Injections: Drugs D Policy

Page updated: March 2024

This section outlines policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs C Policy*
- *Injections: Drugs E Policy*
- *Injections: Drugs F Policy*
- *Injections: Drugs G Policy*
- *Injections: Drugs H Policy*
- *Injections: Drugs I Policy*
- *Injections: Drugs J-L Policy*
- *Injections: Drugs M Policy*
- *Injections: Drugs N-O Policy*
- *Injections: Drugs P-Q Policy*
- *Injections: Drugs R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

Dalbavancin

The use of HCPCS code J0875 (dalbavancin, 5mg) is restricted to patients 18 years of age and older.

Daptomycin

Daptomycin binds to bacterial cell membranes and causes a rapid depolarization of membrane potential. This loss of membrane potential causes inhibition of DNA, RNA, and protein synthesis, which results in bacterial cell death.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be one year of age or older (Baxter only).

Must be 18 years of age or older (Hospira only).

Billing

HCPCS codes:

J0873 (injection, daptomycin [xellia], not therapeutically equivalent to J0878, 1 mg).

J0874 (injection, daptomycin [baxter], not therapeutically equivalent to J0878, 1mg).

J0877 (injection, daptomycin [hospira], not therapeutically equivalent to J0878, 1 mg).

J0878 (injection, daptomycin, 1 mg).

Darbepoetin Alfa

Darbepoetin alfa is an erythropoiesis-stimulating protein that is produced in Chinese hamster ovary cells by recombinant DNA technology. It is a 165-amino acid protein that differs from recombinant human erythropoietin in containing five N-linked oligosaccharide chains, whereas recombinant human erythropoietin contains three chains. The two additional N-glycosylation sites result from amino acids substitutions in the erythropoietin peptide backbone. Darbepoetin alfa stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. Increased hemoglobin levels are not generally observed until two to six weeks after initiating treatment with darbepoetin alfa.

Indications

For the treatment of anemia due to:

- Chronic kidney disease (CKD) in patients on dialysis and not on dialysis.
- The effects of myelosuppressive chemotherapy in patients with non-myeloid malignancies and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Limitations of Use

Darbepoetin alfa has not been shown to improve quality of life, fatigue or patient well-being.

Darbepoetin alfa is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.

- In patients with cancer receiving myelosuppressive chemotherapy, when the anticipated outcome is cure.
- As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

In the appropriate circumstances, darbepoetin alfa may be self-administered.

CKD Patients on Hemodialysis

Darbepoetin alfa treatment may be initiated when the hemoglobin (Hgb) level is less than 10 g/dL, taking into consideration specific patient characteristics such as functional and cognitive status, life expectancy and other factors. For continuing and ongoing treatment, the current Hgb level must be less than 11.5 g/dL. If the Hgb level approaches or exceeds 11 g/dL, it is recommended that the dose of darbepoetin alfa should be reduced or interrupted. Darbepoetin alfa treatment will be denied if the Hgb level is greater than 11.5 g/dL at the time of darbepoetin alfa administration.

CKD Patients Not on Hemodialysis

These patients may have darbepoetin alfa initiated when the Hgb level is less than 10 g/dL and the following conditions apply:

- The rate of Hgb decline indicates the likelihood of requiring an RBC transfusion, and
- Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.

If the Hgb level exceeds 10 g/dL, it is recommended that the dose of darbepoetin alfa be reduced or interrupted.

Myelosuppressive Chemotherapy-Associated Anemia

Darbepoetin alfa is recommended as a treatment option when the Hgb level has decreased below 10 g/dL and there is a minimum of two additional months of planned chemotherapy.

Required Codes

ICD-10-CM diagnosis codes are required on the claim form in the *Diagnosis or Nature Illness or Injury* field (Box 21 or Box 67) of the *CMS-1500* form or in the *Diagnosis Codes* field (Box 66-67) of the UB-04 form.

- CKD patients with anemia on dialysis require ICD-10-CM code N18.6 for HCPCS code J0882.
- CKD patients with anemia not on dialysis require ICD-10-CM codes N18.1 thru N18.5 or N18.9 for HCPCS code J0881.
- Chemotherapy-associated anemia in non-myeloid malignancies requires ICD-10-CM code D63.0 or D64.81 for HCPCS code J0881.

Dosage

Evaluate the iron status in all patients before and during treatment and maintain iron repletion. Correct or exclude other causes of anemia (for example, vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) before initiating darbepoetin alfa.

The dose of darbepoetin alfa varies according to the condition being treated. Please refer to appropriate medical literature for specific dosage recommendations.

Billing

The following HCPCS codes are used to bill darbepoetin alfa:

HCPCS Code	Description
J0881	Injection, darbepoetin alfa, 1 microgram (non-ESRD use)
J0882	Injection, darbepoetin alfa, 1 microgram (for ESRD on dialysis)

If darbepoetin alfa is administered by the provider, the claim must include current and previous:

- Darbepoetin alfa dose
- Patient weight in kilograms
- Hemoglobin levels

If darbepoetin alfa is self-administered, the provider must submit the following information:

- A statement that the drug was provided to the patient for self-administration.
- The date and quantity of drug given to the patient, darbepoetin alfa doses, patient weight in kilograms and Hbg levels for the previous three months.

Documentation may be included in the *Remarks* field (Box 80) on the *UB-04* or the *Additional Claim Information* field (Box 19) on the *CMS-1500*, or on an attachment to the claim.

If darbepoetin alfa is administered outside of the general guidelines above or dosage is more than 800 mcg per month, documentation must be submitted in order to establish medical necessity.

Delafloxacin (Baxdela®)

Delafloxacin belongs to the fluoroquinolone class of antibacterial drugs and is anionic in nature. The antibacterial activity of delafloxacin is due to the inhibition of both bacterial topoisomerase IV and DNA gyrase (topoisomerase II) enzymes which are required for bacterial DNA replication, transcription, repair, and recombination.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for all FDA-approved indications and dosages.
- Patient must be 18 years of age or older.

- Patient must have a diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or Community-Acquired Bacterial Pneumonia (CABP).
- Documentation of an inadequate response or intolerance or not a candidate for a clinically appropriate first-line therapy based on the current treatment guidelines for the specified indication (for example Amoxicillin, Amoxicillin-Calvulanate, Azithromycin, Levofloxacin, Moxifloxacin, Trimethoprim-Sulfamethoxazole, Doxycycline, Clindamycin, Vancomycin, Aztreonam, Linezolid, etc.).
- Culture and sensitivity report shows isolated pathogen is susceptible to Delafloxacin, or documentation to show obtaining a culture and sensitivity report is not feasible.
- Dose does not exceed IV: 600 mg (two vials) per day.
- The duration of treatment does not exceed the following: for ABSSSI: five to 14 days, for CABP: five to 10 days.

Approval: treatment course (up to 14 days).

Age Limit

Must be 18 years of age and older.

Billing

HCPCS code C9462 (injection, delafloxacin, 1 mg).

One (1) unit of C9462 equals 1 mg delafloxacin.

Prescribing Restrictions

Frequency of billing equals 600 mg/600 units per day for up to 14 days.

Maximum billing unit(s) equals 600 mg/600 units.

Delandistrogene Moxeparvovec (ELEVIDYS™)

Delandistrogene moxeparvovec is a recombinant gene transfer therapy designed to target the production of functional components of dystrophin in muscle tissue. elandistrogene moxeparvovec is administered as a single intravenous dose, which leads to production of delandistrogene moxeparvovec micro-dystrophin, a shortened protein, thereby addressing the underlying cause of DMD.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

- Must be used for FDA-approved indications and dosages.
- Patient must be age four through five.
- Patient has a definitive diagnosis of DMD based on genetic laboratory studies that confirm mutation in the DMD gene.
- Must be prescribed by or in consultation with a neurologist or a pediatric neuromuscular specialist with expertise in the treatment of DMD.
- Patient has no current nor scheduled future treatment with concurrent or exon skipping therapies (for example, Amondys 45™, Exondys 51™, Vyondys 53™, Viltepso®).

- Patient is ambulatory.
- Patient's current baseline weight.
- One day prior to infusion, initiate corticosteroid to be continued for at least 60 days after the infusion, modifying dose if clinically indicated.
- Mandated laboratory studies:

1. Baseline liver function test (LFT) which includes:
   - Gamma-gluatamyl transferase (GGT)
   - Alkaline Phosphatase (ALP)
   - Alanine aminotransferase (ALT)
   - Aspartate transaminase (AST)
   - Total bilirubin
     - ❖ Weekly LFT must be done for the first three months after administration of Elevidys as a mandatory safety monitoring.
2. Baseline platelet count
   - ❖ Weekly platelet monitoring should be done for the first two weeks as a mandatory safety monitoring.
3. Baseline Troponin-I
   - ❖ Weekly troponin-I monitoring should be done for the first four weeks after infusion as a mandatory safety monitoring.
4. Baseline Creatine Kinase
5. rAAVrh74 antibody titers less than or equal to 1:400 within eight weeks prior to planned infusion date or within four weeks prior if anyone in the household has recently been infused with delandistrogene moxeparvovec-rokl with an FDA-approved assay (if available).

6. Baseline left ventricular ejection fraction (LVEF) by cardiac echocardiography.
   - Mandatory cardiac LVEF if patient develops elevated troponin I or troponin T

- Clinical assessment, which include all of the following:
  - North Star Ambulatory Assessment (NSAA) score more than 17 and less than or equal to 26
  - Time to stand from supine
  - four-stair climb
  - 10-meter run/walk
  - 100-meter run/walk
- Patient does not have:
  - Liver injury or is at risk of hepatotoxicity, liver injury, chronic hepatic condition, or acute liver disease
  - Acute or chronic cardiac dysfunction.
  - Severe immune-mediated myositis
  - Active infection
  - Any deletion mutation, which fully includes exons 9-13
  - Any deletion in exon eight and/or exon nine in the DMD gene
  - History of *AAV-Based* Gene Therapy
- Recommended dose: 1.33 × 10^14 vector genomes per Kg.
- The infusion date must be prior to the age of six years.

Authorization is for three months (one treatment in a lifetime).

Reauthorization is not approvable.

<u>Important Billing Instructions</u>

- Due to system limitations, providers are to take the following steps when submitting a TAR/SAR and claims for Elevidys.

TAR/SAR Submission

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “4” in the Units box.

Claim Submission

4. Bill using HCPCS code J1413.
5. Completion of Claim forms:

a) This billing methodology is restricted to hospital outpatient services. Note that pharmacies and clinics cannot bill using this methodology.

b) Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms with the following conditions:

   i. Provider must submit one (1) service line for four (4) units on the TAR/SAR request and will submit four (4) claim lines.
   ii. Each claim line to represent one unit.
   iii. Claims submitted with one or two claim lines will be denied
   iv. Provider must submit an invoice for reimbursement.
   v. This process will ensure that the total reimbursement paid for the four claim lines is no more than provider submitted invoice paid price.
   vi. Elevidys must be billed on its own with no other drug or biologics.

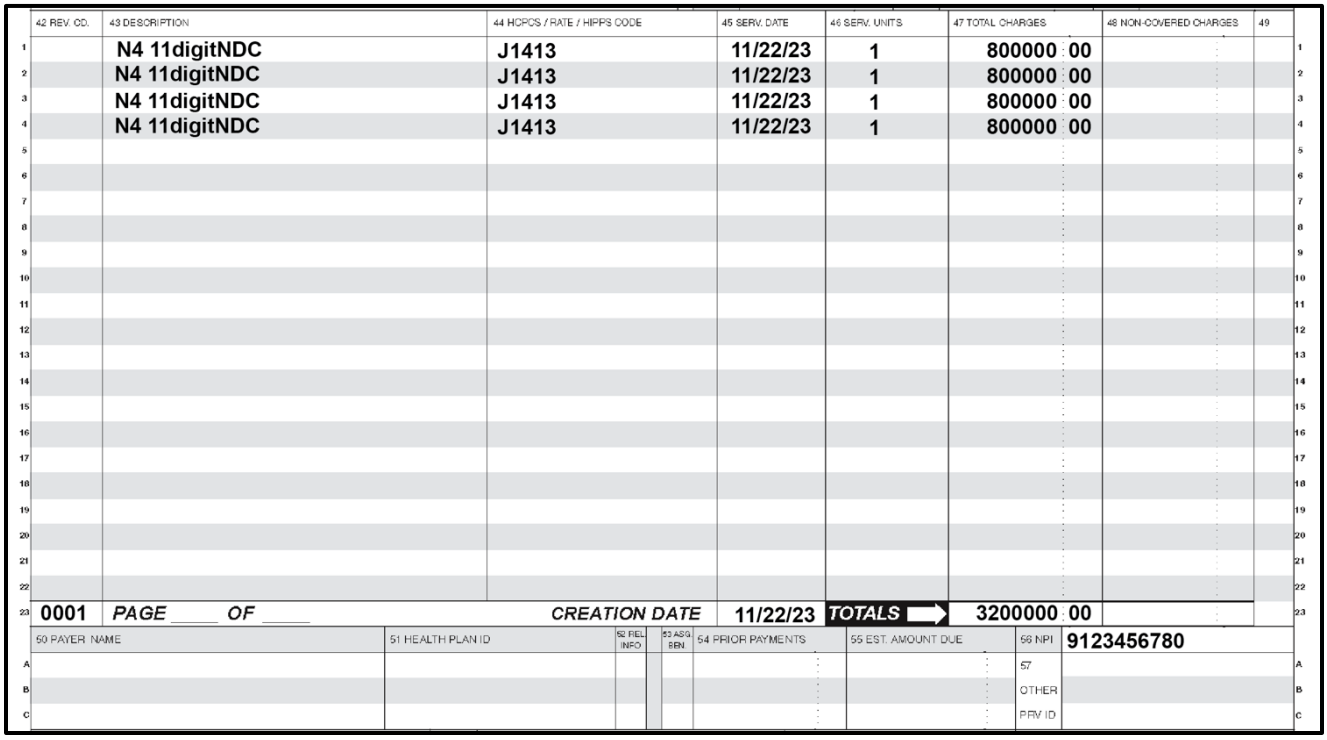
6. Providers are advised to take the following steps in order to ensure that Elevidys claims are identified and processed expeditiously:

- Paper claims may be identified by notation of “Elevidys” on the “Remarks” section of the UB-04 claim form (Field #80) and submitted to:

  Attention: Claims Manager
  Medi-Cal Fiscal Intermediary/DXC
  P.O. Box 526006
  Sacramento, CA 95852-6006

- Electronic claims may be identified by notation of “Elevidys” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form

7. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
8. Payment for Elevidys shall be a once in a lifetime reimbursement under J1413 or any other code (HCPCS, CPT®, or by NDC).
9. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and UB-04 claim forms.



	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1		N4 11digitNDC	J1413	11/22/23	1	800000 00			1
2		N4 11digitNDC	J1413	11/22/23	1	800000 00			2
3		N4 11digitNDC	J1413	11/22/23	1	800000 00			3
4		N4 11digitNDC	J1413	11/22/23	1	800000 00			4
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	50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	9123456780	
A							57		A
B							OTHER		B
C							PRV ID		C

Image 1: Delandistrogene Moxeparvovec Gene Therapy UB-04 Billing Example

- The total invoice cost of Elevidys is $3,200,000.
- Note that each provider's invoice cost may be different.
- If this is split evenly between the four lines, each claim line will have a total of $800,000.
- The sum of the four claim lines must equal the paid price on the invoice.
- Note that it is not necessary to include the unit of measure qualifier and numeric quantity.

Age Limits

Must be ages four through five.

Billing

HCPCS code J1413 (injection, delandistrogene moxeparvovec-rokl, per therapeutic dose [Elevidys]).

Required ICD-10-CM Diagnosis Codes

G71.01

Prescribing Restriction(s)

Frequency of billing equals one treatment in a lifetime.

‹‹Denosumab (Prolia®, Xgeva®)

Denosumab binds to RANKL, a transmembrane or soluble protein essential for the formation, function and survival of osteoclasts, the cells responsible for bone resorption. It prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone.››

Indications

‹‹All FDA-approved indications.››

Dosage

‹‹FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.››

‹‹TAR Criteria

Denosumab is considered medically necessary when all of the following criteria are met:

Prolia

For the treatment of postmenopausal women with osteoporosis at high risk for fracture, and for the treatment to increase bone mass in men with osteoporosis at high risk for fracture:

Initial Criteria:

- Prescribed for all FDA-approved indications and dosages.
- Diagnosis of osteoporosis.
- Documentation that the patient is at high risk for fracture (for example, multiple risk factors for fracture, history of fracture).
- History of failure, intolerance or contraindication to other available osteoporosis therapies (for example, alendronate, zoledronic acid, etc.).

For the treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture:

Initial Criteria:

- Prescribed for all FDA-approved indications and dosages.
- Diagnosis of osteoporosis induced by glucocorticoid therapy.
- Documentation that the patient is at high risk for fracture (for example, multiple risk factors for fracture, history of fracture).
- History of failure, intolerance or contraindication to other available osteoporosis therapies (for example, alendronate, zoledronic acid, etc.).

For the treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer:

Initial Criteria:

- Prescribed for all FDA-approved indications and dosages.
- Diagnosis of nonmetastatic prostate cancer.
- Patient is receiving androgen deprivation therapy.
- History of failure, intolerance or contraindication to other available osteoporosis therapies (for example, alendronate, zoledronic acid, etc.).››

‹‹For the treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:

Initial Criteria:

- Prescribed for all FDA-approved indications and dosages.
- Diagnosis of breast cancer.
- Patient is receiving aromatase inhibitor therapy.
- History of failure, intolerance or contraindication to other available osteoporosis therapies (for example, alendronate, zoledronic acid, etc.).

Xgeva

For the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors:

Initial Criteria:

- Must be used for all FDA-approved indications and dosages.
- Must be 18 years of age or older.
- Diagnosis of multiple myeloma or bone metastases from solid tumors.
- Patient does not have pre-existing hypocalcemia.

For the 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:

Initial Criteria:

- Must be used for all FDA-approved indications and dosages.
- Patient does not have pre-existing hypocalcemia.
- Diagnosis of giant cell tumor of bone and tumor is either unresectable or surgical resection is likely to result in severe morbidity.
- Must be at least 18 years of age or skeletally mature adolescents (13-17 years of age) defined by at least one mature long bone (for example, closed epiphyseal growth plate of the humerus) and a body weight greater than or equal to 45 kg.››

‹‹For the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy:

Initial Criteria:

- Must be used for all FDA-approved indication and dosages.
- Must be 18 years of age or older.
- Diagnosis of hypercalcemia of malignancy (for example, albumin-corrected calcium of greater than 12.5 mg/dL (3.1 mmol/L).
- Inadequate response, intolerance or contraindication to intravenous bisphosphonate therapy seven to 30 days prior to initiation of Xgeva.

Continued Therapy Criteria for All Approved Indications for Both Prolia and Xgeva

- Patient meets the initial TAR criteria for each indication.
- Documentation of positive clinical response to therapy.

For both Prolia and Xgeva, initial authorization is for 12 months. Re-authorization is for 12 months.››

Billing

HCPCS code J0897 (injection, denosumab, 1 mg).

The correct National Drug Code (NDC) must be included on the claim(s) to correctly price the drug.

Diclofenac Sodium Injection

Diclofenac sodium injection is a nonsteroidal anti-inflammatory drug (NSAID) for intravenous (I.V.) administration.

Indications

Diclofenac sodium injection is reimbursable for use in patients 18 years of age or older for:

- The management of mild to moderate pain; or
- The management of moderate to severe pain alone or in combination with opioid analgesics.

Dosage

37.5 mg administered I.V. every six hours as needed (maximum dose is not to exceed 150 mg/day).

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must document the following:

- The service is medically necessary.
- Alternative drugs (for example, ibuprofen, ketorolac, etc.) have been tried or considered, have failed or are contra-indicated.
- A doctor’s order, prescription, and/or treatment plan written for the service requested.

Billing

HCPCS code J1130 (injection, diclofenac sodium, 0.5 mg).

One (1) unit equals 0.5 mg of diclofenac sodium injection solution.

Difelikefalin (Korsuva™)

Korsuva is a kappa opioid receptor (KOR) agonist. The relevance of KOR activation to therapeutic effectiveness is not known.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Korsuva is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patient has end-stage renal disease (ESRD) and has been on hemodialysis three times per week for at least three months.
- Patient has at least two single-pool Kt/V measurements equal to or greater than 1.2, or at least two urea reduction ratio measurements equal to or greater than 65 percent, or one single pool Kt/V measurement equal to or greater than 1.2 and one urea reduction ratio measurement equal to or greater than 65 percent on different dialysis days during the prior three-month period.
- Patient has completed the following assessments at baseline:
  - Mean baseline Worst Itching Intensity NRS indicative of moderate to severe uremic pruritus

- Patient has tried and failed the following unless contraindicated or clinically inappropriate:
  - Emollients and/or topical analgesics (if dry skin)
  - Oral antihistamines (for example diphenhydramine, hydroxyzine, loratadine, etc.)
  - Gabapentin or pregabalin
- Patient cannot undergo or does not respond to UVB therapy.
- Patient is not scheduled to receive kidney transplant.
- Patient does not have pruritus only during the dialysis session (by patient report)
- Patient is not receiving ongoing ultraviolet B.

Initial approval is for six months.

Continued treatment:

- Patient has experienced reduction of itch intensity as evidenced by one of the following:
  - Improvement from baseline in intensity of itch measured using Numerical Rating Scale (WI-NRS) or other standard scale
  - Improvement from baseline in itch-related quality of life as assessed by standard scale
- Patient does not have adverse events from prior treatments.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J0879 (injection, difelikefalin, 0.1 microgram).

Prescribing Restriction(s)

Frequency of billing equals 0.5 mcg/kg at the end of each HD treatment.

Dolasetron Mesylate Injection (ANZEMET® Injection)

Dolasetron is a selective serotonin receptor (5-HT3) antagonist which blocks serotonin both peripherally (primary site of action) and centrally at the chemoreceptor trigger zone.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosage.

TAR Requirement

No TAR is required for reimbursement.

Age Limit

Must be two years of age or older.

Billing

HCPCS code J1260 (injection, dolasetron mesylate, 10 mg).

One (1) unit equals 10 mg.

Doripenem

Doripenem, 10 mg (HCPCS code J1267) has a usual dosage of 500 mg every eight hours with a maximum daily dosage of 1,500 mg. For quantities exceeding the daily limitation, appropriate documentation is required.

Doxercalciferol

Doxercalciferol is reimbursable for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Dosage

The recommended initial dose of doxercalciferol is 4 mcg administered intravenously as a bolus dose three times weekly at the end of dialysis. The maximum dosage should not exceed 18 mcg weekly.

Billing

HCPCS code J1270 (injection, doxercalciferol, 1 mcg).

One (1) unit equals 1 mcg.

Note: Code J1270 cannot be block billed.

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.
*	References: 1) The 2014 ERS/ATS (European Respiratory Society/ American Thoracic Society) Task Force Report Guidelines on Severe Asthma and 2) The 2007 NAEPP (National Asthma Education and Prevention Program) Expert Panel Report 3, U.S. Department of Health and Human Services National Institutes of Health
∞	Represents a majority of authorized networks of full-line wholesalers that are eligible to inventory Cabenuva provided they service eligible class of trade.