Injections: Drugs N-O 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 P-Q Policy*
- *Injections: Drugs R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

Nafcillin Injection

‹‹Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.››

TAR Requirement

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

Billing

HCPCS codes:

J2290 (injection, nafcillin sodium, 20 mg).

‹‹J2291 (injection, nafcillin sodium [baxter], 20 mg).››

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

Indications, Dosage and Age

Refer to FDA-approved labeling

TAR Requirement

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

Billing

HCPCS code J2312 (injection, naloxone hydrochloride, not otherwise specified, 0.01 mg).››

Naloxone Hydrochloride (ZIMHI™)

Indications, Dosage and Age

‹‹Refer to FDA-approved labeling››

TAR Requirement

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

Billing

‹‹HCPCS code J2313 (injection, naloxone hydrochloride [zimhi], 0.01 mg).››

Prescribing Restriction(s)

‹‹Frequency of billing equals 5mg/500 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.

NICARDIPINE HYDROCHLORIDE Injection

Nicardipine inhibits the transmembrane influx of calcium ions into cardiac muscle and smooth muscle without changing serum calcium concentrations. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. The effects of nicardipine are more selective to vascular smooth muscle than cardiac muscle. In animal models, nicardipine produced relaxation of coronary vascular smooth muscle at drug levels which cause little or no negative inotropic effect.

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 J2404 (injection, nicardipine, 0.1 mg).

Natalizumab-sztn Injection (Tyruko®)

Natalizumab products bind to the α4-subunit of α4β1 and α4β7 integrins expressed on the surface of all leukocytes except neutrophils, and inhibits the α4-mediated adhesion of leukocytes to their counter-receptor(s). The receptors for the α4 family of integrins include vascular cell adhesion molecule-1 (VCAM-1), which is expressed on activated vascular endothelium, and mucosal addressin cell adhesion molecule-1 (MAdCAM-1) present on vascular endothelial cells of the gastrointestinal tract. Disruption of these molecular interactions prevents transmigration of leukocytes across the endothelium into inflamed parenchymal tissue.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

Universal Criteria:

- Used for all FDA approved indications and dosages.
- Prescribed by or in consultation by a gastroenterologist or neurologist.
- Patient is at least 18 years of age.
- Prescriber and patient must be enrolled in the Tyruko REMS program.
- Patient is being monitored for the development of progressive multifocal leukoencephalopathy (PML) **and**

Crohn's Disease (CD):

1. Confirmed diagnosis of moderate to severe disease utilizing an objective measure/tool (for example, Crohn's Disease Activity Index [CDAI]).
2. Unless contraindicated, documented trial and failure of at least one oral immunosuppressive therapy for at least 3 moths (for example, corticosteroids, methotrexate).
3. Unless contraindicated, documented trial and failure of at least one inhibitor of TNF-α. for at least three months (for example, infliximab, certolizumab, or adalimumab).
4. Used as monotherapy (patient is not currently taking immunosuppressants (for example, 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.

Initial authorization is for 12 weeks.

Multiple Sclerosis (MS):

1. Confirmed diagnosis of MS (i.e., MRI).
2. Patient has been diagnosed with a relapsing form of MS (for example, relapsing remitting disease, active secondary progressive disease, or clinically isolated syndrome).
3. Used as monotherapy.

Initial Authorization is for six months.

Universal Re-authorization Criteria

1. Patient continues to mee the initial criteria.
2. Absence of unacceptable toxicity (e.g., hypersensitivity reactions, signs and symptoms of PML, hepatotoxicity, infections including pneumonias, herpes, vaginal infection, tooth infection, etc.) **and**

Crohn's Disease

1. Initial renewal
    a. Remission and clinical response (for example, greater than or equal 70-point decrease in CDAI from baseline or CDAI score less than150) is observed by 12 weeks.
2. For continued re-authorization:
    a. Patient has a clinical response (for example, greater than or equal 70-point decrease in CDAI from baseline or CDAI score less than150)
    b. If on corticosteroid therapy, patient has been tapered off within six months of starting Tyruko.
    c. Patient does not require additional steroid use that exceeds three months in a calendar year to control CD.

Re-authorization is for 12 months.

Multiple Sclerosis (MS):

1. Documentation of positive response to therapy as indicated by the acceptable measuring tools (i.e. MS disease activity, annualized relapse rate (ARR), improvement in MRI, etc.)

Re-authorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code Q5134 (Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg)

Required ICD-10-CM Diagnosis Codes

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

- G35
- K50.00 thru K50.919

Prescribing Restriction(s)

Frequency of billing equal to every 28 days**.**

Maximum billing unit(s) equal to 300 mg/300 units.

‹‹Nipocalimab-aahu

Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

TAR Requirement

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

Billing

HCPCS code C9305 (injection, nipocalimab-aahu, 3 mg).››

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:

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

- 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.
- 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.
- 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:

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.

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.

Genetic laboratory confirmation of diagnosis.

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:
   - 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.

- 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.
   - The State CCS Program office will issue the authorization.
   - The State CCS Program office will issue initial authorization for a period of 12 months or until the end of program eligibility period.
   - Reauthorization shall be granted every twelve months following review of documentation described above unless there are significant adverse effects or change in eligibility.
   - 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 (OCREVUS) and Ocrelizumab and Hyaluronidase-ocsg (OCREVUS ZUNOVO)

Indications, Dosages and Age

Refer to the FDA-approved labeling.

Must be 18 years of age or older.

TAR Requirement

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

Required Codes

ICD-10-CM diagnosis code G35.

Billing

HCPCS codes:

J2350 (injection, ocrelizumab, 1 mg).

J2351 (injection, ocrelizumab, 1 mg and hyaluronidase-ocsg).

Prescribing Restriction(s)

Maximum billing unit(s) equals:

- 600 mg / 600 units for J2350
- 920 mg / 920 units for J2351

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

‹‹Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

TAR Requirement››

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

‹‹Required ICD-10 Diagnosis 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)
- L50.1 (Idiopathic uticaria)
- L50.8 (Other urticaria)

Billing

HCPCS codes:

J2357 (injection, omalizumab, 5 mg).

‹‹Q5154 (injection, omalizumab-igec [omlyclo], biosimilar, 5 mg).››

OnabotulinumtoxinA

For detailed clinical and billing policy information about onabotulinumtoxinA, refer to the “Botulinum Toxins A and B” topic in the *Injections: Drugs B 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:

- The patient is under the age of two years.
- 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)
- Patient does not have advanced SMA, as evidenced by any of the following:
  - Invasive ventilator support (tracheostomy with ventilator)
  - Complete paralysis of limbs

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.

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.

There is no indication of significant liver injury.

Patient is not currently being treated with nusinersen or treatment with nusinersen will be discontinued prior to the administration of onasemnogene abeparvovec-xioi.

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

1. Onasemnogene abeparvovec is not covered by a Service Code Grouping (SCG) authorization and a separate authorization is needed for outpatient administration.

2. 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
3. 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.
4. The State CCS Program office will issue the authorization.
5. 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).

6. Requesting providers must adhere to the following special instructions when filing a claim:
   - Provider must submit one (1) service line for three (3) units on the TAR/SAR request, and enter “3” in the Units box
   - 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
   - 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 paid price.
   - Zolgensma must be billed on its own with no other drug or biological.
   - 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.
   - 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.
   - 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**	
	N4 11digitNDC	**J3399**	070120	**1**		**708,334**		**00**	
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 six 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 one 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 three times the upper limit of normal (ULN) or total bilirubin greater than or equal to two 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.

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.