Q4 HCPCS Level I and II Update (October 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.

Q4 Code Additions

Chemotherapy

The following chemotherapy codes have special billing policies.

C9142, J1932, J9274, J9298, Q2056, Q5125

C9142

Bevacizumab-maly (Alymsys®) is a vascular endothelial growth factor inhibitor indicated for the treatment of metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment; metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan or fluoropyrimidineoxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.

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

Alymsys 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
- Alamsys will be used as a treatment for one the following:
  - Cervical cancer (persistent/recurrent/metastatic):
    - Treatment of persistent, recurrent, or metastatic cervical cancer (in combination with paclitaxel and either cisplatin or topotecan)
    - Treatment of persistent, recurrent, or metastatic cervical carcinoma (in combination with pembrolizumab, paclitaxel [conventional], and either cisplatin or carboplatin) – (± individualized radiation therapy and/or palliative care)
  - Colorectal cancer, metastatic
    - First- or second-line treatment of metastatic colorectal cancer (CRC) (in combination with fluorouracil-based chemotherapy)
    - Second-line treatment of metastatic CRC (in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy) after progression on a first-line treatment containing bevacizumab
    - Drug is not being used for the adjuvant treatment of colon cancer
  - Glioblastoma, recurrent
    - Treatment of recurrent glioblastoma in adults
  - Non-small cell lung cancer, nonsquamous

- First-line treatment of unresectable, locally advanced, recurrent or metastatic nonsquamous non-small cell lung cancer (in combination with carboplatin and paclitaxel)

– Ovarian (epithelial), fallopian tube, or primary peritoneal cancer:

- *Stage III or IV disease, following initial surgical* resection: Treatment of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection (in combination with carboplatin and paclitaxel, followed by single-agent bevacizumab)
- *Platinum-resistant recurrent:* Treatment of platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (in combination with paclitaxel, doxorubicin [liposomal], or topotecan) in patients who received no more than 2 prior chemotherapy regimens
- *Platinum-sensitive recurrent:* Treatment of platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (in combination with carboplatin and paclitaxel or with carboplatin and gemcitabine and then followed by single-agent bevacizumab)

– Renal cell carcinoma, metastatic:

- Treatment of metastatic renal cell carcinoma (in combination with interferon alfa).

Initial authorization is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced positive clinical response such as stabilization of disease or decrease in tumor size or spread.
- Patient has absence of unacceptable toxicity such as gastrointestinal perforations and fistula, severe arterial thromboembolic events (ATE), grade four venous thromboembolic events (VTE), hypertensive crisis or hypertensive encephalopathy, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome (greater than 2g of proteins in urine), severe infusion-related reactions, congestive heart failure (CHF), etc.

Reauthorization is for 12 months.

Modifiers SA, UD, U7, 99 are allowed.

Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg.

J1932

Lanreotide (Cipla), is a somatostatin analog indicated for: The long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy. (1.1) The treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Must submit clinical documentation to substantiate the following:

Universal Criteria

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient has tried Somatuline Depot and has a documented intolerance, contraindication; or it was clinically inappropriate
- Lanreotide is being used for one of the following diagnoses:
  – Acromegaly
  – Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

Acromegaly

- Patient meets the above Universal Criteria
- Must be prescribed by or in consultation with an endocrinologist
- Patient has a diagnosis of acromegaly based on biochemical tests and medical history
- Patient had an inadequate response to surgery and/or radiotherapy, or surgery and/or radiotherapy is not an option
- Documentation of a high pretreatment insulin-like growth factor 1 (IGF-1) level for age and/or gender based on the laboratory reference range
- Documentation of elevated growth hormone (GH) level defined as a GH level equal to or greater than 1ng/mL following an oral glucose tolerance test (OGTT)

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

- Patient meets the above Universal Criteria
- Must be prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.
- Patient has a diagnosis of neuroendocrine tumor originating from the pancreas, midgut, hindgut or are of unknown origin, and disease is unresectable, locally advanced or metastatic.
- Tumor is well or moderately differentiated confirmed by histology
- Tumor lesions are measurable by a CT or MRI scan

Initial authorization is for six months

Continued therapy

- Patient continues to meet initial authorization criteria
- For acromegaly, patient’s insulin-like growth factor 1 (IGF-1) level for age and gender has reduced or normalized; or patient has a reduction in pretreatment serum growth hormone (GH) concentration
- For GEP-NETs, patient has shown documented clinical response such as lack of disease progression and does not have unacceptable toxicity

Reauthorization is for 12 months.

Modifiers SA, UD, U7, 99 are allowed.

Injection, lanreotide, (cipla), 1 mg.

Frequency of billing equals 120 mg /120 units every 4 weeks.

Maximum billing unit(s) equals 120 mg /120 units.

J9274

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 0 or 1
- 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 monoclonal antibodies
  - 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, 99 are allowed.

Injection, tebentafusp-tebn, 1 mcg.

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.

J9298

Nivolumab and relatlimab-rmbw (Opdualag™) is a combination of nivolumab, a programmed death receptor-1 (PD-1) blocking antibody, and relatlimab, a lymphocyte activation gene-3 (LAG-3) blocking antibody, indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

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

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

Modifiers SA, UD, U7, 99 are allowed.

Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg.

Frequency of billing equals 480 mg nivolumab and 160 mg relatlimab/160 units every four weeks.

Maximum billing unit(s) equals 480 mg nivolumab and 160 mg relatlimab/160

Q2056

Ciltacabtagene autoleucel; cilta-cel (Carvykti™) is a B-cell maturation antigen (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.

- 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
- Outpatient administration is restricted to Hospital Outpatient Services only

Approval is for three months (one treatment only).

Reauthorization is not approvable.

<u>REMS</u>

- 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).

<u>Important Instructions for Billing</u>

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 Q2056.
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, 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.

Q5125

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, 99 are allowed

Injection, filgrastim-ayow, biosimilar, [releuko], 1 microgram.

Injection

The following injection codes have special billing policies.

C9101, J1302

C9101

Oliceridine (Olinvyk®) is an opioid agonist indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

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

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

- Must be used for FDA-approved indications and dosages
- Patient is 18 years of age or older
- Patient has moderate to severe acute pain.
- Pain is severe enough to require an intravenous opioid analgesic
- Alternative treatments such as non-opioid analgesics are inadequate
- Patient has tried I.V. opioids such as morphine, Hydromorphone, fentanyl, etc., unless intolerance, inadequate pain control or clinically inappropriate
- The cumulative total daily dose will not exceed 27 mg

Approval is for seven days (treatment duration will be limited to 48 hours).

Modifiers SA, UD, U7, 99 are allowed.

Injection, oliceridine, 0.1 mg.

Frequency of billing equals up to 27 mg/270 units per day.

Maximum billing unit(s) equals up to 27 mg /270 units.

J1302

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.

<u>Continued therapy:</u>

- 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 12 g/dL or more or Hgb level increased by 2 g/dL or more 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.

Ophthalmology

The following ophthalmology codes have special billing policies:

J2777

J2777

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.

Preventive Services

The following codes have special billing policies and are reimbursable for Presumptive Eligibility for Pregnant Women (PE4PW) services.

G0310, G0311, G0312, G0313, G0314, G0315

Note: For code G0310-G0313- co not report with other E & M procedure codes: 99202-99205, 99211-99215, 99241-99245 and 99401-99404

G0310

Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 5 to 15 minutes time.

Minimum age is 21.

Modifiers SA, U7 are allowed.

G0311

Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 16 to 30 minutes time.

Minimum age is 21.

Modifiers SA, U7 are allowed.

G0312

Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 5 to 15 minutes time.

Modifiers SA, U7 are allowed.

G0313

Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 16 to 30 minutes time.

Modifiers SA, U7 are allowed.

G0314

Immunization counseling by a physician or other qualified health care professional for COVID-19, ages under 21, 16 to 30 minutes time.

Modifiers SA, U7, SB are allowed.

G0315

Immunization counseling by a physician or other qualified health care professional for COVID-19, ages under 21, 5 to15 minutes time.

Modifiers SA, U7, SB are allowed.

Proprietary Laboratory Analyses (PLA)

The following PLA codes have special billing policies.

0333U, 0334U, 0337U, 0338U, 0339U, 0341U, 0342U, 0343U, 0344U, 0353U, 0354U

0333U, 0334U, 0337U, 0338U, 0342U, 0344U

Modifiers 33, 90 and 99 are allowed.

Frequency is limited to once in a lifetime.

0341U

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

Modifiers 33, 90, 99, are allowed.

Frequency is limited to once in a lifetime.

0342U

Required ICD-10 diagnosis codes: C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9

0339U, 0343U

Modifiers 33, 90, 99 are allowed.

Frequency is limited to once in 36 months.

Sex restriction is male only.

Must be 15 years of age or older.

Required ICD-10 diagnosis codes: C61, D07.5.

0353U

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

Modifiers 33, 90, 99 are allowed.

Frequency is limited to three times a year.

0354U

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

Modifiers 33, 90, 99 are allowed.

Frequency is limited to three times in a lifetime.

Radiology

The following radiology codes have special billing policies:

A9602

Fluorodopa F 18 is a radioactive diagnostic agent indicated for use in positron emission tomography (PET) to visualize dopaminergic nerve terminals in the striatum for the evaluation of adult patients with suspected Parkinsonian syndromes (PS). Fluorodopa F 18 PET is an adjunct to other diagnostic evaluations.

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

Fluorodopa F 18 is medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient is being evaluated for Parkinsonian syndrome (PS)
- Patient has possible Parkinsonian syndrome (PS) as evidenced by at least two of the cardinal features of PS: bradykinesia, rigidity, tremor, and/or gait disorder.
- The diagnosis was based on United Parkinson's Disease Rating Scale (UPDRS), either confirmed or amended as the referral diagnosis based on treatment response.
- Patient is free from neurological or psychological problems and not on any medication known to affect the dopaminergic system.
- Fluorodopa F 18 PET is an adjunct to other diagnostic evaluations

Authorization is for three months.

Modifiers UD, U7 and 99 are allowed.

Frequency of billing equals 185 megabecquerels (MBq) [5 millicuries (mCi)]/5 units for one dose.

Maximum billing unit(s) equals 185 megabecquerels (MBq) [5 millicuries (mCi)]/5 units.

A9607

Lutetium Lu 177 vipivotide tetraxetan (Pluvicto™) is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

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 oncologist or urologist
- Patient has a diagnosis of Prostate Cancer - Metastatic Castration Resistant (mCRPC)
- Disease is prostate specific membrane antigen (PSMA)-positive
- Patient meets both of the following criteria:

  - Has tried at least one androgen receptor pathway inhibitor (for example, abiraterone, abiraterone acetate tablets, enzalutamine apalutamide or darolutamide)
  - Has tried at least one taxane-based chemotherapy regimen (for example: docetaxel, cabazitaxe, etc.)
- The medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (for example leuprolide acetate, triptorelin pamoate, goserelin acetate, etc.) or patient has had a bilateral orchiectomy

Initial authorization is for six months

Continued therapy

- Patient continues to meet initial approval criteria
- Patient has experienced positive clinical response such as lack of disease progression or lack of increase in tumor size or spread.
- Patient has no evidence of unacceptable toxicity

Reauthorization is for 12 months

Modifiers UD, U7, 99 are allowed.

Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie.

Frequency of billing equals 7.4 GBq (200 mCi)/200 units every six weeks for up to six doses.

Maximum billing unit(s) equals 7.4 GBq (200 mCi)/200 units.

A9800

Gallium Ga 68 Gozetotide Injection (Locametz® Preparation Kit), after radiolabeling with gallium-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; with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level;for selection of patients with metastatic prostate cancer, for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated.

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
- Patients must be 18 years of age or older
- Patient has biopsy proven prostate adenocarcinoma 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 suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
  - Has metastatic prostate cancer, and lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated

- Patient has intermediate to high-risk disease as determined by at least one of the following criteria:
  – Serum PSA of at least 10 ng/ml
  – Tumor stage ct2b or greater
  – Gleason score greater than six
- Karnofsky performance status of equals to or greater than 50 (or Eastern Cooperative Oncology Group [ECOG]/World Health Organization [WHO] equivalent)
- Patient has not had androgen deprivation therapy or other neoadjuvant treatments prior to PET imaging and surgery

Authorization is for three months.

Modifiers UD, U7 and 99 are allowed.

Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie.

Codes A9800 is separately billable and not split-billable.

- Providers must complete a *CMS-1500* form including the medically justified ICD-10-CM diagnosis code
- Providers must include an invoice showing the acquisition cost of the product to the claim. The invoice must have a date prior to the date of service, or the claim will be denied

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

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

Skin Substitutes

The following skin substitute codes have special billing policies:

A2014, A2015, A2016, A2018

A2014, A2015, A2016, A2017, A2018

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

Modifiers U7 and 99 are allowed

Q4 Code Deletions

Table of HCPCS Q4 Code Deletions

Subject	Deleted Code
Chemotherapy	C9095 (replaced by J9274) C9096 (replaced by Q5125) C9098 (replaced by Q2056
Injection	C9094 (replaced by J1302)
Ophthalmology	C9097 (replaced by J2777)
Proprietary Laboratory Analysis	0012U 0013U 0014U 0056U