTI

Indicate 1 for the CPT code

SAMPLE CLAIM FORM

SAMPLE CMS-1450, HOSPITAL OUTPATIENT SITE OF SERVICE[11,12]



Box 42. Revenue Codes: Product
Medicare: Use revenue code 0636 (drugs requiring detailed coding)

Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer)

Related Administration Procedure
Use most appropriate revenue code or cost center where services were performed (eg, 0510, clinic)

Box 46. Service Units:
Indicate 60 units for use of 60 mg prefilled syringe of OSVYRTI

Indicate 1 for the CPT code

Box 43. Description:
Indicate the drug name and unit of measure: OSVYRTI 60 mg

Box 44. Product and Product Procedure Codes:

Product
Use Q5166 (injection, denosumab-desu (OSVYRTI), biosimilar, 1 mg)

JW/JZ Discard Modifier
JW (discarded units) or JZ (no discarded units) modifier required following HCPCs code with a hyphen (eg, Q5166-JZ) for Medicare Part B claims for drugs in single-use containers

Related Administration Procedure
Determine appropriate product administration CPT code

Box 47. Total Charges:
Report appropriate charges for product used and related procedures

Box 67. Diagnosis Codes:
Indicate appropriate ICD-10-CM diagnosis code as reflected in patient's medical record. Example: M80.0___(Age-related osteoporosis with current pathological fracture)

Box 80. Remarks:
Include additional information such as product name, "OSVYRTI," total dose (eg, 60 mg), and NDC as required by the payer.

Please see Important Safety Information on pages 3-5 and scan to see the OSVYRTI full Prescribing Information, including Boxed Warning.

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®

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Please see Important Safety Information on pages 3-5 and scan to see the OSVYRTI full Prescribing Information, including Boxed Warning.

OSVYRTI®
(denosumab-desu) injection
60 mg/mL

Scan to see the OSVYRTI full Prescribing Information, including Boxed Warning.

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