Effective July 1, 2020

2020 HCPCS CODE ADDITIONS

Bolded Codes
Bolded codes indicate notation of a special billing policy.

Chemotherapy
J9177, J9198, **J9245**, **J9246, J9358, Q5119,** Q5120

J9177
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Padcev will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient must have a diagnosis of locally advanced or metastatic urothelial cancer
- Failure of both of the following in the neoadjuvant/adjuvant, locally advanced or metastatic setting
    a. A programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. Examples of these are avelumab, atezolizumab, durvalumab, nivolumab, and pembrolizumab; and
    b. A platinum-containing chemotherapy (cisplatin or carboplatin based)

Approval duration: six months

Continued Therapy

I. Patient continues to meet initial approval criteria
II. Patient is responding positively to therapy with improvement or stabilization of disease
III. Patient has no unacceptable toxicity such as severe hyperglycemia, severe peripheral neuropathy, thrombosis, pancreatitis, etc.

Reauthorization is for six months

Must be 18 years of age or older

Suggested ICD-10 diagnosis codes: C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0, C67.1, C67.2, C67.3, C67.4, C67.5, C67.6, C67.8, C67.9, C68.0.

Modifiers SA, UD, U7 and 99 are allowed

J9245
An approved *Treatment Authorization Request* (TAR) is required for reimbursement
Melpalan Hydrochloride will be considered medically necessary when ALL of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient must have a diagnosis of multiple myeloma
- Patient is taking this as palliative treatment
- Patient is unable to take oral therapy

Approval duration is six months

Continued Therapy

i. Patient continues to meet initial approval criteria

ii. Patient is responding positively to therapy with improvement or stabilization of disease.

iii. Patient has no disease progression or unacceptable toxicity

Reauthorization is for 12 months

Must be 18 years of age or older

Modifiers SA, UD, U7 and 99 are allowed

J9246

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

Evomela will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient is taking this as:
  - I. A high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation
    - a. Must show documentation of approval of stem cell transplantation and tentative procedure date
  - II. A palliative treatment when oral therapy is not appropriate

Approval duration: one month for stem cell transplant and six months for palliative treatment

Continued Therapy

i. Patient continues to meet initial approval criteria

ii. Patient is responding positively to therapy with improvement or stabilization of disease

iii. Patient has no unacceptable toxicity such as anaphylaxis

Reauthorization is for 12 months for palliative treatment

Must be 18 years of age or older

Modifiers SA, UD, U7 and 99 are allowed

J9358

Must be 18 years of age or older

Frequency 5.4 mg/kg every 21 days

Modifiers SA, UD, U7 and 99 are allowed

Q5119

Must be 18 years of age or older

Modifiers SA, UD, U7 and 99 are allowed

Injections

C9059, C9063, C9122, J0691, J0742, J0791, J0896, J1201, J1429, J1558, J3399, J7169, J7323, Q5121

C9059

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

Anjeso will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be used for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics
- Must not be intended for long-term use
- Must not be used in the setting of coronary artery bypass graft (CABG) surgery

Must be 18 years or older

Maximum billing units = 30 mg/30 units

Modifiers SA, UD, U7 and 99 are allowed

C9063

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

Vyepti will be considered medically necessary initially for six months when all of the following criteria are met:

a. Must be prescribed for FDA-approved indications and dosing regimens

b. Patient must be 18 years of age or older

c. Patient must have a diagnosis of one of the following:

   a. Episodic migraine defined as 4 to 14 headache days per month, at least four of which were migraine days during the previous three-month period; or

   b. Chronic migraine defined as 15 to 26 headache days per month, at least eight of which were migraine days for over three months

      - Patient must have tried and failed or is intolerant to or has contraindication to at least one drug from two oral classes used for migraine prophylaxis, including antiepileptic medications, beta-blockers, calcium channel blockers or antidepressants
      - Must not be taken in combination with any other monoclonal antibody targeting the CGRP pathway, such as Ajovy (fremanezumab), Emgality (galcanezumab), Aimovig (erenumab), Nurtec ODT (rimegepant) and Ubrelvy (ubrogepant).

Continued Therapy

I. Patient continues to meet initial approval criteria

II. Patient has experienced a positive clinical response to therapy as demonstrated by a reduction in headache frequency and/or severity

Reauthorization will be for 12 months

Must be 18 years of age or older

Maximum billing unit(s) = 300 mg/300 units

Modifiers SA, UD, U7 and 99 are allowed

C9122
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Sinuva is considered medically appropriate if ALL of the following criteria are met:

- For FDA approved indications and dosages
- Patient must be 18 years of age or older
- Sinuva is prescribed and implanted by or in consultation with an otolaryngologist
- Patient has undergone ethmoid sinus surgery
- Patient has a diagnosis of recurrent nasal polyps and chronic sinusitis.
- Patient must have tried and failed, is intolerant or has a contraindication of inhaled nasal corticosteroids for at least three months at the maximum recommended dosage
- Patient does not have a known hypersensitivity to mometasone furoate or any ingredient of the Sinuva sinus implant

Approval is for 90 days.

Reauthorization
For repeat implant placement, patient must have ethmoid sinus polyps grade ≥ 1 on either side
One time repeat allowable after 90 days if patient meets criteria for repeat placement

Must be 18 years of age or older

Modifiers SA, UD, U7 and 99 are allowed

Modifiers RT and LT are required

J0223
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Givosiran is considered medically appropriate if all of the following criteria are met:

- Must be for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a documented diagnosis of AHP, including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria or ALA dehydratase deficient porphyria (ADP)
- Patient has a documentation of elevated urinary or plasma PBG and/or ALA within the past year
- The patient is not anticipating having a liver transplant
- The patient does not have a history of recurrent pancreatitis
- Documentation of a minimum of two porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous hemin administration in the previous six months

Initial authorization is for 12 months

Reauthorization

- Patient continues to meet initial approval criteria
- Patient shows absence of unacceptable toxicity from the drug (e.g. severe or clinically significant hepatic toxicity [transaminase elevations]), severe renal toxicity (increases in serum creatinine levels and decreases in estimated glomerular filtration rate [eGFR], etc.)
- Patient has shown a clinical response to therapy as evidenced by a reduction in the rate of porphyria attacks that required hospitalizations, urgent healthcare visits, or intravenous hemin administration

Reauthorization is for 12 months

Patient must be 18 years of age or older

Frequency of billing = 2.5 mg/kg every month

HCPCS code J0223 is only reimbursable when billed in conjunction with one of the following ICD-10-CM diagnosis codes: E80.20, E80.21 and E80.29.

Modifiers SA, UD, U7 and 99 are allowed

J0691
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

A TAR approval requires clinical documentation to show the following:

- For FDA-approved indications and treatment regiments and
- Must be 18 years of age or older and
- Must verify negative pregnancy status in females of child-bearing age and
- Establishment of diagnosis; microbiologic Gram stain and culture of sputum for Community-acquired Pneumonia (CAP) and
- Must show justification for failure to use formulary alternatives such as macrolides, fluoroquinolones, or beta-lactam antibiotics, such as allergy or intolerance

Documentation of recent hospitalization and parenteral antibiotics and/or locally validated risk factors for MRSA alone may also satisfy TAR requirements.

Must be 18 years of age or older

Frequency of billing = 150 mg/150 units every 12 hours for five to seven days

Maximum billing units = 150 mg/150

J0742
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Recarbrio™ is considered medically appropriate if all of the following criteria are met:

- Prescribed for FDA-approved indications and dosing regimens; and
- Patient must be 18 years of age or older; and
- Patient must have one of the following diagnosis
  - Complicated intra-abdominal infection (cIAI); or
  - Complicated urinary tract infection (cUTI), including pyelonephritis; and
    - The prescriber must verify that limited or no alternative treatment options are available; and
    - The prescriber to clinically document why the patient cannot use other clinically appropriate and cost-effective therapeutic equivalent alternatives, such as penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidine) in combination with metronidazole(s).

Must be 18 years of age or older

Frequency of billing = 1.25 gm/125 units every six hours for 4-14 days

Maximum billing units = 1.25 gm/125 units

Modifiers SA, UD, U7 and 99 are allowed

J0791
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates the following:

- Prescribed for FDA-approved indications and dosing regimens
- Patient must be 16 years of age or older
- Patient must have a diagnosis of sickle cell disease, identified by any genotype (e.g. HbSS, HbSC, HbS/Beta0 Thalassemia or HbS/Beta+ Thalassemia)
- Patient has experienced at least two vaso-occlusive crises (VOCs) in the previous 12 months or
- Patient has a history of other VOCs such as cute chest syndrome, hepatic sequestration, splenic sequestration and priapism (requiring a medical facility visit)

Initial approval: 12 months

Reauthorization

Approvable for lifetime if patient shows continued clinical benefits such as reduction in the annual rate of VOCs leading to a healthcare visit.

Patient must be 16 years of age older

Frequency of billing = 5 mg/kg on week zero, week two and every four weeks thereafter

HCPCS code J0896 is only reimbursable when billed in conjunction with one of the following ICD-10-CM diagnosis codes: D57.00, D57.01, D57.02, D57.20, D57.211, D57.212, D57.219, D57.3, D57.40, D57.411, D57.412, D57.419, D57.811, D58.812, D57.819.

Modifiers SA, UD, U7 and 99 are allowed

J0896

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

Reblozyl will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient has a clinically documented diagnosis of β-thalassemia or Hemoglobin E/β-thalassemia. (β-thalassemia with mutation and/or multiplication of alpha globin is allowed)
- Patient is regularly transfused, defined as: 6-20 Red Blood Cell (RBC) units in the 24 weeks prior and no transfusion-free period for ≥ 35 days during that period
- Patient does not have a diagnosis of Hemoglobin S/β-thalassemia or alpha (α)-thalassemia (e.g., Hemoglobin H)
- Patient is not pregnant or breastfeeding
- Patient must not have any of the following conditions:
    i. Active hepatitis C (HCV) infection
    ii. Active infectious hepatis B (HBV) as demonstrated by a positive HCV-RNA test of sufficient sensitivity
    iii. Known human immunodeficiency virus (HIV) that is not controlled by antiretroviral (ART) therapy
    iv. Recent deep vein thrombosis or stroke requiring medical intervention ≤ 24 weeks prior
    v. Major organ damage as evidenced by any of the following:
        - Liver disease with an ALT > 3x the ULN or history of evidence of cirrhosis
        - Heart disease, heart failure NYHA classification three or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within six months of treatment
        - Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant i.e. ≥ Grade 3
        - Renal insufficiency such as creatinine clearance < 60 mL/min
- Reblozyl must be prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and treatment of β-thalassemia.

Initial authorization will be for six months.

Reauthorization will be for 12 months if:

- Patient continues to meet the initial coverage criteria
- Patient has experienced a clinically significant reduction in transfusion burden from baseline
- Patient has an absence of unacceptable toxicity from the drug such as severe thromboemobolic events or hypertension

Must be 18 years or age or older

Frequency of billing = 1.25 mg/kg every 3 weeks

HCPCS code J0896 is only reimbursable when billed in conjunction with one of the following ICD-10-CM diagnosis codes: D46.1, D46.4, D46.9, D46.A, D46.B, D46.Z, D56.1, D56.5.

Modifiers SA, UD, U7 and 99 are allowed

J1201
Must be six months of age or older
Modifiers SA, SB, UD, U7 and 99 are allowed

J1429
An approved *Treatment Authorization Request* (TAR) or CCS Program Service Authorization Request (SAR) is required for reimbursement.

A. Initial Authorization

Golodirsen is both a Medi-Cal and CCS Program benefit when the following criteria are met:

1. Must be for FDA-approved indications and dosages
2. Patient must be 6 years of age or older
3. Patient has documented Duchenne muscular dystrophy (DMD) with dystrophin gene mutation, amenable to exon 53 skipping documented by genetic test(s).
4. Care is under the supervision and monitoring of a neurologist, or for CCS patients, a CCS-paneled neurologist or physical medicine and rehabilitation specialist at a CCS Neuromuscular Medicine Special Care Center (SCC).
5. Documentation of the following information must be provided and for CCS patients, CCS Neuromuscular Medicine SCC or neurology center has provided the following information using the Antisense Oligonucleotide Request Form:
   a. Documentation of percent forced vital capacity (FVC) ≥ 30 percent
   b. Baseline 6-minute walk test (6MWT) or explanation of why the test cannot be performed
6. Patient is on a corticosteroid or has documented reason not to be on this medication
7. Patient is ambulatory

Initial authorization is for six months.

B. Reauthorization

Golodirsen shall be reauthorized for **up to one year** when the initial coverage criteria are met, in addition to the following:

1. Patient has not had significant decline in FVC while on the antisense oligonucleotide treatment.
2. Motor function has improved compared to pretreatment assessment as evidenced by improved score in 6MWT, Brooke Score and/or other standardized assessment of motor function, or quantifiable description of improvement by the physician or physical therapist in the medical record.
3. Patient has not experienced significant adverse effects attributable to golodirsen.

C. Patients with percent FVC < 30 percent and Brooke Score of six **may** not be granted TAR/SAR authorizations because at the time of this policy, there is insufficient evidence of efficacy in that population.

I. POLICY IMPLEMENTATION FOR CCS PATIENTS

A. Submission of authorization requests for golodirsen are not included in Service Code Groupings (SCGs). SCCs should submit a separate Service Authorization Request (SAR) with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, clinical progress notes from a visit within the past 6 months, and a copy of Antisense Oligonucleotide Request Form.

1. For patients residing in an independent county, SARs should be submitted to the CCS independent county office, which shall review and authorize according to the policy above.
2. For patients residing in a dependent county, SARs should be submitted to dependent county office. The dependent county program office shall pend and submit the SAR and Antisense Oligonucleotide Request Form to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at CCSOperations@dhcs.ca.gov or via secure RightFax at (916) 440-5768.

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

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

Must be 6 years or age or older

Frequency of billing = 30 mg/kg once weekly

HCPCS code J1429 is only reimbursable when billed in conjunction with one of the following ICD-10-CM diagnosis codes: G71.01.

Modifiers SA, UD, U7 and 99 are allowed

To complete a request, refer to the Antisense Oligonucleotide Request Form.

J1558
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Cuvitru and Xembify will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indication and dosing regimen
- Patient must be 2 years of age or older
- Patient must have a diagnosis of Primary Humoral Immunodeficiency (PI) requiring IgG replacement treatment, which may include one of the following:
  a. Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
     i. History of recurrent difficult to treat infections
     ii. Impaired ability to produce antibody in response to pneumococcal polysaccharide vaccine
     iii. Any of the following pre-treatment laboratory findings:
     - Persistent hypogammaglobulinemia (IgG < 500 mg/dL or ≥ SD below normal, on at least two occasions)
     - The IgA or IgM serum level is in the normal range or higher (age-adjusted and according to the normal reference range for the reporting laboratory) measured on at least two occasions more than three weeks apart
     - IgG subclass deficiency: IgG1, IgG2, or IgG3, or IgG3 ≥ 2 SD below mean for age assessed on at least two occasions; normal IgG (total) and IgM levels, normal/low IgA levels
     - Specific antibody deficiency: normal IgG, IgA and IgM levels

b. SCID (severe combined immunodeficiency disease) or Agammaglobulinemia with one of the following:
   i. Confirmed diagnosis by genetic or molecular testing
   ii. Pretreatment IgG level < 200 mg/dL
   iii. Absence or very low number of T cells (CD3 T cells < 300/microliter) or presence of maternal T cells in the circulation (SCID) only

c. Wiskott Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency)
   I. Diagnosis confirmed by genetic or molecular testing (if applicable), and
   II. History of recurrent bacterial infections (e.g. pneumonia, ear infections, sinus infections, sepsis, deep skin or organ abscesses, infections requiring IV antibiotics, etc.), and
   III. Impaired antibody response to pneumococcal polysaccharide vaccine

d. CVID (common variable immunodeficiency disease) with all of the following:
   i. History of recurrent bacterial infections
   ii. Impaired antibody response to pneumococcal vaccine
   iii. Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy)
   iv. The patient's pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age

Approval is for 12 months

Continued therapy:

Approval if patient is responding positively to therapy as shown by the following:

- Patient continues to meet initial approval criteria
- Patient has a decrease in the frequency of bacterial infections
- Patient has a decrease in the severity of infections; or
- Patient previously received intravenous immune globulin or is continuing therapy with subcutaneous immune globulin

Reauthorization is for 12 months

Must be 2 years of age or older

Presumptive Eligibility for Pregnant Women (PE4PW) services

Modifiers SA, UD, U7, 99 are allowed

J3399

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

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
   a. Genetic documentation of bi-allelic mutations in SMN1 gene (deletions or point mutations)
   b. Documentation of up to three copies of survival motor neuron 2 (SMN2)
3. Patient does not have advanced SMA, as evidenced by any of the following:
   a. Invasive ventilator support (tracheostomy with ventilator)
   b. Complete paralysis of limbs
   c. Inability to feed orally
4. The patient is under the care of 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:

a. 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

b. Medical documentation of SCC visit with history and physical examination including description of plan for onasemnogene abeparvovec-xioi administration

c. Genetic laboratory confirmation of diagnosis and number of SMN2 copies.

d. Documentation of AAV9 titer that is less than 1:50, within 90 days of planned administration

e. At least one neuromotor assessment, performed within 12 months of the authorization request, with a score used to establish a clinical baseline

f. 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:
   a. CCS Program Service Authorization (SAR) with Outpatient National Provider Identifier # for:
      1) HCPCS code J3399, injection onasemnogene abeparvovec-xioi, per treatment up to 5x10^15 vector genomes
      2) Supporting clinical documentation should justify medical necessity and that the service is the least costly to meet the patient's needs
      3) 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 J3590, 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. 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).

If you have any questions regarding this N.L., contact the ISCD Medical Director or designee, via email at ISCD-MedicalPolicy@dhcs.ca.gov

Must be less than 2 years of age

HCPCS code J3399 is only reimbursable when billed in conjunction with one of the following ICD-10-CM diagnosis codes: G12.0, G12.1, G12.9.

Modifiers UD and 99 are allowed

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 5x10^15 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:
    - 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 claim lines is no more than provider submitted invoice paid price
        - 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.

   I. 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/DXC
   P.O. Box 526006
   Sacramento, CA 95852-6006

   II. 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 Medi-Cal website, forms section for completion of *837I* form and *UB-04* form.

To complete a request, refer to the Onasemnogene Abeparvovec (Zolgensma) Request Form.

Below is a Zolgensma billing example using UB-04 form and with three 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 AMC

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES		48 NON-COVERED CHARGES	49
	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**	CREATIO N DATE	070220	***TOTALS***	**2,125,002**	**.00**		

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

J7169
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Andexxa (andexanet alfa) will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Must show clinical documentation that andexxa is being used for reversal of anticoagulation due to life-threatening or uncontrolled bleeding in patients treated with rivaroxaban or apixaban
- Patient must have received the last dose of apixaban or rivaroxaban, ≤ 18 hours prior to the start of the Andexxa bolus
- Patient must not be a pregnant or lactating female
- Patient is not scheduled to undergo surgery in less than 12 hours with the exception of minimally invasive surgeries or procedures
- Patient has no recent history (within two weeks) of a diagnosed thrombotic event prior to the bleeding event

Approval is limited to one course of treatment

Must be 18 years of age or older

Maximum dose = 1,800 mg/180 units

Modifiers SA, UD, U7 and 99 are allowed

Q5121
An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates the following:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 6 years of age or older
- The service is medically necessary
- Alternative, conventional therapy has been tried or considered, has failed, or is contra-indicated.
- Patient was screened and showed absence of latent (untreated) tuberculosis prior to therapy initiation
- Patient has been screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
- Patient has no active infection

Initial authorization is for six months

Reauthorization

This may be granted if:

- Patient continues to meet initial coverage criteria
- Patient has shown a positive clinical response such as symptoms improvement or lack of disease progression

Reauthorization is for 12 months

Age six years or older

Modifiers SA, UD, U7 and 99 are allowed

Skin Substitutes

C1849, Q4227 – Q4242, Q4244 - Q4248

C1849, Q4227 – Q4242, Q4244 – Q4248
An approved *Treatment Approved Request* (TAR) is required for reimbursement.
Modifiers SA, U7 and 99 are allowed, however, modifier SA is not allowable for podiatrists.

Surgery

C1748, C9759, C9764, C9765, C9766, C9767, G2170, G2171

C1748
Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 53, 54, 55, 62, 66, 76, 77, 78, 79, 80 and 99 are allowed. HCPCS code C1748 is not reimbursable for the assistant surgeon.

C9759
Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 53, 54, 55, 62, 66, 76, 77, 78, 79, 80 and 99 are allowed. HCPCS code C9759 is not reimbursable for the assistant surgeon.

C9764 – C9767
Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 53, 54, 55, 62, 66, 76, 77, 78, 79, 80 and 99 are allowed.

G2170 – G2171
Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 53, 54, 55, 62, 66, 76, 77, 78, 79, 80 and 99 are allowed. HCPCS codes G2170-G2171 are not reimbursable for the assistant surgeon.

2020 HCPCS CHANGE CODES

Bolded Codes
Bolded codes indicate notation of a special billing policy.

Injections

J7321
Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection

2020 HCPCS DELETED CODES

Chemotherapy

Deleted Code
C9058
J9199

Injections

Deleted Code
C9053
C9054
C9056
C9057

Surgery

Deleted Code
C9754
C9755