Q3 HCPCS Level I and II Update (July 1, 2022)

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.

Q3 Code Additions

Chemotherapy

The following chemotherapy codes have special billing policies.

C9095, C9096, C9098, J9331

C9095

Tebentafusp-tebn (Kimmtrak®) is a bispecific gp100 peptide-HLA-A*02:01 directed T cell receptor CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

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

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

- Must be used for FDA indications and dosages
- Patient must be 18 years of age or older
- Patient must have a histologically or cytologically confirmed metastatic uveal melanoma (mUM)
- Patient meets one of the following criteria for prior treatment:
  - No prior systemic therapy in the metastatic or advanced setting including chemotherapy, immunotherapy, or targeted therapy
  - No prior regional, liver-directed therapy including chemotherapy, radiotherapy, or embolization
  - Prior neoadjuvant or adjuvant therapy is allowed provided administered in the curative setting in patients with localized disease
- Patient is human leukocyte antigen (HLA)-A*02:01 positive by central assay
- Patient has Eastern Cooperative Oncology Group (ECOG) performance status score of zero or one
- Female patients of reproductive potential to use effective contraception
- Patient does not have the following:
  - Systemic or untreated CNS metastases
  - History of severe hypersensitivity reactions to other iologic drugs or mAbs
  - Clinically significant cardiac or impaired cardiac function
  - Active infections or inflammations

- Documentation of ALT, AST, and total bilirubin at baseline and periodically during treatment

Initial Authorization is for six months

Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced clinical benefit as evidenced by overall survival, lack of disease progression or other documented clinical benefit
- Patient does not have unacceptable toxicity

Reauthorization is for 12 months

Modifiers SA, UD, U7 and 99 are allowed.

Required ICD-10 Diagnosis Codes: C69.31, C69.32, C69.41, C69.42, C69.61, C69.62, Z85.840.

Frequency of billing equals 20 mcg/20 units on day one, 30 mcg /30 units on day eight, 68 mcg/68 units on day 15, and 68 mcg/68 units once every week thereafter.

Maximum billing unit(s) equals 68 mcg/68 units.

C9096

Filgrastim-ayow (Releuko®) is a filgrastim biosimilar. Filgrastim is a granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. G-CSFs stimulate the production, maturation, and activation of neutrophils to increase both their migration and cytotoxicity.

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

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

- Must be for FDA approved indications and dosages
- It is being prescribed for ONE of the following conditions:
  - Patient has nonmyeloid malignany and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and Releuko is being used to decrease the incidence of infection, as manifested by febrile neutropenia
  - Patient has acute myeloid leukemia (AML) and Releuko is being used to reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment
  - Patient has nonmyeloid malignancy and is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) and Releuko is being used to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia
  - Patient has symptomatic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia and Releuko is being used to reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers)
- Must not be used in combination with other granulocyte colony-stimulating factors (G-CSF) such as Neupogen, Granix, Zarxio, Nivestym, etc.

Initial approval is for six months.

Continued therapy:

Patient continues to meet initial approval requirements.

Reauthorization is for six months.

Modifiers SA, UD, U7 and 99 are allowed.

Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram.

C9098

Citacabtagene-autoleucel (Carvykti™) is a BCMA-directed, genetically modified autologous T cell immunotherapy, indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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 relapsed or refractory multiple myeloma (RRMM)
- RRMM is histologically or cytologically confirmed according to International Myeloma Working Group (IMWG) criteria
- 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)
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status grade of zero or one
- Patient has no current or prior history of central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of multiple myeloma
- Patient has left ventricular ejection fraction of 45 percent or more
- Patient has no active infection or inflammatory disorders
- Patient has not been previously treated with CAR-T therapy in RRMM
- Carvykti will not be used concurrently with another CAR-T therapy
- Carvykti must be administered at a healthcare facility certified by the manufacturer based on the Risk Evaluation and Mitigation Strategy (REMS) requirements defined by the FDA
- The provider facility is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) for Immune Effector Cell Therapy (IECT)
- Outpatient administration is restricted to Hospital Outpatient Services only

Approval is for three months (one treatment only).

Reauthorization is not approvable.

REMS

- Due to the risk of cytokine release syndrome (CRS) and neurologic toxicities, Carvykti is available only through a restricted program under a REMS called the Carvykti REMS
- Healthcare facilities that dispense and administer Carvykti must be enrolled and must comply with the REMS requirements
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer Carvykti are trained in the management of CRS and neurologic toxicities

Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (bcma) directed CAR-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Administration code: CPT code 96413 (chemo administration, intravenous infusion; up to one hour, single or initial substance/drug).

Important Instructions for billing:

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

1. Submit and receive back an approved Treatment Authorization Request (TAR)/Service Authorization Request (SAR)
2. Bill using HCPCS code C9098
3. Completion of claim forms:
   - Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied
   - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I
   - Providers must submit one (1) service line on the TAR/SAR request, and enter “5” in the Units box
   - On the 837I or *UB-04* 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
   - Carvykti must be billed on its own with no other drug or biological
4. For instructions regarding physician claim form completion, refer to the page on the Medi-Cal Providers website, for completion of 837I and *UB-04* claim forms.
5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 96413.

Modifiers UD and 99 are allowed.

Required ICD-10 Diagnosis Codes: C90.00, C90.02

Frequency of billing equals one dose/five units per lifetime.

Maximum billing unit(s) equals one dose/five units.

J9331

Sirolimus (protein bound) (Fyarro™) is an mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

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

Modifiers SA, UD, U7 and 99 are allowed.

Frequency of billing equals 100 mg/m2 administered on days one and eight of each 21-day cycle.

Injection

The following injection codes have special billing policies.

C9094, J0739, J1306, J1551, J2356, J2998, J3299, J9332

C9094

Sutimlimab-jome (Enjaymo™) is a classical complement inhibitor indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

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

Enjaymo 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 hematologist, immunologist or oncologist
- Patient has a diagnosis of primary cold agglutinin disease (CAD) as defined by all of the following:
  - Evidence of hemolysis (for example: high reticulocyte count, high LDH, high indirect bilirubin, low haptoglobin)
  - Positive direct antiglobulin (Coombs) test for C3d only (or, in a minority, C3d plus weak IgG)
  - Cold agglutinin titer of equals to or greater than 64 at 4°C
- Patient has had at least one blood transfusion in the previous six months
- Patient has chronic hemolysis with a hemoglobin (Hgb) level of less than10g/dL
- Patient has symptomatic anemia or cold-induced ischemic symptoms interfering with daily living (for example, fatigue, dyspnea, acrocyanosis, Reynaud's phenomenon, pain or discomfort in swallowing cold food or liquids, etc.
- Patients has received vaccinations against Neisseria meningitidis, Haemophilus influenzae, and Streptococcus pneumoniae at least two weeks before initiating sutimlimab; if therapy is started urgently, vaccines should be provided as soon as possible

- Patient does not have cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy

Initial approval is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced clinical benefit as evidenced by at least one of the following:
  – Patient did not receive a blood transfusion or achieved transfusion independence
  – Patient's hemoglobin (Hgb) level became Hgb level equal to or greater than 12 g/dL or Hgb level increased by equal to or greater than 2 g/dL from baseline
  – Patient had a decrease in mean bilirubin and LDH values compared to baseline

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Required ICD-10 Diagnosis Code: D59.12

Frequency of billing equals 7,500 mg/750 units weekly for two weeks then every two weeks.

Maximum billing unit(s) equals 7,500 mg/750 units.

J0739

Cabotegravir extended-release (Apretude) is a Human Immunodeficiency Virus Type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in at-risk adults and adolescents weighing at least 35 kg for Pre-Exposure Prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

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

Must be 12 years of age or older (weighing at least 35 kg).

Modifiers SA, UD, U7 and 99 are allowed.

Frequency of billing equals 600 mg/600 units one month apart for two consecutive months on the last day of an oral lead-in if used or within three days and continue every two months thereafter.

Maximum billing unit(s) equals 600 mg/600 units.

Note to providers:

- HIV-1 Screening: Screen all individuals for HIV-1 infection immediately prior to initiating Apretude for HIV-1 PrEP and prior to each injection while taking Apretude
- Prior to initiating Apretude, an oral lead-in dosing may be used for approximately one month to assess the tolerability of Apretude

J1306

Inclisiran (Leqvio®) is a double-stranded small interfering ribonucleic acid (siRNA), directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with

heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).

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 cardiologist, endocrinologist, a lipid specialist or other specialist with expertise in treating heterozygous familial hypercholesterolemia (HeFH)
- Patient has a diagnosis of HeFH and elevated LDL-C; or a diagnosis of atherosclerotic cardiovascular disease (ASCVD); or ASCVD-Risk Equivalents and elevated LDL-C

Diagnosis of HeFH is 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, mutations in proprotein convertase subtilisin/kexin type 9 (PCSK9), or homozygous mutations in the LDL-R adaptor protein-1

  – A first-degree relative with familial hypercholesterolemia, elevated cholesterol or early heart disease that may indicate familial hypercholesterolemia

  – 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

  – A Dutch Lipid Clinic Network Criteria score of six or more

  – A diagnosis of a “definite” or “probable” FH per the Simon Broome FH diagnostic criteria

Diagnosis of ASCVD or ASCVD-Risk Equivalents based on a history of ASCVD (coronary heart disease [CHD], cardiovascular disease [CVD], or peripheral arterial disease [PAD]) as shown by at least one of the following:

  – Angina (stable or unstable)

  – Prior myocardial infarction or acute coronary syndrome; or

  – History of stroke or transient ischemic attack; or

  – Peripheral artery disease

  – Coronary or other arterial revascularization

  – ASCVD-R-risk equivalents such as diabetes mellitus (DM), heterozygous familial hypercholesterolaemia, etc.

- Patient has atherosclerotic cardiovascular disease (ASCVD) and a serum LDL-C equal to or greater than 70 mg/dL at baseline; OR ASCVD-risk equivalent and a serum LDL-C equal to or greater than100 mg/dL at baseline

- Patient is on statin and is receiving high dose (atorvastatin 80 mg or rosuvastatin 40 mg) or a maximally tolerated dose (defined as the maximum dose of statin that can be taken on a regular basis without intolerable adverse events) with or without ezetimibe or
  - Patient is not on statin, and has a documentation of intolerance to all doses of at least two different statins; OR intolerance to only one statin with a documented history of rhabdomyolysis attributed to that statin
- If patient is on statin and/or ezetimibe), patient should be on a stable dose for ≥30 days prior to treatment initiation.
- Patient must have tried and failed, is intolerant to or has a clinical contraindication to a PCSK9 inhibitor [e.g., Repatha (evolocumab) or Praluent (alirocumab)]
- Patient will not take Leqvio concurrently with other PCSK9 inhibitor [e.g., Repatha (evolocumab) or Praluent (alirocumab)]

Initial approval is for six months.

Continued therapy:

- Patient continues to meet initial coverage criteria
- Positive clinical response as evidenced by reduction of LDL-C from baseline

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Required ICD-10 Diagnosis Codes: E78.00, E78.01, E78.2, E78.4, E78.49, E78.5, E78.9

Frequency of billing equals 284 mg/ 284 units initially, again at three months, and then every six months.

Maximum billing unit(s) equals 284 mg/284 units.

J1551

Immune globulin subcutaneous (human), 20 percent solution (Cuvitru and Xembify) and 16.5 percent solution (Cutaquiq), supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. They also contain a spectrum of antibodies capable of interacting with and altering the activity of cells of the immune system as well as antibodies capable of reacting with cells such as erythrocytes. The mechanism of action in primary humoral immunodeficiency (PI) has not been fully elucidated; however adequate doses may restore abnormally low immune globulin G levels to the normal range and thus help in preventing infections.

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 two years of age or older
- Patient has a confirmed diagnosis of primary humoral immunodeficiency (PI) requiring IgG replacement therapy due to hypogammaglobulinemia or agammaglobulinemia and diagnosis is defined by one or two below:

1. Diagnosis is based on European Society for Immunodeficiencies (ESID) and Pan-American Group for Immunodeficiency
2. Diagnosis is based on the following criteria and patient requires IgG therapy to treat the PIs (which include but are not limited to the following):

Common Variable Immunodeficiency (CVID)

Patient is over four years of age with all the following:

- Recurrent bacterial infections of the ears, nasal sinuses, bronchi and lungs
- Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy)
- The patient's pretreatment IgG level is less than 500 mg/dL or equal to or greater than two standard deviations (SD) below the mean for age
- Low levels of IgA and/or IgM (more than two SD below mean for age)
- Lack of functional antibody response to vaccine (for example, tetanus or diphtheria, MMR, hemophilus or Pneumovax)

Chronic Granulomatous Disease (CGD)

Patient has abnormal Nitroblue Tetrazolium (NBT) reduction test or respiratory burst in activated neutrophils (less than 5 percent of control) with one of the following:

- Genetic testing showing mutation in gp91, p22, p47 or p67 phox
- Absent mRNA for one of the above genes by Northern blot analysis
- Maternal cousins, uncles or nephews with an abnormal NBT or respiratory burst
- Recurrent bacterial or fungal infections of lung, skin, lymph nodes, and liver, etc. (CGD-type infections include Staphylococcus aureus, Burkholderia cepacia complex, Serratia marcescens, Nocardia and Aspergillus)
- Formation of granulomata in tissues or organs
- Failure to thrive and hepatosplenomegaly or lymphadenopathy

DiGeorge syndrome

Patient has reduced numbers of CD3+ T cells (less than 500/mm3) and two out of three of a-c below or d alone or e alone:

a. Genetic testing showing deletion of chromosome 22q11.2
b. Hypocalcemia of greater than three weeks' duration that requires therapy
c. Conotruncal cardiac defect (truncus arteriosus, tetrology of Fallot, interrupted aortic arch or aberrant right subclavian); or
d. Patient has reduced numbers of CD3+ T cells (less than 1500/mm3) and a deletion of chromosome 22q11.2; or
e. Patient has recurrent infections and classic features such as abnormal facial features, cardiac defect, hypoplastic thymus, hypocalcemia, and cleft palate

IgA Deficiency

Patient is over four years of age with one of the following:

- Serum IgA of less than 7 mg/dl (0.07 g/L) but normal serum IgG and IgM and other causes of hypogammaglobulinemia have been excluded (Patient has a normal IgG antibody response to vaccination)
- Serum IgA at least two SD below normal for age but normal serum IgG and IgM, and other causes of hypogammaglobulinemia have been excluded (Patient has a normal IgG antibody response to vaccination)
- Frequent upper respiratory tract infections, persistent or recurrent infections, autoimmune disease, and allergies

IgG subclass deficiency

Patient is seven years or older with all of the following:

- Recurrent severe ear and/ or sinus infections
- Measurement of IgG subclass level showing deficiency (based on lab and age) or equal to or greater than two SD below the mean for age. Repeated at least once in separate sample. Normal levels of IgM and IgA
- Poor response to some vaccines (for example, Pneumovax)

Severe Combined Immunodeficiency (SCID

Patient has at least one of the following:

- Molecular or genetic confirmation of mutation in the cytokine common gamma chain (γc) or in one of these genes; JAK3, RAG1 or RAG2, IL-7Rα
- ADA activity of less than 2 percent of control or mutations in both alleles of ADA
- Autologous CD3+ T cells less than 300 cells/microL in typical SCID and 300 to less than 1500 cells/microL in leaky SCID
- Detection of T-cells of maternal origin with normal lymphocyte count
- Serious or life-threatening infections, especially viral infections, which may result in pneumonia and chronic diarrhea, failure to thrive
- Absent or extremely low T cell mitogen response
- Very low levels of IgA and IgM; absent to elevated IgE
- Positive family history of SCID or positive SCID newborn screening test
- Pretreatment IgG level less than 200 mg/dL

Wiskott-Aldrich Syndrome (WAS)

Patient is male with congenital thrombocytopenia (less than 70,000 platelets/mm3), small platelets, and at least one of the following:

- Genetic testing showing mutation of the WAS gene
- Absent WAS messenger RNA (mRNA) on Northern blot analysis of lymphocytes
- Absence of WAS protein (WASP) in lymphocytes
- Maternal male cousins, uncles, or nephews with small platelets and thrombocytopenia
- Eczema (localized or generalized)

- Unusual bleeding and bruises, congenital or early onset thrombocytopenia, and small platelet size
- Defective antibody responses to some vaccine antigens (for example, Pheumovax)
- Recurrent bacterial or viral infections
- Elevated IgA and IgE, low to normal IgG and IgM levels
- Autoimmune diseases, lymphoma, leukemia, or brain tumor

<u>X-linked agammaglobulinemia (XLA; Bruton's Agammaglobulinemia or Congenital Agammaglobulinemia)</u>

Male patient with less than two percent CD19+ B cells and at least one of the following:

- Genetic testing with mutation in Bruton's Tyrosine Kinase (BTK)
- Absent BTK mRNA on Northern blot analysis of neutrophils or monocytes
- Absent BTK protein in monocytes or platelets
- Maternal cousins, uncles, or nephews with less than two percent CD19+ B cells
- Recurrent or severe bacterial infections, especially with small or absent tonsils and lymph nodes
- Onset of recurrent bacterial infections in the first five years of life, serum IgG, IgM, and IgA more than 2 SD below normal for age, absent isohemagglutinins and /or poor response to vaccines, and other causes of hypogammaglobulinemia have been excluded

<u>X-linked hyper IgM syndrome (XHIM)</u>

Patient is male and has a serum IgG concentration at least 2 SD below normal for age and one of the following:

- Genetic testing with a mutation in the CD40L gene
- Patient's maternal cousins, uncles, or nephews have confirmed diagnosis of XHIM.
- One or more of the following infections or complications:
  – Recurrent bacterial infections in the first five years of life
  – Pneumocystis carinii infection in the first year of life
  – Neutropenia
  – Cryptosporidium-related diarrhea
  – Sclerosing cholangitis
  – Parvovirus-induced aplastic anemia
- Absent CD40 ligand cell surface staining on activated CD41 T cells as assessed by binding to soluble CD40 or by binding of monoclonal antibody to CD40 ligand.
- Serum concentration of IgG is less than 200 mg/dL; IgM may be low, normal or elevated.

Initial authorization is for 12 months

<u>Continued therapy</u>

- Patient continues to meet initial coverage criteria.
- Patient has experienced positive clinical response as evidenced by at least one of the following:
  – Patient has a decrease in the frequency of infections
  – Patient has a decrease in the severity of infections
  – Patient previously received intravenous immune globulin or is continuing therapy with subcutaneous immune globulin

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

J2356

Tezepelumab-ekko (Tezspire™) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ) indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

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 12 years of age or older
- Patient has a physician-diagnosed asthma for at least 12 months
- Must be prescribed by or in consultation with a pulmonologist, allergist or immunologist
- Patient is adherent on medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (such as long acting beta2 agonist (LABA), with or without oral corticosteroids (OCS)
- Patient has persistent uncontrolled asthma as defined by at least one of the following:
  – An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline
  – A history of at least two asthma exacerbation events within prior 12 months
  – A history of at least one severe asthma exacerbation resulting in hospitalization within prior 12 months
  – Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90 percent in adolescents] despite regular treatment with high dose inhaled corticosteroid (ICS) or with medium or high dose ICS plus a LABA with or without oral corticosteroids (OCS) and additional asthma controller medications such as leukotriene receptor inhibitors, long-acting anti-muscarinics (LAMA), or sustained-release theophylline
- Patient will not use tezepelumab-ekko as monotherapy

Initial approval is for 12 months.

Continued therapy

Patient has experienced improvement in asthma control as evidenced by at least one of the following:

- Reductions in Annual Asthma Exacerbation Rate as shown by any of the following:
  - Improvement in patient's Forced Expiratory Volume in 1 Second (FEV1), peak expiratory flow, nighttime awakenings, or any other symptoms that would require an increase in OCS dose
  - Reduction in Emergency Department (ED) visits requiring use of oral/systemic corticosteroids and/or hospitalization
  - Reduction in use of short-acting bronchodilator rescue medications
- Improvement from baseline in Asthma Control Questionnaire-6(ACQ-6) or Asthma Control Test (ACT) score

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Required ICD-10 CM Diagnosis Codes: J45.50, J45.51

Frequency of billing equals 210 mg/210 units every four weeks.

Maximum billing unit(s) equals 210 mg/210 units.

J2998

Ryplazim® (plasminogen, human-tvmh) is plasma-derived human plasminogen indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).

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 11 months of age or older
- Must be prescribed by or in consultation with a geneticist, hematologist, or specialist with experience in treating hypoplasminogenemia
- Patient has a diagnosis of plasminogen deficiency type one shown by at least two of the following:
  - Biallelic mutations in the plasminogen (PLG) gene confirmed by genetic testing
  - A baseline plasminogen activity level less than 45 percent of normal
  - A documented history of typical lesions and symptoms (for example, ligneous conjunctivitis, ligneous gingivitis and tonsillar lesions, ligneous airway disease, ligneous lesions of the hands and feet, impaired wound healing, etc.)
- For patients with respiratory tract involvement, spirometry measurements (forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), peak expiratory flow, and FEV1/FVC ratio) at baseline and every four weeks

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial approval criteria
- Patient has shown clinical benefit as evidenced by at least one of the following:
  - Improvement in lesion number or size from baseline

- Absence of new lesions compared to baseline
- Improvement in wound healing
- Improvement in spirometry measurements from baseline if respiratory tract involvement

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

ICD-10 CM diagnosis code E88.02 is required on the claim.

J9332

Efgartigimod alfa-fcab (Vyvgart™) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

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
- 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 class 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 5 (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 authorization 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 Quantitative Myasthenia Gravis (QMG) score from baseline
  - Documented reduction in symptoms that impact daily function

Reauthorization is for 12 months

Modifiers SA, UD, U7 and 99 are allowed.

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

Frequency of billing equals 10 mg/kg once weekly for four weeks.

Maximum billing unit(s) equals 1200 mg/600 units.

Ophthalmology

The following ophthalmology codes have special billing policies.

C9097, J2779, J3299

C9097

Faricimab (Vabysmo™) is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME).

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

Must submit clinical documentation to substantiate the following:

Universal Criteria:

- Must be used for FDA-approved indications and dosages
- Must be prescribed by or in consultation with an ophthalmologist
- Patient must have a diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (nAMD) or Diabetic Macular Edema (DME)
- Documentation of patients' best corrected visual acuity (BCVA) at baseline and periodically during treatment
- Patient does not have active ocular inflammation or suspected or active ocular or periocular infection in either eye
- Patient does not have untreated intraocular pressure or uncontrolled glaucoma
- Patient has tried and failed an intravitreal vascular endothelial growth factor (VEGF) inhibitor (e.g., bevacizumab, aflibercept or ranibizumab) unless contraindicated or clinically inappropriate

Neovascular (Wet) Age-Related Macular Degeneration (nAMD):

- Patient must be 50 years of age or older
- Patient has a diagnosis of choroidal neovascularization (CNV) secondary to age-related macular degeneration (nAMD)
- Patient does not have CNV due to causes other than AMD, such as ocular histoplasmosis, trauma, pathological myopia, angioid streaks, choroidal rupture, or uveitis
- Patient is not on any concomitant treatment for CNV or vitreomacular-interface abnormalities

Diabetic Macular Edema (DME)

- Patient must be 18 years of age or older

- Patient has a diagnosis of DME and decreased visual acuity attributable primarily to DME
- Macular thickening secondary to diabetic macular edema (DME) involving the center of the fovea

Initial authorization is for six months.

Continued therapy
- Patient continues to meet initial approval criteria
- Patient has experienced a clinical response as evidenced by improvement in best corrected visual acuity (BCVA) score from baseline
- Patient has absence of unacceptable toxicity from the drug such as endophthalmitis or retinal detachment, increase in intraocular pressure, arterial thromboembolic events (ATEs), etc.

Reauthorization is for 12 months.

Modifiers UD and 99 are allowed.

Frequency of billing equals six mg /60 units each eye every four weeks.

Maximum billing unit(s) equals six mg /60 units each eye.

J2779

Susvimo™ (ranibizumab injection) a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

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

Susvimo is considered medically necessary when all the following conditions 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 an ophthalmologist
- Patient has a diagnosis of Neovascular (wet) Age-related Macular Degeneration (AMD) within the prior nine months
- Patient has received three or more doses of anti-VEGF intravitreal agents in the affected eye within the prior six months and demonstrated a response to an anti-VEGF intravitreal agent (for example, aflibercept, bevazicumab, brolucizumab, etc.)
- Documentation of distance Best Corrected Visual Acuity (BCVA) score at baseline and periodically during treatment
- Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary
- Patient does not have active ocular or periocular infections
- Patient does not have active intraocular inflammation

Initial authorization is for six months

Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has shown clinical response as evidenced by improvement from baseline in distance Best Corrected Visual Acuity (BCVA) score
- Patient does not have unacceptable toxicity such as endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival retraction, conjunctival erosion, and conjunctival bleb

Reauthorization is for six months.

Modifiers UD and 99 are allowed.

Frequency of billing equals two mg/20 units each eye every 24 weeks. Maximum billing unit(s) equals two mg/20 units each eye.

J3299

Xipere™ (triamcinolone acetonide injectable suspension) is indicated for the treatment of macular edema associated with uveitis.

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 an ophthalmologist
- Patient has a diagnosis of macular edema associated with non-infectious uveitis
- Patient does not have uveitis due to infections such as herpes simplex or herpes zoster
- Documentation of patients' best corrected visual acuity (BCVA) at baseline and periodically during treatment
- Patient will not concomitantly use intravitreal corticosteroid injections or intravitreal corticosteroid implant
- Patient does not have untreated intraocular pressure or uncontrolled glaucoma
- Patient has tried and failed topical and oral corticosteroids unless contraindicated or clinically inappropriate
- Dose does not exceed 4 mg (one vial) per eye every 12 weeks

Initial authorization is for six months (two injections per eye)

Continued therapy

- Patient continues to meet initial approval criteria
- Patient has absence of unacceptable toxicity from the drug such as glaucoma, increase in intraocular pressure, cataracts, etc.
- Patient has experienced clinical response as evidenced improvement or stabilization in best corrected visual acuity from baseline

Six months (two injections per eye).

Modifiers SA, UD, U7 and 99 are allowed.

Frequency of billing equals 4 mg/4 units each eye as a single dose every three months. Maximum billing unit(s) equals 4 mg/4 units each eye as a single dose.

Pathology

The following Pathology codes have special billing policies.

87913

Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s).

This code is reimbursable for Presumptive Eligibility for Pregnant Women (PE4PW) services.

Modifiers 33, 90, 99 are allowed.

Frequency of billing equals one unit per day.

Proprietary Laboratory Analyses (PLA)

The following PLA codes have special billing policies.

0323U, 0324U, 0325U, 0326U, 0327U, 0328U, 0329U, 0330U, 0331U

0323U, 0324U, 0325U, 0327U, 0328U, 0330U

These codes are reimbursable for Presumptive Eligibility for Pregnant Women (PE4PW) services.

Modifiers 33, 90 and 99 are allowed.

Frequency is limited to one unit per day.

0326U, 0329U, 0331U

Modifiers 33, 90 and 99 are allowed.

Frequency is limited to one unit per day.

Radiology

The following radiology codes have special billing policies.

A9596

Illuccix® (after radiolabeling with Ga 68) is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: with suspected metastasis who are candidates for initial definitive therapy; or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

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

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient has a diagnosis of biopsy-proven prostate cancer that meets at least one of the following criteria:

  - Has suspected metastasis and is a candidate for initial definitive therapy such as prostatectomy and pelvic lymph node dissection
  - Has a biochemical recurrence (BCR) after initial definitive therapy defined by serum PSA of greater than 0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy
  - Has nonmetastatic castration-resistant prostate cancer (nmCRPC) with increasing PSA or radiographic evidence of metastases
  - Has suspected recurrence of prostate cancer based on elevated serum prostate-specific antigen (PSA) level
  - Has progression of disease on androgen deprivation therapy (ADT), or localized on observation
  - Has progression of nonmetastatic and metastatic castration-naïve prostate cancer
  - Has an initial staging of unfavorable intermediate, high or very high-risk prostate cancer; and
- Patient meets at least one of the following criteria:
  - Has a serum prostate-specific antigen (PSA) of at least 10 ng/ml
  - Has a tumor stage ct2b or greater
  - Has a Gleason score greater than six

Authorization is for three months.

Modifiers UD, U7 and 99 are allowed.

Frequency of billing equals 259 MBq (7 mCi) /seven units for one dose.

Maximum billing unit(s) equals 259 MBq (7 mCi)/ seven units.

A9601

Flortaucipir F 18 (Tauvid™) is a radioactive diagnostic agent indicated for positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD).

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

A TAR must be submitted with clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 50 years of age or older
- Patient is being evaluated for Alzheimer's Disease
- Patient is cognitively impaired
- Patient has mild cognitive impairment (MCI) or dementia with suspected neurodegenerative cause
- Patient has mini-mental status exam (MMSE) score of 20-27
- Patient is not known to have a structural brain lesion that would interfere either with PET imaging or pathological assessment

- Patient is not being evaluated for chronic traumatic encephalopathy (CTE)

Authorization is for three months.

Modifiers UD, U7 and 99 are allowed.

Frequency of billing equals 370 MBq (10 mCi)/ 10 units administered as a single dose.

Maximum billing unit(s) equals 370 MBq (10 mCi)/ 10 units.

Skin Substitutes

The following skin substitute codes have special billing policies:

Q4259, Q4260, Q4261

Q4259, Q4260, Q4261

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

Modifiers U7 and 99 are allowed

Surgery

The following surgery codes have special billing policies.

G0308, G0309

G0308

Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training.

G0309

Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180-day implantable sensor, including system activation.

Assistant surgeon services are not payable for these procedures.

Modifiers SA, UD, U7 and 99 are allowed.

Q3 Code Deletions

Table of HCPCS Q3 Code Deletions

Subject	Deleted Code
Chemotherapy	C9091 (replaced by J9331)
Injection	C9090 (replaced by J2998)
Ophthalmology	C9092 (replaced by J3290) C9093 (replaced by J2779)