Injections: Drugs U-Z Policy

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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 D 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: Hydration*
- *Immunizations*

Ublituximab-xiiy (Briumvi™)

Ublituximab is a chimeric IgG monoclonal antibody directed against the CD20 antigen on pre-B and mature B lymphocytes. The precise mechanism by which Ublituximab exerts its therapeutic effects in multiple sclerosis is unknown, but is presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, Ublituximab results in antibody-dependent cellular cytolysis and complement-mediated lysis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a neurologist.
- Patient has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).
- Documentation of MRI of brain with abnormalities consistent with MS.
- Greater than or equal to two relapses in prior two years or one relapse in the prior year and/or greater than or equal to 1 T1 gadolinium (Gd) enhancing lesion in the prior year.

- No active HBV confirmed by positive results for Hepatitis B surface antigen (HBsAg) and anti-HBV tests.
- Must monitor levels of immunoglobulins at the beginning, during, and after discontinuation of treatment.
  - Ubilituximab is not covered in presence of documented persistent hypogammaglobulinemia, unless provider submits documentation demonstrating that there is no effective alternative treatment.
- Expanded Disability Status Scale (EDSS) 0 to 5.5.
- Not pregnant or nursing
- Patient does not have Primary Progressive MS (PPMS)

Initial Authorization is up to 12 months.

Continued Treatment

Patient has experienced positive clinical response as evidenced by improvement or stability in disease activity, or slowing of disability, based on at least one of the following from baseline:

- Reduction or stabilization in the total number of magnetic resonance imaging (MRI) T1 gadolinium-enhancing lesions
- Reduction or stabilization in the total number of new or enlarging MRI T2 hyperintense lesions.
- Lack of disability progression, defined as an increase in Expanded Disability Status Scale (EDSS) score.
- Stabilization, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.

Reauthorization is up to 12 months.

Age Limit

Must be 18 years of age and older.

Billing

HCPCS code: J2329 (injection, ublituximab-xiiy, 1mg).

Required ICD-10 Diagnosis Code

G35

Prescribing Restriction(s)

Frequency of billing initial equals 150 mg/150 units on day 1, followed by 450 mg/450 units 2 weeks after, then 450 mg/450 units every 24 weeks.

Maximum billing unit(s) equals 450 mg/450 units.

Ustekinumab (STELARA®)

‹‹Ustekinumab is a human monoclonal antibody that binds to and interferes with the proinflammatory cytokines, interleukin (IL)-12 and IL-23. Biological effects of IL-12 and IL-23 include natural killer (NK) cell activation, CD4+ T-cell differentiation and activation. Ustekinumab also interferes with the expression of monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor-alpha (TNF-α), interferon-inducible protein-10 (IP-10) and interleukin-8 (IL-8). Significant clinical improvement in psoriasis and psoriatic arthritis patients is seen in association with reduction of these proinflammatory signalers.››

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be six years of age or older (J3357)

Must be 18 years of age or older (J3358)

Billing

HCPCS code J3357 (ustekinumab, for subcutaneous injection, 1 mg).

HCPCS code J3358 (ustekinumab, for intravenous injection, 1 mg).

Suggested ICD-10-CM Diagnosis Codes

L40.0	K50.81	K51.31
L40.5	K50.91	K51.51
K50	K51	K51.81
K50.01	K51.01	K51.91
K50.11	K51.21	

‹‹Ustekinumab-aauz (OTULFI)

Indications and Dosages

Refer to the FDA-approved labeling.

TAR Requirement

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

Age Limits

Must be 6 years of age or older.

Billing

HCPCS code Q9999 (injection, ustekinumab-aauz [otulfi], biosimilar, 1 mg).››

‹‹Ustekinumab-auub (WEZLANA™) and Ustekinumab-ttwe (PYZCHIVA®)››

Ustekinumab is a human monoclonal antibody that binds to and interferes with the proinflammatory cytokines, interleukin (IL)-12 and IL-23. Biological effects of IL-12 and IL-23 include natural killer (NK) cell activation, CD4+ T-cell differentiation and activation. Ustekinumab also interferes with the expression of monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor-alpha (TNF-α), interferon-inducible protein-10 (IP-10) and interleukin-8 (IL-8). Significant clinical improvement in psoriasis and psoriatic arthritis patients is seen in association with reduction of these proinflammatory signalers.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

Universal Criteria

- Must be used for FDA-approved indications and dosages.
- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection.
- Patient has baseline liver enzymes and bilirubin levels prior to treatment initiation.
- Must avoid use of live vaccines.
- Patient must meet A, B, C or D below:

A. Moderate to Severe Plaque Psoriasis (Ps)

- Must be prescribed by or in consultation with a dermatologist.
- Patient must be six years of age or older.
- Patient must have a diagnosis of plaque psoriasis (with or without psoriatic arthritis) for at least six months before treatment initiation.
- Patient has stable moderate to severe chronic plaque-type psoriasis with or without psoriatic arthritis and meets all of the following:
- Static Physician Global Assessment (sPGA) score of at least three (moderate).
- Psoriasis Area and Severity Index (PASI) greater than or equal to 12.
- Body Surface Area (BSA) greater than or equal to 10 percent.
- Patient is a candidate for systemic therapy or phototherapy.
- Patient must have a history of inadequate response to at least one of the following:
  - Systemic therapies up to maximally indicates doses, unless intolerant, contraindicated or clinically inappropriate:
    - ❖ Methotrexate
    - ❖ Cyclosporine
    - ❖ Acitretin
- ‹‹If patient is 18 years of age or older:
  - Patient must have tried and failed one of the biologic therapies (for example, Enbrel, Humira, Cosentyx, Remicade) unless intolerant, inadequate response or contraindication.››

B. Active Psoriatic Arthritis (PsA)

- Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- Patient must be 6 years of age or older.
- Patient has a clinical diagnosis of PsA with symptom onset at least six months prior based on the Classification Criteria for PsA (CASPAR).
- Patient has active disease at Baseline defined as greater than or equal to five tender joints (based on 68 joint counts) and greater than or equal to five swollen joints (based on 66 joint counts).
- Patient must have a history of failure of a three-month trial of at least one conventional Disease-Modifying Antirheumatic Drug (DMARD) such as methotrexate at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate.

- ‹‹If patient is 18 years of age or older:
  - Patient must have tried and failed one of the biologic therapies (for example, Enbrel, Humira, Cosentyx, Remicade) unless intolerant, inadequate response or contraindication.››

C. Moderately to severely active Crohn's disease (CD)

- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a gastroenterologist.
- Patient has a diagnosis of CD for at least three months prior to Baseline.
- Patient has a confirmed diagnosis of moderate to severe CD as assessed by stool frequency (SF), abdominal pain (AP) score and Simple Endoscopic Score for Crohn's Disease (SES-CD).
- Crohn's disease activity index (CDAI) score 220 - 450 at Baseline.
- Inadequate response, intolerance or contraindication to at least one conventional therapy option such as corticosteroids (for example, prednisone, methylprednisolone, budesonide), mercaptopurine (Purinethol), azathioprine (Imuran) or methotrexate (Rheumatrex, Trexall).
- ‹‹Patient must have tried and failed one of the biologic therapies (for example, Enbrel, Humira, Cosentyx, Remicade) unless intolerant, inadequate response or contraindication.››

D. Ulcerative Colitis, Moderate-To-Severe

- Patient has a documented diagnosis of moderately to severely active ulcerative colitis. for at least three months prior to Baseline.
- Must be prescribed by or in consultation with a gastroenterologist.
- Patient must be 18 years of age or older.
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates (e.g., sulfasalazine, mesalamine), glucocorticoids (e.g., prednisone, budesonide), immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate), unless clinically inappropriate.
- ‹‹Patient must have tried and failed one of the biologic therapies (for example, Enbrel, Humira, Cosentyx, Remicade) unless intolerant, inadequate response or contraindication.››

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response as evidenced by disease improvement or stabilization compared to baseline.

Reauthorization is for 12 months.

Age Limits

‹‹Must be six years of age or older (Q5137 and Q9996).

Must be 18 years of age or older (Q5138 and Q9997).››

Billing

HCPCS codes:

Q5137 (injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg).

Q5138 (injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg).

‹‹Q9996 (injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg).

Q9997 (injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg).

Prescribing Restriction(s)

Frequency of billing is equal to 90 mg/90 units every four weeks (Q5137 and Q9996).

Maximum billing unit(s) is equal to 90 mg/90 units (Q5137 and Q9996).

Maximum billing unit(s) is equal to 520 mg/520 units (Q5138 and Q9997).››

‹‹Ustekinumab-aekn (SELARSDI™)

Ustekinumab is a human monoclonal antibody that binds to and interferes with the proinflammatory cytokines, interleukin (IL)-12 and IL-23. Biological effects of IL-12 and IL-23 include natural killer (NK) cell activation, CD4+ T-cell differentiation and activation. Ustekinumab also interferes with the expression of monocyte chemotactic protein-1

(MCP-1), tumor necrosis factor-alpha (TNF-α), interferon-inducible protein-10 (IP-10) and interleukin-8 (IL-8). Significant clinical improvement in psoriasis and psoriatic arthritis patients is seen in association with reduction of these proinflammatory signalers.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Age Limits

Must be six years of age or older.

TAR Requirement

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

TAR Criteria

Ustekinumab-aekn is considered medically necessary in appropriate patients when the following criteria are met:

Universal Criteria

- Must be used for FDA-approved indications and dosages.
- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection.
- Patient has baseline liver enzymes and bilirubin levels prior to treatment initiation.
- Must avoid use of live vaccines.››

‹‹A. Moderate to Severe Plaque Psoriasis (Ps)

- Must be prescribed by or in consultation with a dermatologist.
- Patient must be six years of age or older.
- Patient must have a diagnosis of plaque psoriasis (with or without psoriatic arthritis) for at least six months before treatment initiation.
- Patient has stable moderate to severe chronic plaque-type psoriasis with or without psoriatic arthritis and meets all the following:
  - Static Physician Global Assessment (sPGA) score of at least three (moderate)
  - Psoriasis Area and Severity Index (PASI) greater than or equal to 12
  - Body Surface Area (BSA) greater than or equal to 10 percent.
- Patient is a candidate for systemic therapy or phototherapy.
- Patient must have a history of inadequate response to at least one of the following:
  - Systemic therapies up to maximally indicates doses, unless intolerant, contraindicated or clinically inappropriate:
    - ❖ Methotrexate
    - ❖ Cyclosporine
    - ❖ Acitretin
- If patient is 18 years of age or older
  - Patient must have tried and failed one of the biologic therapies (e.g., Enbrel, Humira, Cosentyx, Remicade) unless intolerant, inadequate response or contraindication.

B. Active Psoriatic Arthritis (PsA)

- Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- Patient must be 6 years of age or older.
- Patient has a clinical diagnosis of PsA with symptom onset at least six months prior based on the Classification Criteria for PsA (CASPAR).
- Patient has active disease at Baseline defined as greater than or equal to five tender joints (based on 68 joint counts) and greater than or equal to five swollen joints (based on 66 joint counts)››

- ‹‹Patient must have a history of failure of a three-month trial of at least one conventional Disease-Modifying Antirheumatic Drug (DMARD) such as methotrexate at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate.
- If patient is 18 years of age or older
  - Patient must have tried and failed one of the biologic therapies (for example, Enbrel, Humira, Cosentyx, Remicade) unless intolerant, inadequate response or contraindication.

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response as evidenced by disease improvement or stabilization compared to baseline.

Reauthorization is for 12 months.

Billing

HCPCS code Q9998 (injection, ustekinumab-aekn [selarsdi], 1 mg).

Prescribing Restriction(s)

Frequency of billing is equal to 90 mg/90 units every four weeks.

Maximum billing unit(s) is equal to 90 mg/90 units.››

Valoctocogene Roxaparvovec-rvox (ROCTAVIAN™)

Valoctocogene roxaparvovec-rvox is an adeno-associated virus serotype 5 (AAV5) based gene therapy vector, designed to introduce a functional copy of a transgene encoding the B-domain deleted SQ form of human coagulation factor VIII (hFVIII-SQ). Transcription of this transgene occurs within the liver, using a liver-specific promoter, which results in the expression of hFVIII-SQ. The expressed hFVIII-SQ replaces the missing coagulation factor VIII needed for effective hemostasis.

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 a male, 18 years of age or older.
- Must be prescribed by or in consultation with a hematologist.
- Patient has a diagnosis of severe hemophilia A (congenital factor VIII (FVIII) levels of less than or equal to 1 IU/dl as evidenced by the medical history.
- Patient has no active inhibitors to Factor VIII.
- Patient does not have pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) capsid detected by FDA-approved companion diagnostic test AAV5 DetectCDx.

- Patient does not have active infections, (either acute or uncontrolled chronic) or immunosuppressive disorder, including HIV.
- Patients does not have known significant hepatic fibrosis (stage three or four on the Batts-Ludwig scale or METAVIR scoring systems [scale 0-4] or an equivalent) grade of fibrosis if an alternative scale is used.
- Patient does not have known hypersensitivity to mannitol.
- Patient does not have significant liver dysfunction with the following laboratory abnormalities:
  - AST/ALT/GGT/Bilirubin/alkaline phosphatase/ international normalized
- Required lab:
  - FVIII showing less than or equal to 1 IU/d
  - Factor VIII inhibitor test
  - Liver function tests:
    - ALT (alanine aminotransferase)
    - AST (aspartate aminotransferase)
    - GGT (gamma-glutamyl transferase)
    - ALP (alkaline phosphatase)
    - Total Bilirubin
    - INR (international normalized ration
- Ultrasound and elastography or laboratory assessments for liver fibrosis.
- No previous history of gene therapy.
- Outpatient administration is restricted to hospital outpatient services and Hemophilia Treatment Centers (HTCs) only.

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

Reauthorization is not approvable.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1412 (injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10^13 vector genomes)

Important Billing Instructions

Due to systems limitations, providers must take the following steps when billing J1412 for appropriate reimbursement:

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 “3” in the Units box.

Claim Submission

4. Bill using miscellaneous HCPCS code, J1412 (injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10^13 vector genomes).
5. Completion of caim forms:

- This billing methodology is restricted to hospital outpatient services and HTCs. Pharmacies and clinics cannot bill using this methodology.
- Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms with the following conditions:
  - On the 837I or UB-04 claim form, provider must submit three (3) claim lines to represent one (1) service.
    - ❖ Each claim line to represent one unit.
    - ❖ Claims submitted with one or two claim lines will be denied.

Provider must submit an invoice for reimbursement.

- This process will ensure that the total reimbursement paid for the three (3) claim lines is no more than provider submitted invoice paid price.
- Roctavian must be billed on its own with no other drug or biologics.

6. Providers must provide the total dose administered to patient in milliliters (mls).
7. Providers are advised to take the following steps in order to ensure that Roctavian claims are identified and processed expeditiously:

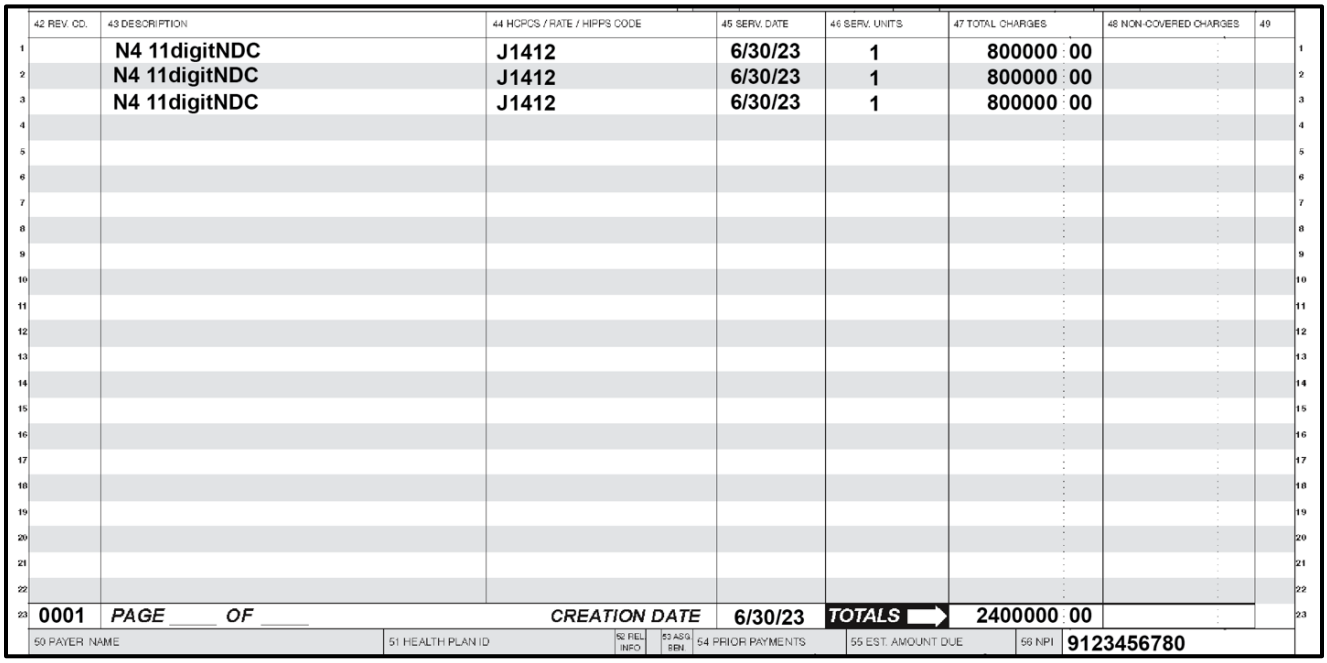
Paper claims may be identified by notation of “Roctavian” on the “Remarks” section of the UB-04 claim form (Field #80) and submitted to:

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

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

8. 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.
9. Payment for Roctavian shall be one dose in a lifetime reimbursement under J1412 or any other code (HCPCS, CPT® or by NDC).

10. 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	J1412	6/30/23	1	800000 00		
2		N4 11digitNDC	J1412	6/30/23	1	800000 00		
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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

Figure 1: Valoctocogene Roxaparvovec-rvox Gene Therapy UB-04 Billing Example

- The total cost of Roctavian in the example is $2,400,00. Note that this may vary based on the patient's weight and the dosage administered.
- Note that each provider's invoice cost may be different.
- If this is split evenly between the three lines, each claim line will have a total of $800,000.
- The sum of the three 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.

Required ICD-10-CM Diagnosis Codes

D66

Prescribing Restriction(s)

Frequency of billing equals one treatment in a lifetime.

Vancomycin

Vancomycin is a glycopeptide antibiotic. The bactericidal action of vancomycin results primarily from inhibition of cell-wall biosynthesis. In addition, vancomycin alters bacterial-cell-membrane permeability and RNA synthesis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

J3370 (injection, vancomycin HCl, 500 mg).

J3371 (injection, vancomycin hcl [mylan] not therapeutically equivalent to J3370, 500 mg).

J3372 (injection, vancomycin hcl [xellia] not therapeutically equivalent to J3370, 500 mg).

Prescribing Restriction(s)

Frequency of billing equals 2 g/4 units per 24 hours.

Maximum billing unit(s) equals 2 g/4 units.

Vasopressin

Vasopressin causes vasoconstriction by binding to V1 receptors on vascular smooth muscle coupled to the Gq/11-phospholipase C-phosphatidyl-inositol-triphosphate pathway, resulting in the release of intracellular calcium. In addition, vasopressin stimulates antidiuresis via stimulation of V2 receptors which are coupled to adenyl cyclase.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS codes:

J2598 (injection, vasopressin, 1 unit).

J2599 (injection, vasopressin [American Regent] not therapeutically equivalent to J2598, 1 unit).

J2601 (injection, vasopressin [baxter], 1 unit).

Vedolizumab

Vedolizumab is a humanized IgG_1 monoclonal antibody produced in Chinese hamster ovary cells that binds to the human α4β7 integrin and blocks the interaction of α4β7 integrin with mucosal addressin cell adhesion molecule-1 (MAdCAM-1) and inhibits migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. The interaction of the α4β7 integrin with MAdCAM-1 has been implicated as an important contributor to the chronic inflammation that is a hallmark of ulcerative colitis (UC) and Crohn's disease (CD).

Indications

Ulcerative Colitis:

Adult patients 18 years of age and older with moderately to severely active UC who have had an inadequate response with lost response to or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to or demonstrated dependence on corticosteroids.

Crohn's Disease:

Adult patients 18 years of age and older with moderately to severely active CD who have had an inadequate response with lost response to or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to or demonstrated dependence on corticosteroids.

Authorization

An approved TAR is required for reimbursement.

Dosage

The recommended and maximum dosage is 300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter.

Billing

HCPCS code J3380 (injection, vedolizumab, intravenous,1 mg).

Viltolarsen (Viltepso™)

Viltolarsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR/SAR Requirement

An approved *Treatment Authorization Request* (TAR) or CCS Program *Service Authorization Request* (SAR) is required for reimbursement.

TAR/SAR Criteria

Must submit clinical documentation that demonstrates the following:

- Must be prescribed for FDA-approved indications and dosages.
- Patient must be four years of age or older.
- Must be prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD. For California Children's Services (CCS) patients, must be under the supervision and monitoring of a CCS-paneled neurologist or physical medicine and rehabilitation specialist who is fellowship trained in neuromuscular medicine at a CCS Neuromuscular Medicine Special Care Center (SCC), or at a neurology clinic.
- Must have a diagnosis of Duchene Muscular Dystrophy (DMD) with mutation amenable to exon 53 skipping as documented by genetic test(s).

- The following are completed as part of the assessment for antisense oligonucleotide therapy:
  - Forced Vital Capacity (FVC)
  - Brooke score
  - six minute walk test (6MWT), if ambulatory, and
  - Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C
- The FVC is greater than 30 percent predicted or the Brooke score is less than or equal to five.
- Only one antisense oligonucleotide treatment shall be authorized at a time.
- Patient is on a corticosteroid or has documented medical reason not to be on this medication.
- Patient must start on the less expensive, equivalent or superior drug.
- Continuation of a more expensive alternative must be justified with a compelling reason for doing so.
- For CCS patients, CCS Neuromuscular Medicine SCC or CCS-paneled neurologist has included the following supporting documentation in the medical record:
  - Documentation of recent FVC
  - Brooke Score or baseline 6MWT if ambulatory
  - Laboratory indicator of renal function

Initial approval is for 12 months.

Reauthorization

- Patient has finished the initial course and has not had significant decline in FVC beyond the pre-treatment disease trajectory while on the antisense oligonucleotide treatment.

- Motor function has improved or has not declined beyond pretreatment trajectory, evidenced by improved or maintained score in 6MWT, timed function tests, Performance of Upper Limb (PUL), Brooke score, other standardized assessment of motor function, or quantifiable description of improvement by the physician or physical therapist in the medical record.
- Patient has not experienced significant adverse effects attributable to viltolarsen.
- Patients with a FVC score of less than or equal to 30 percent and Brooke score of six will not be granted authorizations because, at the time of this policy, there is insufficient evidence of efficacy in that population.

Additional consideration for medical necessity determination:

- For CCS patients who do not meet the criteria described above, SCCs may also submit other clinical documentation and/or evidence that would support the medical necessity for initial or reauthorization of the patient's antisense oligonucleotide treatments. SCCs should submit this documentation to the Integrated Systems of Care Division (ISCD) Medical Director or designee.

Reauthorization is for 12 months.

Policy Implementation for CCS Patients

A. Submissions of authorization requests for eteplirsen, golodirsen, or viltolarsen are not included in Service Code Groupings.

1. For clients residing in an independent county, SARs should be submitted to the CCS independent county office, which shall review and authorize according to the policy above.
2. For clients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at CCSExpeditedReview@dhcs.ca.gov or via secure RightFax (916) 440-5306.

B. All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding the policy for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

After the transition of pharmacy benefit to Medi-Cal RX in 2021, all requests for prior authorization of medications billed by National Drug Code and dispensed by a Medi-Cal enrolled pharmacy provider, shall be sent from the pharmacy provider to the Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (Magellan). The Medi-Cal RX website provides guidance.

Age Limit

Must be four years of age or older.

Billing

HCPCS code J1427 (injection, viltolarsen, 10mg)

Suggested ICD-10-CM Codes

G71.01

Prescribing Restrictions

Frequency of billing equal 80 mg/kg once every seven days.

Deletions That May Be Amenable to Exon Skipping

The list displays common Duchenne Muscular Dystrophy (DMD) deletions that are potentially amenable to exon skipping.

Exon Deletions Potentially Amenable to Exon 51

3-50	19-50	33-50	47-50
4-50	21-50	34-50	48-50
5-50	23-50	35-50	49-50
6-50	24-50	36-50	50
9-50	25-50	37-50	52
10-50	26-50	38-50	52-58
11-50	27-50	39-50	52-61
13-50	28-50	40-50	52-63
14-50	29-50	41-50	52-64
15-50	30-50	42-50	52-76
16-50	31-50	43-50	52-77
17-50	32-50	45-50	

Exon Deletions Potentially Amenable to Exon 53

3-52	19-52	33-52	47-52
4-52	21-52	34-52	48-52
5-52	23-52	35-52	49-52
6-52	24-52	36-52	50-52
9-52	25-52	37-52	52
10-52	26-52	38-52	54-58
11-52	27-52	39-52	54-61
13-52	28-52	40-52	54-63
14-52	29-52	41-52	54-64
15-52	30-52	42-52	54-66
16-52	31-52	43-52	54-76
17-52	32-52	45-52	54-77

Voretigene neparvovec-rzyl

Voretigene neparavovec-rzyl is an adeno-associated virus vector-based gene therapy for injection into the retina of the eye.

Indications

Voretigene neparvovec-rzyl is used for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

Age Limit

One to 64 years of age.

Dosage

1.5 by 10^{11} vector genomes (vg) administered into one eye by subretinal injection. If both eyes require treatment, each eye should be injected on separate days within a close interval, but no fewer than six days apart.

Authorization

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

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

- The service is medically necessary to treat retinal dystrophy due to confirmed RPE65 mutation(s) in both alleles by molecular pathology report.
- The patient has viable retinal cells in the eye indicated for treatment as determined by:
  - An area of retina within the posterior pole of greater than 100 µm thickness measured by OCT (optical coherence tomography); or
  - Equal to or greater than 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole (a “disc area” is equivalent to the area of the optic disc); or
  - A remaining visual field within 30 degrees of fixation as measured by a III43 isopter or equivalent.
- The physician’s legible, complete, and signed treatment plan/order for voretigene neparvovec-ryzl.

Required Codes

One of the following ICD-10-CM diagnosis codes is required for reimbursement:

- H35.50 (Unspecified retinal dystrophy)
- H35.52 (Pigmentary retinal dystrophy)
- H35.54 (Dystrophies primarily involving the retinal pigment epithelium)

Billing

HCPCS code J3398 (injection, voretigene neparvovec-rzyl, one billion vector genomes).

One (1) unit of J3398 equals one billion voretigene neparvovec-rzyl vector genomes.

Vutrisiran (AMVUTTRA™)

Vutrisiran is a double-stranded small interfering ribonucleic acid (siRNA)-N-acetylgalactosamine (GalNAc) conjugate that causes degradation of mutant and wild-type transthyretin (TTR) messenger ribonucleic acid (RNA) (mRNA) through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be for FDA-approved indications and dosing regimens.
- Must be 18 years of age or older.
- Must be prescribed by or in consultation with a neurologist, hematologist, cardiologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
- Patient has a diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with documented mutation in transthyretin (TTR) gene; or tissue biopsy results consistent with amyloid deposition.
- Patient has clinical signs and symptoms of the disease (for example, peripheral sensorimotor neuropathy, autonomic neuropathy, motor disability, etc.).
- Patient had one of the following test results at baseline:
  - Neuropathy Impairment Score of (five to 130)
  - Polyneuropathy disability (PND) score stage 3B or less (equal to or less than IIIb)
- Other causes of peripheral neuropathy have been ruled out.
- Patient has not had a liver transplant and is not planning to undergo one.
- Patient is receiving supplementation with vitamin A at the recommended daily allowance.
- Patient is not currently taking diflunisal, tafamidis, doxycycline, or inotersen.

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial coverage criteria.
- Patient has shown clinical improvement or lack of disease progression from baseline as evidenced by at least one of the following:
  - Improvement in neurologic impairment or motor function
  - Improvement or stability in Neuropathy Impairment score, or Polyneuropathy disability (PND) score

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J0225 (injection, vutrisiran, 1 mg).

Required ICD-10 Diagnosis Code

E85.1

Prescribing Restriction(s)

Frequency of billing equals 25 mg/ 25 units.

Maximum billing unit(s) equals 25 mg/25 units once every three months.

Ziprasidone

Ziprasidone is reimbursable for acute and long-term treatment of adult schizophrenia.

Ziprasidone has been shown to be effective for the acute and long-term management of agitation experienced by patients with schizophrenia.

Note: There is a Food and Drug Administration warning on ziprasidone about its greater capacity to prolong the QT/QTc intervals as opposed to other antipsychotic drugs. Prolongation of the QTc interval has been associated with the development of a potentially fatal condition of ventricular tachycardia and sudden death.

Dosage

The maximum dosage is 40 mg per day.

Billing

For billing ziprasidone mesylate, 10 mg injection, use HCPCS code J3486.

Zoledronic Acid

Zoledronic acid is a bisphosphonic acid which is an inhibitor of osteoclastic bone resorption. Although the antiresorptive mechanism is not completely understood, several factors are thought to contribute to this action. In vitro, zoledronic acid inhibits osteoclastic activity and induces osteoclast apoptosis. It also blocks the osteoclastic resorption of mineralized bone and cartilage through its binding to bone. Finally, it inhibits the increased osteoclastic activity and skeletal calcium release induced by various stimulatory factors released by tumors.

Indications

Zoledronic acid is used for both malignant and non-malignant conditions and is indicated for the treatment of:

- Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.
- Prevention of postmenopausal osteoporosis.
- Osteoporosis in men.
- Prevention of glucocorticoid-induced osteoporosis.
- Paget’s disease of bone in men and women.
- Hypercalcemia of malignancy.

Dosage

The dose varies depending upon which disease or condition is being treated.

Billing

HCPCS code J3489 (injection, zoledronic acid, 1 mg).

For the use of zoledronic acid in non-malignant conditions, coverage is limited to one 5 mg injection, once every 12 months.

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.