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## **Injections: Drugs N-R Policy**

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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)

## 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.

## 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 beneficiary 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. «For non-sitters:
    - Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) or
    - Hammersmith Infant Neurological Exam-Part 2 (HINE-2)
  - ii. For sitters:
    - Hammersmith Functional Motor Scale, Expanded (HFMSE) or,
    - Revised Upper Limb Module (RULM).
  - iii. For walkers:
    - The Timed up and Go test (TUG),
    - The 6-minute walk test or,
    - The 10-meter run/walk test.
  - iv. For non-ambulatory older patients:
    - 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 1, 15, 29 and 59, and maintenance doses every 4 months thereafter.»

#### «IV. Policy Implementation for CCS Patients

##### Nusinersen (Spinraza)

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.

4. The State CCS Program office will issue the authorization.
5. The State CCS Program office will issue initial authorization for a period of twelve months or until the end of program eligibility period.
6. Reauthorization shall be granted every twelve months following review of documentation described above unless there are significant adverse effects or change in eligibility.
7. 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 = 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 cytotoxicity 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)

## 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  $\geq$  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 = 200 mg stat, then 100 mg daily for 7-14 days

Maximum billing units = 1,500 mg = 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

6 years and older

## Dosage

The recommended dose is based on the treatment condition:

- For asthma: 75 to 375 mg SQ given once every 2 or 4 weeks.
- For CIU: 150 or 300 mg SQ 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 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  $\geq$  the previous one year or the use of systemic glucocorticoids for  $\geq$  50% of the previous year.‡
  - Persistent uncontrolled asthma as defined by at least one of the following‡:
    - ❖ An ACQ score consistently  $>$  1.5 (Asthma Control Questionnaire) or an ACT score  $<$  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<sub>1</sub> (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.

- 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<sub>1</sub> 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 urticaria)
- L50.8 (Other urticaria)

### **Billing**

HCPCS code J2357 (injection, omalizumab, 5 mg)

One (1) unit of J2357 = 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 2 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 >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

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 beneficiaries' 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  $5 \times 10^{15}$  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](mailto: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:
  - 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 2 years of age

### **Billing**

HCPCS code J3399 (injection, onasemnogene abeparvovec-xioi, per treatment, up to  $5 \times 10^{15}$  vector genomes)

### **«Required ICD-10 Diagnosis Codes»**

G12.0, G12.1, G12.9

### **Prescribing Restrictions**

Frequency of billing =  $1.1 \times 10^{14}$  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  $5 \times 10^{15}$  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  $5 \times 10^{15}$  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 3 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		39		40		41		42	
		d		CODE	VALUE CODES AMOUNT	CODE	VALUE CODES AMOUNT	CODE	VALUE CODES AMOUNT	48 NON-COVERED CHARGES	
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	46 SERV. UNITS	47 TOTAL 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				
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50 PAYER NAME		51 HEALTH PLAN ID		52 REG. IN. P. Q.	53 AGG. BE. N.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NP	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-HT<sub>3</sub> 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 2 to 5 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 Staphylococcus 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)  $\geq 3$  times the upper limit of normal (ULN) or total bilirubin  $\geq 2$  times ULN

**Authorization is once per treatment.**

### **Age Limits**

Must be 18 years of age or older

### **Billing**

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

### **Suggested ICD-10-CM Diagnosis Codes**

A49.02, Z16.11, Z16.21, Z16.22, Z16.24, Z16.35

### **Prescribing Restrictions**

Frequency of billing = 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)

### **Suggested ICD-10-CM Diagnosis Codes**

A49.02, Z16.11, Z16.21, Z16.22, Z16.24, Z16.35

### **Prescribing Restrictions**

Frequency of billing = 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**

Injectable paliperidone palmitate is a long-acting drug used for the treatment of schizophrenia in patients 18 years of age and older.

### **Dosage**

The maximum dosage is 350 mg.

### **Billing**

HCPCS code J2426 (injection, paliperidone palmitate, 1 mg)

One unit = 1 mg

## **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 (intravenous infusion for therapy prophylaxis or diagnosis; initial, up to one hour) and 96366 (...each additional hour) when billed for outpatient treatment with one of the following ICD-10-CM diagnosis code

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 = 1 mcg.

**Note:** Code J2501 cannot be block billed.

## Patisiran (Onpattro)

Patisiran is a double-stranded siRNA that causes degradation of mutant and wild-type TTR mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

## Indications

All FDA-approved indications

## Dosage

FDA-approved dosages

## TAR Requirement

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

- Must be for FDA-approved indications and dosing regimens
- Must be 18 years of age or older
- Must have both of the following:
  - Biopsy verification of amyloidosis
  - Genetic testing results confirming a TTR gene mutation

- Patient is experiencing clinical signs and symptoms of the disease such as peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.
- Patient has tried or is currently receiving at least one systemic agent for symptoms of polyneuropathy from one of the following pharmacologic classes: a GABA analogue such as gabapentin, pregabalin or a tricyclic antidepressant such as nortriptyline, amitriptyline, etc.
- Must not be taken concurrently with inotersen (Tegsedi), tafamidis meglumine (Vyndaqel), tafamidis (Vyndamex) or diflunisal

### **Age Limits**

Must be 18 years of age or older

### **Billing**

HCPCS code J0222 (injection, patisiran, 0.1 mg)

### **Prescribing Restrictions**

Frequency of billing = Every 21 days

Maximum billing units = 30 mg = 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.

## **Pegfilgrastim**

Pegfilgrastim is reimbursable for the management of neutropenia associated with chemotherapy in patients who have non-myeloid malignancies and are at high risk for infection.

### **Dosage**

The recommended dosage of pegfilgrastim is a single 6 mg subcutaneous injection. Pegfilgrastim should not be given to patients who weigh less than 45 kg.

### **Required Codes**

Pegfilgrastim is reimbursable when billed with ICD-10-CM diagnosis codes D70.1, Z41.8, Z51.11 or Z51.89.

### **Billing**

HCPCS code J2505 (injection, pegfilgrastim, 6 mg).  
One (1) unit = 6 mg.

## **Pegfilgrastim-apgf (Nyvepria™)**

Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

### **Indications**

All FDA-approved indications

### **Dosages**

FDA-approved dosages

### **TAR Requirement**

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

## **Billing**

HCPCS code Q5122 (injection, pegfilgrastim-apgf, biosimilar, [nyvepria], 0.5 mg)

## **Prescribing Restrictions**

Frequency of billing = 6 mg/12 units per chemotherapy cycle»

## **Pegfilgrastim-cbqv**

Pegfilgrastim-cbqv is a leukocyte growth factor for subcutaneous (SQ) injection.  
Pegfilgrastim-cbqv is biosimilar to pegfilgrastim.

## **Indications**

Pegfilgrastim-cbqv is reimbursable when used to reduce the incidence of neutropenia-related infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

## **Age**

All ages

## **Dosage**

For patients who weigh 45 kg or more, a single 6 mg SQ injection is administered once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. Pegfilgrastim-cbqv should not be administered within the time period of 14 days before starting chemotherapy and until 24 hours after ending chemotherapy.

For patients who weigh less than 45 kg, two SQ injection doses are administered one week apart based on the patient's body weight:

- Less than 10 kg: 0.1 mg/kg
- 10 to 20 kg: 1.5 mg
- 21 to 30 kg: 2.5 mg
- 31 to 44 kg: 4 mg

## Authorization

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

## Required Codes

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

- D70.1 (Agranulocytosis secondary to cancer chemotherapy)
- Z51.11 (Encounter for antineoplastic chemotherapy)

## Billing

HCPCS code Q5111 (Injection, pegfilgrastim-cbqv, biosimilar, (udenyc), 0.5 mg)

One (1) unit of Q5111 equals 0.5 mg of pegfilgrastim-cbqv

## 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).

## **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 pneumoniae*, *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 = Every 24 hours for 4-7 days

Maximum billing units = 3,400 mg = 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 = 1 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**

Policy for intravitreal ranibizumab (HCPCS code J2778) is 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 C5b-9. Ultomiris inhibits terminal complement-mediated intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH).

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. Initiation of ravulizumab-cwvz is considered medically necessary in appropriate patients for the treatment of documented paroxysmal nocturnal hemoglobinuria (PNH) when the following criteria are met:

- FDA-approved indications and dosing regimens
- 18 years of age or older, and
- Documented diagnosis of PNH with granulocyte or monocyte clone size of 5 percent or more, and

For treatment of 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 3 months of screening:
  - Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia (hemoglobin less than 10 g/dl), history of major adverse vascular events (MAVE) (including thrombosis), dysphagia or erectile dysfunction; or history of pRBC transfusion due to PNH
- Must be vaccinated against meningococcal infections within three years prior to, or at the time of, initiating ravulizumab-cwvz. If ravulizumab-cwvz is initiated less than two weeks after vaccination, patients must receive prophylactic antibiotics until two weeks after vaccination.

For eculizumab conversion patients:

- Hemolysis as measured by LDH level less than 1.5 times the ULN at screening, and
- Treatment with eculizumab for at least six months
- Vaccinated against meningococcal infections within three years prior to, or at the time of, initiating therapy. If ravulizumab-cwvz is initiated less than two weeks after vaccination, patients must receive prophylactic antibiotics until two weeks after vaccination.

Continuation of therapy:

- Continuation of therapy in appropriate patients is considered medically necessary for the treatment of an individual with documented PNH who is currently receiving treatment with ravulizumab-cwvz and one of the following:
  - Hemolysis control measured by LDH level less than 1.5 times the ULN, or
  - Transfusion avoidance defined as elimination of transfusion requirements or reduced need for transfusions, or
  - Stabilization of hemoglobin levels, or
  - Improvement in FACIT-Fatigue scores

## Age Limits

Must be 18 years of age or older

## Billing

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

## Suggested Codes

ICD-10 CM Diagnosis code D59.5

## Prescribing Restrictions

Frequency of billing = 3,000 mg/ 300 units initially, 3,600 mg/360 units after two weeks, then 3,600 mg/360 units every eight weeks

Maximum billing units = 3,600 mg = 360 units

## Remdesivir (Veklury)

Remdesivir is an inhibitor of the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp), which is essential for viral replication. Remdesivir 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.

Remdesivir is approved by the Food and Drug Administration (FDA) for the treatment of COVID-19 in hospitalized adult and pediatric patients (aged  $\geq 12$  years and weighing  $\geq 40$  kg). It is also available through an FDA [Emergency Use Authorization \(EUA\)](#) for the treatment of COVID-19 in hospitalized pediatric patients weighing 3.5 kg to  $< 40$  kg or aged  $< 12$  years and weighing  $\geq 3.5$  kg. Remdesivir should be administered in a hospital or a health care setting that can provide a similar level of care to an inpatient hospital.

## FDA-Approved Indications

VEKLURY is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. VEKLURY should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

**Remdesivir may be prescribed through two methods:**

- A. FDA approved use for the treatment of COVID-19 in patients  $\geq 12$  years of age and  $\geq 40$  kg
- B. [EUA](#) for the treatment of COVID-19 in hospitalized pediatric patients weighing 3.5 kg to  $< 40$  kg or aged  $< 12$  years and weighing  $\geq 3.5$  kg.

**A. Remdesivir FDA Approved Usage**

Remdesivir is FDA approved for the treatment of COVID-19 in patients  $\geq 12$  years of age and weigh  $\geq 40$  kg.

**Dosages**

Testing: In all patients, before initiating VEKLURY and during treatment as clinically appropriate, perform renal and hepatic laboratory testing and assess prothrombin time.

- The recommended dosage for adults and pediatric patients 12 years of age and older and weighing at least 40 kg is a single loading dose of VEKLURY 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of VEKLURY 100 mg from Day 2 via intravenous infusion over 30 to 120 minutes.
- The recommended treatment duration for patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO) is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.
- The recommended total treatment duration for patients requiring invasive mechanical ventilation and/or ECMO is 10 days.
- VEKLURY must be diluted prior to intravenous infusion. Refer to Dose preparation and Administration in package insert for detailed prescribing information.

Renal Impairment: VEKLURY is not recommended in patients with eGFR less than 30 mL per minute.

**TAR Requirement**

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

## TAR Criteria

Must submit clinical documentation to establish the following:

- Must be used for FDA approved indications and dosages
- Patient must be 12 years of age or older and  $\geq 40$  kg in weight
- Must be administered in a hospital or a health care setting capable of providing acute care comparable to inpatient hospital care.
- Must comply with the following Testing Before Initiating and During Treatment with VEKLURY:
  - a. Renal function tests:
    - Determine estimated glomerular filtration rate (eGFR) before starting VEKLURY and monitor while receiving VEKLURY.
    - Monitor serum creatinine and CrCl.
    - Do not administer if eGFR less than 30 mL per minute
  - b. Monitor for signs and symptoms of infusion reactions.
  - c. Hepatic function tests:
    - Monitor ALT, AST, bilirubin, alkaline phosphatase.
    - Avoid use if ALT  $\geq 10$  times the Upper limit of normal (ULN)
    - Discontinue use if ALT elevation and signs or symptoms of liver inflammation.
  - d. Hematology:
    - Determine prothrombin time and monitor serum chemistries before starting VEKLURY and monitor while receiving VEKLURY.
- Those who are younger than 12 years of age and do not meet these criteria may still qualify to receive remdesivir under the restrictions of the FDA [Emergency Use Authorization \(EUA\)](#).

## **B. Remdesivir EUA Use for Pediatric Patients**

Remdesivir has EUA for the treatment of COVID-19 in hospitalized pediatric patients weighing 3.5 kg to  $< 40$  kg or aged  $< 12$  years and weighing  $\geq 3.5$  kg.

See full details on the authorized use of remdesivir and mandatory EUA requirements, patient selection criteria and monitoring in [Fact Sheet for Health Care Providers](#).

### **EUA Patient Selection Criteria**

- Patient is <12 years old and weighs  $\geq 3.5$  kg to < 40 kg.
- Patient is hospitalized with suspected or confirmed COVID-19.
- Patients >28 days old must have an estimated glomerular filtration rate (eGFR) determined and full-term neonates ( $\geq 7$  days to  $\leq 28$  days old) must have serum creatinine determined before treatment initiation and during treatment as clinically appropriate.
  - Do not administer if eGFR is less than 30 mL per minute in pediatric patients (greater than 28 days old).
  - Do not administer in full-term neonates (at least 7 days to less than or equal to 28 days old) with serum creatinine greater than or equal to 1 mg/dL.
- Monitor hepatic function before treatment initiation and during treatment as clinically appropriate. Confirmed AST/ALT <10x ULN
  - Discontinue use if ALT elevation and signs or symptoms of liver inflammation.
- Determine prothrombin time in all patients before treatment initiation and during treatment as clinically appropriate.

### **Dosages in Pediatric Patients:**

Infants and Children <12 years: Lyophilized powder only:

- 3.5 kg to <40 kg: 5 mg/kg IV once, then 2.5 mg/kg IV daily.
- $\geq 40$  kg: IV: 200 mg IV once, then 100 mg IV daily.

Children  $\geq 12$  years:

- <40 kg: Lyophilized powder only: IV: 5 mg/kg IV once, then 2.5 mg/kg IV daily

### **Duration:**

- For patient who do not require mechanical ventilation or ECMO, recommended treatment duration is 5 days. May extend for up to 5 additional days to a total of up to 10 days if patient does not improve clinically.
- For patients who require ECMO, the recommended treatment duration is 10 days. For full EUA Prescribing Information, And Recommended Dosage in Pediatric Patients, see the [Fact Sheet for Health Care Providers](#).



## Billing

HCPCS, J3490, Unclassified drugs

- Remdesivir is restricted to hospital outpatient services capable of providing acute care comparable to inpatient hospital care. It cannot be billed by pharmacies and clinics.
- Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms.
- Provider must submit an invoice for reimbursement.
- For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of [837I form](#) and [UB-04 form](#).

## Resources:

- When used under the restrictions of an Emergency Use Authorization, Remdesivir is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to healthcare providers and patients/caregivers respectively:
  - [Fact Sheet for Health Care Providers](#): Emergency Use Authorization (EUA) of Remdesivir (GS-5734)
  - [Fact Sheet for Patients and Parent/Caregivers](#): Emergency Use Authorization (EUA) of Remdesivir for Coronavirus Disease 2019 (COVID-19)
- Veklury distribution and access
  - ✓ ABC is used by Gilead as the sole distributor of VEKLURY®.
  - ✓ Hospitals are to order from ABC Specialty Division directly by calling 1-800-746-6273 or by emailing [remdesivir@amerisourcebergen.com](mailto:remdesivir@amerisourcebergen.com). The order quantity to be shipped will be confirmed.
  - ✓ The order will be shipped directly to hospitals by ABC.

## Reslizumab

Reslizumab is an interleukin-5 antagonist monoclonal antibody (IgG4 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<sub>1</sub> (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<sub>1</sub>, 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 = 1 mg of reslizumab solution

## 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 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 = 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.

## **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 = Every month

Maximum billing units = 120 mg = 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<sub>2</sub>) 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<sub>2</sub> 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 = Every 14 days

Maximum billing units = 50 mg=100 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 = 10 mg of rituximab injection solution

## Romozosumab-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 romozosumab-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, zoledronic 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 = Every month

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



## **Legend**

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

<b>Symbol</b>	<b>Description</b>
«	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.