# Quarter 4 HCPCS/CPT® Update

## Quarter 4 Code Additions (Effective October 1, 2021)

### Blood and Blood Derivatives

The following blood and blood derivatives codes have special billing policies:

P9025, P9026

P9025

Pathogen Reduced Plasma, Cryoprecipitate reduced is indicated for:

- Transfusion or therapeutic plasma exchange (TPE) in patients with thrombotic thrombocytopenic purpura (TTP)
- It may be used to provide coagulation factors, except fibrinogen, factor VIII, factor XIII, and von Willebrand factor (vWF), for transfusion support of patients with appropriate clinical indications

Billed with instructions:

- Code P9025 requires an invoice submission for reimbursement
- Outpatient claims may be billed by paper claim using *CMS-1500* or electronically using ASC X12N 837P v.5010
- Providers must include the medically justified ICD-10-CM diagnosis code on the claim form
- Providers must include an invoice showing the acquisition cost of the product in addition to the product catalog number in the *Remarks* section of the claim form for appropriate reimbursement

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

P9026

Pathogen Reduced Cryoprecipitated Fibrinogen Complex is indicated for:

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency
- Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available
- Second-line therapy for von Willebrand disease (vWD)
- Control of uremic bleeding after other treatment modalities have failed

Billed with instructions:

- Code P9026 requires an invoice submission for reimbursement

- Outpatient claims may be billed by paper claim using *CMS-1500* or electronically using ASC X12N 837P v.5010
- Providers must include the medically justified ICD-10-CM diagnosis code on the claim form
- Providers must include an invoice showing the acquisition cost of the product in addition to the product catalog number in the *Remarks* section of the claim form for appropriate reimbursement

Limitations of Use: Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII.

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

## Chemotherapy

The following chemotherapy codes have special billing policy:

C9081, C9082, C9083, C9084, J1448, J9247, J9318, J9319, Q2054

C9081

Idecabtagene vicleucel is a CAR-T therapy indicated for the treatment of relapsed and refractory multiple myeloma (RRMM) in patients 18 years of age or older and has a frequency limitation of once in a lifetime.

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

The TAR must include clinical documentation that demonstrates the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an oncologist or a hematologist
- Patient must have a diagnosis of RRMM
- Patient has received four or more myeloma treatment regimens including a proteasome inhibitor (for example, bortezomib, carfilzomib, ixazomib), an immunomodulatory agent (for example, lenalidomide, pomalidomide, thalidomide) and an anti-CD38 antibody (for example, daratumumab, daratumumab/hyaluronidase, isatuximab)
- Eastern Cooperative Oncology Group (ECOG) performance status of two or less
- Patient has no history of central nervous system (CNS) disease (for example, seizure or cerebrovascular ischemia)
- Patient must have creatinine clearance greater than 30 mL/min
- Patient has left ventricular ejection fraction greater than or equal to 45 percent
- Patient has no active infection or inflammatory disorders
- Patient must not have any of the following:

  - Aspartate aminotransferase (AST) and/or Alanine Aminotransferase (ALT) greater than 2.5x ULN
  - Absolute neutrophil count (ANC) less than 1000cells/mm3 and platelet count less than 50,000/mm3
- Patient has not been previously treated with CAR-T therapy in RRMM
- ABECMA will not be used concurrently with another CAR-T therapy
- ABECMA must be administered at a healthcare facility certified by the manufacturer based on the REMS requirements defined by the FDA

Initial approval is for three months (one treatment only).

Reauthorization: Repeat treatment is not approvable.

ABECMA REMS

Because of the risk of Cytokine Release Syndrome (CRS) and neurologic toxicities, ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.

The required components of the ABECMA REMS are:

- Healthcare facilities that dispense and administer ABECMA must be enrolled and comply with the REMS requirements
- Certified healthcare facilities must have on-site, immediate access to tocilizumab
- Ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within two hours after ABECMA infusion, if needed for treatment of CRS
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer ABECMA are trained in the management of CRS and neurologic toxicities

Further information is available at www.AbecmaREMS.com or contact Bristol-Myers Squibb at 1-888-423-5436.

Important instructions for billing: Due to systems limitations, providers are to take the following steps when submitting claims for ABECMA:

1. Submit and receive back an approved *Treatment Authorization Request* (TAR)/Service Authorization Request (SAR)
2. Bill using C9081 (idecabtagene vicleucel, up to 460 million autologous anti-bcma car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose)
3. 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
- ABECMA must be billed on its own with no other drug or biological

4. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, for completion of 837P and *CMS-1500* claim forms

Frequency of billing equals one dose per lifetime.

Modifiers UD and 99 are allowed.

C9082

Dostarlimab-gxly is indicated for the treatment of mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer in patients 18 years of age or older.

Frequency of billing equals 500 mg/5 units every 3 weeks for 4 doses, then 3 weeks after dose 4, continue with 1,000 mg/10 units every 6 weeks.

Modifiers SA, UD, U7 and 99 are allowed.

C9083

Amivantamab-vmjw is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations in patients 18 years of age or older.

Frequency of billing equals 1400 mg/140 units weekly for 4 weeks, then every 2 weeks thereafter. Note that the initial dose is administered as a split infusion in week 1 on days 1 and 2.

Modifiers SA, UD, U7 and 99 are allowed.

C9084

Loncastuximab tesirine-lpyl is indicated for the treatment of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma, in patients 18 years of age or older.

Frequency of billing equals 0.15 mg/kg every three weeks for two cycles, then 0.075 mg/kg every three weeks for subsequent cycles.

Modifiers SA, UD, U7 and 99 are allowed.

Quarter 4 HCPCS/CPT Codes Update

J1448

Trilaciclib is indicated for the treatment of to decrease the incidence of chemotherapy-induced myelosuppression when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer in patients 18 years of age or older.

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

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

- Must be used for FDA-approved indications and dosing regimens
- 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.

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

Modifiers SA, UD, U7 and 99 are allowed.

J9247

Melphalan Flufenamide is indicated in combination with dexamethasone, for the treatment of patients 18 years of age and older with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

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.

J9318

Romidepsin, non-lypohilized is indicated for the treatment of cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL) in patients 18 years of age and older who have received at least one prior therapy.

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 regimens
- Patient must be 18 years of age or older
- Patient must have one of the following diagnoses:
  - Cutaneous T-cell lymphoma (CTCL)
  - Peripheral T-cell lymphoma (PTCL)
- Patient must have received at least one prior therapy with relapse or disease progression.

Initial authorization is for 6 months.

Continued Therapy:

- Patient continues to meet initial coverage criteria
- Positive clinical response as evidenced by disease stabilization or lack of disease progression

Reauthorization is for 12 months.

Frequency of billing equals 14 mg/m2 on days 1, 8, and 15 of a 28-day cycle. Repeat cycles every 28 days.

Modifiers SA, UD, U7 and 99 are allowed.

J9319

Romidepsin (Istodax) is indicated for the treatment of cutaneous T-cell lymphoma (CTCL) in patients 18 years of age and older who have received at least one prior systemic therapy.

One of the following ICD-10-CM diagnosis codes is required on the claim: C84.00 thru C84.19.

Modifiers SA, UD, U7 and 99 are allowed.

Q2054

Lisocabtagene Maraleucel is a CAR-T therapy indicated for the treatment of patients 18 years of age and older with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma,

primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. It has a frequency limitation of once in a lifetime.

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

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

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following large B-cell lymphoma subtypes (LBCL):
  - 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 Hematopoietic stem cell transplantation (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 (ALT) equal to or less than 5 times the upper limit of normal
- Left ventricular ejection fraction equal to or greater than 40 percent
- 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 (R/R) 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 three 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

Important Instructions for billing:

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

1. Submit and receive back an approved *Treatment Authorization Request* (TAR)/Service Authorization Request (SAR)
2. Bill using Q2054 (lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose)
3. 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, provider 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
4. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, for completion of 837P and *CMS-1500* claim forms

Modifiers UD and 99 are allowed.

## Family Planning

The following family planning codes have special billing policy:

J7294, J7295

J7294

Segesterone acetate and ethinyl estradiol yearly vaginal system (Annovera) is indicated for use by women to prevent pregnancy.

A 12-month supply of the same product of J7294 may be dispensed twice in one year. A *Treatment Authorization Request* (TAR) is required for a third dispensing of the same product requested within a 12-month period.

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

HCPCS code J7294 is reimbursable for Medi-Cal and Family Planning, Access, Care and Treatment (Family PACT) programs.

J7295

Ethinyl estradiol and etonogestrel monthly vaginal ring (NuvaRing) is indicated for use by women to prevent pregnancy.

A 12-month supply of the same product of J7295 may be dispensed twice in one year. A *Treatment Authorization Request* (TAR) is required for a third dispensing of the same product requested within a 12-month period.

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

HCPCS code J7295 is reimbursable for Medi-Cal and Family Planning, Access, Care and Treatment (Family PACT) programs.

## Injections

The following injection codes have special billing policy:

J0699, J0741, J1305, J1426, J1445, J2406

J0699

Cefiderocol is a cephalosporin antibacterial indicated in patients 18 years of age or older for the treatment of infections caused by susceptible Gram-negative microorganisms such as complicated urinary tract infections (cUTI), including pyelonephritis, and Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia (HABP/VABP).

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 must have a diagnosis of the following infections caused by susceptible gram-negative microorganisms:

A. Clinical diagnosis of either cUTI with or without pyelonephritis or acute uncomplicated pyelonephritis

- ❖ The infection is caused by the following susceptible gram-negative microorganisms: E. coli, K. pneumoniae, Proteus mirabilis, P. aeruginosa, and E. cloacae complex
- ❖ Patient was treated previously with an empiric antibiotic but failed treatment, both clinically and microbiologically

- ❖ Patient had an identified Gram-negative uropathogen that was not susceptible to the previously used empiric treatment and likely to be susceptible to Fetroja
- ❖ Patient was receiving antibiotic prophylaxis for UTI but presents with signs and symptoms consistent with an active new UTI

B. Patient has a diagnosis of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), or healthcare-associated bacterial pneumonia (HCABP)

- ❖ Patient must have a suspected Gram-negative infection involving the lower respiratory tract
- ❖ Infection was caused by the following susceptible gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens
- ❖ Patient does not have known or suspected community-acquired bacterial pneumonia (CABP), atypical pneumonia, viral pneumonia, or chemical pneumonia (including aspiration of gastric contents, inhalation injury)

Must meet the following criteria for both diagnoses:

- The prescriber must verify that limited or no alternative treatment options are available; and
- The prescriber must clinically document why the patient cannot use other clinically appropriate and cost-effective therapeutic equivalent alternatives such as imipenem/cilastatin, meropenem, fluoroquinolones, etc.

Authorization is for 14 days treatment duration.

Billing instructions:

Since the same injection will be administered more than once on the same day, each injection must be listed on a separate claim line.

Providers must use modifier XE (separate encounter) for each subsequent claim line to ensure appropriate reimbursement.

Frequency of billing equals 2 g/200 units every 6 hours for 7 to 14 days.

Maximum billing unit(s) equals 8 g/800 units.

Modifiers SA, UD, U7, XE and 99 are allowed.**Error! Reference source not found.**

J0741

Cabotegravir ER/Rilpivirine ER injection is indicated as a complete regimen for the treatment of HIV-1 infection in patients 18 years of age or older, to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

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.**Error! Reference source not found.**

J1305

Evinacumab-dgnb is indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH).

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

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

- 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 than 300 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.

ICD-10-CM diagnosis code E78.01 is required on the claim.

Frequency of billing equals 15 mg/kg once monthly (every 4 weeks).

Modifiers SA, UD, U7 and 99 are allowed.

J1445

Triferic AVNU is an iron replacement product indicated for the replacement of iron to maintain hemoglobin in patients 18 years of age or older with hemodialysis-dependent chronic kidney disease (HDD-CKD).

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

Triferic AVNU is considered medically necessary when all of the following criteria are met:

- Patient must be 18 years of age or older
- Patient must have a diagnosis of hemodialysis-dependent chronic kidney disease (HDD-CKD)
  - The diagnosis of HDD-CKD is greater than or equal to 4 months and patient requires hemodialysis at least three times per week
- Patient has serum ferritin less than or equal to 200 ng/mL
- Patient has Serum Transferrin Saturation (TSAT) less than or equal to 20 percent
- Patient has Hemoglobin less than 10 grams per deciliter (g/dL) or is being treated with an Erythropoiesis-Stimulating Agent (ESA) to maintain Hemoglobin at target and a TSAT at 30 percent or less and ferritin at 500 ng/mL or less
- Patient is not receiving peritoneal dialysis
- Patient is not receiving home hemodialysis

Initial authorization is for 3 months.

Continued Treatment:

- Patient is monitored and continues to meet initial approval criteria
- Patient has positive clinical response evidenced by mean change in hemoglobin from baseline

Reauthorization is for 3 months.

Important billing instructions:

Due to systems limitations, only whole numbers in units can be processed. Providers must bill for 68 units rather than 67.5 units.

Frequency of billing equals 6.75 mg/67.5 units at each hemodialysis session.

Maximum billing unit(s) equals 6.75 mg/67.5 units.

Modifiers SA, UD, U7 and 99 are allowed.

J1426

Casimersen is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.

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

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

- 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.

Frequency of billing equals 30 mg/kg once weekly.

J2406

Oritavancin (Kimyrsa) is a lipoglycopeptide antibacterial drug indicated for the treatment of patients 18 years of age and older with acute bacterial skin and skin structure infections

caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganism.

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

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:
  a. Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication or vancomycin, or
  b. Staphylococcus aureus with reduced susceptibility to vancomycin (vancomycin intermediate Staphylococcus aureus [VISA], or vancomycin-resistant Staphlyococcus aureus [VRSA])
- Patient has medical reason why oral antibiotics are not appropriate
- Patient does not have any of the following:
  - Concomitant infection at another site not including a secondary ABSSSI lesion (for example, septic arthritis, endocarditis, osteomyelitis)
  - Infected burns
  - Infections known to be caused by an organism resistant to oritavancin
  - Catheter site infections
  - Known liver function tests (LFTs) greater than or equal to 3 times the upper limit of normal (ULN) or total bilirubin greater than or equal to 2 times ULN

Authorization is once per treatment.

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

Modifiers SA, UD, U7 and 99 are allowed.

## Orthotics and Prosthetics

The following orthotics and prosthetics code has special billing policy:

K1022

HCPCS code K1022 has a frequency limit of one in 5 years.

Additions to lower extremity prostheses may be authorized and reimbursed for recipients that meet the established criteria.

The recipient has an existing or authorized lower limb prosthesis that is compatible with the requested addition(s) and requires a specialized knee joint to allow functional use of the prosthesis (all codes).

Addition codes will be authorized and reimbursed separately only when the base appliances has been provided or when the addition is being replaced or repaired.

HCPCS code K1022 requires all of the following documentation:

- The recipient has an existing or authorized appliance that is compatible with the requested addition(s)
- Past history, including prior prosthetic use, if applicable; and,
- Current medical condition, including status of the residual limb and the nature of other medical problems; and,
- Ability to reach or maintain a defined functional state within a defined and reasonable period of time; and
- Motivation to ambulate
- A functional level of “1” or higher. Recipients with a functional level of “0” will not be authorized and reimbursed for lower limb prostheses

This item is exempt from California state sales tax and will be reimbursed at the non-tax rate. Sales tax will be disallowed if billed.

HCPCS code K1022 must be billed with either the modifier LT (left side) or RT (right side).

## Pathology and Clinical Laboratory

The following pathology and clinical laboratory codes have special billing policy:

0268U, 0269U, 0271U, 0275U, 0276U, 0279U thru 0284U

0268U

CPT code 0268U has a frequency limit of once in a lifetime.

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

- The patient has clinical signs or symptoms suspicious for atypical hemolytic uremic syndrome [aHUS], and
- The patient requires the service as a diagnostic test for atypical hemolytic uremic syndrome [aHUS]

Modifiers 33, 90 and 99 are allowed.

0269U

CPT code 0269U has a frequency limit of once in a lifetime.

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

- The patient has clinical signs or symptoms suspicious for autosomal dominant congenital thrombocytopenia, and
- The patient requires the service as a diagnostic test for autosomal dominant congenital thrombocytopenia

Modifiers 33, 90 and 99 are allowed.

0271U

CPT code 0271U has a frequency limit of once in a lifetime.

One of the following ICD-10-CM diagnosis codes is required on the claim: D70.0 thru D70.9.

Modifiers 33, 90 and 99 are allowed.

0275U

Modifiers 33, 90 and 99 are allowed.

0276U

CPT code 0276U has a frequency limit of once in a lifetime.

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

- The patient has clinical signs or symptoms suspicious for inherited thrombocytopenia, and
- The patient requires the service as a diagnostic test for inherited thrombocytopenia

Modifiers 33, 90 and 99 are allowed.

0279U thru 0284U

Modifiers 33, 90 and 99 are allowed.

## Skin Substitutes

The following skin substitutes codes have special billing policy:

Q4251 thru Q4253

Q4251 thru Q4253

An approved *Treatment Authorization Request* (TAR) by the physician or podiatrist is required for reimbursement.

Modifiers U7 and 99 are allowed.

## Veterans Affairs Counseling/Assessments

The following veteran's affairs counselling/assessment codes have special billing policy:

Q9004

HCPCS code Q9004 is indicated for the treatment of patients 18 years of age or older.

Modifiers SA, U7, and 99 are allowed.

# Quarter 4 Code Changes (Effective October 1, 2021)

## Injections

The following injection codes have updated billing policy:

J2407

Oritavancin (Orbactiv®) is a lipoglycopeptide antibacterial drug indicated for the treatment of patients 18 years of age and older with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms.

Modifiers SA, UD, U7 and 99 are allowed.

# Quarter 4 Code Deletions (Effective October 1, 2021)

**Table of Quarter 4 Code Deletions**

| Department | Deleted Code |
|---|---|
| Chemotherapy | C9065<br>C9076<br>C9078<br>C9080<br>J9315 |
| Injection | C9075<br>C9077<br>C9079<br>J0693 |
| Family Planning | J7303 |
| Pathology and Clinical Laboratory | 0139U<br>0168U |
| Surgery | Q4228<br>Q4236 |

**Note:** HCPCS code J9315 was deleted for Medi-Cal and California Children's Services (CCS) programs.

HCPCS code J7303 was deleted for Medi-Cal and Family Planning, Access, Care and Treatment (Family PACT) programs.