Quarter 1 HCPCS Update

Effective January 1, 2021

Quarter 1 HCPCS Code Additions

Chemotherapy

The following chemotherapy codes have special billing policy:

C9069, C9070, J9144, J9223, J9316, J9317

C9069

HCPCS code C9069 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM diagnosis codes are suggested on the claim: C90.00, C90.02.

Frequency of billing = 2.5 mg/kg once every 21 days.

Modifiers SA, UD, U7 and 99 are allowed.

C9069 is available only through a restricted program under a Risk Evaluation and Mitigation Strategies (REMS) called the Blenrep® REMS because of the risks of ocular toxicity.

Notable requirements of the Blenrep® REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training in the Blenrep REMS.
- Prescribers must counsel patients receiving belantamab mafodotin-blmf about the risk of ocular toxicity and the need for ophthalmic examinations prior to each dose.
- Patients must be enrolled in the Blenrep REMS and comply with monitoring.
- Healthcare facilities must be certified with the program and verify that patients are authorized to receive belantamab mafodotin-blmf.
- Wholesalers and distributers must only distribute belantamab mafodotin-blmf to certified healthcare facilities.

Further information is available at the BLENREP REMS page and 1-855-209-9188.

C9070

HCPCS code C9070 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM diagnosis codes are suggested on the claim: C83.30 thru C83.39.

Frequency of billing = 12 mg/kg according to the following dosing schedule

- Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle.
- Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle.
- Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.

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

- Must be used for FDA-approved indications and dosing regiments
- Patient must be 18 years of age or older

- Patient must have a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma
  - Patient has relapsed and/or refractory disease
  - Patient has at least one bidimensional measurable disease site
- Patient has received at least one but no more than three previous systemic regimens for the treatment of DLBCL. A CD20 targeted therapy ((e.g. rituximab) must have been included in one therapy line
- Patients was not eligible for autologous stem cell transplant (ASCT)
- Patient has not received an allogeneic stem cell transplant or autologous stem cell transplant within the prior 3 months of therapy
- Patient was not previously treated with CD19 targeted therapy (e.g., axicabtagene, tisagenlecleucel, etc.)
- Patient has not received prior therapy with immunomodulatory imide (IMiDs) agents (e.g., lenalidomide)
- Patient does not have a history of positive hepatitis B and/or hepatitis C serology, or known seropositivity for HIV
- Patient has not received a live vaccine or required parenteral antimicrobial therapy for an active infection within 14 days prior to first dose
- Patient does not have CNS lymphoma involvement
- Patient is using Monjovi:
  - In combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity; or
  - As monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity.

Initial authorization is for 6 months

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has absence of unacceptable toxicity from the drug such as severe infusion reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc.
- Patient has a positive clinical response evidenced by stabilization of disease or decrease in size of tumor or tumor spread

Reauthorization is for 12 months

Modifiers SA, UD, U7 and 99 are allowed.

J9144

HCPCS code J9144 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM codes are suggested on the claim: C90.00 thru C90.02.

Frequency of billing = 1800 mg/ 180 units every seven days. Maximum billing unit(s)= 1800 mg/ 180 units

Modifiers SA, UD, U7 and 99 are allowed.

J9223

HCPCS code J9223 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM diagnosis codes are suggested on the claim: C33, C34.00 thru C34.02, C34.10 thru C34.12, C34.2, C34.30 thru C34.32, C34.80 thru C34.82, C34.90 thru C34.92.

Frequency of billing= 3.2 mg/m2 every 21 days.

Modifiers SA, UD, U7 and 99 are allowed.

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
- Patients must be 18 years of age or older
- Patient must have a diagnosis of small cell lung cancer (SCLC).
- Patient has experienced disease progression or relapse following initial platinum-based chemotherapy (i.e., cisplatin, carboplatin, etc.).
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status (PS) less than or equal to 2
- Patient must not be a pregnant or breast-feeding female.
- Patient does not have central nervous system (CNS) involvement.
- Patient does not have active infection such as HIV (human immunodeficiency virus), Hepatitis B, Hepatitis C, etc.

Initial authorization is for 6 months

Continued therapy:

- Patient continues to meet initial coverage criteria
- Patient does not have unacceptable toxicity such as severe hypersensitivity reactions, severe hepatic toxicity or severe myelosuppression.
- Patient shows positive clinical benefit as evidenced by lack of disease progression, disease stabilization, or reduction in tumor size or spread.

Reauthorization is for 12 months

J9316

HCPCS code J9316 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing = 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase initially, followed every 21 days by a dose of 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase

Modifiers SA, UD, U7 and 99 are allowed.

J9317

HCPCs code J9316 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM diagnosis codes are suggested: C50.919, C50.929.

Frequency of billing = 10 mg/kg once weekly on days 1 and 8 of 21-day treatment cycles.

Modifiers SA, UD, U7 and 99 are allowed.

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

- Must be used for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient must have a diagnosis of metastatic triple-negative breast cancer (mTNBC)
- Patient has received at least two prior therapies for metastatic disease.

Initial approval is for 12 months

Continued Therapy:

- Patient continues to meet initial approval criteria
- Patient has shown positive clinical response as evidenced by disease stabilization or reduction of tumor size and spread.

Reauthorization is for 12 months.

Hemostatic Agents

The following hemostatic code has special billing policy:

C1052

C1052

Modifiers PA, PB, PC, U7, 22, and 99 are allowed.

Immunization

The following immunization codes have special billing policy:

M0239, M0243

M0239, M0243

HCPCS codes M0239 and M0243 are administration codes. M0239 is used to bill the infusion and post administration monitoring of Bamlanivimab, while M0243 is used to bill the infusion and post administration monitoring of Casirivi and Imdevi. These are monoclonal antibodies which are indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients 12 years of age and older.

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

Implants

The following implant codes have special billing policy:

C1062, C1825

C1062

Modifiers GY, PB, PC, U7, 22, and 99 are allowed.

C1825

Modifiers GY, PA, PB, PC, U7, 22 and 99 are allowed.

Injections

The following injection codes have special billing policy:

C9071, C9072, C9073, J0693, J1823, J7352, Q5122

C9071

HCPCS code C9071 is indicated for the treatment of Duchene Muscular Dystrophy (DMD) in patients 4 years of age and older. The following ICD-10-CM diagnosis code is suggested on the claim: G71.01.

Modifiers SA, UD, U7 and 99 are allowed.

Frequency of billing = 80 mg/kg administered once every seven days.

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

- Must be for FDA-approved indications and dosages.
- Patient must be 4 years of age or older
- Must be prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD. For CCS patients, must be under the supervision and monitoring of a CCS-paneled neurologist or physical medicine and rehabilitation who is fellowship trained in neuromuscular medicine at a CCS Neuromuscular Medicine Special Care Center (SCC), or at a neurology clinic.
- Must have a diagnosis of DMD with mutation amenable to exon 53 skipping as documented by genetic test(s)
- The following are completed as part of the assessment for antisense oligonucleotide therapy:
    a. Forced Vital Capacity (FVC),
    b. Brooke score,
    c. 6-minute walk test (6MWT), if ambulatory, and
    d. Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C.
- The FVC is greater than 30 percent predicted or the Brooke score is less than or equal to 5.
- Only one antisense oligonucleotide treatment shall be authorized at a time
- Patient is on a corticosteroid or has documented medical reason not to be on this medication.

- For CCS patients, CCS Neuromuscular Medicine SCC or CCS-paneled neurologist has provided a completed Antisense Oligonucleotide Request Form (see link below) that includes the following information:
    a. Documentation of recent FVC.
    b. Brooke Score or baseline 6MWT if ambulatory.
    c. Laboratory indicator of renal function.

Initial Approval is for 12 months

Reauthorization

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

Additional consideration for medical necessity determination:

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

Reauthorization is for 12 months.

Policy Implementation for CCS Patients

A. Submissions of authorization requests for eteplirsen, golodirsen, or viltolarsen are not included in Service Code Groupings. Until 4/1/21, providers should submit a separate SAR with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, and clinical progress notes from a visit within the past 6 months.
    1. For clients residing in an independent county, SARs should be submitted to the CCS independent county office, which shall review and authorize according to the policy above.
    2. For clients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at CCSExpeditedReview@dhcs.ca.gov or via secure RightFax (916) 440-5306
B. All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical

Director or designee before authorization.

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

Beginning April 1, 2021, all requests for prior authorization of medications billed by National Drug Code and dispensed by a Medi-Cal enrolled pharmacy provider, shall be sent from the pharmacy provider to the Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (Magellan). The Medi-Cal RX website provides guidance: https://medi-calrx.dhcs.ca.gov/home/.

C9072

HCPCS code C9072 is indicated for the treatment of patients 12 years of age and older.

Modifiers SA, UD, U7 and 99 are allowed.

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must state not only the diagnoses, but also must contain sufficient clinical information to establish medical necessity.

C9073

HCPCS code C9073 is indicated for the treatment of patients 18 years of age and older and has a frequency of once in a lifetime. The following ICD-10-CM diagnosis codes are suggested on the claim: C83.10 thru C83.19.

Modifiers UD and 99 are allowed.

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 administered in a health care facility registered with the Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program
- Patient must be 18 years of age or older
- Patient must have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)
- Patient previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody (e.g rituximab), and a Bruton tyrosine kinase inhibitor (BTKi) e.g acalabrutinib, ibrutinib, zanubrutinib)
- Patient had disease progression after their last regimen or refractory disease to their most recent therapy
- Patient must have adequate bone marrow, cardiac, pulmonary, renal, and organ functions
- Patients does not have the following:
  - Active or serious infections
  - Prior allogeneic hematopoietic stem cell transplant (HSCT),
  - Detectable cerebrospinal fluid malignant cells or brain metastases,
  - History of central nervous system (CNS) lymphoma or CNS disorders.

- Tecartus is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Kymriah, Yescarta)

Initial Authorization is for 3 months (One dose only)

Reauthorization

Continued therapy is not approvable.

REMS

Tecartus is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta and Tecartus REMS Program. This is due to Cytokine Release Syndrome and Neurological Toxicities. Tecartus must be administered in a certified health care facility.

Special billing instructions for Tecartus (C9073):

Providers are to take the following steps when submitting claims for Tecartus:

- Submit and receive back an approved Treatment Authorization Request (TAR)/Service Authorization Request (SAR)
- Completion of Claim forms:
  - Outpatient claims may be billed by paper claim using CMS-1500 or electronically using ASC X12N 837P v.5010.
  - Providers must submit one (1) service line on the TAR/SAR request, and enter "4" in the Units box
  - On the 837P or CMS-1500 claim form, provider must submit one claim line to represent one (1) service.
    - ❖ Claims submitted with more than one claim line will be denied
  - Provider must submit an invoice for reimbursement.
  - This process will ensure that the total reimbursement paid for the quantity of four (4) is no more than the paid price on the provider submitted invoice
  - Tecartus must be billed on its own with no other drug or biological.
  - For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of 837P and *CMS-1500* claim forms.

J0693

HCPCS code J0693 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing = 2 g/400 units every 6 to 8 hours for 7 to 14 days. Max dose 8 g/1600 units in 24 hours.

Modifiers SA, UD, U7 and 99 are allowed.

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

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older

- Patient must have a diagnosis of the following infections caused by susceptible Gram-negative microorganisms:
    1. Clinical diagnosis of either complicated urinary tract infections (cUTI) with or without pyelonephritis or acute uncomplicated pyelonephritis
        I. The infection is caused by the following susceptible gram-negative microorganisms: E. coli, K. pneumoniae, Proteus mirabilis, P. aeruginosa, and E. cloacae complex.
        II. Patients who were treated previously with an empiric antibiotic but failed treatment, both clinically and microbiologically
        III. Patient had an identified Gram-negative uropathogen that was not susceptible to the previously used empiric treatment and likely to be susceptible to Fetroja
        IV. Patient was receiving antibiotic prophylaxis for UTI and presents with signs and symptoms consistent with an active new UTI
    2. Patient has a diagnosis of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), or healthcare-associated bacterial pneumonia (HCABP)
        V. Patient must have a suspected Gram-negative infection involving the lower respiratory tract
        VI. Infection was caused by the following susceptible gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens,
        VII. Patient does not have known or suspected community-acquired bacterial pneumonia (CABP), atypical pneumonia, viral pneumonia, or chemical pneumonia (including aspiration of gastric contents, inhalation injury)

Must meet the following criteria for both diagnoses:

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

Authorization is for 14 days treatment duration

<u>J1823</u>

HCPCS code J1823 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM code is suggested on the claim: G36.0.

Frequency of billing = 300 mg/300 units initially, 300 mg/ 300 units after two weeks, then beginning six months after initial dose, 300 mg/300 units every six months. Max billing unit(s) = 300 mg/ 300 units.

Modifiers SA, UD, U7 and 99 are allowed.

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
- Must be prescribed by or in consultation with an immunologist, hematologist, or other physician specialized in the treatment of the disease
- Patient must have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
- All vaccines must be administered at least four weeks prior to inebilizumab treatment initiation
- Patient has been screened for hepatitis B virus (HBsAg and anti-HBc measurements) and active tuberculosis prior to treatment initiation
- Patient is anti-aquaporin-4 (AQP4) antibody seropositive
- Patient has a history of one or more relapses that required rescue therapy during the previous 12 months or 2 or more relapses requiring rescue therapy during the previous 24 months
- Patient will not receive inebilizumab concurrently with other biologics used to treat NMOSD (e.g., eculizumab [Soliris], or satralizumab [Enspryng]).

Initial authorization is for six months

Continuation of Therapy:

- Patient continues to meet initial approval criteria
- The patient had clinical benefit evidenced by any one of the following:
  - Reduction in frequency and number of attacks.
  - Disease stabilization while on inebilizumab treatment.
  - Reduction in number of NMOSD-related hospitalizations.
- Absence of unacceptable toxicity from the drug such as serious or life-threatening infusion related reactions, serious infections including Progressive Multifocal Leukoencephalopathy (PML), hypogammaglobulinemia necessitating intravenous Immunoglobulin (IVIG) or leading to recurrent infections.

Reauthorization is for 12 months

J7352

HCPCS code J7352 is indicated for the treatment of patients 18 years of age and older.

Frequency of billing = 16 mg/ 16 units every two months. Max dose 16 mg/ 16 units

Modifiers UD and 99 are allowed.

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 the characteristic symptoms of erythropoietic protoporphyria (EPP) phototoxicity and a biochemically-confirmed diagnosis of EPP
- It must be prescribed by or in consultation with a dermatologist or other physician with expertise in treating EPP
- Patient must not be a pregnant or lactating female
- Patient does not have any of the following:
  - Significant EPP-associated hepatic involvement
  - Personal history of melanoma or dysplastic nevus syndrome.
  - Current Bowen's disease, basal cell carcinoma, squamous cell carcinoma, or other malignant or premalignant skin lesions.
  - Any other photodermatosis such as polymorphic light eruption, actinic prurigo, discoid lupus erythematosus, chronic actinic dermatitis or solar urticaria

Initial authorization is for 6 months

Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced clinical improvement as evidenced by improvement in at least one of the following:
  - Combined Sun Exposure and Phototoxic Pain. Time in direct sunlight exposure between 10 am and 6 pm on days when no or mild pain was experienced (Likert scores of 0 to 3)
  - Sun Exposure. Duration of direct sunlight exposure between 10 am and 6 pm while on medication
  - Number of hours spent outdoors between 10 am and 3 pm, mostly in direct sunlight, shade, or a combination of both, and if any phototoxic pain was experienced that day
  - Quality of life measure measured with the Dermatology Life Quality Index (DLQI) score 0 thru 30, or the Erthropoietic protoporphyria quality of life measure (EPP-QoL) score 0 thru 100

Reauthorization is for 6 months

<u>Q5122</u>

HCPCS code Q5122 is indicated for treatment of patients ages two and older.

Frequency of billing = 6 mg/12 units once every chemotherapy cycle.
Maximum billing unit(s) = 6 mg/12 units

Modifiers SA, UD, U7 and 99 are allowed.

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

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 2 years of age or older

- Patient must have one of the following diagnoses of metastatic triple-negative breast cancer (mTNBC)
  - Prevention of chemotherapy-induced febrile neutropenia; or
  - Treatment of chemotherapy-induced febrile neutropenia
- It must not be used in combination will any other granulocyte colony-stimulating factor (G-CSF) such as Neulasta, Neulasta Onpro, Fulphila, Udenyca or Ziextenzo

Initial approval is for 6 months

Continued Therapy:

- Patient continues to meet initial approval criteria.

Reauthorization is for 6 months.

Medicine

The following Medicine codes have special billing policy:

G0088, G0089, G2213

G0088, G0089

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

- The service is medically necessary
- Diagnosis and prescription are written by physician or licensed professional practitioner
- Name of medication/solution, route, frequency, duration, strength and total units.
- A trained registered nurse or licensed health professional following the physician's orders provides these services, including documentation of patient status for the duration of treatment

Note: This process does not replace medication authorization that requires prior authorization through Pharmacy Benefits division.

Modifiers EP, SA, TD, U7 and 99 are allowed.

G2213

Modifiers SA, UD, U7 and 99 are allowed.

Non-Injectable Drugs

The following non-injectable drugs have special billing policy:

J9281, S0013

J9281

HCPCS code J9281 is indicated for the treatment of patients 18 years of age and older. The following ICD-10-CM codes are suggested on the claim: C65.1, C65.2, C65.9.

Frequency of billing= initially, 60 mg/ 60 units every seven days for six weeks. After three months, maintenance monthly dose of 60 mg/ 60 units for a maximum of 11 additional

doses. Maximum billing unit(s) = 60 mg/ 60 units

Modifiers SA, UD, U7 and 99 are allowed.

S0013

HCPCs code S0013 is indicated for the treatment of patients 18 years of age and older and is reimbursable for Medicare non-covered services.

Frequency = 84 mg/ 84 units twice weekly. Maximum billing unit(s) = 84 mg/ 84 units.

Modifiers UD and 99 are allowed.

Outpatient Procedures

The following codes have special billing policy:

C9770, C9771

C9770, C9771

HCPCS codes C9770 and C9771 are reimbursable for the primary surgeon only. Assistant surgeon services are not reimbursable.

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.

Radiology

The following radiology codes have special billing policy:

A9591, C9068

A9591

HCPCS code A9591 is indicated for treatment of patients 18 years of age and older and is separately billable, not split-billable. Providers must complete the *CMS 1500* form including the medically justified ICD-10-CM diagnosis code(s). Providers must include an invoice showing the acquisition cost of the product for the claim.

Maximum billing unit(s)= 6 mCi/ 6 units

Modifiers SA, UD, U7 and 99 are allowed.

Recommended dose is 222 MBq (6 mCi), with a range of 111 MBq to 222 MBq (3 mCi to 6 mCi), administered as an intravenous injection over one to two minutes.

Recommended imaging start time is 80 minutes (range 20 minutes to 80 minutes) after drug administration.

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

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older.
- Patient must have an approval for a PET scan and the PET scan code must be billed on the same date of service

- Patient has first recurrence of breast cancer or stage IV disease as defined by the American Joint Committee on Cancer staging system for breast cancer
- Patient had documented histologically confirmed invasive breast carcinoma
- Patient is scheduled to undergo core needle biopsy or surgery for histological confirmation and determination of ER status of recurrent or distant metastatic cancer within 15 days after FES scan; or
  - Patient had core needle biopsy of recurrent or distant metastatic cancer within 30 days before FES scan and biopsy specimens are available for determination of ER status.
- Patient discontinued selective ER modulators or fulvestrant for at least 60 days prior to FES scan.
- Patient has Eastern Cooperative Oncology Group performance status of less than or equal to 2.

Approval is for three months

C9068

HCPCS code C9068 is indicated for treatment of patients 18 years of age and older and is separately billable, not split-billable. Providers must complete the *CMS 1500* form and include the medically justified ICD-10-CM diagnosis. 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.

The recommended amount of radioactivity to be administered for PET imaging is 148 MBq (4 mCi) administered as an intravenous injection over a period of approximately one minute. Begin aqcqiring images 45 to 90 minutes after drug administration.

Maximum billing unit(s)= 4 mCi/ 4 units

Modifiers SA, UD, U7 and 99 are allowed.

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

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have an approval for a PET scan and the PET scan code must be billed on the same date of service
- Patient must have at least one of the following:
  - Confirmed or suspicion of neuroendocrine tumor (NET) based on histology/biopsy report.
  - Confirmed or suspicion of NET based on conventional imaging scans of affected area such as MRI and/or contrast enhanced CT and/or an FDG PET-CT scan and/or NaF PET-CT scan and/or OctreoScan® and/or clinical symptoms performed within 8 weeks prior to administration of Copper Cu 64 Dotatate.
- Patient must not be a pregnant or breast-feeding female
  - Breast feeding patients to interrupt breastfeeding for 12 hours after Detectnet

administration

- Patient does not have either of the following:
  - Therapeutic use of any somatostatin analogue, including Sandostatin® LAR and Lanreotide (within 28 days) and Sandostatin (within two days) prior to administration with Copper Cu 64 Dotatate.
  - History or presence of significant hematological abnormalities or immunodeficiency or any condition that might compromise the immune system (infections, vaccinations), of any etiology as indicated by clinically significantly abnormal values of any of the following hematologic parameters: platelets, hemoglobin, WBC count and ANC

Approval is for 3 months

Surgery

The following cardiology codes have special billing policy:

C9772, C9773, C9774, C9775

C9772, C9773, C9774, C9775

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.

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

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following:
  - Treatment-resistant depression (TRD).
  - Major depressive disorder (MDD) with acute suicidal ideation or behavior.
- Must be prescribed by or in consultation with a psychiatrist or other specialist in the treatment of disease.

A. Treatment-Resistant Depression (TRD)

Must meet the following criteria:

1. Diagnosis of Major Depressive Disorder (MDD) by Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria;
2. Patient must meet the DSM-5 diagnostic criteria for single-episode major depressive disorder (MDD) (if single-episode MDD, the duration must be two years or more) or recurrent MDD, without psychotic features, based upon clinical assessment.
3. Must have a documented therapeutic trial of antidepressants with inadequate response (less than or equal to 25 percent reduction on Montgomery-Asberg Depression Rating Scale [MADRS] with minimum score greater than or equal to 28 for adults, greater than or equal to 24 for geriatric) to treatment with at least prior two antidepressants from different classes, given at adequate dose and duration (at least six weeks), including in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced.
4. Must have a documented therapeutic trial (duration of six weeks or more) of antidepressant augmentation therapy in the current depressive episode with one or more of the following, unless contraindicated, clinically significant adverse effects are experienced, or patient is at high risk for suicidality:
   I. Atypical antipsychotic
   II. Lithium
   III. Antidepressant from a different class used in the previous therapeutic trials
   IV. Electroconvulsive therapy
   V. Transcranial Magnetic Stimulation (TMS)

B. Depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Must meet the following criteria:

1. Patient has a severe depressive episode (cannot care for self, participate in life, has persistent thoughts of hopelessness, persistently sad, anxious or "empty" mood, thoughts of suicide)

2. Provider has attested that acute psychiatric hospitalization is clinically warranted due to participant's imminent risk of suicide

- For both diagnoses:
  - Patient must have documentation of concurrent antidepressant therapy
  - Prescriber must attest that:
    - An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified
    - Dosing schedule has been reviewed with the patient
    - The patient understands and is committed to dosing schedule and requirements (e.g., treatment visits, transportation)
  - Patient does not have any of the following conditions:
    - Pregnancy
    - History of psychotic disorder (including MDD with psychotic symptoms), bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, borderline personality disorder, dementia or intellectual disability.
    - Other major medical conditions including coronary artery disease.

Initial approval is for three months.

Continuation of therapy:

- Patient continues to meet initial approval criteria
- Prescriber attestation of patient compliance with doses and treatment visits
- Attestation or documentation of improvement in diagnosis as evidenced by improvement in the same validated rating scale used for baseline depression assessment
- Documentation of concurrent use of antidepressant.

Reauthorization is for 12 months.

REMS

Spravato is available through a REMS program to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and abuse and misuse of Spravato by ensuring that:

- Spravato is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients.
- Ensuring pharmacies and healthcare settings that dispense Spravato are certified.
- Each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring.

  All patients who receive treatment are enrolled in an outpatient healthcare setting in a registry to further characterize the risks and support safe use.

HCPCS/CPT® Deleted Codes

Dental
D3427
D5994
D6052
D7960

Immunology
87450 (effective date 1/5/2020)

Medical Services
M1015
M1023
M1024
M1033
M1061
M1062
M1063
M1064
M1065
M1066
M1136
M1137
M1138
M1139
M1140
M1144

Outpatient Procedures
C9060
C9062
C9062
C9064
C9066
C9745
C9747
C9749

Procedures/ Professional Services
G0297
G1005
G1006
G2058
G2089
G2102
G2103
G2104
G2114
G2117
G2119
G2120
G2123
G2124
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G9265

Procedures/Professional Services (continued)

G9263
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