Injections: Drugs N-R Policy

Page updated: September 2020

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:

- *Injections: Drugs A-D Policy*
- *Injections: Drugs E-H Policy*
- *Injections: Drugs I-M Policy*
- *Injections: Drugs S-Z Policy*
- *Injections: Hydration*
- *Immunizations*

Naltrexone

Naltrexone is an opioid antagonist with highest affinity for the mu opioid receptor and has little or no opioid agonist activity.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

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

Note: Naltrexone injection must be used as part of a comprehensive management program that includes psychosocial support. It has an FDA-approved Risk Evaluation and Mitigation Strategies (REMS) program, which consists of a Medication Guide, Communication Plan, and a timetable for REMS assessments that must be submitted to the FDA. It requires that the healthcare providers should counsel patients on the risks associated with the use of naltrexone injection.

Billing

HCPCS code J2315 (injection, naltrexone, depot form, 1 mg)

‹‹Naloxone Hydrochloride (ZIMHI™)

Naloxone is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. Naloxone hydrochloride reverses the effects of opioids, including respiratory depression, sedation, and hypotension. Also, it can reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS Code J2311 (injection, naloxone hydrochloride [zimhi], 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 5mg/5 units times one. May repeat every two to three minutes until patient responsive or EMS arrives.››

Natalizumab

Natalizumab, 1 mg injection (HCPCS code J2323), is reimbursable for the treatment of multiple sclerosis (ICD-10-CM diagnosis code G35) or regional enteritis (ICD-10-CM diagnosis code range K50.00 thru K50.919). The maximum daily dosage is 300 mg. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.

‹‹Nitroglycerin

Nitroglycerin forms free radical nitric oxide. In smooth muscle, nitric oxide activates guanylate cyclase which increases guanosine 3’5’ monophosphate (cGMP) leading to dephosphorylation of myosin light chains and smooth muscle relaxation. Produces a vasodilator effect on the peripheral veins and arteries with more prominent effects on the veins. Primarily reduces cardiac oxygen demand by decreasing preload (left ventricular end-diastolic pressure); may modestly reduce afterload; dilates coronary arteries and improves collateral flow to ischemic regions. For use in rectal fissures, intra-anal administration results in decreased sphincter tone and intra-anal pressure.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2305, (Injection, nitroglycerin, 5 mg)››

Nusinersen (Spinraza)

SPINRAZA is an antisense oligonucleotide (ASO) designed to treat (Spinal Muscular Atrophy) SMA caused by mutations in chromosome 5q that lead to SMN protein deficiency. Using in vitro assays and studies in transgenic animal models of SMA, SPINRAZA was shown to increase exon 7 inclusion in SMN2 messenger ribonucleic acid (mRNA) transcripts and production of full-length SMN protein.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR/SAR Requirement

An approved *Treatment Authorization Request* (TAR) or California Children's Services (CCS) Program Service Authorization Request (SAR) is required for reimbursement.

TAR/SAR Criteria

Nusinersen is a benefit when all the following criteria are met:

a. Genetic testing results demonstrate homozygous SMN1 deletion, or any combination of SMN1 deletions or other mutations that result in the functional loss of all SMN1 genes.

b. In addition to demonstrating loss of functional SMN1 genes, genetic test results include the number of copies of SMN2.

c. The patient is under the care of a neurologist or for CCS patients, one of the following CCS Program approved center types: Neuromuscular Medicine SCC, Neuromusculoskeletal SCC or Pediatric Rehabilitation SCC.

d. The patient has either of the following:

- Pre-symptomatic: Defined by genetic testing demonstrating a homozygous SMN1 deletion or mutation, and less than or equal to three copies of SMN2.
- Symptomatic: Patient with clinical signs of SMA with level of function necessary to preserve communication, for instance finger or eye movements in response to prompt by examiner.

e. For nusinersen, it can be safely administered intrathecally (IT), taking into consideration the patient's scoliosis status. Specifically, for older patients with SMA, the drug may only be authorized if patient has any of the following:

- No scoliosis.
- Scoliosis without spine surgery
- Scoliosis post spine surgery with preserved window of accessibility for intrathecal injection, under fluoroscopic or ultrasound guidance if needed.
- Scoliosis post spine surgery for example, fusion) but with surgical placement of an indwelling catheter or establishment of a new window for IT accessibility.

f. The patient does not have a coexisting terminal condition or a condition with which the risk of nusinersen treatment outweighs the potential benefit.

Authorization

For initial authorizations, a CCS Program approved rehabilitation, neuromuscular or neuromusculoskeletal SCC should submit the following:

1. Medical note from neuromuscular specialist at the SCC containing:
   - Patient demographics, including age of onset
   - Results of genetic testing, including name of laboratory, number of copies of SMN2, and whether SMN1 sequencing was done
   - Neurologic status, specifically if patient is non-sitter, sitter or walker
   - Pulmonary status (for example hours of ventilation or Bilevel Positive Airway Pressure [BiPAP])
   - Nutrition and dietary status (with review by registered dietitian), results of at least one neuromotor assessment with a score, performed by or under the direction of the authorized SCC, used to establish a clinical baseline

The following are suggested, but any validated assessment may be used at baseline and repeated annually

i. <u>For non-sitters:</u>
   - ❖ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) or
   - ❖ Hammersmith Infant Neurological Exam-Part 2 (HINE-2)

ii. <u>For sitters:</u>
   - ❖ Hammersmith Functional Motor Scale, Expanded (HFMSE) or,
   - ❖ Revised Upper Limb Module (RULM).

iii. <u>For walkers:</u>
   - ❖ The Timed up and Go test (TUG),
   - ❖ The six-minute walk test or,
   - ❖ The 10-meter run/walk test.

iv. <u>For non-ambulatory older patients:</u>
   - ❖ Revised Upper Limb Module (RULM),
   - ❖ Standard muscle strength assessment.

2. Copy of nusinersen prescription by CCS Program paneled neurologist or physical medicine and rehabilitation specialist at the SCC where the patient completed evaluation for nusinersen.
3. Genetic laboratory confirmation of diagnosis.
4. Patient has not received onasemnogene abeparvovec.

Reauthorization

The CCS Program may reauthorize nusinersin treatment if a CCS-approved rehabilitation, neuromuscular or neuromusculoskeletal SCC has submitted the following documentation to the independent county CCS Program or to Integrated Systems of Care Division (ISCD):

1. Date of initial nusinersen treatment.
2. SCC progress notes documented within six months of the authorization request, including a specific description of changes in neuromotor status since initiation of medication, and any drug-related toxicity.
3. Copy of nusinersen prescription by CCS Program paneled neurologist or physical medicine and rehabilitation specialist, or designee, at SCC where evaluation was completed.
4. Neuromotor assessment, completed at the SCC within 12 months of the reauthorization request, which demonstrates improvement or lack of deterioration since initiation of nusinersen with positive response to medication documented by comparing scores to the results prior to medication.

The request is for the FDA-approved dosage only, with the approved loading and maintenance schedules.

1. Nusinersen is a 12 mg suspension, to be administered intrathecally.
2. The nusinersen treatment schedule consists of four loading doses of 12mg, at days one, 15, 29 and 59, and maintenance doses every 4 months thereafter.

IV. Policy Implementation for CCS Patients

<u>Nusinersen (Spinraza)</u>

1. Nusinersen is not covered by a Service Code Grouping (SCG) authorization. SCCs or pharmacies should submit a separate Service Authorization Request (SAR) and supporting documentation in the following manner:
    a. For nusinersen outpatient administration, as a Hospital or Physician Administered Drug (PAD):
        - ❖ Dates of service beginning January 1, 2018, use Healthcare Common Procedure Coding system (HCPCS) code, J2326. One unit of J2326 is equal to injection, nusinersen, 0.1mg.
        - ❖ SCG02 or SCG01 with additional codes needed for procedures and equipment related to nusinersen administration.
    b. For pharmacy dispensing nusinersen, when the drug is dispensed by a pharmacy provider and delivered to the provider administering the drug:
        - ❖ Authorize its National Drug Code (NDC) to pharmacy.

2. Requesting CCS Program providers must submit the following items to their patients' local CCS Program county office for patients who live in independent counties, or directly to the ISCD Special Populations Authorization Unit for patients who live in dependent CCS counties:
   - CCS Program SAR
   - Medical documentation from the CCS Program approved SCC, with neuromotor assessment scores every 12 months and summary of changes in neuromotor status every six months.
   - Supporting documentation described in the "Authorization and Reauthorization" sections above.
3. When the County CCS Program determines that the request and documentation submitted by the SCC is complete, the county will pend a SAR and forward the request) and supporting documentation to:

   CCSExpeditedReview@dhcs.ca.gov or via secure Right fax number: (916) 440-5306.

   a. The State CCS Program office will issue the authorization.
   b. The State CCS Program office will issue initial authorization for a period of twelve months or until the end of program eligibility period.
   c. Reauthorization shall be granted every twelve months following review of documentation described above unless there are significant adverse effects or change in eligibility.
   d. Reauthorizations will be done by the independent county CCS Program or ISCD Special Populations Authorization Unit for dependent counties.

Required ICD-10 Diagnosis Codes

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

- G12.0 (Infantile spinal muscular atrophy, type I [Werdnig-Hoffman])
- G12.1 (Other inherited spinal muscular atrophy)

Billing

HCPCS code J2326 (injection, nusinersen, 0.1 mg)
One (1) unit of J2326 equals 0.1 mg of nusinersen

Ocriplasmin

Policy for ocriplasmin (HCPCS code J7316) is located in the *Ophthalmology* section of the Part 2 manual.

Ocrelizumab

Ocrelizumab is a recombinant humanized monoclonal antibody directed against CD20-expressing B-cells. The precise mechanism by which ocrelizumab 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, ocrelizumab results in antibody-dependent cellular cytolysis and complement-mediated lysis.

Indication

Ocrelizumab is indicated for the treatment of patients 18 years of age or older with relapsing or primary progressive forms of multiple sclerosis.

Dosage

Hepatitis B virus screening is required before the first dose.

- Pre-medicate with methylprednisolone (or an equivalent corticosteroid) and an antihistamine (for example, diphenhydramine) prior to each infusion
- Administer Ocrevus™ by intravenous infusion:
  - Start dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion
  - Subsequent doses: 600 mg intravenous infusion every six months
- Must be diluted prior to administration
- Monitor patients closely during and for at least one hour after infusion

Required Codes

ICD-10-CM diagnosis code G35

Billing

HCPCS code J2350 (injection, ocrelizumab, 1 mg)

‹‹Olanzapine

Olanzapine is a second generation thienobenzodiazepine antipsychotic which displays potent antagonism of serotonin 5-HT2Aand 5-HT2C, dopamine D1-4, histamine H1, and alpha1-adrenergic receptors. Olanzapine shows moderate antagonism of 5-HT3 and muscarinic M1-5 receptors, and weak binding to GABA-A, BZD, and beta-adrenergic receptors. Although the precise mechanism of action in schizophrenia and bipolar disorder is not known, the efficacy of olanzapine is thought to be mediated through combined antagonism of dopamine and serotonin type 2 receptor sites. Olanzapine's activity at the dopamine (D2), 5-HT2C, and 5-HT3receptors may be responsible for the antiemetic effect (Navari 2016).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 13 years of age or older.

Billing

HCPCS code J2359 (injection, olanzapine, 0.5 mg)››

Oliceridine (Olinvyk®)

Oliceridine is a full opioid agonist and is relatively selective for the mu-opioid receptor. The principal therapeutic action of oliceridine is analgesia. Like all full opioid agonists, there is no ceiling effect to analgesia for oliceridine. Clinically, dosage is titrated to provide adequate analgesia and may be limited by adverse reactions, including respiratory, and Central Nervous System (CNS) depression. The precise mechanism of the analgesic action is unknown. However, specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and are thought to play a role in the analgesic effects of this drug.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Olinvyk 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 moderate to severe acute pain
- Pain is severe enough to require an intravenous opioid analgesic
- Alternative treatments such as non-opioid analgesics are inadequate
- Patient has tried intravenous (I.V.) opioids such as morphine, Hydromorphone, fentanyl unless intolerance, inadequate pain control or it is clinically inappropriate
- The cumulative total daily dose will not exceed 27 mg

Approval is for seven days. (Treatment duration will be limited to 48 hours).

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9101 (injection, oliceridine, 0.1 mg).

Prescribing Restriction (s)

Frequency of billing equals up to 27 mg/270 units per day.

Maximum billing unit(s) equals up to 27 mg /270 units.

Omadacycline Tosylate (Nuzyra®)

Omadacycline is an aminomethylcycline antibacterial within the tetracycline class of antibacterial drugs. Omadacycline binds to the 30S ribosomal subunit and blocks protein synthesis. Omadacycline is active in vitro against Gram-positive bacteria expressing tetracycline resistance active efflux pumps (*tetK* and *tetL*) and ribosomal protection proteins (*tetM*). In general, omadacycline is considered bacteriostatic; however, omadacycline has demonstrated bactericidal activity against some isolates of *S. pneumoniae* and *H. influenzae*.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

- FDA-approved indications
- Must be 18 years of age or older
- Failure of greater than or equal to two formulary antibiotics indicated for member's diagnosis and sufficiently effective against offending pathogen unless contraindicated or intolerable side effects
- Approval quantity to be based on prescribing information and FDA-approved dosages

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0121 (injection, omadacycline, 1 mg)

Prescribing Restrictions

Frequency of billing equals 200 mg stat, then 100 mg daily for seven to 14 days

Maximum billing units equals 1,500 mg equals 1,500 units.

Omalizumab

Omalizumab is a recombinant anti-IgE monoclonal antibody (IgG1κ) in solution for subcutaneous (SQ) administration.

Indications

Omalizumab is used to treat the following conditions:

- Moderate-to-severe persistent asthma in patients who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
- Chronic idiopathic urticaria (CIU) in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Omalizumab is not indicated for:

- The treatment of other allergic conditions or other forms of urticaria.
- The relief of acute bronchospasm or status asthmaticus

Age

Six years and older

Dosage

The recommended dose is based on the treatment condition:

- For asthma: 75 to 375 mg SQ given once every two or four weeks.
- For CIU: 150 or 300 mg SQ given once every four weeks.

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 CIU, or
- The service is medically necessary to treat moderate-to-severe persistent asthma.
  - Severe asthma as defined by symptoms that are persistent and uncontrolled despite the use of high dose inhaled corticosteroids combined with a long-acting beta2 agonist, leukotriene receptor agonist, or theophylline for the previous one year or longer, or the use of systemic glucocorticoids for 50% or more of the previous year.‡

- Persistent uncontrolled asthma as defined by <u>at least one</u> of the following ‡:
  - ❖ An ACQ score consistently greater than 1.5 (Asthma Control Questionnaire) or an ACT score less than 20 (Asthma Control Test).
  - ❖ Two or more exacerbations in the previous year, each requiring 3 or more days of treatment with systemic glucocorticoids.
  - ❖ A history of hospitalization, intensive care unit stay, or mechanical ventilation in the previous year.
  - ❖ A FEV_1 (Forced Expiratory Volume in 1 second) at less than 80% of predicted after bronchodilator administration measured by pulmonary function testing <u>or</u> spirometry and documented by report and interpretation.
- A positive skin test or *in vitro* reactivity to a perennial aeroallergen.
- Symptoms are inadequately controlled with inhaled corticosteroids.
- Pre-treatment serum IgE level between 30 and 700 IU/ml.
- For continued use, documentation of clinical improvement after the administration of omalizumab, as measured by parameters such as an asthma control questionnaire, a decreased use of beta-agonists, an increase in FEV_1 from pre-treatment baseline, a reduction in acute exacerbations or hospitalizations, etc.

Required Codes

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

- J45.40 (Moderate persistent asthma, uncomplicated)
- J45.50 (Severe persistent asthma, uncomplicated)
- J82 (Pulmonary eosinophilia, not elsewhere classified)
- L50.1 (Idiopathic uticaria)
- L50.8 (Other urticaria)

Billing

HCPCS code J2357 (injection, omalizumab, 5 mg)
One (1) unit of J2357 equals 5 mg of omalizumab

OnabotulinumtoxinA

For detailed clinical and billing policy information about onabotulinumtoxinA, refer to the "Botulinum Toxins A and B" topic in the *Injections: Drugs A-D Policy* section of the manual.

Onasemnogene abeparvovec-xioi (Zolgensma)

Zolgensma is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein. SMA is caused by a bi-allelic mutation in the SMN1 gene, which results in insufficient SMN protein expression. Intravenous administration of Zolgensma that results in cell transduction and expression of the SMN protein has been observed in two human case studies.

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

Onasemnogene abeparvovec-xioi (Zolgensma) is a benefit when all of the following criteria are met:

1. The patient is under the age of two years
2. The patient has bi-allelic mutations in survival motor neuron 1 (SMN1) gene, demonstrated by genetic testing results with documentation of both of the following
   - Genetic documentation of bi-allelic mutations in SMN1 gene (deletions or point mutations)
   - Documentation of up to and including four copies of survival motor neuron 2 (SMN2)
3. Patient does not have advanced SMA, as evidenced by any of the following:
   - Invasive ventilator support (tracheostomy with ventilator)
   - Complete paralysis of limbs

4. The patient is under the care of a neurologist or for SSC patients, an approved Neuromuscular Special Care Center (SCC) Neuromusculoskeletal SCC, or Pediatric Rehabilitation SCC
5. The patient does not have Adeno-Associated Virus Serotype 9 (AAV9) titer greater than 1:50 as determined by Enzyme-Linked Immunosorbent Assay (ELISA) binding immunoassay
6. There is no indication of significant liver injury
7. Patient is not currently being treated with nusinersen or treatment with nusinersen will be discontinued prior to the administration of onasemnogene abeparvovec-xioi
8. Patient was not previously treated with onasemnogene abeparvovec-xioi.

Approval is limited to one dose in a lifetime.

Authorization

Providers requesting authorization of onasemnogene abeparvovec-xioi must provide the following documentation:

- Copy of onasemnogene abeparvovec-xioi prescription by CCS Program paneled neurologist or physical medicine and rehabilitation specialist at the SCC where evaluation for onasemnogene abeparvovec-xioi was completed
- Medical documentation of SCC visit with history and physical examination including description of plan for onasemnogene abeparvovec-xioi administration
- Genetic laboratory confirmation of diagnosis and number of SMN2 copies.
- Documentation of AAV9 titer that is less than 1:50, within 90 days of planned administration
- At least one neuromotor assessment, performed within 12 months of the authorization request, with a score used to establish a clinical baseline
- Documentation of baseline liver function test, platelet counts, and troponin-I

Additional considerations for medical necessity determination:

For patients who do not meet the approval criteria described above, requesting SCCs may demonstrate medical necessity by submitting any other clinical documentation and/or evidence that would support the initial or reauthorization of the patient’s treatment for 5q SMA. SCCs should submit this documentation to the ISCD Medical Director or designee.

Policy Implementation for CCS

9. Onasemnogene abeparvovec is not covered by a Service Code Grouping (SCG) authorization and a separate authorization is needed for outpatient administration.
10. ‹‹Requesting CCS Program providers must submit the following items to their patients' local CCS Program county office or Integrated Systems of Care Division (ISCD) Special Populations Authorization Unit:››
    - CCS Program Service Authorization (SAR) with Outpatient National Provider Identifier number for:
      - ❖ HCPCS code J3399, injection onasemnogene abeparvovec-xioi, per treatment up to 5x10^15 vector genomes
      - ❖ Supporting clinical documentation should justify medical necessity and that the service is the least costly to meet the patient's needs
      - ❖ SCG02 or SCG01 with additional codes needed for procedures and equipment related to onasemnogene abeparvovec-xioi administration
11. When the County CCS Program determines that the request and documentation submitted by the SCC is complete, the county will pend a Service Authorization Request (SAR) and forward the request and supporting documentation to *CCS_Operations@dhcs.ca.gov* or via secure Right fax number: (916) 440-5768.
12. The State CCS Program office will issue the authorization
13. Each CCS patient is eligible to receive only one treatment of onasemnogene abeparvovec, under J3399, or any other code (HCPCS, Current Procedural Terminology [CPT], or by NDC).
14. Requesting providers must adhere to the following special instructions when filing a claim:
    a. Provider must submit one (1) service line for three (3) units on the TAR/SAR request, and enter "3" in the Units box
    b. On the *837I* (institutional) electronic form *or UB-04* 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
    c. Provider must submit an invoice for reimbursement.

d. This process will ensure that the total reimbursement paid for the three (3) claim lines is no more than the paid price on the provider submitted invoice paid price
e. Zolgensma must be billed on its own with no other drug or biological
f. Providers must identify Zolgensma paper claims by notation as such in the remarks section of the paper claim. For electronic claims, provider shall indicate claim is for Zolgensma on a coversheet, to ensure that these are processed expeditiously.
g. Providers should note that except for the first claim line, payment for any additional line will be delayed for 2-3 additional weeks due to systems constraints.
h. Payment for Zolgensma shall be a once-in-a-lifetime reimbursement under J3399, (or by specific CPT code or NDC).

Age Limits

Must be less than two years of age

Billing

HCPCS code J3399 (injection, onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes)

Required ICD-10 Diagnosis Codes

G12.0, G12.1, G12.9

Prescribing Restrictions

Frequency of billing equals 1.1x1014 vector genomes (vg) per kg for single dose administration. No repeat administration.

Notice to providers regarding the special billing of Zolgensma™ claims effective July 1, 2020

The Department of Health Care Services (DHCS) would like to notify providers of the special billing and claims processing requirements for Zolgensma™ (onasemnogene abeparvovec-xioi) suspension for intravenous infusion, when billed under a Healthcare Common Procedural Coding System (HCPCS) code, J3399.This communication supersedes the department's related communication, dated April 22, 2020.

Under the Healthcare Common Procedural Coding System (HCPCS), and effective July 1, 2020, Zolgensma™ was assigned the unique code, J3399 (injection, onasemnogene abeparvovec-xioi, per treatment, up to 5 $x10^{15}$ vector genomes.). A non-specific HCPCS code, J3590, was used previously.

Coverage and policy details for Zolgensma™ under the Medi-Cal and California Children's Service (CCS) Programs are covered elsewhere.

National Standards and system limitations for J3399 do not allow for accurate claims adjudication when billing a single claim line. National Council for Prescription Drug Programs (NCPDP) standards and the *UB-04* or other standard claim forms do not accommodate the large dollar amount of the claim, which is in excess of $2 million.

When submitting claims for Zolgensma™, providers are instructed to do the following:

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. Bill using J3399, injection, onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes.
3. Completion of claim forms:
   - Zolgensma™ may be administered during a Diagnosis Related Group (DRG) inpatient hospital stay as carve-out service and must be billed and submitted separately as a hospital outpatient service.
   - This billing methodology is restricted to hospital outpatient services. Note that 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:
     - ❖ The TAR/SAR is not negotiated
     - ❖ Provider must submit one (1) service line on the TAR/SAR request, and enter "3" in the Units box

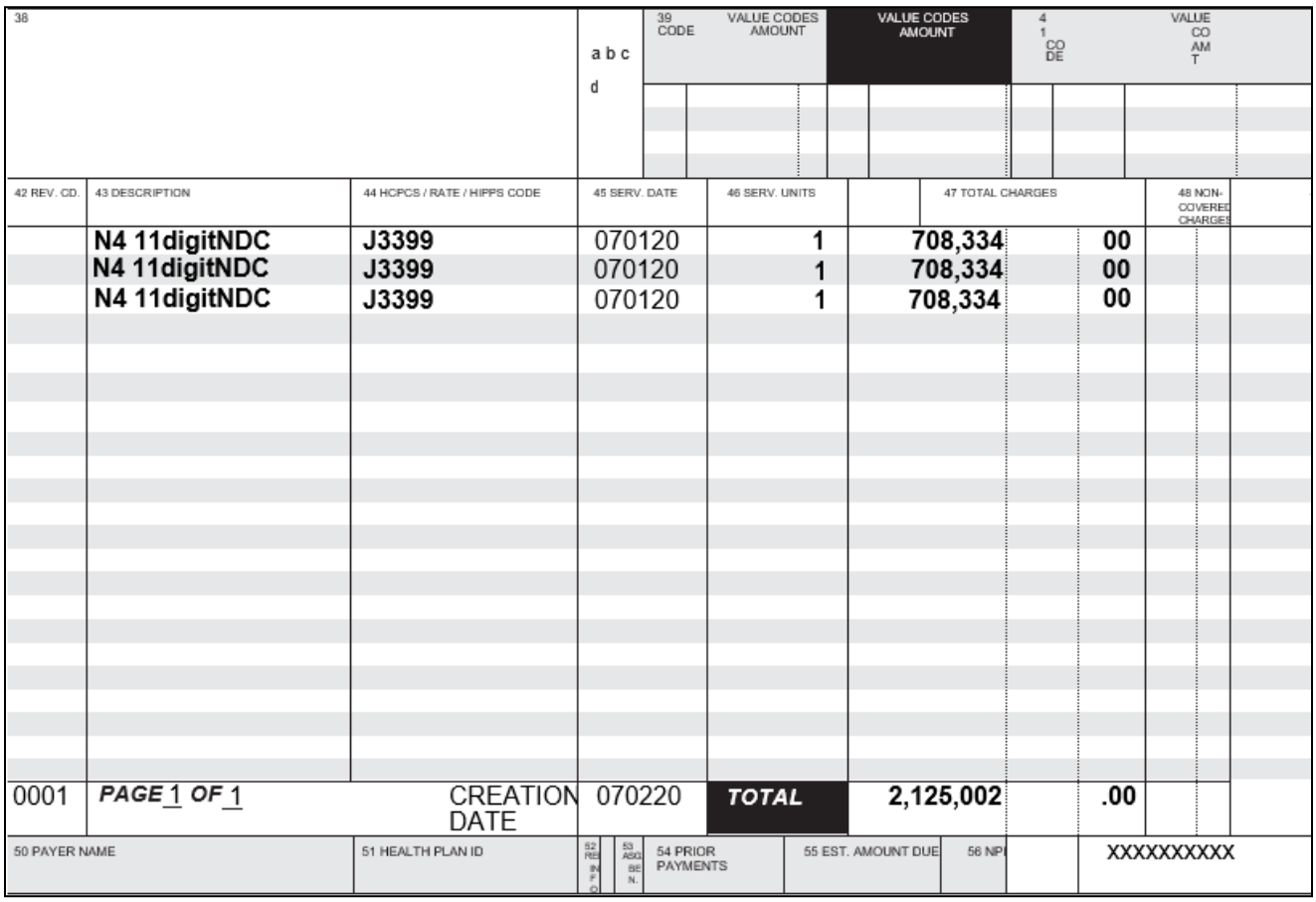
- ❖ On the 837I or *UB-04* claim form, provider must submit three (3) claim lines to represent one (1) service.
  - Each claim line to represent one unit.
  - Claims submitted with one or two claim lines will be denied
- ❖ Provider must submit an invoice for reimbursement.
- ❖ This process will ensure that the total reimbursement paid for the three (3) claim lines is no more than the paid price on the provider submitted invoice
- ❖ Zolgensma must be billed on its own with no other drug or biological

4. Providers are advised to take the following steps in order to ensure that Zolgensma claims are identified and processed expeditiously.
   - Paper claims may be identified by notation of “Zolgensma” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary/Gainwell Technologies
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Zolgensma” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
5. 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.
6. Payment for Zolgensma shall be a once-in-a-lifetime reimbursement under J3399 or any other code (HCPCS, CPT or by NDC).
7. For instructions regarding physician claim form completion, refer to the Med-Cal website, forms section for completion of 837I form and *UB-04* form.

Below is a Zolgensma billing example using *UB-04* form and with 3 claim lines:

- In this example, the total invoice cost of J3399 is $2,125,002.00
- 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 $708,334.00
- 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



38			a b c d	39 CODE	VALUE CODES AMOUNT	VALUE CODES AMOUNT	41 CODE	VALUE CO AM T

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
	N4 11digitNDC	**J3399**	070120	**1**	**708,334 00**	
	N4 11digitNDC	**J3399**	070120	**1**	**708,334 00**	
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0001	***PAGE 1 OF 1***	CREATION DATE	070220	***TOTAL***	**2,125,002 .00**	

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INF.	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	XXXXXXXXXX

Figure 1: Zolgensma Billing Example using a *UB-04* form

Note: To complete a request, refer to the *Onasemnogene Abeparvovec (Zolgensma) Request* Form

Ondansetron HCl

Ondansetron HCl is a selective 5-HT3 receptor antagonist.

Indications

For the prevention of nausea and vomiting associated with the initial and repeated courses of cancer chemotherapy and the prevention of postoperative nausea and/or vomiting.

Dosage

Prevention of chemotherapy-induced nausea and vomiting:

- Adults: The recommended adult intravenous dosage is three 0.15-mg/kg doses up to a maximum of 16 mg per dose. The first dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg up to a maximum of 16 mg per dose) are administered four and eight hours after the first dose
- Pediatrics: For pediatric patients 6 months through 18 years of age, the intravenous dosage is three 0.15-mg/kg doses up to a maximum of 16 mg per dose. The first dose is to be administered 30 minutes before the start of moderately to highly emetogenic chemotherapy. Subsequent doses (0.15 mg/kg up to a maximum of 16 mg per dose) are administered four and eight hours after the first dose

Prevention of postoperative nausea and vomiting:

- Adults: The recommended adult intravenous dosage is 4 mg *undiluted* administered intravenously in not less than 30 seconds, preferably over 2 to 5 minutes, immediately before induction of anesthesia, or postoperatively if the patient did not receive prophylactic antiemetics and experiences nausea and/or vomiting occurring within two hours after surgery. Alternatively, 4 mg *undiluted* may be administered intramuscularly as a single injection for adults
- Pediatrics: For pediatric patients 1 month through 12 years of age, the dosage is a single 0.1-mg/kg dose for patients weighing 40 kg or less, or a single 4-mg dose for patients weighing more than 40 kg. The rate of administration should not be less than 30 seconds, preferably over two to five minutes immediately prior to or following anesthesia induction, or postoperatively if the patient did not receive prophylactic antiemetics and experiences nausea and/or vomiting occurring shortly after surgery

Administration of a second I.V. dose of 4 mg ondansetron postoperatively does not provide additional control of nausea and vomiting.

Billing

HCPCS code J2405 (ondansetron hydrochloride, per 1 mg)

Oritavancin (Kimyrsa™)

Oritavancin is an antibacterial drug with three mechanisms of action: (i) inhibition of the transglycosylation (polymerization) step of cell wall biosynthesis by binding to the stem peptide of peptidoglycan precursors; (ii) inhibition of the transpeptidation (crosslinking) step of cell wall biosynthesis by binding to the peptide bridging segments of the cell wall; and (iii) disruption of bacterial membrane integrity, leading to depolarization, permeabilization, and cell death. These multiple mechanisms contribute to the concentration-dependent bactericidal activity of oritavancin.

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
- Patient must have a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) suspected or confirmed to be caused by a gram-positive pathogen requiring intravenous therapy.
  - An ABSSSI includes wound infections, cellulitis/erysipelas, major cutaneous abscess
- Culture and sensitivity report documents one of the following:
  - Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication or vancomycin, or
  - Staphylococcus aureus with reduced susceptibility to vancomycin (vancomycin intermediate Staphylococcus aureus [VISA], or vancomycin-resistant Staphlyococcus aureus [VRSA])
- Patient has medical reason why oral antibiotics are not appropriate
- Patient does not have any of the following:
  - Concomitant infection at another site not including a secondary ABSSSI lesion (for example, septic arthritis, endocarditis, osteomyelitis)
  - Infected burns
  - Infections known to be caused by an organism resistant to oritavancin
  - Catheter site infections
  - Known liver function tests (LFTs) greater than or equal to 3 times the upper limit of normal (ULN) or total bilirubin greater than or equal to 2 times ULN

Authorization is once per treatment.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J2406 (injection, oritavancin [Kimyrsa], 10 mg)

Prescribing Restrictions

Frequency of billing equals 1,200 mg/120 units as a single dose

Oritavancin (Orbactiv®)

Oritavancin is an antibacterial drug with three mechanisms of action: (i) inhibition of the transglycosylation (polymerization) step of cell wall biosynthesis by binding to the stem peptide of peptidoglycan precursors; (ii) inhibition of the transpeptidation (crosslinking) step of cell wall biosynthesis by binding to the peptide bridging segments of the cell wall; and (iii) disruption of bacterial membrane integrity, leading to depolarization, permeabilization, and cell death. These multiple mechanisms contribute to the concentration-dependent bactericidal activity of oritavancin.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J2407 (injection, oritavancin [Orbactiv], 10 mg)

Prescribing Restrictions

Frequency of billing equals 1,200 mg/120 units as a single dose

Palifermin

Reimbursement for palifermin, 50 mcg injection (HCPCS code J2425) is allowed up to a maximum of 140 units.

‹‹Paliperidone Palmitate (Invega Sustenna®, Invega Trinza®, Invega Hafyera™)

Paliperidone palmitate is hydrolyzed to paliperidone [see Clinical Pharmacology (12.3)]. Paliperidone is the major active metabolite of risperidone. The mechanism of action of paliperidone is unclear. However, its efficacy in the treatment of schizophrenia could be mediated through a combination of central dopamine D2 and serotonin 5HT2A receptor antagonism.

Invega Sustenna, Invega Trinza and Invega Hafyera are dosed monthly, every 3 months, or every 6 months, respectively, per their individual Prescribing Information.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 18 years of age or older

Billing

HCPCS codes:

- J2426 (Injection, paliperidone palmitate extended release [Invega Sustenna], 1 mg)
- J2427(Injection, paliperidone palmitate extended release [Invega Hayera, or Invega Trinza), 1 mg

Suggested ICD-10CM Diagnosis Codes

F20, F20.0, F20.1, F20.2, F20.3, F20.5, F20.8, F20.9

Invega Sustenna only: F25.0, F25.1, F25.9››

Palonosetron

Palonosetron, 25 mcg (HCPCS code J2469) is reimbursable for acute and delayed emesis due to emetogenic chemotherapy. Palonosetron may be combined with aprepitant and dexamethasone for maximal patient benefit for both acute and delayed emesis due to highly emetogenic chemotherapy.

Dosage

A single intravenous dose of 0.25 mg delivered over 30 seconds is given 30 minutes before chemotherapy. CPT® code 96375 (therapeutic, prophylactic or diagnostic injection; each additional sequential intravenous push of a new substance/drug) may be reimbursed when billed in conjunction with palonosetron.

Pamidronate

Pamidronate, 30 mg, an aminohydroxypropylidene biphosphonate, is reimbursable for the outpatient treatment of hypercalcemia of malignancy with or without bone metastases, Paget's disease and osteolytic bone lesions of breast and prostate cancer and osteolytic bone lesions of multiple myeloma.

Required Codes

Pamidronate must be billed in conjunction with CPT codes 96365 (intraveous infusion for therapy prophylaxis or diagnosis; initial, up to one hour) and 96366 (intraveous infusion for therapy prophylaxis or diagnosis; each additional hour) when billed for outpatient treatment with one of the following ICD-10-CM diagnosis codes:

C50.011 thru C50.929	C90.00 thru C90.02
C61	E83.52
C79.51	M88.0 thru M88.9

Billing

For billing, use HCPCS code J2430 (injection, pamidronate disodium, per 30 mg).

Dosage

The maximum dosage is 90 mg per day.

Paricalcitol

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

Dosage

The recommended initial dose of paricalciferol is 0.04 mcg/kg to 0.1 mcg/kg administered intravenously as a bolus dose no more frequently than every other day at any time during dialysis. The maximum dose should not exceed 30 mcg weekly.

Billing

HCPCS code J2501 (injection, paricalcitol, 1 mcg).
One (1) unit equals 1 mcg.

Note: Code J2501 cannot be block billed.

Patisiran (Onpattro®)

Patisiran is a double-stranded small interfering ribonucleic acid (siRNA) that causes degradation of mutant and wild-type transthyretin (TTR) mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Serum TTR is a carrier of retinol binding protein, which is involved in the transport of vitamin A in the blood.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Must summit 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
- 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 (5 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 Limits

Must be 18 years of age or older

Billing

HCPCS code J0222 (injection, patisiran, 0.1 mg)

Suggested ICD-10-CM Diagnosis Codes

E85.1

Prescribing Restrictions

Frequency of billing equals 30 mg/300 units every 21 days

Maximum billing units equals 30 mg equals 300 units

Pegademase Bovine

Claims for pegademase bovine, 25 IU, (HCPCS injection code J2504) must be billed with ICD-10-CM codes D81.3 (adenosine deaminase [ADA] deficiency).

Pegaptanib Sodium

Policy for intravitreal pegaptanib sodium (HCPCS code J2503) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Pegloticase

Pegloticase is a uric acid specific enzyme which is a PEGylated product that consists of recombinant modified mammalian urate oxidase (uricase) produced by a genetically modified strain of *Escherichia coli*. It is a uric acid specific enzyme which is a recombinant uricase and achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid.

Indications

For the treatment of chronic gout in adult patients refractory to conventional therapy who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Pegloticase is not recommended for the treatment of asymptomatic hyperuricemia.

Required Codes

Pegloticase is reimbursable only with ICD-10-CM diagnosis codes M1A.00 thru M10.9.

Dosage

The recommended dose and regimen of pegloticase for adult patients is 8 mg given as an intravenous infusion every two weeks.

Restricted to patients 18 years of age and older.

Billing

HCPCS code J2507 (injection, pegloticase, 1 mg).

Peramivir

Peramivir is an antiviral drug with activity against influenza virus. It is an inhibitor of influenza virus neuraminidase, an enzyme that releases viral particles from the plasma membrane of infected cells.

Indications

For the treatment of acute uncomplicated influenza in patients 18 years of age and older who have been symptomatic for no more than two days.

Dosage

The recommended dose is a single 600 mg dose administered intravenously over 15 to 30 minutes.

Billing

HCPCS code J2547 (injection, peramivir, 1 mg).

Phenobarbital Sodium (Sezaby™)

The precise mechanism of action for phenobarbital for the treatment of neonatal seizures is not fully understood, but it is thought to involve potentiation of synaptic inhibition through an action on the GABAA receptor.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2561 (Injection, phenobarbital sodium [Sezaby], 1 mg)

Phenylephrine Hydrochloride

Potent, direct-acting alpha-adrenergic agonist with virtually no beta-adrenergic activity; produces systemic arterial vasoconstriction. Such increases in systemic vascular resistance may result in dose-dependent increases in systolic and diastolic blood pressure and reductions in heart rate and cardiac output (most noticeable in patients with preexisting cardiac dysfunction).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Billing

HCPCS code J2371 (Injection, phenylephrine hydrochloride, 20 mcg)

Phenylephrine Hydrocholoride (Biorphen)

Potent, direct-acting alpha-adrenergic agonist with virtually no beta-adrenergic activity; produces systemic arterial vasoconstriction. Such increases in systemic vascular resistance may result in dose-dependent increases in systolic and diastolic blood pressure and reductions in heart rate and cardiac output (most noticeable in patients with preexisting cardiac dysfunction).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Billing

HCPCS code J2372 (Injection, phenylephrine hydrochloride [Biorphen], 20 mcg)

Plasminogen, human-tvmh (Ryplazim®)

Treatment with Ryplazim temporarily increases plasminogen levels in blood.

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 11 months of age or older
- Must be prescribed by or in consultation with a geneticist, hematologist, or specialist with experience in treating hypoplasminogenemia
- Patient has a diagnosis of plasminogen deficiency type 1 as evidenced by at least two of the following:
  - Biallelic mutations in the plasminogen (PLG) gene confirmed by genetic testing
  - A baseline plasminogen activity level less than 45 percent of normal.
  - A documented history of typical lesions and symptoms (for example, ligneous conjunctivitis, ligneous gingivitis and tonsillar lesions, ligneous airway disease, ligneous lesions of the hands and feet, impaired wound healing, etc.).
- For patients with respiratory tract involvement, spirometry measurements (forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), peak expiratory flow, and FEV1/FVC ratio) at baseline and every four weeks.

Initial authorization is for 12 months

Continued therapy

- Patient continues to meet initial approval criteria
- Patient has shown clinical benefit as evidenced by at least one of the following:
  - Improvement in lesion number or size from baseline
  - Absence of new lesions compared to baseline
  - Improvement in wound healing
  - Improvement in spirometry measurements from baseline if respiratory tract involvement

Reauthorization is for 12 months

Billing

HCPCS code J2998 (injection, plasminogen, human-tvmh, 1 mg)

Required ICD-10 Diagnosis Codes

E88.02

Prescribing Restriction(s)

Frequency of billing equals 6.6 mg/kg every two to four days

Plazomicin (Zemdri)

Plazomicin is an aminoglycoside antibacterial which interferes with bacterial protein synthesis by binding to 30S ribosomal subunit resulting in a defective bacterial cell membrane.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

- Must be for an FDA-approved indication and dosing regimen
- Must have a diagnosis of complicated urinary tract infection (cUTI) including pyelonephritis caused by Escherichia coli, Klebsiella penumoniae, Proteus mirabilis and Enterobacter cloacae
- Must be 18 years of age or older
- Must not be pregnant
- Must justify why patient cannot use formulary alternatives such as an aminoglycoside, carbapenems, fluoroquinolone or other therapeutic equivalent
- Must provide the patient's recent weight for dose determination

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0291 (injection, plazomicin, 5 mg)

Prescribing Restrictions

Frequency of billing equals every 24 hours for four to seven days

Maximum billing units equals 3,400 mg equals 680 units

Plerixafor

Plerixafor is used to enhance mobilization of stem cells for autologous transplantation in patients with non-Hodgkin lymphoma and multiple myeloma.

Required Codes

Plerixafor is reimbursable when billed in conjunction with an ICD-10-CM diagnosis code in the range C82.00 thru C86.6, C88.4 or C90.00 thru C90.02.

Billing

HCPCS code J2562 (injection, plerixafor, 1 mg) one unit equals1 mg.

Protein C Concentrate

Protein C concentrate, intravenous, human, 10 IU (HCPCS code J2724) is reimbursable when billed with ICD-10-CM diagnosis code D68.59 and has a maximum daily dosage of 16,360 IU.

Prothrombin Complex Concentrate (Human)

Prothrombin complex concentrate is a purified, heat-treated, nanofiltered and lyophilized non-activated, four-factor drug prepared from human plasma. It contains the vitamin K-dependent coagulation Factors II, VII, IX, X and the antithrombotic proteins C and S. A dose-dependent acquired deficiency of the vitamin K dependent coagulation factors occurs during vitamin K antagonist treatment. The administration of prothrombin complex rapidly increases plasma levels of these factors as well as anti-thrombotic Proteins C and S.

Indications

For the urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist therapy in adult patients with acute major bleeding.

It is not indicated for urgent reversal of vitamin K antagonist anticoagulation in patients without acute major bleeding.

The safety and efficacy of prothrombin complex concentrate has not been studied in the pediatric population.

Authorization

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

Dosage

The recommended dosage should be individualized based on the patient's baseline International Normalized Ratio (INR) value and body weight.

The maximum recommended dosage is 5,000 units.

Billing

HCPCS code J7168 Prothrombin complex concentrate (human), kcentra per i.u. of factor IX activity.

Ranibizumab

Policies for intravitreal ranibizumab (HCPCS codes J2778, J2779, Q5124, and Q5128) are located in the *Ophthalmology* section of the provider manual.

Ravulizumab-cwvz (Ultomiris®)

Ravulizumab-cwvz is a terminal complement inhibitor that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a (the proinflammatory anaphylatoxin) and C5b (the initiating subunit of the terminal complement complex [C5b-9]) and preventing the generation of the terminal complement complex C5b9. ULTOMIRIS inhibits terminal complement-mediated intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH) and complement-mediated thrombotic microangiopathy (TMA) in patients with atypical hemolytic uremic syndrome (aHUS).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Ravulizumab-cwvz is considered medically necessary in appropriate patients when the following criteria are met:

Universal criteria

1. Must be used for FDA-approved indications and dosages
2. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies
3. Patient must be vaccinated against meningococcal infections within 3 years prior to, or at the time of initiating ravulizumab (at least 2 weeks prior to treatment, if not previously vaccinated). In emergent situations, antibiotics may be appropriate with vaccination less than two weeks prior to treatment.
4. Patient does not have Shiga toxin-producing Escherichia coli (E. coli) infection.
5. Prescriber is enrolled in the ULTOMIRIS REMS program

A. Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Patient has a documented diagnosis of PNH with granulocyte or monocyte clone size of greater than five percent and:

Treatment Naïve Patients

- Active hemolysis as measured by lactic acid dehydrogenase (LDH) level of 1.5 times the upper limit of normal (ULN) at screening and one of the following within three months of screening:
  - Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia (hemoglobin less than10 g/dl), history of MAVE (including thrombosis), dysphagia, or erectile dysfunction; or history of pRBC transfusion due to PNH

Eculizumab Conversion Patients

- Hemolysis as measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) at screening AND
- Treatment with eculizumab for at least six months

Initial authorization for up to six months

- Continuation of therapy in appropriate patients is considered medically necessary for the treatment of a patient with documented PNH who is currently receiving treatment with ravulizumab-cwvz **and** one of the following:
  - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) or
  - Transfusion avoidance defined as elimination of transfusion requirements or reduced need for transfusions or

- Stabilization of hemoglobin levels or
- Improvement in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT Fatigue) scores

Reauthorization for up to 12 months

B. Atypical Hemolytic Uremic Syndrome (aHUS)

- Confirmed diagnosis of atypical hemolytic uremic syndrome as evidenced by **all** of the following:
  - Diagnosis of thrombocytopenic purpura (TTP) has been excluded (for example, normal ADAMTS13 activity) OR a trial of plasma exchange did not result in clinical improvement

Initial authorization for up to six months

Continuation of therapy:

- Patient continues to meet initial approval criteria
- Patient has a documentation of clinical response such as improvement in platelet count and LDH, reduced hemolysis, improved kidney function, reduction in thrombocytopenia, etc.

Reauthorization for up to 12 months

REMS

- Due to the risk of meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)
- Prescribers must enroll in the program. Enrollment and additional information are available by telephone: 1-888-765-4747 or at *www.ultomirisrems.com*

Billing

HCPCS code J1303 (injection, ravulizumab-cwvz, 10 mg)

Suggested Codes

ICD-10 CM Diagnosis code D59.5, D58.8, D59.3, D59.4, D59.8.

Remdesivir (Veklury®)

Veklury is an inhibitor of the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp), which is essential for viral replication. Veklury is an adenosine nucleotide prodrug that is metabolized to the pharmacologically active nucleoside triphosphate metabolite after being distributed into cells. Remdesivir triphosphate (GS-443902) acts as an adenosine triphosphate analog and competes for incorporation into RNA chains by the SARS-CoV-2 RdRp, resulting in delayed chain termination during viral RNA replication. Remdesivir triphosphate can also inhibit viral RNA synthesis due to incorporation into the viral RNA template.

Veklury should be administered in a hospital or a health care setting with immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), if necessary.

Indications

Veklury is indicated for the treatment of COVID-19 in adults and pediatric patients (at least 28 days old and weighing at least 3 kg) with positive results of SARS-CoV-2 viral testing, who are:

- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death

Dosages

For adults and pediatric patients weighing 40 kg or more: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2, administered only via intravenous infusion.

For pediatric patients at least 28 days old and weighing 3 kg to 40 kg: 5 mg/kg on Day 1, followed by once-daily maintenance doses of 2.5 mg/kg from Day 2, administered only via intravenous infusion.

Treatment duration:

Hospitalized patients:

- For patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO): 5 days; may be extended up to 5 additional days (10 days total) if clinical improvement is not observed.
- For patients requiring invasive mechanical ventilation and/or ECMO: 10 days.
- Initiate treatment as soon as possible after diagnosis of symptomatic COVID-19 is made.

Non-hospitalized patients:

- For non-hospitalized patients diagnosed with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death: 3 days.
- Initiate as soon as possible and within 7 days of symptom onset.

Testing prior to and during treatment: Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating Veklury and during use as clinically appropriate.

Renal impairment: Veklury is not recommended in individuals with eGFR less than 30 mL/min.

Dose preparation and administration: There are two different formulations of Veklury: Veklury for injection (supplied as 100 mg lyophilized powder in vial), the only approved dosage form of Veklury for pediatric patients weighing 3 kg to less than 40 kg; and Veklury injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). See Veklury Package Insert for detailed prescribing information.

TAR Requirement

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

Billing

HCPCS code: J0248 (injection, remdesivir, 1 mg)

Important Billing Instructions

DHCS will reimburse Veklury for the treatment of COVID-19 when administered in accordance with FDA approval.

Prior authorization is not required. Provider must meet the following patient selection and monitoring criteria in accordance with FDA approval:

- Patient meets FDA requirements for age and weight.
- Patient has a positive result of direct SARS-CoV-2 viral testing.
- Veklury will be administered in settings where severe hypersensitivity reactions, such as anaphylaxis, can be managed and emergency services activated, such as skilled nursing facilities, home healthcare settings and outpatient facilities such as infusion centers.
- The treatment course is being initiated within 7 days of symptom onset.

- Must comply with the following testing before initiating and during treatment with Veklury:
  - Renal function tests:
    - ❖ Determine estimated glomerular filtration rate (eGFR) before starting Veklury and monitor while receiving Veklury as clinically appropriate.
    - ❖ Monitor serum creatinine and CrCl.
    - ❖ Should not be administered if eGFR is less than 30 mL per minute.
  - Monitor for signs and symptoms of infusion reactions.
  - Hepatic function tests:
    - ❖ Monitor ALT, AST, bilirubin, alkaline phosphatase.
    - ❖ Avoid use if ALT is at least 10 times the upper limit of normal (ULN)
    - ❖ Discontinue use if ALT elevation and signs or symptoms of liver inflammation.
  - Hematology:
    - ❖ Determine prothrombin time and monitor serum chemistries before starting Veklury and monitor while receiving Veklury.

Suggested ICD-10 Diagnosis Codes

U07.1

Prescribing Restrictions

Frequency of billing equals 200 mg on day 1, followed by 100 mg daily for up to 10 days total.

Maximum billing units equals 200 mg/200 units

Resources:

- Veklury Package Insert
- Outpatient Product Information Guide
- NIH COVID-19 Treatment Guidelines
- COVID-19 Treatments

Veklury ordering and access information

- Hospital ordering process: Hospitals can place orders with any of the following distributors by calling directly:
  - AmerisourceBergen Specialty Distribution, 1-800-746-6273
  - Cardinal Specialty, 1-855-855-0708
  - McKesson Plasma, 1-877-625-2566
- Non-hospital ordering process: Non-hospitals can contact AmerisourceBergen Specialty Distribution by calling 1-800-746-6273 or emailing C19therapies@AmerisourceBergen.com for more information.

‹‹Remimazolam (Byfavo®)

Byfavo is a benzodiazepine. Byfavo binds to brain benzodiazepine sites (gamma amino butyric acid type A [GABAA] receptors), while its carboxylic acid metabolite (CNS7054) has a 300 times lower affinity for the receptor. Byfavo, like other benzodiazepines, did not show clear selectivity between subtypes of the GABAA receptor.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Remimazolam 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 American Society of Anesthesiologists (ASA) Physical Status Score I-III or III-IV (at the discretion of the physician)
- Drug is being used for the induction and maintenance of procedural sedation
- Procedure is expected to last 30 minutes or less (for example, colonoscopy, bronchoscopy, etc.)››

- ‹‹Documentation of reason why midazolam or proprofol is not appropriate for patient
- Patient is not a pregnant or lactating female
- Patient has no known sensitivity to benzodiazepines, flumazenil, opioids, naloxone, or a medical condition such that the use of these medications is contraindicated

Authorization is for one procedure.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J2249 (Injection, remimazolam, 1 mg)››

Reslizumab

Reslizumab is an interleukin-5 antagonist monoclonal antibody (lgG4 kappa) solution for intravenous (IV) administration.

Indications

Reslizumab is used for the add-on maintenance treatment of severe asthma with an eosinophilic phenotype.

Reslizumab is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus. Reslizumab is not indicated for use in combination with any of the following: benralizumab, mepolizumab or omalizumab.

Age

18 years and older.

Dosage

The recommended dose is 3 mg/kg IV given once every 4 weeks.

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 severe asthma with an eosinophilic type as add-on maintenance therapy:
  - Severe asthma as defined by symptoms that are persistent and uncontrolled despite the use of high dose inhaled corticosteroids combined with a long-acting beta2-agonist, leukotriene receptor agonist, or theophylline for greater than or equal to the previous one year or the use of systemic glucocorticoids for greater than or equal to 50% of the previous year.‡
  - Persistent uncontrolled asthma as defined by at least one of the following‡:
    - ❖ An ACQ score consistently higher than 1.5 (Asthma Control Questionnaire) or an ACT score lower than 20 (Asthma Control Test).
    - ❖ Two or more exacerbations in the previous year, each requiring 3 or more days of treatment with systemic glucocorticoids.
    - ❖ A history of hospitalization, intensive care unit stay, or mechanical ventilation in the previous year.
    - ❖ A FEV_1 (Forced Expiratory Volume in 1 second) at less than 80% of predicted after bronchodilator administration measured by pulmonary function testing or spirometry and documented by report and interpretation.
  - Eosinophilia as defined by a blood eosinophil count of greater than or equal to 400 cells/microliter at the initiation of therapy and documented by laboratory report (in the absence of other causes of eosinophilia such as a documented or suspected parasitic infection, neoplastic disease, or hyper-eosinophilic syndromes, etc.).
- For continuation of therapy, documentation of improvement by clinical measurements such as FEV_1, asthma control questionnaire, the decreased use of beta-agonists, a decreased incidence of hospitalization, intensive care, or mechanical ventilation, etc.

Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

J82 (Eosinophilic asthma)

Billing

HCPCS code J2786 (injection, reslizumab, 1 mg)

One (1) unit of J2786 equals 1 mg of reslizumab solution

‹‹Rezafungin (REZZAYO)

Rezafungin is a semi-synthetic echinocandin antifungal drug that inhibits the 1,3-β-D-glucan synthase enzyme complex, which is present in fungal cell walls but not in mammalian cells. This results in inhibition of the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall of many fungi, including *Candida* species (spp.).

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 the following:

- Must be used for an FDA-approved indication and dosage.
- Patient must be 18 years of age or older.
- Not used to treat endocarditis, osteomyelitis, and meningitis due to *Candida*.
- Patient had a trial of at least caspofungin, micafungin, anidulafungin, fluconazole, amphotericin B, voriconazole.
- Must show documentation of culture or other laboratory data.

Duration of approval is for 4 weeks.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J0349 (injection, rezafungin, 1 mg)

Prescribing Restriction(s)

Frequency of billing equals 400 mg/400 units on day 1, then 200 mg/200 units weekly beginning on day 8 for up to 4 doses.

Maximum billing unit(s) equals 400 mg/400 units.››

Rilonacept

Rilonacept is an interleukin-1 blocker and is used in the treatment of Cryopyrin-Associated Periodic Syndrome, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 years of age and older.

Authorization

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

Dosage

In adult patients 18 years of age and older, treatment is initiated with a loading dose of 320 mg, delivered as two subcutaneous injections of 160 mg on the same day at two different sites, then once-weekly injections of 160 mg.

In pediatric patients 12 to 17 years of age, treatment is initiated with a loading dose of 4.4 mg/kg, up to a maximum of 320 mg in either one or two subcutaneous injections on the same day (at two different sites if two injections), then once-weekly injections up to a maximum of 160 mg.

Billing

HCPCS code J2793 (injection, rilonacept, 1 mg)
One unit equals 1 mg

RimabotulinumtoxinB

For detailed billing policy information about rimabotulinumtoxinB, refer to the “Botulinum Toxins A and B” topic in the *Injections: Drugs A-D Policy* section of the manual.

Risankizumab-rzaa (SKYRIZI®)

Risankizumab-rzaa is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines.

Indications

All FDA-approved indications.

Dosage

FDA approved dosages

TAR Requirements

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

TAR Criteria

TAR Criteria

Must submit clinical documentation to substantiate the following:

Universal Criteria

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- 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.
- Patient does not have a known hypersensitivity to risankizumab.
- Must avoid use of live vaccines.

Patient must meet A, B or C below:

A. Plaque Psoriasis (PsO)

- Must be prescribed by or in consultation with a dermatologist.
- 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) 12 or more
  - Body Surface Area (BSA) 10 percent or more

- Patient has a history of failure of one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced. Corticosteroids (for example, betamethasone, clobetasol, desonide), Vitamin D analogs (for example, calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (for example, tacrolimus, pimecrolimus), Anthralin, coal tar or phototherapy.
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.

B. Psoriatic Arthritis (PsA)

- Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- 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 five or more tender joints (based on 68 joint counts) and five or more swollen joints (based on 66 joint counts).
- Patient has a diagnosis of active plaque psoriasis with at least one psoriatic plaque of two cm or more in diameter or nail changes consistent with psoriasis at baseline.
- 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.
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.
- Patient has not had a previous treatment with biologic agent.

C. Crohn’s Disease (CD)

- 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).

- Patient has Crohn's disease activity index (CDAI) score 220 to 450 at baseline.
- Patient had 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 preferred products (Remicade or Humira, unless intolerant, inadequate response or contraindication.
- If female, participant must meet the contraception recommendations.
- Patient does not have a current diagnosis of ulcerative colitis or indeterminate colitis.
- Patient has not received Crohn's disease approved biologic agents (Remicade, Humira, Cimzia, Entyvio, Tysabri within eight weeks prior to Baseline or Stelara within 12 weeks prior to baseline).

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.
- Liver enzymes and bilirubin levels are being monitored up to at least 12 weeks of treatment and thereafter as needed.

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J2327, (injection, risankizumab-rzaa, intravenous, 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 600 mg/600 units every four weeks.

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

Risperidone ER SQ Injection (Perseris)

Perseris is an atypical antipsychotic with an unclear mechanism of action in schizophrenia. Its therapeutic activity in schizophrenia could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major metabolite, 9-hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and 5HT2 may explain some of the other effects of risperidone.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

- Must be for FDA-approved indications
- The patient must be 18 to 65 years of age
- The patient must have a documented history of poor adherence to oral risperidone
- The patient must be able to tolerate at least 3 mg/day of oral risperidone

Note: Neither a loading dose nor an overlap with oral risperidone is necessary

Age Limits

Must be 18 to 65 years of age

Billing

HCPCS code J2798 (injection, risperidone, (Perseris), 0.5 mg)

Prescribing Restrictions

Frequency of billing equals every month

Maximum billing units equals 120 mg equals 240 units

Risperidone Injection (Risperdal Consta)

Risperdal Consta is an atypical, antipsychotic with an unclear mechanism of action in schizophrenia. Its therapeutic activity in schizophrenia could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 ($5HT_2$) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major active metabolite, 9hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and $5HT_2$ may explain some of the other effects of risperidone.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval

- FDA-approved indications
- Must be 18 years of age or older
- Must be able to tolerate at least 2 mg/day of oral risperidone
- Must have a documented history of poor adherence to oral risperidone
- Oral risperidone or other antipsychotics administered with Risperdal Consta should be tapered off after three (3) weeks

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J2794 (injection, risperidone [Risperdal Consta], 0.5 mg)

Prescribing Restrictions

Frequency of billing equals every 14 days

Maximum billing units equals 50 mg equals 100 units

‹‹Risperidone (UZEDY)

Risperidone is a benzisoxazole atypical antipsychotic with high 5-HT2 and dopamine-D2 receptor antagonist activity. Alpha1, alpha2 adrenergic, and histaminergic receptors are also antagonized with high affinity. Risperidone has low to moderate affinity for 5-HT1C, 5-HT1D, and 5-HT1A receptors, weak affinity for D1 and no affinity for muscarinics or beta1 and beta2 receptors.

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 psychiatrist.
- Patient must have a diagnosis of schizophrenia based on DSM-5 criteria for more than 1 year and has had 1 or more episodes of relapse in the last 24 months.
- Patient has an established stability and tolerability of oral risperidone.
  - Neither a loading dose nor overlap with oral risperidone is needed. Initiate Uzedy the day after the last dose of oral therapy.
- The patient must have a documented history of poor adherence to oral risperidone or has relapsed due to medication nonadherence or other reason why an oral formulation is clinically inappropriate.
- Must provide documentation justifying why formulary alternative injections such as Perseris or Risperdal Consta are not clinically appropriate.
- Patient has no history of hypersensitivity (eg, anaphylaxis, angioedema) to risperidone, paliperidone, or any component of the formulation.

Initial authorization is for 6 months.››

‹‹Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced documented positive clinical response from baseline.

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code: C9158, Injection, risperidone, (uzedy), 1 mg

Prescribing Restrictions

Frequency of billing equals 50 mg/50 units to 125 mg/125 units once monthly **or** 100 mg/100 units to 250 mg/250 units every two months.

Maximum billing units equals 250 mg/250 units.››

Rituximab

Rituximab is a CD20-directed cytolytic antibody for intravenous (IV) administration.

Indications

Rituximab is used to treat both oncologic and non-oncologic diseases including the following conditions:

- Non-Hodgkin's Lymphoma
- Chronic Lymphocytic Leukemia
- Rheumatoid Arthritis
- Granulomatosis with polyangiitis (Wegener's Granulomatosis)
- Microscopic Polyangiitis

For the use of rituximab in oncologic conditions, refer to the *Chemotherapy: Drugs P-Z Policy* section in the appropriate Part 2 Medi-Cal manual.

Age

18 years and older

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab as a single agent or in combination with other agents, the use of rituximab for induction or maintenance therapy, and the patient's response to treatment.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab.

Billing

HCPCS code J9312 (injection, rituximab, 10 mg)
One (1) unit of J9312 equals 10 mg of rituximab injection solution

Romosozumab-aqqg (Evenity)

Evenity® inhibits the action of sclerostin, a regulatory factor in bone metabolism. Evenity increases bone formation and, to a lesser extent, decreases bone resorption. Animal studies showed that romosozumab-aqqg stimulates new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity resulting in increases in trabecular and cortical bone mass and improvements in bone structure and strength.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates the following:

- For FDA-approved indications and dosages
- Treatment of osteoporosis in postmenopausal women at high risk of fracture
- Bone mineral density (BMD) T-score of less than or equal to -2.5 or FRAX Score indicating major fracture risk greater than 20 percent or HIP Fracture greater than 3 percent, or non-traumatic fracture.
- Patient has tried and failed, or is intolerant, or has a contraindication to bisphosphonate therapy.
- Patient has tried and failed, or is intolerant, or has a contraindication to injectable osteoporosis treatment drugs such as teriparatide, denosumab and abaloparatide.
- Must correct pre-existing hypocalcemia prior to initiation of therapy
- Patient had no myocardial infarction or stroke within one year of starting Evenity.
- Patient is taking a minimum 500 mg calcium and 600 IU vitamin D daily or contraindication
- Patient is not using Evenity in combination with denosumab, bisphosphonates, calcitonin, raloxifene, zolendronic acid, teriparatide or abaloparatide.
- Must be limited to 12 monthly doses only

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J3111 (injection, romosozumab-aqqg, 1 mg)

Prescribing Restrictions

Frequency of billing equals every month

Maximum billing units equals 210 mg (2 syringes) equals 210 units

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.