Quarter 3 HCPCS/CPT® Update

Quarter 3 Code Additions (Effective May 6, 2021)

Immunizations

The following immunization codes have special billing policy:

M0244

HCPCS code M0244 is for billing infusion and post administration monitoring of casirivimab and imdevimab in the home or residence, including a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency. This code is indicated for the treatment of patients 12 years of age and older and is reimbursable for Presumptive Eligibility for Pregnant Women services.

Providers must maintain appropriate medical documentation that supports the medical necessity of the service, including documentation that supports that the terms of the EUAs are met. The documentation should also include the name of the provider who ordered or made the decision to administer the infusion.

It is important to provide monoclonal antibody recipients EUA fact sheet for patients/caregivers for the applicable product.

DHCS allows a broad range of providers and suppliers to administer these treatments, including but not limited to:

- Freestanding and hospital-based infusion centers
- Home health agencies
- Nursing homes
- Entities with whom nursing homes contract to administer treatment

Modifiers SA, SB, UD, U7 and 99 are allowed.

M0246

HCPCS code M0246 is for billing infusion and post administration monitoring of bamlanivimab and etesevimab in the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the COVID-19 public health emergency. This code is indicated for the treatment of patients 12 years of age and older and is reimbursable for Presumptive Eligibility for Pregnant Women services.

Providers must maintain appropriate medical documentation that supports the medical necessity of the service, including documentation that supports that the terms of the EUAs are met. The documentation should also include the name of the provider who ordered or made the decision to administer the infusion.

It is important to provide monoclonal antibody recipients EUA fact sheet for patients/caregivers for the applicable product.

DHCS allows a broad range of providers and suppliers to administer these treatments, including but not limited to:

- Freestanding and hospital-based infusion centers
- Home health agencies
- Nursing homes
- Entities with whom nursing homes contract to administer treatment

Modifiers SA, SB, UD, U7 and 99 are allowed.

Quarter 3 Code Additions (Effective July 1, 2021)

Chemotherapy

The following chemotherapy codes have special billing policy:

C9076, C9078, C9080, J9348, J9353, Q5123

C9076

HCPCS code C9076 is indicated for the treatment of patients 18 years of age and older and has a frequency limit of once in a lifetime.

Due to systems limitations, providers are to take the following steps when submitting claims for Breyanzi:

Submit and receive back an approved *Treatment Authorization Request* (TAR)/*Service Authorization Request* (SAR)

Bill using C9076 (lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose)

Completion of claim forms:

- Outpatient claims may be billed by paper claim using *CMS-1500* or electronically using ASC X12N 837P v.5010
- Providers must submit one (1) service line on the TAR/SAR request, and enter “5” in the Units box
- On the 837P or *CMS-1500* claim form, providers must submit one claim line to represent one (1) service
  - ❖ Claims submitted with more than one claim line will be denied

- ❖ Providers must submit an invoice for reimbursement.
- ❖ This process will ensure that the total reimbursement paid for the quantity of five (5) is no more than the paid price on the provider submitted invoice
- ❖ Breyanzi must be billed on its own with no other drug or biological

For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of 837P and *CMS-1500* claim forms

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include documentation of all of the following criteria:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following large B-cell lymphoma (LBCL) subtypes:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including:
    - ❖ de novo DLBCL
    - ❖ DLBCL, transformed from indolent lymphoma
  - High-grade B-cell lymphoma
  - Primary mediastinal large B-cell lymphoma
  - Follicular lymphoma, grade 3B
- Patient has relapsed or refractory disease after receiving 2 or more lines of systemic therapy
  - Patients may have received prior autologous or allogeneic HSCT
- Eastern Cooperative Oncology Group (ECOG) performance status equal to or less than 2
- Creatinine clearance equal to or greater than 30 mL/min
- Alanine aminotransferase equal to or less than 5 times the upper limit of normal
- Left ventricular ejection fraction equal to or greater than 40%
- Adequate bone marrow function, as determined by the treating physician
- No primary central nervous system (CNS) lymphoma
  - Authorized patients may include those with secondary CNS lymphoma involvement
- No active infection or inflammatory disorders
- No prior CAR T-cell therapy in relapsed or refractory LBCL
- Must be administered in a healthcare facility certified by the manufacturer based on the Risk Evaluation and Mitigation Strategy (REMS) called the Breyanzi™ REMS Program.

Initial authorization is for 3 months (1 dose only). Reauthorization is not approvable.

Breyanzi REMS Requirements

- All hospitals and their associated clinics must be certified and enrolled in the Breyanzi REMS to be able to infuse Breyanzi
- All relevant staff involved in the prescribing, dispensing, or administering of Breyanzi are trained on Breyanzi REMS requirements, and must successfully complete the Breyanzi REMS Knowledge Assessment

Modifiers UD and 99 are allowed.

C9078

HCPCS code C9078 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing equals 240 mg/m^2 administered prior to each chemotherapy regimen

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

- Must be used for FDA approved indications and dosing regiments
- Patient must be 18 years of age or older
- Patient has a diagnosis of extensive-stage small cell lung cancer (SCLC) by histology or cytology
- Trilaciclib will be administered prior to a myelosuppressive chemotherapy with one of the following:
  - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; or
  - Topotecan-containing regimen
- Trilaciclib is used to decrease the incidence of chemotherapy-induced myelosuppression
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2

Initial approval is for 6 months.

Continued Therapy:

- Patient continues to meet initial approval criteria
- Absence of unacceptable toxicities such as severe injection site reactions, acute drug hypersensitivity reactions, interstitial lung disease/pneumonitis, etc.
- Patient is undergoing a myelosuppressive chemotherapy with a platinum/etoposide-containing regimen or topotecan-based regimen

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Quarter 3 HCPCS/CPT Codes Update

C9080

HCPCS code C9080 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing equals 40 mg/40 units on day 1 of each 28-day cycle.

Maximum billing unit(s) equals 40 mg/40 units.

Modifiers SA, UD, U7 and 99 are allowed.

J9348

HCPCS code J9348 is indicated for patients 1 year of age and older.

Frequency of billing equals 3 mg/kg/dose IV x1 on days 1, 3, 5 of 28-day cycle until complete or partial response achieved, then give x5 additional cycles q28 days, then may give subsequent cycles q56 days.

A *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include documentation of all of the following criteria:

- Must be used for FDA-approved indications and dosages
- Patient must be 1 year of age or older
- Patient must have a diagnosis of high-risk, refractory or relapsed neuroblastoma (NB) in the bone or bone marrow
- Patient has a partial response, minor response, or stable disease to prior therapy
- Patient is resistant to standard therapy
- Patient has been off chemotherapy and immunotherapy for a minimum of three weeks
- Must be used in combination with granulocyte-macrophage colony-stimulating factor (GM- CSF), for example, sargramostim
- Patient is not a pregnant female

Authorization is for 6 months

Continuation of Therapy:

- Patient continues to meet initial approval criteria
- Patient has shown positive clinical benefit as evidenced by lack of disease progression or reduction in tumor size or spread
- Absence of unacceptable toxicity such as neurotoxicity (peripheral neuropathy, neurological disorders of the eye, and prolonged urinary retention) or severe hypertension

Reauthorization is for 6 months.

Modifiers SA, UD, U7 and 99 are allowed.

Quarter 3 HCPCS/CPT Codes Update

J9353

HCPCS code J9353 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing equals 15 mg/kg for the initial dose, then every 3 weeks for all subsequent doses.

Modifiers SA, UD, U7 and 99 are allowed.

Q5123

HCPCS code Q5123 is indicated for the treatment of patients 18 years of age and older.

A *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include documentation of all of the following criteria:

- Must be used for FDA approved indications and dosing regiments
- Patient has been screened for hepatitis B virus (HBV) infection prior to therapy initiation (for example, hepatitis B surface antigen [HBsAG] and hepatitis B core antibody measurements).

Non-Hodgkin's Lymphoma (NHL)

- Must be 18 years of age or older
- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens

Chronic Lymphocytic Leukemia (CLL)

- Must be 18 years of age or older
- Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- Patient must be 18 years of age or older
- Riabni must be used in combination with glucorticoids such as methylprednisolone, prednisone, etc.

Initial approval is for 12 months.

Reauthorization:

- Patient continues to meet initial approval criteria
- Patient does not have unacceptable toxicity such as infusion-related reactions. progressive multifocal leukoencephalopathy, tumor lysis syndrome, severe mucocutaneous skin reactions, etc

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Immunizations

The following immunization code has special billing policy:

90758

CPT code 90758 (Zaire ebolavirus vaccine, live for intramuscular use) is indicated for the treatment of patients 18 years of age and older.

Modifier SK is required. Modifiers SA, UD, U7 and 99 are allowed.

Injections

The following injection codes have special billing policy:

C9075, C9077, C9079, J0224, J1951, J7168

C9075

HCPCS code C9075 is indicated for the treatment of pediatric patients.

ICD-10-CM diagnosis code G71.01 is required on the claim.

Frequency of billing equals 30 mg/kg once weekly.

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

- Must be used for FDA-approved indications and dosages.
- Patient must have a genotypically confirmed Duchenne Muscular Dystrophy (DMD), with genetic deletion amenable to exon 45 skipping.

- 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).
- The following are completed as part of the assessment for antisense oligonucleotide therapy:
  - Forced Vital Capacity (FVC)
  - Brooke score
  - 6-minute walk test (6MWT), if ambulatory, and
  - Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C
- The FVC is greater than 30% predicted or the Brooke score is less than or equal to 5
- Only one antisense oligonucleotide treatment shall be authorized at a time
- Patient is on a corticosteroid, or has documented medical reason not to be on this medication

Initial authorization is for 12 months

Reauthorization:

Patient has finished the initial course of treatment and all of the following apply:

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

Reauthorization is for 12 months.

Additional Consideration for Medical Necessity Determination:

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

Policy Implementation for CCS Patients:

A. Submissions of authorization requests for eteplirsen, golodirsen, viltolarsen, or casimersen are not included in Service Code Groupings. Providers should submit a separate SAR with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, and clinical progress notes from a visit within the past 6 months.
    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 the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at *CCSExpeditedReview@dhcs.ca.gov* or via secure RightFax (916) 440-5306
B. All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization

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

Modifiers UD and 99 are allowed.

C9077

HCPCS code C9077 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing equals initiate Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine)/300 units on the last day of oral lead-in and continue with Cabenuva (400 mg of cabotegravir and 600 mg of rilpivirine)/200 units every month thereafter.

Modifiers SA, UD, U7 and 99 are allowed.

C9079

HCPCS code C9079 is indicated for the treatment of patients 12 years of age and older. ICD-10-CM diagnosis code E78.01 is required on the claim.

Frequency of billing equals15 mg/kg once monthly (every 4 weeks).

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

- Must be used for FDA approved indications and dosages
- Patient must be 12 years of age or older

- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by at least one of the following:
  - Genetic testing showing mutations of pathogenic variants of the low-density lipoprotein receptor (LDL-R) gene, or pathogenic variants of the apolipoprotein (ApoB) gene, or homozygous mutations in the LDL-R adaptor protein-1
  - Patient has very high LDL-C (greater than 500 mg/dL untreated or greater than300 mg/dL if on maximal lipid-lowering therapy), and cholesterol deposits in the first decade of life in the setting of a strong family history; and physical manifestations such as xanthomas, xanthelasmas (cholesterol deposits in the eyelids or skin), or corneal arcus
  - Patient has a low-density lipoprotein-cholesterol (LDL-C) level of equal to or greater than 190 mg/dL, or lower with strong family histories and/or physical findings such as xanthomas, xanthelasmas (cholesterol deposits in the eyelids or skin), or corneal arcus
- If undergoing LDL apheresis, must have initiated LDL apheresis at least 3 months prior to treatment initiation and must have been on a stable weekly or every other week schedule and/or stable settings for at least 8 weeks
- Must be prescribed by or in consultation with a lipid specialist or other specialist experienced in the treatment of HoFH.
- Patient must have tried and failed, is intolerant to or has a clinical contraindication to high dose statin therapy (with atorvastatin 80 mg or rosuvastatin 40 mg) or lower if indicated, and 10 mg ezetimibe.
- Patient did not achieve their LDL-C goal after 3 months on statin and ezetimibe and Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (for example, evolocumab) unless intolerant or clinically contraindicated.
- Patient will take Evkeeza in combination with other LDL-C lowering therapies such as statins, ezetimibe, etc.
- Patient is not a pregnant or breastfeeding female.

Initial authorization is for 6 months.

Continued Therapy:

- Patient continues to meet initial coverage criteria.
- Positive clinical response as evidenced by reduction of LDL-C from baseline.
- Patient continues treatment with other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (for example, statin, ezetimibe) in combination with Evkeeza.

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Quarter 3 HCPCS/CPT Codes Update

J0224

HCPCS code J0224 is indicated for the treatment of patients of all ages. ICD-10-CM diagnosis code E72.53 is required on the claim.

Frequency of billing equals every 28 days.

The recommended dose is based on body weight.

Recommended Dose Based on Body Weight Table

Body Weight	**Loading Dose**	**Maintenance Dose (begin one month after the last loading dose)**
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly)
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly)

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

- Must be for FDA-approved indications and dosages
- Must be prescribed by, or in consultation with, a nephrologist, endocrinologist, or other healthcare provider who is specialized in treating primary hyperoxaluria type 1 (PH1)
- Patient has a diagnosis of PH1 confirmed with one of the following:
  - Genetic testing confirmation of mutation of Alanine glyoxylate aminotransferase (AGXT)
  - Liver biopsy demonstrating decreased or absent activity of AGT for type 1 disease; and
- Patient has at least one of the following:
  - Elevated urinary oxalate excretion persistently greater than 0.7 mmol/1.73 m2/day or above the upper limit of normal (ULN) for age
  - Urinary oxalate-to-creatinine ratio greater than ULN for age in two of three single-void collections
  - Elevated urinary glycolic acid (glycolate) concentration
- Patient has tried and failed at least three months of pyridoxine (vitamin B6) at up to the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
- Patient has not had a kidney or liver transplant
- Patient does not have a history of extrarenal systemic oxalosis

Initial approval is for six months

Reauthorization:

- Patient continues to meet the initial approval criteria
- Patient has experienced clinical benefit as evidenced by reduction in signs and symptoms of PH1 with lumasiran treatment
- Patient has shown improvement or normalization of laboratory values such as urinary oxalate excretion from baseline, or the percent change in spot urinary oxalate-to-creatinine ratio from baseline

Reauthorization is for 12 months

Modifiers SA, UD, U7 and 99 are allowed.

J1951

HCPCS code J1951 is indicated for the treatment of patients between the ages of 2 years and 12 years.

Frequency of billing equals 45 mg/180 units every 6 months.

Maximum billing unit(s) equals 45 mg/180 units.

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

- Must be used for FDA-approved indications and dosages
- Patient must be 2 to 12 years of age
- Must be prescribed by or in consultation with an endocrinologist or other specialists who have expertise in treating precocious puberty
- Patient has a diagnosis of central precocious puberty (CPP) as confirmed by blood concentrations of luteinizing hormone (basal or stimulated with a gonadotropin-releasing hormone [GnRH] analog), sex steroids, and bone age assessment
- The rate of sexual maturation, height velocity, and bone age advancement is rapid for age
- Puberty occurs before the age of 8 for females and the age of 9 for males
- Diagnostic tests have been done to rule out tumors such as brain imaging (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid-secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin-secreting tumor), and adrenal steroid measurements (to exclude congenital adrenal hyperplasia)

Initial authorization is for 6 months

Reauthorization:

- Patient continues to meet the initial approval criteria
- Improvement or stabilization of condition as evidenced by reduction or stabilization in pubertal development and growth or in bone age advancement
- Female patient is less than 12 years of age and male patient is less than 13 years of age

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

J7168

HCPCS code J7168 is indicated for the treatment of patients 18 years of age and older 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.

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.

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

Modifiers SA, UD, U7 and 99 are allowed.

Radiology

The following radiology codes have special billing policy:

A9593, A9594

HCPCS codes A9593 and A9594 are radioactive diagnostic agents indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer. Ga 68 PSMA-11 is indicated for patients 18 years of age and older.

The recommended adult dose is 111 MBq to 259 MBq (3 mCi to 7 mCi) as a bolus intravenous injection. Use appropriate aseptic technique and radiation safety handling measures to maintain sterility during all operations involved in the manipulation and administration of Ga 68 PSMA-11 Injection. A diuretic expected to act within the uptake time period may be administered at the time of radiotracer injection. Initiate imaging 50 to 100 minutes after administration. The patient should void immediately prior to initiation of imaging. Scan should begin caudally and proceed cranially.

Billing: Codes A9593 & A9594 are separately billable and not split-billable. Providers must complete a *CMS-1500* form including the medically justified ICD-10-CM diagnosis code. Providers must include an invoice showing the acquisition cost of the product to the claim. The invoice must have a date prior to the date of service or the claim will be denied.

Maximum billing unit(s) equals 7 mCi/7 units

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

- Must be used for FDA approved indications and dosages
- Patient must be 18 years of age or older
- Patient has a diagnosis of prostate cancer:
  - with suspected metastasis who are candidates for initial definitive therapy.
  - with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

- Patient had biopsy-proven prostate cancer and considered a candidate for prostatectomy and pelvic lymph node dissection, and meets at least one of the following criteria:
  - Patient has a serum prostate-specific antigen (PSA) of at least 10 ng/mL
  - Patient has a tumor stage cT2b or greater
  - Patient has a Gleason score greater than 6; or
- Patient has a biochemical evidence of recurrent prostate cancer after definitive therapy, defined by serum PSA of greater than0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy.

Approval is for 3 months.

Modifiers UD and 99 are allowed.

Quarter 3 Code Deletions Effective April 17, 2021

Table of Quarter 3 Code Deletions

Department	Deleted Code
Immunizations	M0239 Q0239

Quarter 3 Code Deletions Effective July 1, 2021

Table of Quarter 3 Code Deletions

Department	Deleted Code
Injection	C9074 C9132