Q3 HCPCS Level I and II Update (July 1, 2023)

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

Note: The Policy PDF has been updated after its initial publication on June 30, 2023, to reflect the CMS-directed removal of J9321. The Medi-Cal Provider Manual will also reflect this change at a later update.

Q3 Code Additions

Chemotherapy

The following Chemotherapy codes have special billing policies:

J9029, J9056, J9058, J9059, J9063, J9259, J9322, J9323, J9347, J9350, J9380

J9029

Nadofaragene firadenovec-vncg (Adstiladrin®)

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
- Patient has a Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (CIS) with or without papillary tumors following transurethral resection
  - BCG-unresponsive high-risk NMIBC is defined as persistent disease following adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG
  - Adequate BCG is defined as the administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course
- Patient had declined or is ineligible for cystectomy
- Prior to treatment, patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components). Residual CIS (Tis components) not amenable to complete resection is allowed
- Patient does not have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma
- Patient is not immunosuppressed or immunodeficient
- Patient does not have a hypersensitivity to interferon alfa

Initial approval is for 6 months

Continuation of Therapy

- Patient continues to meet initial approval criteria
- Patient has experienced treatment response defined by stabilization of disease or decrease in size of tumor or tumor spread
- Patient does not have high-grade recurrence
- Patient does not have unacceptable toxicity

Reauthorization is for 12 months

Age must be 18 years of age or older.

Suggested ICD-10-CM Diagnosis Codes: C65.1, C65.2, C65.9

Frequency of billing equals 75 ml every 3 months for up to 12 months (four doses)

Maximum dose equals 75 mL (1 dose)/1 unit

Modifiers SA, UD, U7 and 99 are allowed.

J9056, J9058, J9059

Bendamustine

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
- Prescribed or in consultation by an oncologist
- Patient is at least 18 years of age
- Patient has chronic lymphocytic leukemia (CLL) or indolent B-cell non-Hodgkin lymphoma (NHL)

Chronic lymphocytic leukemia (CLL):

- Patient has not received bendamustine therapy in the past, unless otherwise specified
- Patient does not have autoimmune hemolytic anemia or autoimmune thrombocytopenia, Richter's syndrome, or transformation to prolymphocytic leukemia

Indolent B-cell non-Hodgkin lymphoma (NHL):

- Patient has not received bendamustine therapy in the past, unless otherwise specified
- Patient with relapse within 6 months of either the first dose (monotherapy) or last dose (maintenance regimen or combination therapy) of rituximab

Authorization is for 6 months.

Age must be 18 years of age or older.

Frequency of billing equals
CLL: Days 1 and 2 of a 28-day cycle, up to 6 cycles
NHL: Days 1 and 2 of a 21-day cycle, up to 8 cycles

Modifiers SA, UD, U7 and 99 are allowed.

J9063

Mirvetuximab Soravtansine-gynx (Elahere™)

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
- Prescribed by or in consultation with an oncologist
- Patient must be 18 years of age or older
- Patient has tumors that are positive for FRα expression
- Patient has not responded to or is no longer responding to treatment with platinum-based chemotherapy
- Conduct an ophthalmic exam (visual acuity and slit lamp exam) prior to initiation of mirvetuximab soravtansine, every other cycle for the first 8 cycles, and as clinically indicated
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Patient has received one to three prior systemic treatment regimens, including at least one line of therapy containing bevacizumab
- Patient does not have moderate or severe hepatic impairment (total bilirubin more than 1.5 ULN)

Initial approval is for 6 months.

Continued Therapy

- Patient continues to meet initial approval criteria
- Patient has experienced positive clinical response as evidenced by disease stabilization, decrease in tumor size, or lack of tumor spread
- Patient has unacceptable toxicity such as ocular toxicities, pneumonitis, severe peripheral neuropathy, pulmonary toxicity, etc.

Reauthorization is for 12 months.

Age must be 18 years of age or older.

Suggested ICD-10 Diagnosis Codes: C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8

Modifiers SA, UD, U7 and 99 are allowed.

J9259

Paclitaxel Protein-Bound Particles (American Agent)

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

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

Universal Criteria

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

- Patient must be 18 years of age or older
- Patient must have one of the following diagnoses:

Breast cancer, metastatic:

- Patient has a diagnosis of breast cancer
- Disease is metastatic
- Patient had failed combination chemotherapy for metastatic disease or had a relapse within 6 months of adjuvant chemotherapy
  - Prior therapy must include an anthracycline (for example, doxorubicin, pegylated liposomal doxorubicin, epirubicin) unless clinically contraindicated

Non-small cell lung cancer, locally advanced or metastatic:

- Patient has a diagnosis of non-small cell lung cancer
- Disease is locally advanced or metastatic
- Drug is first-line treatment (in combination with carboplatin)
- Patient is not a candidate for curative surgery or radiation therapy

Pancreatic adenocarcinoma, metastatic:

- Patient has a diagnosis of pancreatic adenoma
- Disease is metastatic, unresectable, or borderline resectable
- Drug is first-line treatment in combination with gemcitabine

Initial approval is for 6 months

Continuation of Therapy

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

Reauthorization is for 12 months.

Age must be 18 years of age or older.

Suggested ICD-10-CM Diagnosis Codes: C25.00 thru C25.3, C25.7 thru C25.9, C34.00 thru C34.92, C50.011 thru C50.929

Modifiers SA, UD, U7 and 99 are allowed.

J9322, J9323

Pemetrexed (Alimta®, Teva, Accord, Hospira and Bluepoint)

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

Age must be 18 years of age or older.

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

Modifiers SA, UD, U7 and 99 are allowed.

J9347

Tremelimumab-actl (Imjudo®)

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

Age must be 18 years of age or older.

Frequency of billing:

- Unresectable Hepatocellular Carcinoma (uHCC): 300 mg/300 units one time only
- Metastatic non-small cell lung cancer (NSCLC): 75 mg/75 units per 4 doses every 21 days, followed by 75 mg/75 units per 1 dose after 28 days (on day 112)

Modifiers SA, UD, U7 and 99 are allowed.

J9350

Mosunetuzumab-axgb (Lunsumio™)

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

Age must be 18 years of age or older.

Suggested ICD-10-CM Diagnosis Codes: C82.00 thru C82.09, C82.10 thru C82.19, C82.20 thru C82.29, C82.30 thru C82.39, C82.80 thru C82.89, C82.90 thru C82.99

Frequency of billing equals 60 mg/60 units every seven days.

Maximum billing units equals 60 mg/60 units.

Modifiers SA, UD, U7 and 99 are allowed.

J9380

Teclistamab-cgyv (TECVAYLI™)

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

Age must be 18 years of age or older.

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

Modifiers SA, UD, U7 and 99 are allowed.

Injection

The following Injection codes have special billing policies:

C9151, J0137, J0206, J0216, J0457, J0665, J0736, J0737, J1576, J1805, J1806, J1811, J1812, J1813, J1814, J1836, J1920, J1921, J1941, J1961, J2249, J2305, J2329, J2371, J2372, J2427, J2561, J2598, J2599, J9381, Q5131

C9151

Pegcetacoplan (Empaveli™)

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 at least 18 years of age or older
- Must be prescribed by or in consultation with a hematologist
- Patient must have a primary diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by high-sensitivity flow cytometry

- Patient has a hemoglobin level less than 10 g/dL
- Patient has lactate dehydrogenase (LDH) at least 1.5 times the upper limit of normal (ULN) at baseline
- Patient must be vaccinated against meningococcal infections, Streptococcus pneumoniae and Haemophilus influenzae Type B (Hib) within 2 years prior to, or at the time of initiating Empaveli. If Empaveli is initiated less than 2 weeks after vaccination, patients must receive prophylactic antibiotics until 2 weeks after vaccination
- Patient does not have hepatitis B, C, or HIV infections
- Patient does not have hereditary complement deficiency
- Patient does not have history of bone marrow transplantation
- Patient is not on concurrent complement inhibitor for PNH, unless plan is to change therapy
  - If switching to Empaveli from C5 inhibitors (eg, eculizumab, ravulizumab):
    - ❖ Switching from eculizumab: Initiate Empaveli while continuing eculizumab at its current dose; after four weeks, discontinue eculizumab before continuing on monotherapy with Empaveli
    - ❖ Switching from ravulizumab: Initiate Empaveli no more than four weeks after last ravulizumab dose
- The healthcare provider is enrolled in Empaveli REMS

Initial authorization is for six months.

Continued Treatment

Patient has shown significant clinical response as evidenced by one of the following:

- Hemoglobin stabilization in the absence of transfusion
- Hemolysis control measured by lactic acid dehydrogenase (LDH) reduction from pretreatment baseline
- Transfusion avoidance defined as elimination of transfusion requirements or reduced need for transfusions
- Improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score

Reauthorization is for 12 months.

Empaveli REMS

Because of the risk of serious infections, Empaveli is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)

Under the Empaveli REMS, prescribers must do the following:

- Enroll in the program
- Counsel patients about the risk of serious infection
- Provide the patients with the REMS educational materials
- Ensure patients are vaccinated against encapsulated bacteria

Enrollment and additional information are available by telephone: 1-888-343-7073 or at the EMPAVELI REMS website.

Age must be 18 years of age or older.

Required ICD-10-CM Diagnosis Code: D59.5

Frequency of billing equals 1,080 mg/1,080 units twice weekly.

Maximum billing unit(s) equals 1,080 mg/1,080 units.

Modifiers SA, UD, U7 and 99 are allowed.

J0137

Acetaminophen

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

Frequency of billing equals 4,000 mg/400 units per day.

Maximum billing unit(s) equals 4,000 mg/400 units.

Modifiers SA, UD, U7 and 99 are allowed.

J0206

Allopurinol Sodium for Injection (Aloprim®)

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

The TAR must include clinical documentation that demonstrates the following:

- Prescribed for FDA-approved indications and dosing regimens
- Prescribed by or in consultation with an oncologist
- Patient receiving cancer therapy which causes elevations of serum and urinary uric acid levels
- Patient cannot tolerate oral allopurinol
- Patient is not known to be at risk of allopurinol hypersensitivity syndrome (AHS) or not a carrier of HLA-B*58:01 allele

Authorization is for six months.

Modifiers SA, UD, U7 and 99 are allowed.

J0216

Alfentanil Hydrochloride (Alfenta®)

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

The TAR must include clinical documentation that demonstrates the following:

- Must be for FDA-approved indications and dosing regimens
- Must be prescribed by or in consultation with a pain specialist in accordance with the Clinical Practice Guidelines for Prescribing Opioids
- Must be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids in accordance to Infusion Dosage Guidelines for Continuous Infusion

- Patient must be 12 years of age or older
- Patient does not have:
  - Severe sleep apnea syndrome (apnea-hypopnea index is more than 40) or baseline hypoxia with measured peripheral capillary oxygen saturation (SpO_2) is less than 90 percent in room air
  - A history of alcohol abuse or current use of any psychiatric medication
  - Neurologic disorders or other conditions contributing to difficulty in assessing a conscious response

Approval is for 30 days (treatment duration will be for the length of the medical procedure).

Age must be 12 years of age or older.

Modifiers SA, UD, U7 and 99 are allowed.

J0457

Aztreonam

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

Modifiers SA, UD, U7 and 99 are allowed.

J0665

Bupivacaine Hydrochloride

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

Modifiers SA, UD, U7 and 99 are allowed.

J0736, J0737

Clindamycin Phosphate

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

Modifiers SA, UD, U7 and 99 are allowed.

J1576

Immune Globulin (Panzyga)

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

TARs may be approved for any of the FDA-approved indications. In many instances, immune globulin is not considered first line therapy and may be used as second line therapy or in special circumstances. The TAR must not only state the diagnoses but also must contain sufficient clinical information to establish medical necessity.

Immune globulin may be administered intravenously, intramuscularly or subcutaneously. In most cases, products are designed for a specific route of administration, although some preparations designed for intravenous administration can also be given subcutaneously. Subcutaneous and intramuscular products are generally more concentrated than intravenous preparations.

Age must be two years of age or older.

Modifiers SA, UD, U7 and 99 are allowed.

J1805, J1806

Esmolol Hydrochloride (BREVIBLOC)

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

Modifiers SA, UD, U7 and 99 are allowed.

J1811

Insulin aspart (Fiasp®)

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

Maximum dose equals 200 units/4 units

Modifiers SA, UD, U7 and 99 are allowed.

J1812

Insulin aspart (Fiasp®)

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

Modifiers SA, UD, U7 and 99 are allowed.

J1813, J1814

Insulin lispro-aabc (Lyumjev™)

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

Modifiers SA, UD, U7 and 99 are allowed.

J1836

Metronidazole

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

Maximum billing unit(s) equals 400 units/day.

Modifiers SA, UD, U7 and 99 are allowed.

J1920, J1921

Labetalol (Trandate)

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

Maximum billing unit(s) equals 300 mg/60 units.

Modifiers SA, UD, U7 and 99 are allowed.

J1941

Furosemide (FUROSCIX)

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 dosage
- Patient has a diagnosis of NYHA Class II or Class III chronic heart failure
- Patient must be 18 years of age or older

- Patient has an active prescription for an oral diuretic, equivalent to a daily total furosemide dose of 40 to 160 mg
- Provider attests that the patient is showing signs of volume expansion due to chronic heart failure
- Provider must show justification for failure to use furosemide intravenous injection
- Patient is stable and suitable for at-home treatment with parenteral diuresis as evidenced by all of the following:
  - Oxygen saturation is at least 90 percent on exertion
  - Respiratory rate is less than 24 breaths per minute
  - Resting heart rate is less than 100 beats per minute
  - Systolic blood pressure is more than 100 mmHg

Authorization is for 12 months.

Age must be 18 years of age or older.

Maximum billing unit(s) equal 80 mg/4 units.

Modifiers SA, UD, U7 and 99 are allowed.

J1961

Lenacapavir (Sunlenca®)

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

Age must be 18 years of age or older.

Required ICD-10-CM Diagnosis Code: B20

Frequency of billing equals 927 mg/927 units every 24 weeks from the date of previous injection

Maximum billing unit(s) equals 927 mg/927 units

Modifiers SA, UD, U7 and 99 are allowed.

J2249

Remimazolam (Byfavo®)

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

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

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient has American Society of Anesthesiologists (ASA) Physical Status Score I-III or III-IV (at the discretion of the physician)
- Drug is being used for the induction and maintenance of procedural sedation
- Procedure is expected to last 30 minutes or less (for example, colonoscopy, bronchoscopy, etc.)
- Documentation of reason why midazolam or proprofol is not appropriate for patient

- Patient is not a pregnant or lactating female
- Patient has no known sensitivity to benzodiazepines, flumazenil, opioids, naloxone, or a medical condition such that the use of these medications is contraindicated

Authorization is for one procedure.

Age must be 18 years of age or older.

Modifiers SA, UD, U7 and 99 are allowed.

J2305

Nitroglycerin

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

Modifiers SA, UD, U7 and 99 are allowed.

J2329

Ublituximab-xiiy (Briumvi™)

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 relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)
- Documentation of MRI of brain with abnormalities consistent with MS
- Greater than or equal to two relapses in prior two years or one relapse in the prior year and/or greater than or equal to one T1 gadolinium (Gd) enhancing lesion in the prior year
- No active HBV confirmed by positive results for Hepatitis B surface antigen (HBsAg) and anti-HBV tests
- Must monitor levels of immunoglobulins at the beginning, during, and after discontinuation of treatment
  - Ubilituximab is not covered in presence of documented persistent hypogammaglobulinemia, unless provider submits documentation demonstrating that there is no effective alternative treatment
- Expanded Disability Status Scale (EDSS) 0 to 5.5
- Not pregnant or nursing
- Patient does not have Primary Progressive MS (PPMS)

Initial Authorization is up to 12 months.

Continued Treatment

Patient has experienced positive clinical response as evidenced by improvement or stability in disease activity, or slowing of disability, based on at least one of the following from baseline:

- Reduction or stabilization in the total number of magnetic resonance imaging (MRI) T1 gadolinium-enhancing lesions
- Reduction or stabilization in the total number of new or enlarging MRI T2 hyperintense lesions.
- Lack of disability progression, defined as an increase in Expanded Disability Status Scale (EDSS) score.
- Stabilization, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.

Reauthorization is up to 12 months.

Age must be 18 years and older.

Required ICD-10 Diagnosis Code: G35

Frequency of billing initial equals 150 mg/150 units on day 1, followed by 450 mg/450 units 2 weeks after, then 450 mg/450 units every 24 weeks.

Maximum billing unit(s) equals 450 mg/450 units.

Modifiers SA, UD, U7 and 99 are allowed.

J2371

Phenylephrine Hydrochloride

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

Modifiers SA, UD, U7 and 99 are allowed.

J2372

Phenylephrine Hydrocholoride (Biorphen)

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

Modifiers SA, UD, U7 and 99 are allowed.

J2427

Paliperidone Palmitate (Invega Sustenna®, Invega Trinza®, Invega Hafyera™)

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

Age must be 18 years of age or older.

Suggested ICD-10-CM Diagnosis Codes:

F20, F20.0, F20.1, F20.2, F20.3, F20.5, F20.8, F20.9

Invega Sustenna only: F25.0, F25.1, F25.9

Modifiers SA, UD, U7 and 99 are allowed.

J2561

Phenobarbital Sodium (Sezaby™)

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

Modifiers SA, UD, U7 and 99 are allowed.

J2598, J2599

Vasopressin

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

Age must be 18 years of age or older.

Modifiers SA, UD, U7 and 99 are allowed.

J9381

Teplizumab-mzwv (TZIELD™)

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 8 years of age or older
- Must be prescribed by or in consultation with an endocrinologist
- Patient has a diagnosis of Stage 2 type 1 diabetes (TID) confirmed by at least two positive pancreatic islet cell autoantibodies:
  - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Insulin autoantibodies (IAA)
  - Insulinoma-associated antigen 2 autoantibodies (IA-2A)
  - Zinc transporter 8 autoantibodies (ZnT8A)
  - Islet-cell autoantibodies (ICA)
- Patient has dysglycemia (abnormal blood glucose) without overt hyperglycemia defined using an oral glucose tolerance test (OGTT) OR alternative method if appropriate and OGTT is not available:
  - According to the American Diabetes Association (ADA) 2022 Standards of Medical Care in Diabetes, dysglycemia may be diagnosed based on any of the following:
    - 2-hour plasma glucose (PG) level of 140 to 199 mg/dL (7.8 to 11.0 mmol/L) during OGTT
    - A fasting plasma glucose (FPG) level of 100 to 125 mg/dL (5.6 to 6.9 mmol/L)
- Patient does not have any of the following:
  - Stage 3 type 1 diabetes
  - Clinical history consistent with type 2 diabetes
  - An active serious infection or chronic infection, including but not limited to Epstein-Barr virus or cytomegalovirus.
  - Serological evidence of past current or past HIV, hepatitis B, or hepatitis C infection
  - Prior treatment with other monoclonal antibody in past one year

- CBC and liver chemistries do not show any of the following lab abnormalities
  - Lymphocyte count less than 1,000 lymphocytes/mcL
  - Hemoglobin less than 10 g/dL
  - Platelet count less than 150,000 platelets/mcL
  - Absolute neutrophil count less than 1,500 neutrophils/mcL
  - Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN

Initial authorization is for 3 months (14 day treatment course).

Reauthorization is not approvable.

Age must be 8 years of age or older.

Required ICD-10-CM Diagnosis Codes: E10.8, E10.9

Frequency of billing is one treatment in a lifetime.

Modifiers SA, UD, U7 and 99 are allowed.

Q5131

Adalimumab-aacf (Idacio®)

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

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

Universal criteria:

- Must be used for FDA-approved indications and dosages
- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection
- Patient will not be taking Idacio concurrently with any of the following:
  - Biologic DMARDs (Remicade, Enbrel or Humira), Consentyx (secukinumab), Simponi (golimumab)
  - Janus kinase inhibitor (for example, Xeljanz [tofacitinib])
  - Phosphodiesterase 4 (PDE4) inhibitor (for example, Otezla [apremilast])
- Patient must have one of the following diagnoses:

Rheumatoid Arthritis

- Documented diagnosis of Rheumatoid Arthritis (RA)
- Patient must be 18 years of age or older
- Patient must have a history of failure to a three-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD), (for example, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine), at maximally indicated doses within the last six months, unless intolerant, contraindicated or clinically inappropriate; OR
  - For use as an alternative to methotrexate in DMARD–naive patients with moderate to high disease activity, or as adjunctive therapy in patients who have not met treatment goals despite maximally tolerated methotrexate therapy

- Idacio may be used alone or in combination with other non-biologic DMARDs, glucocorticoids, non-steroidal anti-inflammatory drugs (NSAIDs), and/or analgesics

Juvenile Idiopathic Arthritis

- Documented diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis
- Patient mut be 2 years of age or older
- Inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: NSAID plus a glucocorticoid with or without methotrexate, etc., unless clinically inappropriate
- Idacio may be used alone or in combination with methotrexate

Psoriatic Arthritis

- Documented diagnosis of active psoriatic arthritis
- Patient must be 18 years of age or older
- Patient must have a history of failure of a three-month trial of at least one conventional Disease-Modifying Antirheumatic Drugs (DMARDS) such as methotrexate at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate
- Idacio can be used alone or in combination with non-biologic DMARDS, for example methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, etc.
- May continue methotrexate, other non-biologic DMARDs, corticosteroids, NSAIDs, and/or analgesics with Idacio

Ankylosing Spondylitis

- Documented diagnosis of active ankylosing spondylitis
- Patient must be 18 years of age or older
- Patient must have a history of inadequate response, intolerance or contraindication to at least two NSAIDs, for example, Ibuprofen, Naproxen, etc., unless clinically inappropriate

Crohn’s Disease

- Documented diagnosis of moderately to severely active Crohn’s disease
- Patient must be 6 years of age or older
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates (eg, sulfasalazine, mesalamine), glucocorticoids (eg, prednisone, budesonide), immunomodulators (eg, azathioprine, 6-mercaptopurine, methotrexate); unless clinically inappropriate
- Idacio therapy may be combined with an immunomodulator (ie, thiopurine or methotrexate)

Ulcerative Colitis, Moderate-To-Severe

- Documented diagnosis of moderately to severely active ulcerative colitis

- Patient must be 18 years of age or older
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates (eg, sulfasalazine, mesalamine), glucocorticoids (eg, prednisone, budesonide), immunomodulators (eg, azathioprine, 6-mercaptopurine, methotrexate), unless clinically inappropriate

Plaque Psoriasis

- Documented diagnosis of chronic moderate to severe plaque psoriasis
- Patient must be 18 years of age or older
- Patient is a candidate for systemic therapy or phototherapy
- Patient must have a history of failure of one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced. Corticosteroids (for example, betamethasone, clobetasol, desonide), Vitamin D analogs (for example, calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (for example, tacrolimus, pimecrolimus), Anthralin, coal tar or phototherapy
- Idacio is generally used as systemic monotherapy; may continue adjuvant topical therapies (eg, emollients, corticosteroids) as needed

Initial authorization is for 12 months.

Continued Therapy

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

Reauthorization is for 12 months.

Modifiers SA, UD, U7 and 99 are allowed.

Non Injection

The following Non Injection code has special billing policies:

J1440

J1440

Fecal Microbiota, Live – jslm (Rebyota™)

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

Must submit clinical documentation to substantiate the following:

- May be used for FDA-approved indications and dosages
- Patient is 18 years of age or older
- Patient has a diagnosis of recurrent clostridioides difficile infection (CDI) defined by one of the following:
  - Had at least two recurrences after a primary episode and had completed at least one round of standard-of-care oral antibiotic therapy (for example, vancomycin, metronidazole, fidaxomicin)

  - Had at least two episodes of severe CDI resulting in hospitalization within the last year
- The current episode of CDI was confirmed with a positive stool test for clostridiodes difficile toxin
- Rebyota will be administered 24 to 72 hours after the last dose of antibiotics for the current episode of CDI
- Patient has not received bezlotoxumab (Zinplava) within the last year

Authorization is for six months (up to two doses).

Age must be 18 years of age or older.

Frequency of billing equals 150 ml/150 units as a single dose (up to two doses in six months).

Maximum billing unit(s) equals 150 ml/150 units.

Modifiers SA, UD, U7 and 99 are allowed.

Proprietary Laboratory Analyses (PLA)

The following PLA codes have special billing policies.

0388U, 0391U, 0397U

0388U, 0397U

Modifiers 33, 90 and 99 are allowed.

Frequency is limited to once in a lifetime.

TAR requires documentation of the following criteria:

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

0391U

Modifiers 33, 90 and 99 are allowed.

Frequency is limited to once in a lifetime.

Radiology

The following radiology code has special billing policies:

C9150

C9150

Modifiers SA, U7 and 99 are allowed.

Skin Substitutes

The following skin substitute codes have special billing policies:

Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284

Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284

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

Modifiers SA, U7 and 99 are allowed.

Q3 Code Deletions

Table of HCPCS Q3 Code Deletions

Effective July 1, 2023

Subject	Deleted Code
Chemotherapy	C9146 (replaced with J9063)
Injections	C9147 (replaced with J9347) C9148 (replaced with J9381) C9149 (replaced with J9381) J2370 (replaced with J2371, J2372) S0020 (replaced with J0665) S0077 (replaced with J0736, J0737)
Proprietary Laboratory Analyses	0053U 0143U thru 0150U