# Q1 HCPCS Level I and II Update (January 1, 2024)

Note: Please note that the general code descriptions included are provided to assist with interpreting and navigating the content; providers are responsible for referencing the appropriate codebooks for up-to-date full descriptions when considering which code is appropriate to bill for the services rendered.

Note: Codes G0011, J0750, J0751 and J0799 are effective for dates of service on or after January 2, 2024.

## Q4 Code Additions

### Cardiology

The following Cardiology codes have special billing policies:

92972, 93584, 93585, 93586, 93587, 93588

**92972, 93584, 93585, 93586, 93587, 93588**

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

Modifiers SA, U7 and 99 are allowed.

### Chemotherapy

The following Chemotherapy codes have special billing policies:

C9163, C9165, J9052, J9072, J9258, J9286, J9321, J9324

**C9163**

Talquetamab-tgvs (TALVEY™)

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

**TECVAYLI and TALVEY REMS**

TALVEY is available only through a restricted program under a Risk Evaluation Management Strategy (REMS) called the TECVAYLI and TALVEY REMS because of the risks of cytokine release syndrome (CRS) and neurologic toxicity, including ICANS [see Warnings and Precautions (5.1, 5.2)]. Notable requirements of the TECVAYLI and TALVEY REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Prescribers must counsel patients receiving TALVEY about the risk of CRS and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity (ICANS) and provide patients with Patient Wallet Card.
- Pharmacies and healthcare settings that dispense TALVEY must be certified with the TECVAYLI and TALVEY REMS program and must verify prescribers are certified through the TECVAYLI and TALVEY REMS program.
- Wholesalers and distributers must only distribute TALVEY to certified pharmacies.

Further information about the TECVAYLI and TALVEY REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

Age must be 18 years or older.

Suggested ICD-10-CM Diagnosis Codes: C90.00, C90.02

Modifiers SA, UD, U7 and 99 are allowed.

**C9165**

Elranatamab-bcmm (ELREXFIO™)

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

**ELREXFIO REMS**

ELREXFIO is available only through a restricted program under a REMS called the ELREXFIO REMS because of the risks of CRS and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

Notable requirements of the ELREXFIO REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Prescribers must counsel patients receiving ELREXFIO about the risk of CRS and neurologic toxicity, including ICANS, and provide patients with ELREXFIO Patient Wallet Card.
- Pharmacies and healthcare settings that dispense ELREXFIO must be certified with the ELREXFIO REMS program and must verify prescribers are certified through the ELREXFIO REMS program.
- Wholesalers and distributers must only distribute ELREXFIO to certified pharmacies or healthcare settings.

Further information about the ELREXFIO REMS program is available at www.ELREXFIOREMS.com or by telephone at 1-844-923-7845.

Age must be 18 years or older.

Suggested ICD-10-CM Diagnosis Codes: C90.00, C90.02

Maximum billing units equals 76 mg/76 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J9052**

Carmustine

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

Modifiers SA, UD, U7 and 99 are allowed.

**J9072**

Cyclophosphamide

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

Modifiers SA, UD, U7 and 99 are allowed.

**J9258**

Paclitaxel Protein-Bound Particles (Teva)

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

Paclitaxel protein-bound is medically necessary when all of the following criteria are met:

Universal Criteria

- Must be used for FDA-approved indications and dosing regimens.
- Patient must have one of the following diagnoses:
  - Breast cancer, metastatic:
    - ❖ Patient has a diagnosis of breast cancer
    - ❖ Disease is metastatic
    - ❖ Patient had failed combination chemotherapy for metastatic disease or had a relapse within six months of adjuvant chemotherapy
    - ❖ Prior therapy must include an anthracycline (for example, doxorubicin, pegylated liposomal doxorubicin, epirubicin) unless clinically contraindicated
  - Non-small cell lung cancer, locally advanced or metastatic:
    - ❖ Patient has a diagnosis of non-small cell lung cancer
    - ❖ Disease is locally advanced or metastatic
    - ❖ Drug is first-line treatment (in combination with carboplatin)
    - ❖ Patient is not a candidate for curative surgery or radiation therapy
  - Pancreatic adenocarcinoma, metastatic:
    - ❖ Patient has a diagnosis of pancreatic adenoma
    - ❖ Disease is metastatic, unresectable, or borderline resectable
    - ❖ Drug is first-line treatment in combination with gemcitabine

Initial approval is for six months.

Continuation of Therapy

- Patient continues to meet initial coverage criteria.
- Patient shows documented positive clinical response.

Reauthorization is for 12 months.

Suggested ICD-10-CM Diagnosis Codes: C25.0 thru C25.3, C25.7 thru C25.9, C34.00 thru C34.92, C50.11 thru C50.929.

Modifiers SA, UD, U7 and 99 are allowed.

**J9286**

Glofitamab-gxbm (COLUMVI)

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

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Codes: C83.30 thru C83.39.

Modifiers SA, UD, U7 and 99 are allowed.

**J9321**

Epcoritamab-bysp (EPKINLY™)

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

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Codes: C83.30 thru C83.39.

Modifiers SA, UD, U7 and 99 are allowed.

**J9324**

Pemetrexed (Pemrydi RTU)

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

Pemetrexed is considered medically necessary when the following criteria are met:

Universal Criteria

I. Must be used for FDA labelled indications and dosing regimens.

II. Patient must be 18 years of age or older.

III. Patient must have a diagnosis of malignant pleural mesothelioma or locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC) (A or B below).

A. Patient has a diagnosis of malignant pleural mesothelioma; and

- Used in combination with a cisplatin- or carboplatin-based regimen; or
- Used as a single agent therapy; or
- Used in combination with bevacizumab and either cisplatin or carboplatin followed by single-agent bevacizumab maintenance therapy

  and
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; and
- Patient's disease presentation is unresectable; or

B. Patient has a diagnosis of locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC); and

- Patient is using as a single agent after prior chemotherapy; or
- Patient is using as a first-line therapy in combination with platinum-based chemotherapy with or without bevacizumab (or bevacizumab biosimilar); or
- Patient is using as a single agent for maintenance therapy when disease has not progressed after four cycles of platinum-based, first-line therapy; or
- Patient is using in combination with pembrolizumab and platinum chemotherapy for initial treatment in those confirmed with no EGFR or ALK genomic tumor aberrations; or
- Patient is using as continuous maintenance therapy until disease progression, if given first-line as part of pembrolizumab/platinum chemotherapy/and pemetrexed regimen.
- Pemfetrexed is not approvable for the treatment of patients with squamous cell non-small cell lung cancer.

Initial approval is for six months.

Continuation of therapy:

- Patient continues to meet initial coverage criteria.
- Patient shows positive clinical response as evidenced by disease stabilization or lack of disease progression.
- Patient does not have unacceptable toxicity such as severe hypersensitivity reactions, myelosuppression, renal, skin and gastrointestinal toxicity, etc.

Reauthorization is for 12 months.

Age must be 18 years or older.

Suggested ICD-10-CM Diagnosis Codes: C34.00 thru C34.92 or C45.0 thru C45.9.

Frequency of billing equals 500 mg/$m^2$ on day 1 of each 21-day cycle.

Modifiers SA, UD, U7 and 99 are allowed.

## Durable Medical Equipment

The following Durable Medical Equipment codes have special billing policy:

A4287, E0678, E0679, E0680, E0681, E0682

**A4287**

Modifier NU is required.

Frequency limit is 120 per infant for any provider.

This code is taxable.

**E0678**

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

Suggested ICD-10 Codes: I89.0, Q82.0

Modifier NU is required.

Frequency limit is one in five years for any provider.

This code is taxable.

Cannot be reimbursed with E0650, E0660, E0666, E0667, E0669 thru E0671, E0673 or E0679.

**E0679**

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

Suggested ICD-10 Codes: I89.0, Q82.0

Modifier NU is required.

Frequency limit is one in five years for any provider.

This code is taxable.

Cannot be reimbursed with E0650, E0660, E0666, E0667, E0669 thru E0671 or E0678.

**E0680, E0681**

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

Suggested ICD-10 Codes: I89.0, Q82.0

Modifiers NU, RB and RR are required.

Frequency limit is one in five years for any provider.

This code is taxable.

Cannot be reimbursed with E0650 thru E0652, E0675 thru E0676 or E0681.

**E0682**

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

Suggested ICD-10 Codes: I89.0, Q82.0.

Modifier NU is required.

Frequency limit is one in five years for any provider.

This code is taxable.

Cannot be reimbursed with E0650, E0668 or E0672.

## Immunizations

The following Immunization code has special billing policy:

90589

**90589**

Chikungunya (IXCHIQ)

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

Age must be 18 years or older.

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

Modifier SK is required.

# Injections

The following Injection codes have special billing policies:

C9159, J0184, J0217, J0391, J0402, J0576, J0688, J0873, J1304, J1412, J1413, J1596, J1939, J2404, J2508, J2679, J2799, J3425, J9333, J9334, Q5132

**C9159**

Prothrombin complex concentrate, human-lans (BALFAXAR)

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

Age must be 18 years or older.

Frequency of billing equals 5000 iu/5000 units as a single dose.

Maximum billing unit(s) equals 5000 iu/5000 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J0184**

Amisulpride (BARHEMSYS®)

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.
- Drug is being used under one of the following conditions:
  - Prevention of postoperative nausea and vomiting (PONV) and will be used alone or in combination with an antiemetic of a different class
  - Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis
- Patient has not received a preoperative dopamine-2 ($D_2$) antagonist (for example, metoclopramide).
- Prescriber will monitor electrocardiogram (ECG) for QTc prolongation, as clinically indicated.
- Must provide documentation justifying why other formulary alternatives for the prevention or treatment of PONV (for example, ondansetron, dexamethasone, etc.) are not an option.

Authorization is for one month.

Age must be 18 years or older.

Frequency of billing equals 10 mg/10 units for one dose.

Maximum billing units equals 10 mg/10 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J0217**

Velmanase alfa-tycy (LAMZEDE)

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

The TAR must include documentation that demonstrates the following:

- Must be used for FDA-approved indications and dosages.
- Patient has a diagnosis of alpha-mannosidosis, based on:
  - Deficient levels or activity of the enzyme alpha-mannosidase measured in blood leukocytes or fibroblasts or
  - Genetic testing revealing a variant in the MAN2B1 gene.
- Patient presents with non-central nervous system manifestations of alpha-mannosidosis.
- Patient is not pregnant. Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede is discontinued.

Initial authorization is for 12 months.

Continued therapy:

- Patient continued to meet initial approval criteria.

- Positive clinical response as evidenced by disease improvement or stabilization compared to baseline.

Reauthorization is for 12 months.

Age must be 64 years or younger.

Required ICD-10-CM Diagnosis Code: E77.1.

Frequency of billing equals 1 mg/kg weekly.

**J0391**

Artesunate for injection

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 all FDA-approved indications and dosages.
- Malaria confirmation by microscopy.
- Severe malaria based on at least one of the following:
  - High percent parasitemia (more than or equal to five percent)
  - Impaired consciousness
  - Seizures
  - Circulatory collapse/shock
  - Pulmonary edema or acute respiratory distress syndrome (ARDS)
  - Acidosis
  - Acute kidney injury
  - Abnormal bleeding or disseminated intravascular coagulation (DIC)
  - Jaundice (must be accompanied by at least one other sign)
  - Severe anemia (Hb less than seven g/dL) OR
  - Inability to take oral medications despite attempt after an oral antiemetic

Initial Authorization is for three months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has absence of unacceptable toxicity from the drug (e.g., acute renal failure, jaundice, etc.).

Reauthorization is for three months.

Suggested ICD-10-CM Diagnosis Codes: B52.9, B52.0, B52.8, B53.0, B53.1, B53.8, B54, B50.9, B50.8, B50.0, B51.9, B51.8, B51.0.

Modifiers SA, UD, U7 and 99 are allowed.

**J0402**

Aripiprazole (ABILIFY ASIMTUFII®)

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.
- Must be prescribed by or in consultation with a psychiatrist.
- Patient's diagnosis is based on one of the following:
  - Met the DSM criteria for a diagnosis of schizophrenia.
  - Met the DSM criteria for a diagnosis of bipolar I disorder and the drug is being used as maintenance monotherapy.
- Patient has established tolerability with oral aripiprazole in aripiprazole-naïve patients (may require up to a two-week trial of oral aripiprazole).
- Patient meets one of the following conditions:
  - Has a history of non-adherence, refuses to take oral medication, or oral medication is clinically inappropriate.
  - Treatment was initiated in inpatient during a recent hospitalization, within the last 60 days.
- Patient has no known hypersensitivity to aripiprazole or any of its excipients.

Initial authorization is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has experienced documented positive clinical response from baseline.

Age must be 18 years or older.

Suggested ICD-10-CM Diagnosis Codes:

F20.0 thru F20.9, F25.0 thru F25.9 (Schizophrenia)

F31.0 through F31.31 (Bipolar Disorder)

Frequency of billing equals 960 mg/960 units every two months.

Maximum billing units equals 960 mg/960 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J0576**

Buprenorphine (BRIXADI™)

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

Age must be 18 years or older.

Suggested ICD-10-CM Diagnosis Codes: F11.20, F11.21, F11.220, F11.221, F11.222, F11.229, F11.23, F11.24, F11.250, F11.251, F11.259, F11.281, F11.282, F11.288, F11.29.

Frequency of billing equals maximum of 32 mg/32 units weekly or 128 mg/128 units monthly.

Maximum billing units equals 128 mg/128 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J0688**

Cefazolin sodium (hikma)

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

Modifiers SA, UD, U7 and 99 are allowed.

**J0873**

Daptomycin (xellia)

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

Modifiers SA, UD, U7 and 99 are allowed.

**J1304**

Tofersen (QALSODY)

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.
- Must be prescribed by or in consultation with a neurologist with expertise in ALS.
- Patient has weakness attributable to ALS, and a confirmed diagnosis of ALS (definite or clinically probable) based on revised El Escorial World Federation of Neurology criteria, Awaji or Gold Coast criteria.
- Patient has a confirmed mutation in the superoxide dismutase 1 (SOD1) gene.
- Baseline documentation of functional ability prior to initiating treatment (e.g., muscle strength, respiratory strength, walking, climbing stairs, etc.).
- Patient does not depend on invasive ventilation or tracheostomy.
- Patient was not previously treated for ALS with cellular therapies or gene therapies.

Initial authorization is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Positive clinical response as evidenced by documentation of less functional decline from baseline, reduction in decline in respiratory strength, or reduction in decline in muscle strength, etc.
- Patient does not depend on invasive ventilation or tracheostomy.
- Patient has an absence of unacceptable toxicity from the drug, for example, serious myelitis and/or radiculitis, papilledema, aseptic meningitis, etc.

Reauthorization is for 12 months.

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Code: G12.21

Frequency of billing equals 100 mg/100 units every 14 days for three doses followed by 100 mg/100 units every 28 days.

Maximum billing units equals 100 mg/100 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J1412**

Valoctocogene Roxaparvovec-rvox (ROCTAVIAN™)

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

- Must be used for FDA-approved indications and dosages.
- Patient must be a male, 18 years of age or older.
- Must be prescribed by or in consultation with a hematologist.
- Patient has a diagnosis of severe hemophilia A (congenital factor VIII (F VIII) levels of less than or equal to one IU/dl as evidenced by the medical history.
- Patient has no active inhibitors to Factor VIII.
- Patient does not have pre-existing antibodies to adeno-associated virus serotype five (AAV5) capsid detected by FDA-approved companion diagnostic test AAV5 DetectCDx.
- Patient does not have active infections, (either acute or uncontrolled chronic) or immunosuppressive disorder, including HIV.
- Patients does not have known significant hepatic fibrosis (stage three or four on the Batts-Ludwig scale or METAVIR scoring systems [scale 0-4] or an equivalent) grade of fibrosis if an alternative scale is used.
- Patient does not have known hypersensitivity to mannitol.
- Patient does not have significant liver dysfunction with the following laboratory abnormalities:
  - AST/ALT/GGT/Bilirubin/alkaline phosphatase/ international normalized
- Required lab:
  - F VIII showing less than or equal to 1 IU/dL
  - Factor VIII inhibitor test
  - Liver function tests:
    - ALT (alanine aminotransferase)
    - AST (aspartate aminotransferase)
    - GGT (gamma-glutamyl transferase)
    - ALP (alkaline phosphatase)
    - Total Bilirubin
    - INR (international normalized ration)
- Ultrasound and elastography or laboratory assessments for liver fibrosis.
- No previous history of gene therapy.

- Outpatient administration is restricted to hospital outpatient services only.

Authorization is three months (one treatment in a lifetime).

Reauthorization is not approvable.

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Code: D66.

Frequency of billing equals one treatment in a lifetime.

Important Billing Instructions

Due to systems limitations, providers must take the following steps when billing J1412 for appropriate reimbursement:

TAR/SAR Submission

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter "3" in the Units box.

Claim Submission

4. Bill using miscellaneous HCPCS code, J1412 (injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10^13 vector genomes).
5. 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:
  - On the 837I or UB-04 claim form, provider must submit three (3) claim lines to represent one (1) service.
    - ❖ Each claim line to represent one unit.
    - ❖ Claims submitted with one or two claim lines will be denied.
    - ❖ Provider must submit an invoice for reimbursement.
    - ❖ This process will ensure that the total reimbursement paid for the three (3) claim lines is no more than provider submitted invoice paid price.
    - ❖ Roctavian must be billed on its own with no other drug or biologics.

6. Providers must provide the total dose administered to patient in milliliters (mls).
7. Providers are advised to take the following steps in order to ensure that Roctavian claims are identified and processed expeditiously:

I. Paper claims may be identified by notation of "Roctavian" on the "Remarks" section of the UB-04 claim form (Field #80) and submitted to:

Attention: Claims Manager
Medi-Cal Fiscal Intermediary

P.O. Box 526006
Sacramento, CA 95852-6006

II. Electronic claims may be identified by notation of “Roctavian” on the cover sheet, addressed to “Attention: Claims Manager” and submitted with the 837I claim form.

8. 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.
9. Payment for Roctavian shall be one dose in a lifetime reimbursement under J1412 or any other code (HCPCS, CPT, or by NDC).
10. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and UB-04 claim forms.

Modifiers UD and 99 are allowed.

**J1413**

Delandistrogene Moxeparvovec (ELEVIDYS™)

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

- Must be used for FDA-approved indications and dosages.
- Patient must be age four through five.
- Patient has a definitive diagnosis of DMD based on genetic laboratory studies that confirm mutation in the DMD gene.
- Must be prescribed by or in consultation with a neurologist or a pediatric neuromuscular specialist with expertise in the treatment of DMD.
- Patient has no current nor scheduled future treatment with concurrent or exon skipping therapies (e.g., Amondys 45™, Exondys 51™, Vyondys 53™, Viltepso®).
- Patient is ambulatory.
- Patient’s current baseline weight.
- One day prior to infusion, initiate corticosteroid to be continued for at least 60 days after the infusion, modifying dose if clinically indicated.
- Mandated laboratory studies:

1. Baseline liver function test (LFT) which includes:
   - Gamma-gluatamyl transferase (GGT)
   - Alkaline Phosphatase (ALP)
   - Alanine aminotransferase (ALT)
   - Aspartate transaminase (AST)
   - Total bilirubin
     - ❖ Weekly LFT must be done for the first three months after administration of Elevidys as a mandatory safety monitoring.
2. Baseline platelet count

- ❖ Weekly platelet monitoring should be done for the first two weeks as a mandatory safety monitoring.

3. Baseline Troponin-I
   - ❖ Weekly troponin-I monitoring should be done for the first four weeks after infusion as a mandatory safety monitoring.
4. Baseline Creatine Kinase
5. rAAVrh74 antibody titers less than or equal to 1:400 within eight weeks prior to planned infusion date or within four weeks prior if anyone in the household has recently been infused with delandistrogene moxeparvovec-rokl with an FDA-approved assay (if available).
6. Baseline left ventricular ejection fraction (LVEF) by cardiac echocardiography
   - Mandatory cardiac LVEF if patient develops elevated troponin I or troponin T

- Clinical assessment, which include all of the following:
  - North Star Ambulatory Assessment (NSAA) score more than 17 and less than or equal to 26
  - Time to stand from supine
  - 4-stair climb
  - 10-meter run/walk
  - 100-meter run/walk
- Patient does not have:
  - Liver injury or is at risk of hepatotoxicity, liver injury, chronic hepatic condition, or acute liver disease
  - Acute or chronic cardiac dysfunction.
  - Severe immune-mediated myositis
  - Active infection
  - Any deletion mutation, which fully includes exons 9-13
  - Any deletion in exon 8 and/or exon 9 in the DMD gene
  - History of *AAV-Based* Gene Therapy
- Recommended dose: 1.33 × 10^14 vector genomes per Kg.
- The infusion date must be prior to the age of six years.

Authorization is for three months (one treatment in a lifetime).

Reauthorization is not approvable.

Age must be four through five years.

Required ICD-10-CM Diagnosis Code: G71.01.

Frequency of billing equals one treatment in a lifetime.

<u>Important Billing Instructions</u>

Due to system limitations, providers are to take the following steps when submitting a TAR/SAR and claims for Elevidys:

TAR/SAR Submission

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request, and enter "4" in the Units box.

Claim Submission

4. Bill using J1413.
5. 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 (Institurionall) or UB-04 Medi-Cal claim forms with the following conditions:
  - Provider must submit one (1) service line for four (4) units on the TAR/SAR request and will submit four (4) claim lines.
  - 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 four claim lines is no more than provider submitted invoice paid price.
  - Elevidys must be billed on its own with no other drug or biologics.

6. Providers are advised to take the following steps in order to ensure that Elevidys claims are identified and processed expeditiously:

   I. Paper claims may be identified by notation of "Elevidys" 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 "Elevidys" on the cover sheet, addressed to "Attention: Claims Manager" and submitted with the 837I claim form.

7. Providers to 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.
8. Payment for Elevidys shall be a once in a lifetime reimbursement under J1413 or any other code (HCPCS, CPT, or by NDC).
9. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and UB-04 claim forms.

Modifiers UD and 99 are allowed.

**J1596**

Glycopyrrolate Injection (GLYRX-PF)

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

Modifiers SA, UD, U7 and 99 are allowed.

**J1939**

Bumetanide Injection

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

Age must be 18 years or older.

Frequency of billing equals 10 mg/20 units per day.

Maximum billing unit(s) equals 10 mg/20 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J2404**

NICARDIPINE HYDROCHLORIDE Injection

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

Age must be 18 years or older.

Modifiers SA, UD, U7 and 99 are allowed.

**J2508**

Pegunigalsidase alfa-iwxj (ELFABRIO)

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

Elfabrio 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.
- Must be prescribed by or in consultation with a geneticist or other physician with specialty in treating metabolic disorders.
- Patient has a diagnosis of Fabry’s disease confirmed by one of the following:
  - Genetic determination of the galactosidase alpha (GLA) or alpha-Gal A mutations
  - Leukocyte alpha-galactosidase A (alpha-Gal A) activity (less than three percent) in males
  - Presence of Globotriaosylceramide (Gb3) and globotriaosylsphingosine (lysoGb3) in the plasma and urine
- Documentation of one or more clinical presentation consistent with Fabry's disease (for example, angiokeratomas, telangiectasias, hypohidrosis or anhydrosis, corneal opacities, edema or lymphedema, abnormal cardiac examination (evidence of left ventricular hypertrophy [LVH], arrhythmias, etc.).
- Documentation of plasma GL-3 and/or GL-3 inclusions at baseline.
- Elfabrio will not be used concurrently with another enzyme replacement therapy or Galafold (migalastat).

Initial authorization is for six months.

Continued treatment:

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response as evidenced by:
  - Reduction in plasma GL-3 levels from baseline
  - Reduction of GL-3 inclusions from baseline
  - Stabilization or improvement in in renal function, pain reduction from baseline

Reauthorization is for 12 months.

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Code: E75.21.

Frequency of billing equals one mg/kg every two weeks.

Modifiers SA, UD, U7 and 99 are allowed.

**J2679**

Fluphenazine Hydrochloride Injection

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

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Codes:

F20.0 thru F20.9, F25.0 thru F25.9 (Schizophrenia)

F31.0 through F31.31 (Bipolar Disorder**)**

Frequency of billing equals 10 mg/8 units per day.

Maximum billing unit(s) equals 10 mg/8 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J2799**

Risperidone (UZEDY)

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.
- Must be prescribed by or in consultation with a psychiatrist.
- Patient must have a diagnosis of schizophrenia based on DSM-5 criteria for more than one year and has had one or more episodes of relapse in the last 24 months.
- Patient has an established stability and tolerability of oral risperidone.
  - Neither a loading dose nor overlap with oral risperidone is needed. Initiate Uzedy the day after the last dose of oral therapy

- The patient must have a documented history of poor adherence to oral risperidone or has relapsed due to medication nonadherence or other reason why an oral formulation is clinically inappropriate.
- Must provide documentation justifying why formulary alternative injections such as Perseris or Risperdal Consta are not clinically appropriate.
- Patient has no history of hypersensitivity (e.g., anaphylaxis, angioedema) to risperidone, paliperidone, or any component of the formulation.

Initial authorization is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has experienced documented positive clinical response from baseline.

Reauthorization is for 12 months.

Age must be 18 years or older.

Frequency of billing equals 50 mg/50 units to 125 mg/125 units once monthly **or** 100 mg/100 units to 250 mg/250 units every two months.

Maximum billing units equals 250 mg/250 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J3425**

Hydroxocobalamin for Injection

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

Modifiers SA, UD, U7 and 99 are allowed.

**J9333**

Rozanolixizumab-noli Injection (RYSTIGGO®)

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.
- Must be prescribed by or in consultation with a neurologist.
- Patient is at least 18 years of age.
- Patient is up to date with all vaccination according to vaccination guidelines prior to initiation of therapy.
- Patient is not currently on other immunomodulatory biologic therapy (e.g. efgartigimod, ravulizumab, rituximab, etc.).
- Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., hydroxychloroquine, botulinum toxins, beta-blockers, etc.).
- Patient will not be administered live attenuated or live vaccine during treatment.
- Patient does not have a deficiency of immunoglobulin G (IgG).
- Patient does not have an active infection.

- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease.
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibodies.
- Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.).
- Patient had an inadequate response to initial therapy based on their antibodies:
  - AChR+ disease: a minimum one-year trial of concurrent use with two or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, etc.); OR
  - MuSK+ disease: a minimum one-year trial with immunosuppressive therapy (e.g., corticosteroids, azathioprine, or mycophenolate) and rituxumab; OR
  - Patient required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to their background therapy above

Initial approval is for 16 weeks.

Continued therapy:

- Patient meets the initial criteria described above.
- A minimum of 63 days must have elapsed from the start of the previous treatment cycle.
- Absence of unacceptable toxicity from the drug.
- Patient has had improvement in muscle strength and at least one point from baseline in the MG-ADL total score.

Reauthorization is for six months.

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Codes: G70.00, G70.01.

Frequency of billing equals 850 mg/850 units once weekly for six weeks.

Maximum billing unit(s) equals 850 mg/850 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J9334**

Efgartigimod alfa-fcab and hyaluronidase-qvfc (Vyvgart Hytrulo™)

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.
- Must be prescribed by or in consultation with a neurologist.
- Patient is at least 18 years of age.

- Patient has a diagnosis of Myasthenia Gravis (MG) with generalized muscle weakness.
- Patient meets the criteria of Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV.
- Patient has a positive serological test for anti-AChR antibodies.
- Patient has MG-Activities of Daily Living (MG-ADL) total score of at least five (greater than 50 percent non-ocular).
- Documentation of total Quantitative Myasthenia Gravis (QMG) score.
- Patient is on standard-of-care such as acetylcholinesterase (AChE) inhibitors, steroids and immunosuppressant agents (e.g., azathioprine, methotrexate, cyclosporine, tacrolimus, mycophenolate mofetil, and cyclophosphamide), either alone or in combination.
  - If not on standard-of-care, must have had adequate trial of AChE and at least two immunosuppressant agents with clinical justification why patient is not on them, such as treatment failure, allergy, intolerance, contraindication, etc.

Initial approval is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has shown clinical benefit as shown by one of the following:
  - Two-point or greater reduction in the total MG-ADL score as compared to baseline
  - A reduction of at least three points on the total (QMG) score from baseline
  - Documented reduction in symptoms that impact daily function

Reauthorization is for six months.

Age must be 18 years or older.

Required ICD-10 Diagnosis Codes: G70.00, G70.01

Frequency of billing equals 1,008 mg (504 units)/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase**)** once a week for four weeks.

Maximum billing unit(s) equals 1008 mg (504 units)/11200 units.

Modifiers SA, UD, U7 and 99 are allowed.

**Q5132**

Adalimumab-afzb (Abrilada™) and Adalimumab-aacf (Idacio®)

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

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

Universal criteria:

- Must be used for FDA-approved indications and dosages.
- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection.

- Patient will not be taking Abrilada or Idacio concurrently with any of the following:
  - Biologic DMARDs (Remicade, Enbrel or Humira), Consentyx (secukinumab), Simponi (golimumab)
  - Janus kinase inhibitor (for example, Xeljanz [tofacitinib])
  - Phosphodiesterase 4 (PDE4) inhibitor (for example, Otezla [apremilast])
- Patient must have one of the following diagnoses:

Rheumatoid Arthritis

- Patient has a documented diagnosis of Rheumatoid Arthritis (RA).
- Must be prescribed by or in consultation with a rheumatologist.
- Patient must be 18 years of age or older.
- Patient must have a history of failure of a three-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD), (for example, methotrexate, sulfasalazine, leflunomide, hydroxychloroquine), at maximally indicated doses within the last six months, unless intolerant, contraindicated or clinically inappropriate; OR
  - Abrilada or Idacio is being used as an alternative to methotrexate in DMARD–naive patients with moderate to high disease activity.
- Patient must have tried and failed one of the preferred products. (Remicade, Enbrel, Amjevita, Hadlima, Hyrimoz, Yusimry or Humira) unless intolerant, inadequate response or contraindication.
- Abrilada or Idacio may be used alone or in combination with other non-biologic DMARDs, glucocorticoids, non-steroidal anti-inflammatory drugs (NSAIDs), and/or analgesics.

Juvenile Idiopathic Arthritis

- Patient has a documented diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis.
- Must be prescribed by or in consultation with a rheumatologist.
- Patient mut be two years of age or older.
- Inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: NSAID plus a glucocorticoid with or without methotrexate, etc., unless clinically inappropriate.
- Abrilada or Idacio may be used alone or in combination with methotrexate.
- Patient must have tried at least one preferred biologic agent such as Enbrel, Amjevita, Hadlima, Hyrimoz, Yusimry, Humira, unless intolerant, contraindicated or clinically inappropriate.

Psoriatic Arthritis

- Patient has a documented diagnosis of active psoriatic arthritis.
- Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- Patient must be 18 years of age or older.

- Patient must have a history of failure of a three-month trial of at least one conventional Disease-Modifying Antirheumatic Drugs (DMARDS) such as methotrexate, leflunomide, sulfasalazine, at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate.
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel, Amjevita, Hadlima, Hyrimoz, Yusimry or Humira) unless intolerant, inadequate response or contraindication.
- May continue methotrexate, other non-biologic DMARDs, corticosteroids, NSAIDs, and/or analgesics with Abrilada or Idacio.

Ankylosing Spondylitis

- Patient has a documented diagnosis of active ankylosing spondylitis.
- Must be prescribed by or in consultation with a rheumatologist.
- Patient must be 18 years of age or older.
- Patient must have a history of inadequate response, intolerance or contraindication to at least two NSAIDs, for example, Ibuprofen, Naproxen, etc., unless clinically inappropriate.
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel, Amjevita, Hadlima, Hyrimoz, Yusimry, or Humira) unless intolerant, inadequate response or contraindication.
- Patient may continue NSAIDs and/or analgesics while on Abrilada or Idacio.

Crohn's Disease

- Patient has a documented diagnosis of moderately to severely active Crohn's disease.
- Must be prescribed by or in consultation with a gastroenterologist.
- Patient must be six years of age or older.
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates (e.g., sulfasalazine, mesalamine), glucocorticoids (e.g., prednisone, budesonide), immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate); unless clinically inappropriate.
- Abrilada or Idacio therapy may be combined with an immunomodulator (i.e., thiopurine or methotrexate).
- Patient must have tried and failed one of the preferred products (Remicade, Amjevita, Hadlima, Hyrimoz, Yusimry or Humira, unless intolerant, inadequate response or contraindication.

Ulcerative Colitis, Moderate-To-Severe

- Patient has a documented diagnosis of moderately to severely active ulcerative colitis.
- Must be prescribed by or in consultation with a gastroenterologist.
- Patient must be 18 years of age or older.
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates

(e.g., sulfasalazine, mesalamine), glucocorticoids (e.g., prednisone, budesonide), immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate), unless clinically inappropriate.

- Patient must have tried at least one preferred biologic agent such as Remicade, Amjevita, Hadlima, Hyrimoz, Yusimry, Humira, Avsola, unless intolerant, contraindicated or clinically inappropriate.

Plaque Psoriasis

- Documented diagnosis of chronic moderate to severe plaque psoriasis.
- Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- Patient must be 18 years of age or older.
- Patient is a candidate for systemic therapy or phototherapy.
- Patient must have a history of inadequate response to at least one of the following systemic therapies up to maximally indicates doses, unless intolerant, contraindicated or clinically inappropriate:
  - Methotrexate
  - Cyclosporine
  - Acitretin
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel, Amjevita, Hadlima, Hyrimoz, Yusimry or Humira) unless intolerant, inadequate response or contraindication.

Hidradenitis suppurativa, moderate to severe, refractory (Abrilada only)

- Patient must have a diagnosis of moderate to severe hidradenitis suppurativa (HS).
- Must be prescribed by a dermatologist, rheumatologist, or gastroenterologist.
- Patient must be 18 years of age or older.
- Patient has Hurley Stage II or III disease and with at least three abscesses or inflammatory nodules.
- Patient has a history of failure of at least one of the following at maximally indicated doses, unless, intolerant, contraindicated or clinically inappropriate.
- One oral antibiotic (e.g., doxycycline, clindamycin, rifampin)
  - Hormonal therapy
  - Retinoids
  - Steroid injections
- Patient must have tried at least one preferred biologic agent including Amjevita, Hadlima, Hyrimoz, Yusimry or Humira unless intolerant, contraindicated or clinically inappropriate.

Uveitis, noninfectious (Abrilada only)

- Patient has a diagnosis of non-infectious uveitis.
- Must be prescribed by or in consultation with an ophthalmologist or rheumatologist.

- Patient must be 18 years of age.
- Patient does not have isolated anterior uveitis.
- Patient must have a history of inadequate response (i.e., recurrent uveitis despite use of traditional therapy) or was intolerant to at least one traditional treatment including, systemic corticosteroids and/or immunosuppressive agents (i.e., cyclosporine, azathioprine, methotrexate, etc.).
- Patient must have tried at least one preferred biologic agent such as Amjevita, Hadlima, Hyrimoz, Yusimry , Humira, Avsola,  unless intolerant, contraindicated or clinically inappropriate.

Initial authorization is for 12 months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Positive clinical response as evidence by disease improvement or stabilization compared to baseline.

Reauthorization is for 12 months.

Modifiers SA, UD, U7, 99 are allowed.

## Medicine

The following Medicine codes have special billing policies:

93150, 93151, 93152, 93153, G0011

**93150, 93151, 93152, 93153**

Modifiers SA, U7 and 99 are allowed.

**G0011**

Modifiers SA, SB, U7, 99, and 33 are allowed.

## Non-Injectable Drugs

The following Injection codes have special billing policies:

C9164, J0750, J0751, J0799, J1105, J3401

**C9164**

Cantharidin (YCANTH)

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

The TAR must include clinical documentation that demonstrates the following:

- Must be for FDA-approved indication and dosing regimen.
- Patient must be two years of age or older.
- Health care professional preparing and administering treatment received instruction and training on Ycanth.
- Inadequate response, intolerance, or contraindication to cryotherapy, curettage, podofilox, or salicylic acid.

Authorization is for six months.

Age must be two years or older.

Frequency of billing equals two applicators/two units per treatment every three weeks.

Maximum billing unit(s) equals two applicators/two units.

Modifiers SA, UD, U7 and 99 are allowed.

**J0750, J0751, J0799**

Pre-Exposure Prophylaxis (PrEP) Drugs

**Note:** Providers may bill Truvada and Descovy with J0750 and J0751, as applicable. J0799 is a miscellaneous code for billing other PrEP drugs with no specific HCPCS code. The policy and billing code for Apretude can be found in the injections section of the manual.

Centers for Disease Control and Prevention (CDC) guidelines, and enrollment criteria for clinical trials provide guidance on identifying persons who may be at higher risk for acquiring HIV infection. These include men who have sex with men, persons at risk via heterosexual contact and persons who inject drugs.

The USPSTF and the CDC recommend that PrEP be considered for people who are HIV negative and who have had anal or vaginal sex in the past six months and:

- have a sexual partner with HIV (especially if the partner has an unknown or detectable viral load), or
- have not consistently used a condom, or
- have been diagnosed with a bacterial sexually transmitted disease (STD) in the past six months.

PrEP is also recommended for people without HIV who inject drugs and:

- have an injection partner with HIV, or
- share needles, syringes, or other equipment to inject drugs.

PrEP should also be considered for people without HIV who have been prescribed non-occupational post-exposure prophylaxis (PEP) and:

- report continued risk behavior, or
- have used multiple courses of PEP.

Providers may refer to CDC and USPSTF guidelines under “Resources” section for additional details on eligibility criteria, etc.

Of the three drugs that have been approved for use as PrEP by the FDA, two consist of a combination of drugs in a single oral tablet taken daily; the third is a medication given by injection every two months.

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg: (F/TDF: brand name Truvada® or generic equivalent).
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF: brand name Descovy®).
- Cabotegravir (CAB) 600 mg injection (brand name Apretude®).

Dosages:

These medications are approved to prevent HIV in adults and adolescents weighing at least 77 lb. (35 kg) as follows:

- Daily oral PrEP with F/TDF is recommended to prevent HIV among all people at risk through sex or injection drug use.
- Daily oral PrEP with F/TAF is recommended to prevent HIV among people at risk through sex, **excluding people at risk through receptive vaginal sex**. F/TAF has not yet been studied for HIV prevention for people assigned female at birth who could get HIV through receptive vaginal sex.
- Injectable PrEP with CAB is recommended to prevent HIV among all people at risk through sex. CAB is given as an intramuscular injection. CAB for PrEP is started by administering the first injection followed by a second injection 1 month after the first. CAB injections are given every two months thereafter.

Modifiers SA, SB, UD, U7, 99 and 33 are allowed.

**J1105**

Dexmedetomidine Sublingual Film (IGALMI)

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 all FDA-approved indications and dosages.
- Patient is 18 years of age or older.
- Documentation of a diagnosis of schizophrenia or bipolar I or II.
- Documentation that Igalmi will be used for the acute treatment of agitation.
- Documentation that Igalmi will be used under the supervision of a healthcare provider.
- Patient has not been treated with alpha-1 noradrenergic blockers, benzodiazepines, antipsychotic drugs, or other hypnotics four hours prior to drug administration.
- Patient does not have a history of syncope or syncopal attacks; SBP is not less than 110 mmHg; DBP is not less than 70 mmHg; HR is not less than 55 beats per minute; does not have evidence of hypovolemia or orthostatic hypotension.

Approval is for 24 hours.

Age must be 18 years or older.

Required ICD-10-CM Diagnosis Codes:

F20.0 thru F20.9, F25.0 thru F25.9 (Schizophrenia)

F31.0 through F31.31 (Bipolar Disorder)

Frequency of billing equals 360 mcg/360 units per 24 hour.

Maximum billing unit(s) equals 360 mcg/360 units.

Modifiers SA, UD, U7 and 99 are allowed.

**J3401**

Beremagene geperpavec-svdt (VYJUVEK™)

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

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

- Must be used for FDA-approved indications and dosages.
- Patient must be six months of age or older.
- Patient must have a confirmed diagnosis of dystrophic epidermolysis bullosa (DEB) (either autosomal dominant DEB [DDEB] or autosomal recessive DEB [RDEB]) by genetic testing, including collagen type VII alpha 1 chain (COL7A1) gene.
- Patient has two cutaneous wounds meeting the following criteria:
  - Location: similar in size, located in similar anatomical regions, and similar in appearance.
  - Appearance: clean with adequate granulation tissue, excellent vascularization, and did not appear infected.
- Must be prescribed by or in consultation with a dermatologist with expertise in the treatment of DEB.
- Patient does not have any of the following:
  - Current evidence or a history of squamous cell carcinoma (SCC) in the area that would undergo treatment
  - Receipt of a skin graft in the last three months

Authorization is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has experienced positive response such as a clinically significant wound healing.

Reauthorization is for 12 months.

Required ICD-10-CM Diagnosis Code: Q81.2

Frequency of billing equals 1.6 ml/16 units weekly.

Maximum billing units equals 1.6 ml/16 units.

Modifiers SA, UD, U7 and 99 are allowed.

## Ophthalmology

The following Ophthalmology codes have special billing policies:

C9161, C9162

**C9161**

Aflibercept

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

The TAR must include documentation that demonstrates the following:

- The patient is 18 years of age or older.

- The patient has tried and failed or is intolerant to less expensive, clinically appropriate alternatives (e.g., bevacizumab, aflibercept before aflibercept hd).
- The patient does not have an active ocular or periocular infection.
- The patient does not have an active intraocular inflammation.
- Aflibercept is used for FDA-approved indications, dosages and usages.
- The initial approval is for 12 months.

**Note:** The TAR is renewable if the patient continues to meet the criteria for medical necessity.

Required modifiers are LTor RT. CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

Modifiers UD and 99 are allowed.

The maximum dose is 8 mg/8 units.

**C9162**

Avacincaptad-pegol (IZERVAY)

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

The TAR must include documentation that demonstrates the following:

- Patient is 50 years of age or older.
- Patient has a diagnosis of geographic atrophy secondary to age-related macular degeneration (AMD).
- GA is not secondary to any condition other than AMD.
- Must be prescribed by or in consultation with an ophthalmologist.
- Must be administered by a qualified physician.
- Patient does not have choroidal neovascularization (CNV).
- Patient does not have ocular or periocular infection in the past twelve weeks.

Authorization is for 12 months.

Age must be 50 years or older.

Suggested ICD-10-CM Diagnosis Codes: H35.3113, H35.3123, H35.3133, H35.3114, H35.3124, H35.3134

Frequency of billing equals 2 mg/2 units monthly for up to 12 months per eye.

Maximum billing unit(s) equals 2 mg/2 units per eye.

App modifiers are LT or RT. CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

Modifiers UD and 99 are allowed.

## Orthotics and Prosthetics

The following Orthotics and Prosthetics codes have special billing policies:

A6521, A6523, A6525, A6527, A6529. A6553, A6555, A6556, A6557, A6558, A6559, A6560, A6561, A6562, A6563, A6564, A6565, A6567, A6569, A6571, A6573, A6574, A6576, A6577, A6579, A6580, A6610, L5926

**A6521**

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

Modifiers LT or RT are required.

Frequency limit is once every five years for any provider.

Code is not reimbursable with A6520, S8420, S8421, S8425, S8426 or S8427.

This code is non-taxable.

**A6523**

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

Modifiers LT or RT are required.

Frequency limit is once every five years for any provider.

Code is not reimbursable with A6522, S8420, S8421, S8422, S8423 or S8424.

This code is non-taxable.

**A6525**

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

Modifiers LT or RT are required.

Frequency limit is once every five years for any provider.

Code is not reimbursable with A6524.

This code is non-taxable.

**A6527**

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

Modifiers LT or RT are required.

Frequency limit is once every five years for any provider.

Code is not reimbursable with A6526.

This code is non-taxable.

**A6529**

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

Modifiers LT or RT are required.

Frequency limit is once every five years for any provider.

Code is not reimbursable with A6528.

This code is non-taxable.

**A6553, A6555, A6556, A6557, A6558**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Codes are not reimbursable with A6552 through A6564 and A6610.

These codes are non-taxable.

**A6562, A6563, A6564, A6559, A6560, A6561**

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

Frequency limit is once every 12 months for any provider.

Codes are not reimbursable with A6552 through A6564 and A6610.

These codes are non-taxable.

**A6565**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6582 or S8428.

This code is not taxable.

**A6567**

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

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6566.

This code is non-taxable.

**A6569**

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

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6568.

This code is non-taxable.

**A6571**

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

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6570.

This code is non-taxable.

**A6573**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6572.

This code is non-taxable.

**A6574**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6575, A6576, A6577 A6578, A6579, A6580, A6581 or S8420 through S8427.

This code is non-taxable.

**A6576**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6574, A6575, A6577 through A6581 or S8420 through S8424.

This code is non-taxable.

**A6577**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6574 through A6576, A6578 through A6581 or S8420 through S8424.

This code is non-taxable.

**A6579**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6574 through A6578, A6580, A6581, S8420, S8421 or S8425 through S8427.

This code is non-taxable.

**A6580**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6574 through A6579, A6581, S8420, S8421 or S8425 through S8427.

This code is non-taxable.

**A6610**

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

Modifiers LT or RT are required.

Frequency limit is once every 12 months for any provider.

Code is not reimbursable with A6552 through A6564.

This code is non-taxable.

**L5926**

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

Modifiers LT or RT are required.

Frequency limit is once every five years for any provider.

This code is non-taxable.

## Pathology

The following Pathology codes have special billing policies:

81457, 81458, 81459, 81462, 81517, 82166, 86041, 86042, 86043, 86366, 87523

**81457, 81458, 81459**

Modifiers 33, 90 and 99 are allowed.

Frequency is once in a lifetime.

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

A TAR requires documentation of the following criteria.

For Somatic Testing

- The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and
- The patient either has not been previously tested using the same next-generation sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and
- The decision for additional cancer treatment is contingent on the test results.

For Germline Testing

- The patient has ovarian or breast cancer, and
- The patient has a clinical indication for germline (inherited) testing for inherited breast or ovarian cancer, and
- The patient has a risk factor for germline (inherited) breast or ovarian cancer, and
- The patient has not been previously tested with the same germline test using NGS for the same germline genetic content.
- Independent of the above criteria, either Somatic or Germline testing may be approved if the test is approved by the U.S. Food and Drug Administration (FDA) as a companion diagnostic device, and the decision for additional treatment is contingent on the test results.

**81462**

Modifiers 33, 90 and 99 are allowed.

Frequency is once in a lifetime.

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

TAR requires documentation of the following criteria:

1. The patient has a diagnosis of non-small cell lung cancer, and
2. The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible, and
3. Management is contingent on the test results.

**81517, 86041, 86042. 86043, 86366, 87523,**

Modifiers 33, 90 and 99 are allowed.

**82166**

Modifiers 33, 90 and 99 are allowed.

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

TAR requires documentation of all of the following numbered criteria:

1. Clinical concern for any of the following:
   - Disorder or difference of sex development, or
   - Defect in androgen receptor function, or
   - Ovarian granulosa cell tumor.
2. Management is contingent on the test results.

## Radiology

The following Radiology codes have special billing policies:

75580, 76984, 76987, 76988, 76989, 0815T, 0857T, A9608, A9609, C9794, C9795

**75580, 76984, 76987, 76988, 76989, 0815T**

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

Modifiers SA, U7 and 99 are allowed.

**0857T**

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

Age must be 18 years or older.

Modifiers SA, U7 and 99 are allowed.

Modifiers RT or LT are required.

**A9608**

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

Age must be 18 years or older.

Suggested ICD-10 Codes: C61.0 thru C61.9, C79.82

Modifiers SA, U7 and 99 are allowed.

**A9609, C9794, C9795**

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

Modifiers SA, U7 and 99 are allowed.

## Skin Substitutes

The following skin substitute codes have special billing policies:

Q4279, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304.

**Q4279, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304**

Modifiers SA, U7 and 99 are allowed.

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

## Surgery

The following Surgery codes have special billing policies:

22836, 22837, 22838, 27278, 31242, 31243, 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 52284, 58580, 61889, 61891, 61892, 64596, 64597, 64598, 67516, 96547, 96548.

**22836, 22837, 22838, 27278, 33276, 61889, 61891, 61892,**

Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 52, 53, 54, 55, 62, 66, 76, 77, 78, 79, 80 and 99 are allowed.

**31242, 31243, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 52284, 58580, 64596, 64598, 67516**

Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 52, 53, 54, 55, 62, 66, 76, 77, 78, 79, and 99 are allowed.

Assistant Surgeon services not payable.

**64597**

Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 52, 53, 54, 55, 62, 66, 76, 77, 78, 79, and 99 are allowed.

Assistant Surgeon services not payable.

**96547, 96548**

Modifiers AG, ET, PA, PB, PC, SC, UA, UB, U7, 22, 47, 51, 52, 53, 54, 55, 62, 66, 76, 77, 78, 79, 80, and 99 are allowed.

Exempt from modifier 51.

# Q1 Code Deletions

**Table of HCPCS Q1 Code Deletions**

**Effective November 1, 2023**

| Subject | Deleted Code |
|---|---|
| Immunizations | 0041A, 0042A, 0044A |

**Effective January 1, 2024**

| Subject | Deleted Code |
|---|---|
| Cardiology | G2066 |
| Chemotherapy | C9155 (replaced with J9321), |
| Durable Medical Equipment | K1005 (replaced with A4287), K1031 (replaced with E0681), K1032 (replaced with E0678), K1033 (replaced with E0679) |
| Injection | C9152 (replaced with J0402), C9153 (replaced with J0184), C9155 (replaced with J9321), C9156 (replaced with A9608), C9157 (replaced with J1304), C9158 (replaced with J2799), J9160 |
| Radiology | 0501T (replaced with 75580), 0502T (replaced with 75580), 0503T (replaced with 75580), 0504T (replaced with 75580), 0508T, 0641T, 0642T, 74710, C9156 (Replaced with A9608), C9778 |
| Proprietary Laboratory Analyses | 0014M |
| Orthotics and Prosthetics | K1022 (replaced with L5926) |
| Surgery | C9770 (replaced with 67299), C9771 (replaced with 31299) |
| Pathology | C9803 |