
Chemotherapy: Drugs P-Z Policy

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This section contains policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Chemotherapy: An Overview* section in this manual. Additional policy information for chemotherapy drug services can be found in the *Chemotherapy: Drugs A-D* and *Chemotherapy: E-O* sections in this manual.

Paclitaxel

Paclitaxel is a natural product with antitumor activity and is obtained via a semi-synthetic process from *Taxis baccata*. It is an antimicrotubule agent that promotes the assembly of microtubules from tubulin dimmers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions.

Indications

Paclitaxel is indicated for a wide variety of cancers.

Dosage

The maximum dosage is 575 mg per day.

Inpatient Billing

Paclitaxel may be administered to inpatients by intravenous infusion over a 24-hour period, frequently in an inpatient setting, due to the occurrence of hypersensitivity reactions, which can be serious. Administration in an inpatient setting is not separately reimbursable.

Outpatient Billing

Paclitaxel may be administered as a multi-hour intravenous infusion utilizing CPT® codes 96413 and 96415. CPT code 96415 is reimbursable for a maximum of one additional hour of administration. However, when it is billed in conjunction with paclitaxel, the CPT code may be billed twice and a maximum of two additional hours may be reimbursed. For more information about billing CPT codes 96413 and 96415, see “Intravenous Infusion” in the *Chemotherapy: An Overview* section of this manual.

Billing

HPCS code J9267 (injection, paclitaxel, 1 mg)

Paclitaxel Protein-Bound Particles

The active agent in paclitaxel protein (albumin)-bound particles is paclitaxel. These particles are microtubule inhibitors that promote the assembly of microtubules from tubulin dimers and stabilize microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Paclitaxel induces abnormal arrays or “bundles” of microtubules throughout the cell cycles and multiple asters of microtubules during mitosis.

Indications

Paclitaxel protein-bound particles are indicated for the treatment of the following:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic non-small cell lung cancer, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation treatment
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine

Dosage

Recommended dosage:

- Metastatic breast cancer: 260 mg/m² intravenously over 30 minutes every three weeks
- Non-small cell lung cancer: 100 mg/m² intravenously over 30 minutes on days 1, 8 and 15 of each 21-day cycle in combination with carboplatin
- Metastatic adenocarcinoma of the pancreas: 125 mg/m² over 30 - 40 minutes on days 1, 8 and 15 of each 28-day cycle. Administer gemcitabine on days 1, 8 and 15 of each 28-day cycle immediately after paclitaxel protein-bound particles.

Required Codes

Paclitaxel protein-bound particles (J9264) is reimbursable when billed in conjunction with one of the following ICD-10-CM codes:

C25.0 thru C25.3

C34.00 thru C34.92

C25.7 thru C25.9

C50.011 thru C50.929

Billing

HCPCS code J9264 (injection, paclitaxel protein-bound particles, 1 mg)

Panitumumab

Panitumumab is reimbursable for the treatment of malignant neoplasm of the colon, rectum and rectosigmoid junction.

Dosage

The normal dose is 6 mg/kg with a maximum of 680 mg/day.

Required Codes

Claims must be billed with ICD-10-CM diagnosis codes C18.0 thru C20 or C21.8.

Billing

HCPCS code J9303 (injection, panitumumab, 10 mg)

Providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim, or on an attachment, that the patient weighs more than 113 kg to justify reimbursement for a quantity greater than 680 mg/day. For quantities exceeding the daily limitations, appropriate documentation is required.

Billing Restrictions for Codes J9303 and J9055

Code J9303 will not be reimbursed if J9055 (injection, cetuximab, 10 mg) has been reimbursed in history and J9055 will not be reimbursed if J9303 has been reimbursed in history. However, both drugs may be reimbursed when given sequentially separated by one (1) or more days if the provider establishes medical necessity (for example, intolerant to the first drug) either in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim or with attached information.

Pegaspargase

Pegaspargase (HCPCS code J9266) is reimbursable for acute lymphoid leukemia. Code J9266 must be billed in conjunction with an ICD-10-CM diagnosis code in the range C91.00 thru C91.02. The maximum reimbursable dosage per day is two single dose vials.

Pegfilgrastim-bmez (Ziextenzo)

Pegfilgrastim is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. It stimulates the production, maturation, and activation of neutrophils and activates neutrophils to increase both their migration and cytotoxicity.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age

All ages

Billing

HCPCS code «Q5120» (injection, pegfilgrastim-bmez, biosimilar [ziextenzo], 0.5 mg)

Prescribing Restrictions

Frequency of billing = 6 mg/12 units per chemotherapy cycle

Maximum billing units = 6 mg/12 units

Pegfilgrastim-jmdb

Pegfilgrastim-jmdb is a leukocyte growth factor for subcutaneous (SQ) injection. Pegfilgrastim-jmdb is biosimilar to pegfilgrastim.

Indications

Pegfilgrastim-jmdb is reimbursable when used to reduce the incidence of neutropenia-related infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Age

All ages

Dosage

For patients who weigh greater than or equal to 45 kg, a single 6 mg SQ injection is administered once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. Pegfilgrastim-jmdb should not be administered within the time period of 14 days before starting chemotherapy and until 24 hours after ending chemotherapy.

For patients who weigh less than or equal to 45 kg, two SQ injection doses are administered one week apart based on the patient's body weight.

Weight	Dosage
less than 10 kg	0.1 mg/kg
10 to 20 kg	0.1 mg/kg
21 to 30 kg	0.1 mg/kg
21 to 30 kg	0.1 mg/kg

Authorization

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

Required Codes

One of the following ICD-10-CM diagnosis codes is required for reimbursement:

- D70.1 (Agranulocytosis secondary to cancer chemotherapy)
- Z51.11 (Encounter for antineoplastic chemotherapy)

Billing

HCPCS code Q5108 (injection, pegfilgrastim-jmdb, biosimilar [fulphila], 0.5 mg)

One (1) unit of Q5108 = 0.5 mg of pegfilgrastim-jmdb

Pembrolizumab

Pembrolizumab is an IgG4 kappa humanized monoclonal antibody that binds to the programmed death-1 (PD-1) receptor and blocks its interaction with PD-1 ligands PD-L1 and PG-L2. Binding of the PD-1 receptor to the PD-1 ligands inhibits T-cell proliferation and cytokine production resulting in inhibition of active T-cell immune surveillance of tumors. The binding of pembrolizumab to the PD-1 receptor blocks its interaction with the PD-1 ligands thereby releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor response.

Indications

For the treatment of patients 18 years of age and older with:

- Unresectable or metastatic melanoma.
- Metastatic non-small cell lung cancer whose tumors express PD-L1 as determined by an FDA-approved test with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab.

Authorization

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

Dosage

The recommended dosage is 2 mg/kg as an intravenous infusion every three weeks until disease progression or unacceptable toxicity.

Billing

HCPCS code J9271 (injection, pembrolizumab, 1 mg)

«Pemetrexed (Pemfexy)

Pemetrexed is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication. In vitro studies show that pemetrexed inhibits thymidylate synthase (TS), dihydrofolate reductase (DHFR) and glycinamide ribonucleotide formyltransferase (GARFT), which are folate-dependent enzymes involved in the de novo biosynthesis of thymidine and purine nucleotides. Pemetrexed is taken into cells by membrane carriers, such as the reduced folate carrier and membrane folate binding protein transport systems. Once in the cell, pemetrexed is converted to polyglutamate forms by the enzyme folylpolyglutamate synthetase. The polyglutamate forms are retained in cells and are inhibitors of TS and GARFT.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Pemfexy (pemetrexed) is considered medically necessary when the following criteria are met:

- I. Must be used for FDA labelled indications and dosing regimens
- II. Patient must be 18 years of age or older
- III. Patient has a diagnosis of malignant pleural mesothelioma; and
 - Used in combination with a cisplatin- or carboplatin-based regimen; or
 - Used as a single agent therapy; or
 - Used in combination with bevacizumab and either cisplatin or carboplatin followed by single-agent bevacizumab maintenance therapyand
 - Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; and
 - Patient's disease presentation is unresectable; or>>

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

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

Initial approval is for 6 months.

Continuation of therapy:

- Patient continues to meet initial coverage criteria
- Patient shows positive clinical response as evidenced by disease stabilization or lack of disease progression

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9304 (injection, pemetrexed [pemfexy], 10 mg)

Providers may bill for Alimta using HCPCS code J9305 with no TAR submission.

Suggested ICD-10-CM Diagnosis Codes

C34.00 thru C34.92 or C45.0 thru C45.9.

Prescribing Restrictions

Frequency of billing = 500 mg/m² on day 1 of each 21-day cycle.»

Pemetrexed «(Alimta)

Alimta is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication. In vitro studies show that pemetrexed inhibits thymidylate synthase (TS), dihydrofolate reductase, and glycinamide ribonucleotide formyltransferase (GARFT), which are folate-dependent enzymes involved in the de novo biosynthesis of thymidine and purine nucleotides. Pemetrexed is taken into cells by membrane carriers such as the reduced folate carrier and membrane folate binding protein transport systems. Once in the cell, pemetrexed is converted to polyglutamate forms by the enzyme folylpolyglutamate synthetase. The polyglutamate forms are retained in cells and are inhibitors of TS and GARFT.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J9305 (injection, pemetrexed, «not otherwise specified,» 10 mg)

Partial Dose Is Reimbursable

Providers may bill for an entire vial of pemetrexed when it is necessary to discard the unused portion of the vial because only a partial dose was required to treat the patient.

«Suggested ICD-10-CM Diagnosis Codes

C34.00 thru C34.92 or C45.0 thru C45.9.»

Pertuzumab

Pertuzumab is a recombinant humanized monoclonal antibody that targets the extracellular dimerization domain (Subdomain II) of the human epidermal growth factor receptor 2 protein (HER2). Pertuzumab targets the extracellular dimerization domain of HER2 and, thereby, blocks ligand-dependent heterodimerization of HER2 with other HER family members, including EGFR, HER3 and HER4. As a result, pertuzumab inhibits ligand-initiated intracellular signaling through two major signal pathways, mitogen-activated protein (MAP) kinase and phosphoinositide 3-kinase (PI3K). Inhibition of these signaling pathways can result in cell growth arrest and apoptosis, respectively. In addition, pertuzumab mediates antibody-dependent cell-mediated cytotoxicity (ADCC).

Indications

Pertuzumab is indicated for:

- Use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease
- Use in combination with trastuzumab and docetaxel as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.

Dosing

Please refer to the appropriate literature for recommended dosing schedules.

The maximum dose is 840 mg/day.

Required code

Pertuzumab is reimbursable when billed in conjunction with an ICD-10-CM diagnosis code in the range C50.011 thru C50.929.

Billing

HCPCS code J9306 (injection, pertuzumab, 1 mg)

«Pertuzumab, trastuzumab, and hyaluronidase-zzxf injection (Phesgo)

Pertuzumab targets the extracellular dimerization domain (subdomain II) of human epidermal growth factor receptor 2 (HER2) and, thereby, blocks ligand-dependent heterodimerization of HER2 with other HER family members, including epidermal growth factor receptor (EGFR), human epidermal growth factor receptor 3 (HER3) and human epidermal growth factor receptor 4 (HER4). As a result, pertuzumab inhibits ligand-initiated intracellular signaling through two major signaling pathways, mitogen-activated protein (MAP) kinase and phosphoinositide 3-kinase (PI3K). Inhibition of these signaling pathways can result in cell growth arrest and apoptosis, respectively.

Trastuzumab binds to subdomain IV of the extracellular domain of the HER2 protein to inhibit the ligand-independent, HER2 mediated cell proliferation and PI3K signaling pathway in human tumor cells that overexpress HER2.

Both pertuzumab and trastuzumab-mediated antibody-dependent cell-mediated cytotoxicity (ADCC) have been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2.

While pertuzumab alone inhibited the proliferation of human tumor cells, the combination of pertuzumab and trastuzumab augmented anti-tumor activity in HER2-overexpressing xenograft models.

Hyaluronan is a polysaccharide found in the extracellular matrix of the subcutaneous tissue. It is depolymerized by the naturally occurring enzyme hyaluronidase. Unlike the stable structural components of the interstitial matrix, hyaluronan has a half-life of approximately 0.5 days. Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. In the doses administered, hyaluronidase in Phesgo acts transiently and locally.

The effects of hyaluronidase are reversible and permeability of the subcutaneous tissue is restored within 24 to 48 hours. Hyaluronidase has been shown to increase the absorption rate of a trastuzumab product into the systemic circulation when given in the subcutis of Göttingen Minipigs.

Indications

All FDA-approved indications

Dosing

FDA-approved dosages»

«TAR Requirement

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9316 (injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg)

Prescribing Restrictions

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»

Polatuzumab vedotin-piiq (Polivy)

Polatuzumab vedotin-piiq is an antibody that is attached to a chemotherapy drug. Polivy binds to a specific protein (called CD79b) found only on B cells (a type of white blood cell), then releases the chemotherapy drug into those cells. Polatuzumab vedotin-piiq is a CD79b-directed antibody-drug conjugate with activity against dividing B cells. The small molecule, MMAE is an anti-mitotic agent covalently attached to the antibody via a cleavable linker. The monoclonal antibody binds to CD79b, a B-cell specific surface protein, which is a component of the B-cell receptor. Upon binding CD79b, polatuzumab vedotin-piiq is internalized, and the linker is cleaved by lysosomal proteases to enable intracellular delivery of MMAE. MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Requirement* (TAR) is not required for reimbursement. The TAR must demonstrate clinical documentation of the following:

- FDA-approved indications and dosages; and
- A diagnosis of diffuse large B-cell lymphoma (DLBCL); and
- Must be 18 years of age or older; and
- The patient has relapsed or refractory disease; and
- Polatuzumab vedotin is administered in combination with bendamustine and a rituximab product; and
- The patient has received at least two prior systemic chemotherapies; and
- The patient is not a candidate for autologous hematopoietic stem cell transplantation (HSCT); and
- The patient has not previously undergone allogeneic HSCT; and
- The patient does not have active central nervous system lymphoma or histologically transformed lymphoma

Authorization will be for 12 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J9309, injection, polatuzumab vedotin-piiq, 1 mg

Suggested Codes

ICD-10 CM diagnosis codes C83.30 thru C83.39

Prescribing Restrictions

Frequency of billing = Every 21 days for 6 cycles

Maximum billing unit(s) = 409.1 mg = 409.1 units

Pralatrexate

Pralatrexate is reimbursable for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. It is a folate analog metabolic inhibitor that competitively inhibits dihydrofolate reductase. It is also a competitive inhibitor for polyglutamylation by the enzyme folypolyglutamyl synthetase. This inhibition results in the depletion of thymidine and other biological molecules the synthesis of which depends on single carbon transfer.

Dosage

The recommended dose is 30 mg/m² administered as an intravenous push over 3 - 5 minutes once weekly for six weeks in seven-week cycles until progressive disease or unacceptable toxicity develops.

A dosage more than 80 mg is allowed with documentation that the patient's body surface area is greater than 2.67 m².

Vitamin Supplementation

Patients should take low-dose (1.0 - 1.25 mg) oral folic acid on a daily basis. Folic acid should be initiated during the 10-day period preceding the first dose of pralatrexate and the dose should continue during the full course of therapy and for 30 days after the last dose of pralatrexate. Patients should also receive a vitamin B12 (1 mg) intramuscular injection no more than 10 weeks prior to the first dose of pralatrexate and every 8 - 10 weeks thereafter. Subsequent vitamin B12 injections may be given the same day as treatment with pralatrexate.

Required Codes

Pralatrexate is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

C84.40 thru C84.49

Billing

HCPCS code J9307 (injection, pralatrexate, 1 mg)

Radium Ra 223 Dichloride

For information about diagnostic and treatment applications of Radium Ra 223 Dichloride (HCPCS code A9606), refer to the *Radiology: Oncology* section in this manual.

Ramucirumab

Ramucirumab is a recombinant human IgG1 monoclonal antibody and is a vascular endothelial growth factor receptor 2 (VEGFRs) antagonist that specifically binds VEGFR2 which blocks binding of VEGFR ligands VEGF-A, VEGF-C and VEGF-D. As a result, ramucirumab inhibits ligand-stimulated activation of VEGFR2, thereby inhibiting ligand-induced proliferation and migration of human endothelial cells.

Indications

Ramucirumab is indicated for patients 18 years of age and older:

- As a single agent, or in combination with paclitaxel for advanced or metastatic, gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine-containing or platinum-containing chemotherapy
- In combination with docetaxel for metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy

Dosage

The recommended dose for:

- Gastric cancer is 8 mg/kg by intravenous infusion every two weeks
- Metastatic non-small cell lung cancer is 10 mg/kg by intravenous infusion on day one of a 21-day cycle prior to docetaxel infusion

Authorization

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

Billing

HCPCS code J9308 (injection, ramucirumab, 5 mg)

Rituximab

Rituximab is a CD20-directed cytolytic antibody for intravenous (I.V.) administration.

Indications

Rituximab is used to treat both oncologic and non-oncologic diseases including the following conditions:

- Non-Hodgkin's Lymphoma
- Chronic Lymphocytic Leukemia
- Rheumatoid Arthritis
- Granulomatosis with polyangiitis (Wegener's Granulomatosis)
- Microscopic Polyangiitis

For the use of rituximab in non-oncologic conditions, refer to the *Injections: Drugs N-R Policy* section in the appropriate Part 2 Medi-Cal manual.

Age

18 years and older

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab as a single agent or in combination with other agents, the use of rituximab for induction or maintenance therapy, and the patient's response to treatment.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab.

Billing

HPCS code J9312 (injection, rituximab, 10 mg)

One (1) unit of J9312 = 10 mg of rituximab injection solution

Rituximab-abbs

Rituximab-abbs is a CD20-directed cytolytic antibody for intravenous (I.V.) administration. Rituximab-abbs is biosimilar to rituximab for the listed indications.

Indications

Rituximab-abbs is used to treat the following oncologic diseases:

- Non-Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukemia (CLL)

Age

18 years and older

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab-abbs as a single agent or in combination with other agents, the use of rituximab-abbs for induction or maintenance therapy, and the patient's response to treatment.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab-abbs.

Billing

HCPCS code Q5115 (injection, rituximab-abbs, biosimilar, 10 mg)

One (1) unit of Q5115 = 10 mg of rituximab-abbs

«Rituximab-arrx (Riabni™)

Rituximab-arrx is a monoclonal antibody. Rituximab products target the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab products mediate B-cell lysis. Possible mechanisms of cell lysis include complement dependent cytotoxicity (CDC) and antibody dependent cell mediated cytotoxicity (ADCC).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosing regimens
- Patient has been screened for hepatitis B virus (HBV) infection prior to therapy initiation (for example, hepatitis B surface antigen [HBsAG] and hepatitis B core antibody measurements)

A. Non-Hodgkin's Lymphoma (NHL)

- Must be 18 years of age or older
- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL (as a single agent)
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens»

B. <<Chronic Lymphocytic Leukemia (CLL)

- Must be 18 years of age or older
- Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)

C. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- Patient must be 18 years of age or older
- Riabni must be used in combination with glucocorticoids such as methylprednisolone, prednisone, etc.

Initial approval is for 12 months

Reauthorization:

- Patient continues to meet initial approval criteria
- Patient does not have unacceptable toxicity such as infusion-related reactions, progressive multifocal leukoencephalopathy, tumor lysis syndrome, severe mucocutaneous skin reactions, etc.

Reauthorization is for 12 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code Q5123 (injection, rituximab-arrx, biosimilar, [Riabni], 10 mg)>>

Rituximab and Hyaluronidase

Rituximab and hyaluronidase human is a combination of rituximab, a CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase, for subcutaneous (SQ) administration.

Indications

Rituximab and hyaluronidase human is used to treat oncologic diseases including the following conditions:

- Non-Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukemia (CLL)

Rituximab and hyaluronidase human is not indicated for the treatment of non-oncologic conditions.

Rituximab and hyaluronidase human is initiated only after patients have received at least one full dose of rituximab by intravenous (I.V.) infusion.

Age

18 years and older

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab as a single agent or in combination with other agents, the use of rituximab for induction or maintenance therapy, and the patient's response to treatment.

- For NHL: 1,400 mg/23,400 units administered by SQ injection according to the recommended schedule for rituximab.
- For CLL: 1,600 mg/26,800 units administered by SQ injection according to the recommended schedule for rituximab.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab and hyaluronidase human.

Note: Rituximab and hyaluronidase human is not indicated for the treatment of non-oncologic conditions.

Billing

HCPCS code J9311 (injection, rituximab, 10 mg and hyaluronidase)

One (1) unit of J9311 = 10 mg of rituximab and hyaluronidase injection solution

Rituximab-pvvr (Ruxience)

Rituximab-pvvr is a monoclonal antibody. Rituximab targets the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab products mediate B-cell lysis. Possible mechanisms of cell lysis include complement dependent cytotoxicity (CDC) and antibody dependent cell mediated cytotoxicity (ADCC).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 18 years of age or older

Billing

HCPCS code Q5119 (injection, rituximab-pvvr, biosimilar, [ruxience],10 mg)

Rolapitant

Rolapitant injection is a substance P/neurokinin-1 (NK-1) receptor antagonist anti-emetic drug for intravenous (I.V.) administration.

Indications

Rolapitant is used in combination with dexamethasone and a 5-HT₃ receptor antagonist to prevent nausea and vomiting symptoms associated with initial and repeat courses of highly-emetic cancer chemotherapy (HEC) or moderately-emetic cancer chemotherapy (MEC).

Age

18 years and older

Dosage

Single dose regimen for HEC or MEC:

- 166.5 mg I.V. given as a single dose within two hours before initiation of a chemotherapy cycle. Additional dose(s) given in less than two-week intervals is not considered medically necessary.

Authorization

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

Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

- Z51.11 (Encounter for anti-neoplastic chemotherapy)

Billing

HCPCS code J2797 (injection, rolapitant, 0.5 mg)

One (1) unit of J2797 = 0.5 mg of rolapitant injectable emulsion

«Romidepsin (Istodax)»

Romidepsin is a histone deacetylase (HDAC) inhibitor. HDACs catalyze the removal of acetyl groups from acetylated lysine residues in histones, resulting in the modulation of gene expression. HDACs also deacetylate non-histone proteins, such as transcription factors. In vitro, romidepsin causes the accumulation of acetylated histones and induces cell cycle arrest and apoptosis of some cancer cell lines with IC50 (half maximal inhibitory concentration) values in the nanomolar range. The mechanism of the antineoplastic effect of romidepsin observed in nonclinical and clinical studies has not been fully characterized.

Indications

«All FDA-approved indications.»

TAR Requirement

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

Diagnosis Restrictions

«One of the following to ICD-10-CM diagnosis codes is required for reimbursement: C84.00 thru C84.19 dosage.»

Dosage

«FDA-approved dosages.»

Age Limit

«Must be 18 years of age or older.»

Billing

«HCPCS code J9319 (injection, romidepsin, lyophilized, 0.1 mg).

One billing unit = 0.1 mg.»

Romidepsin Non-Lyophilized

Romidepsin is a histone deacetylase (HDAC) inhibitor. HDACs catalyze the removal of acetyl groups from acetylated lysine residues in histones, resulting in the modulation of gene expression. HDACs also deacetylate non-histone proteins, such as transcription factors. In vitro, romidepsin causes the accumulation of acetylated histones, and induces cell cycle arrest and apoptosis of some cancer cell lines with IC50 values in the nanomolar range. The mechanism of the antineoplastic effect of romidepsin observed in nonclinical and clinical studies has not been fully characterized.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

- 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:
 - Cutaneous T-cell lymphoma (CTCL)
 - Peripheral T-cell lymphoma (PTCL)
- Patient must have received at least one prior therapy with relapse or disease progression.

Initial authorization is for 6 months.

Continued Therapy:

- Patient continues to meet initial coverage criteria
- «Patient has shown positive clinical response as evidenced by disease stabilization or lack of disease progression»

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

«HCPCS code J9318 (injection, romidepsin, non-lyophilized, 0.1 mg)»

Suggested ICD-10-CM Diagnosis Codes

C84.00 thru C84.49, C84.A0 thru C84.A9

Prescribing Restrictions

Frequency of billing equals 14 mg/m² on days 1, 8, and 15 of a 28-day cycle. Repeat cycles every 28 days

Romiplostim

Romiplostim is used for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenia purpura who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

Dosage

The maximum dose for romiplostim is 10 mcg/kg weekly or 1000 mcg/week.

Romiplostim is restricted to patients aged 18 years of age and older.

Required Codes

Romiplostim must be billed in conjunction with ICD-10-CM diagnosis code D69.3.

Billing

HCPCS code J2796 (injection, romiplostim, 10 mcg).

One unit equals 10 mcg

When billing for a quantity greater than 1000 mcg, providers must document that the patient's weight exceeds 100 kg.

Sacituzumab Govitecan-hziy (Trodelvy™)

Sacituzumab govitecan-hziy is a Trop-2 directed antibody and topoisomerase inhibitor conjugate composed of the humanized monoclonal antibody sacituzumab (hRS7 IgG1-kappa), the drug SN-38 and CL2A (a hydrolysable linker). Sacituzumab govitecan-hziy binds to Trop-2-expressing cancer cells and is internalized with subsequent release of SN-38, via hydrolysis of the linker, which interacts with topoisomerase I and prevents re-ligation of topoisomerase I-induced single strand breaks causing DNA damage resulting in apoptosis and cell death. Sacituzumab govitecan-hziy decreased tumor growth in mouse xenograft models of triple-negative breast cancer.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9317 (injection, sacituzumab govitecan-hziy, 2.5 mg).

Suggested ICD-10 Diagnosis Codes

«C50.011 thru C50.319, C50.411, C50.919, C50.929, C65.1 thru C65.9, C66.1 thru C66.9, C67.0 thru C67.9, C68.8 thru C68.9, D05.00 thru D05.02»

Prescribing Restrictions

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

Samarium Sm-153 Lexidronam

For HCPCS code A9604, refer to the *Radiology: Oncology Therapeutic Radiopharmaceuticals* section in this manual.

Sipuleucel-T

Sipuleucel-T consists of autologous peripheral blood mononuclear cells that have been activated during a defined culture period with a recombinant human protein, PAP-GM-CSF, consisting of prostatic acid phosphatase (PAP), an antigen expressed in prostate cancer tissue, linked to granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune cell activator. The patient's peripheral blood mononuclear cells are obtained via a standard leukapheresis procedure approximately three days prior to the infusion date.

Sipuleucel-T is classified as an autologous cellular immunotherapy with an unknown mechanism of action. Sipuleucel-T is designed to induce an immune response targeted against PAP, an antigen expressed in most prostate cancers.

Indications

For the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

The patient should not be receiving simultaneous chemotherapy and should not be receiving immunosuppressive therapy.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must document the following:

- Evidence of metastases
- Testosterone levels less than 50 ng/dL
- Two sequential rising prostate specific antigen (PSA) levels usually obtained two weeks to three months apart or other evidence of disease progression

Dosage

Each dose of sipuleucel-T contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF.

The recommended course of therapy is three complete doses, given at approximately two-week intervals. In controlled clinical trials, the median dosing interval between infusions was two weeks (range 1 to 15 weeks). The maximum dosing interval has not been established.

Billing

HCPCS code Q2043 (sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion). One unit = one infusion

Tafasitamab-cxix (Monjuvi®)

Tafasitamab-cxix is an Fc-modified monoclonal antibody that binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma (DLBCL). Upon binding to CD19, tafasitamab-cxix mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). In studies conducted in vitro in DLBCL tumor cells, tafasitamab-cxix in combination with lenalidomide resulted in increased ADCC activity compared to tafasitamab-cxix or lenalidomide alone.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- 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 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 three months of therapy
- Patient was not previously treated with CD19 targeted therapy (for example, axicabtagene, tisagenlecleucel, etc.)
- Patient has not received prior therapy with immunomodulatory imide (IMiDs) agents (for example, 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 Monjuvi
 - 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

Age Limit

Must be 18 years of age or older

Billing

HCPCS code, J9349 (injection, tafasitamab-cxix, 2 mg)

Suggested ICD-10 Diagnosis Codes

C83.30, C83.31, C83.32, C83.33, C83.34, C83.35, C83.36, C83.37, C83.38, C83.39

Prescribing Restrictions

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

Tagraxofusp-erzs (Elzonris)

Tagraxofusp-erzs is a CD123-directed cytotoxin composed of recombinant human interleukin-3 (IL-3) and truncated diphtheria toxin (DT) fusion protein that inhibits protein synthesis and causes cell death in CD123-expressing cells.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 2 years of age or older

Billing

HCPCS code J9269 (injection, tagraxofusp-erzs, 10 micrograms)

Prescribing Restrictions

Frequency of billing = On days 1-5 of every 21-day cycle

Maximum billing units = 2,730 mcg = 273 units

Talimogene Laherparepvec

Talimogene laherparepvec is a live, attenuated HSV-1 that has been genetically modified to replicate within tumors and produce the immune stimulatory protein huGM-CSF. The parental virus for talimogene laherparepvec was a primary isolate, which was subsequently altered using recombinant methods to result in gene deletions and insertions. Talimogene laherparepvec causes lysis of tumors, followed by release of tumor-derived antigens, which together, with virally derived GM-CSF, promote an antitumor immune response.

Indication

Talimogene laherparepvec is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients 18 years of age or older with melanoma recurrent after initial surgery.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must state that the treatment is for patients with melanoma recurrent after initial surgery.

Dosage

Administer talimogene laherparepvec by injection into cutaneous, subcutaneous and/or nodal lesions.

- Recommended starting dose is a maximum of 4 ml of talimogene laherparepvec at a concentration of 1 million plaque-forming units (PFU) per milliliter. Subsequent doses should be administered up to 4 ml of talimogene laherparepvec at a concentration of 100 million PFU/ml.
- For intralesional injections, the maximum volume per treatment visit for all injected lesions combined is 4 ml. Treatment should continue for at least six months unless other therapy is necessary or until there are no injectable lesions to treat. Reinitiate treatment if new, unresectable lesions appear after a previous complete response.

- Use the following lesion sizes to determine the volume of talimogene laherparepvec to be injected (lesion size is based on longest dimension; when lesions are clustered together, inject them as a single lesion):

Lesion Size	Injection Volume
Greater than 5 cm	Up to 4 ml
Greater than 2.5 cm, Less than or equal to 5 cm	Up to 2 ml
Greater than 1.5 cm, Less than or equal to 2.5 cm	Up to 1 ml
Greater than 0.5 cm, Less than or equal to 1.5 cm	Up to 0.5 ml
Less than or equal to 0.5 cm	Up to 0.1 ml

- During the initial treatment visit, inject up to 4 ml at a concentration of 10⁶ (1 million) PFU/ml. Inject largest lesion(s) first; inject remaining lesion(s) based on lesion size until maximum injection volume is reached or all lesions have been treated.
- During the second treatment visit (three weeks after initial treatment), inject up to 4 ml at a concentration of 10⁸ (100 million) PFU/ml. Inject any new lesion(s) that have developed since initial treatment first; inject remaining lesion(s) based on lesion size until maximum injection volume is reached or all lesions have been treated.
- During all subsequent treatment visits, including reinitiation (two weeks after previous treatment), inject up to 4 ml at a concentration of 10⁸ (100 million) PFU/ml. Inject any new lesion(s) that have developed since previous treatment first; inject remaining lesion(s) based on lesion size until maximum injection volume is reached or all lesions have been treated.

Required Codes

ICD-10-CM diagnosis codes C43.0 thru C43.9, C51.0 thru C58.0, C60.0 thru C60.9, C63.00 thru C63.9 and D03.0 thru D03.9.

Billing

HCPCS code J9325 (injection talimogene laherparepvec, per 1 million plaque forming units)

Tecentriq

Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma. It is a monoclonal antibody that binds to PD-L1 and blocks its interactions with both PD-1 and B7.1 receptors. This releases the PD-L1/PD-1 mediated inhibition of the immune response, including activation of the anti-tumor immune response without inducing antibody-dependent cellular cytotoxicity. In syngeneic mouse tumor models, blocking PD-L1 activity resulted in decreased tumor growth.

Authorization

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

With or without a TAR, the following situations are not reimbursable in the use of Tecentriq:

- For grade 3 or 4 pneumonitis
- For grade 3 or 4 immune-mediated hepatitis
- For grade 4 diarrhea or colitis
- For grade 4 hypophysitis
- For any grade of meningitis or encephalitis; or myasthenic syndrome/myasthenia gravis; or Guillain-Barré syndrome
- For grade 4 or any grade of recurrent pancreatitis
- In patients with grade 3 or 4 infusion reactions. Patients must be monitored for signs of infection.

Dosage

The recommended dose of Tecentriq is 1200 mg administered as an intravenous infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity. If the first infusion is tolerated, all subsequent infusions may be delivered over 30 minutes. Do not administer Tecentriq as an intravenous push or bolus.

Injection: 1200 mg/20 ml (60 mg/ml) solution in a single-dose vial.

Billing

HCPCS code J3490 (unclassified drugs)

Temozolomide

Temozolomide is used in the treatment of adult patients with either of the following:

- Newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and as maintenance treatment
- Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine

Dosage

The maximum dose is 375 mg/day; a greater quantity is allowed if the patient's documented body surface area exceeds 2.5 meters squared.

Required Codes

Temozolomide is reimbursable when billed in conjunction with an ICD-10-CM diagnosis code in the range C71.0 thru C71.9.

Billing

HCPCS code J9328 (injection, temozolomide, 1 mg)

One unit = 1 mg

Temsirolimus

Temsirolimus, 1 mg (HCPCS code J9330), is used in the treatment of malignant neoplasm of the kidney. Claims must be billed with ICD-10-CM diagnosis code C64.1 thru C65.9. The maximum daily dosage is 25 mg.

Thyrotropin Alfa

Thyrotropin alfa may be authorized for the treatment of well-differentiated thyroid carcinoma. Refer to the *Injections: Drugs S-Z Policy* section in the Part 2 manual for details.

Tisagenlecleucel

Tisagenlecleucel suspension is a CD19-directed genetically modified autologous T-cell immunotherapy for intravenous (I.V.) administration.

Indications

Tisagenlecleucel is used to treat oncologic disease including the following conditions:

- B-cell Acute Lymphocytic Leukemia (ALL) refractory to treatment or in second or later relapse in patients up to 25 years of age.
- Large B-cell Lymphoma, refractory or relapsed (r/r) after two or more lines of systemic therapy in adults including:
 - Diffuse Large B-cell Lymphoma (DLBCL), not otherwise specified.
 - High grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Tisagenlecleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

The safety and efficacy of tisagenlecleucel in pediatric patients with relapsed or refractory DLBCL has not been established.

Dosage

The recommended dosage varies based on the treatment condition:

- B-cell ALL in patients up to 25 years of age:
 - Body weight less than or equal to 50 kg:
 - ❖ A single dose of 0.2 to 5.0×10^6 total CAR-positive viable T cells per kg body weight is administered by I.V. infusion.
 - Body weight greater than 50 kg:
 - ❖ A single dose of 0.1 to 2.5×10^8 total CAR-positive viable T cells is administered by I.V. infusion.
- DLBCL, refractory or relapsed, in adults:
 - A single dose of 0.6 to 6.0×10^8 total CAR-positive viable T cells is administered by I.V. infusion.

Authorization

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 to treat:
 - A pediatric or young adult patient with: B-cell ALL, refractory or in second or later relapse, or
 - An adult with DLBCL, refractory or relapsed after two or more lines of systemic therapy.
- The provider facility is certified by the Kymriah™ REMS (Risk Evaluation Management Strategy) Program for tisagenlecleucel administration.
- The provider facility is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) for Immune Effector Cell Therapy (IECT).
- The physician's legible, complete, and signed treatment plan/order for tisagenlecleucel.

Required Codes

One code from one of the following ICD-10-CM diagnosis code groups is required for reimbursement:

- C83.30 thru C83.39 (diffuse large B-cell lymphoma)
- C91.00 (acute lymphoblastic leukemia, not having achieved remission)
- C91.02 (acute lymphoblastic leukemia, in relapse)

Billing

HCPCS code Q2042 (tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose)

One (1) unit of Q2042 = a single infusion of up to 600 million autologous anti-CD19 CAR-positive viable T cells

Topotecan

Topotecan is a semi-synthetic derivative of camptothecin and is an anti-tumor drug with topoisomerase I-inhibitory activity. Topoisomerase I relieves torsional strain in DNA by inducing reversible single-strand breaks. Topotecan binds to the topoisomerase I-DNA complex and prevents relegation of these single-strand breaks. The cytotoxicity of topotecan is thought to be due to double-strand DNA damage produced during DNA synthesis, when replication enzymes interact with the ternary complex formed by topotecan, topoisomerase I and DNA. Mammalian cells cannot efficiently repair these double-strand breaks.

Indications

Topotecan is indicated for:

- Metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy
- Small cell lung cancer sensitive disease after failure of first-line therapy
- In combination with cisplatin Stage IV-B, recurrent or persistent carcinoma of the cervix which is not amenable to curative treatment with surgery and/or radiation therapy

Dosage

In the treatment of ovarian cancer and small cell lung cancer, the recommended dose of topotecan is 1.5 mg/m² by intravenous infusion over 30 minutes daily for five consecutive days, starting on day 1 of a 21-day course. In the absence of tumor progression, a minimum of four courses is recommended because tumor response may be delayed.

In the treatment of cervical cancer, the recommended dose of topotecan is 0.75 mg/m² by intravenous infusion over 30 minutes daily on days 1, 2 and 3; followed by cisplatin 50 mg/m² by intravenous infusion on day 1, repeated every 21 days (a 21-day course).

The maximum dose is 4 mg per day.

Required Codes

Topotecan is reimbursable only when billed in connection with one of the following ICD-10-CM diagnosis codes:

C33 thru C34.92

C56.1 thru C57.4

C53.0 thru C53.9

Billing

HCPCS code J9351 (injection, topotecan, 0.1 mg)

One billing unit = 0.1 mg

Note: When a claim is billed using code J9351 and is authorized by the California Children's Services (CCS) program or the Genetically Handicapped Persons Program (GHPP), the diagnosis restrictions above will be overridden.

Trabectedin

Trabectedin is an alkylating agent against DNA. Unlike conventional alkylating agents, which bind to the major groove of DNA and predominantly form crosslinks to the guanine N7 or O6 position, trabectedin predominantly binds to the minor groove of DNA and to the guanine N2 position.

Indications

Trabectedin is indicated for the treatment of patients 18 years of age or older with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must document that the patient has unresectable or metastatic liposarcoma or leiomyosarcoma.

Required Codes

ICD-10-CM diagnosis codes C49.0 thru C49.9.

Dosage

Administer at 1.5 mg/m² of body surface area as a 24-hour intravenous infusion every 21 days through a central venous line.

Premedication: dexamethasone 20 mg intravenously, 30 minutes before each infusion.

Billing

HCPCS code J9352 (injection, trabectedin, 0.1 mg)

Trastuzumab

Trastuzumab is a HER2/neu receptor antagonist monoclonal antibody (IgG1 kappa) reconstituted in solution for intravenous (I.V.) administration.

Indications

Trastuzumab is used to treat the following conditions:

- HER2-Overexpressing Breast Cancer.
- HER2-Overexpressing Metastatic Gastric Cancer or Gastroesophageal junction Adenocarcinoma.

Age

18 years and older

Dosage

The recommended dosing regimen is based on the patient's weight and treatment condition.

Authorization

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

Required Codes

One code from any one of the following ICD-10-CM diagnosis groups is required for reimbursement:

- C50.111 thru C50.929 (malignant neoplasm of breast)
- C16.0 thru C16.9 (malignant neoplasm of stomach)

Billing

HCPCS code J9355 (injection, trastuzumab, excludes biosimilar, 10 mg)

One (1) unit of J9355 = 10 mg of trastuzumab

HCPCS code Q5112 (injection, trastuzumab-dttb, biosimilar, [Ontruzant], 10 mg)

One (1) unit of Q5112 = 10 mg of trastuzumab-dttb

HCPCS code Q5114 (injection, trastuzumab-dkst, biosimilar, [Ogivri], 10 mg)

One (1) unit of Q5114 = 10 mg of trastuzumab-dkst

Trastuzumab-anns (Kanjinti)

Trastuzumab-anns is a humanized IgG1 kappa monoclonal antibody that selectively binds to the extracellular domain of the human epidermal growth factor receptor 2 protein, HER2, with high affinity. Trastuzumab products are mediators of antibody-dependent cellular cytotoxicity and inhibit the proliferation of human tumor cells with HER2 overexpression.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 18 years of age or older

Billing

HCPCS code Q5117 (injection, trastuzumab-anns, biosimilar, [Kanjinti], 10 mg)

Prescribing Restrictions

Frequency of billing = Every 21 days

Maximum billing units = 1,820 mg = 182 units

Trastuzumab-pkrb

Trastuzumab-pkrb is a HER2/neu receptor antagonist monoclonal antibody (IgG1 kappa) reconstituted in solution for intravenous (IV) administration.

Indications

Trastuzumab is used to treat the following condition:

- HER2-Overexpressing Breast Cancer.

Age

18 years and older

Dosage

The recommended dosing regimen is based on the patient's weight.

Authorization

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

Required Codes

One code from the following ICD-10-CM diagnosis group is required for reimbursement:

C50.111 thru C50.929 (malignant neoplasm of breast)

Billing

HCPCS code Q5113 (injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg)

One (1) unit of Q5113 = 10 mg of trastuzumab-pkrb

Trastuzumab-qyyp (Trazimera)

Trastuzumab products are mediators of antibody-dependent cellular cytotoxicity (ADCC). In vitro, trastuzumab product-mediated ADCC has been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 18 years of age or older

Billing

HCPCS code Q5116 (injection, trastuzumab-qyyp, biosimilar, [Trazimera], 10 mg)

Prescribing Restrictions

Frequency of billing = Every 21 days

Maximum billing units = 1,820 mg = 182 units

Trastuzumab and Hyaluronidase-oysk

Trastuzumab and hyaluronidase-oysk is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, in solution for subcutaneous (SQ) administration.

Indications

Trastuzumab is used to treat the following condition:

- HER2-Overexpressing Breast Cancer.

Age

18 years and older

Dosage

The recommended dose is 600 mg/10,000 units (600 mg trastuzumab and 10,000 units of hyaluronidase) administered subcutaneously over approximately 2-5 minutes once every 21 days.

Authorization

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

Required Codes

One code from the following ICD-10-CM diagnosis code group is required for reimbursement:

C50.111 thru C50.929 (malignant neoplasm of breast)

Billing

HCPCS code J9356 (injection, trastuzumab, 10 mg and hyaluronidase-oysk)

One (1) unit of J9356 = 10 mg of trastuzumab and hyaluronidase-oysk

«Trilaciclib (Cosela™)

Trilaciclib is a transient inhibitor of CDK 4 and 6. Hematopoietic stem and progenitor cells (HSPCs) in the bone marrow give rise to circulating neutrophils, red blood cells (RBCs), and platelets. HSPC proliferation is dependent on CDK4/6 activity.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient has a diagnosis of extensive-stage small cell lung cancer (SCLC) by histology or cytology
- Trilaciclib will be administered prior to a myelosuppressive chemotherapy with one of the following:
 - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; or
 - Topotecan-containing regimen
- Trilaciclib is used to decrease the incidence of chemotherapy-induced myelosuppression
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2

Initial approval is for 6 months

Continued Therapy

- Patient continues to meet initial approval criteria
- Absence of unacceptable toxicities such as severe injection site reactions, acute drug hypersensitivity reactions, interstitial lung disease/pneumonitis, etc.
- Patient is undergoing a myelosuppressive chemotherapy with a platinum/etoposide-containing regimen or topotecan-based regimen.

Reauthorization is for 12 months

Age Limits

Must be 18 years of age or older

Billing

«HCPCS code J1448 (injection, trilaciclib, 1 mg)»

«Suggested ICD-10-CM Diagnosis Codes

C34.00 thru C34.92

Prescribing Restrictions

Frequency of billing = 240 mg/m² administered prior to each chemotherapy regimen»

Triptorelin

Triptorelin is a synthetic decapeptide agonist analog of gonadotropin releasing hormone. After chronic and continuous administration, usually two to four weeks after initiation of therapy, a sustained decrease in luteinizing hormone and follicle stimulating hormone secretion and marked reduction of testicular steroidogenesis are observed. Consequently, the result is that tissues and functions that depend on these hormones for maintenance become quiescent.

Indications

Triptorelin is indicated for the palliative treatment of advanced prostate cancer.

Dosage

Triptorelin is administered by a single intramuscular injection in either buttock. The recommended dosing schedule depends on the product strength selected:

- 3.75 mg every 4 weeks
- 11.25 mg every 12 weeks
- 22.5 mg every 24 weeks

Required Codes

Triptorelin is reimbursable when billed with ICD-10-CM diagnosis code C61 (malignant neoplasm of prostate).

Billing

HCPCS code J3315 (injection, triptorelin pamoate, 3.75 mg)

Reimbursement is restricted to no more than 22.5 mg (six units) every 24 weeks for the same provider and patient.

Vincristine Sulfate

Vincristine sulfate 1 mg (HCPCS code J9370). The maximum dose is 4 mg; however, a dose in excess of 4 mg is allowed with documentation of body surface area greater than 2.75 m².

Vincristine Sulfate Liposome

Vincristine sulfate liposome is vincristine encapsulated in sphingomyelin/cholesterol for intravenous administration. Non-liposomal vincristine sulfate binds to tubulin, altering the tubulin polymerization equilibrium, resulting in altered microtubule structure and function. Non-liposomal vincristine sulfate stabilizes the spindle apparatus, preventing chromosome segregation, triggering metaphase arrest and inhibition of mitosis. The plasma clearance of vincristine sulfate liposome is much slower than non-liposomal vincristine resulting in a much higher area under the curve.

Indications

Vincristine sulfate liposome is indicated for the treatment of adult patients 18 years of age and older with Philadelphia chromosome-negative acute lymphoblastic leukemia in second or greater relapse or whose disease has progressed following two or more anti-leukemic therapies.

Dosage

The recommended dose is 2.25 mg/m² intravenously once every seven days.

Authorization

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

Billing

HCPCS code J9371 (injection, vincristine sulfate liposome, 1 mg)

Vinorelbine Tartrate

Vinorelbine tartrate is a chemotherapeutic agent reimbursable when used in the treatment of the following conditions:

- Small cell and non-small cell lung cancer
- Advanced metastatic breast cancer
- Hormone-refractory prostate cancer
- Lymphatic neoplasm
- Hematopoietic neoplasm

Dosage

Reimbursement is restricted to one injection, once a week, per patient. Reimbursement for dosages greater than 60 mg requires documentation stating “patient’s surface area exceeds 2 m²” in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim or on an attachment.

Billing

HCPCS code J9390 (injection, vinorelbine tartrate, 10 mg)

Physicians and physician groups must bill vinorelbine tartrate using the “line-item” method. Refer to the claim form special billing instructions in the appropriate Part 2 manual for a billing example.

Note: Vinorelbine tartrate should not be billed using the “from-through” method.

Ziv-aflibercept

Ziv-aflibercept is a recombinant fusion protein consisting of Vascular Endothelial Growth Factor (VEGF)-binding portions from the extracellular domains of human VEGF Receptors 1 and 2 fused to the Fc portion of the human IgG1. Ziv-aflibercept acts as a soluble receptor that binds to human VEGF-A, to human VEGF-B, and to human PlGF. By binding to these endogenous ligands, ziv-aflibercept can inhibit the binding and activation of their cognate receptors. This inhibition can result in decreased neovascularization and decreased vascular permeability. In animals, ziv-aflibercept was shown to inhibit the proliferation of endothelial cells, thereby inhibiting the growth of new blood vessels. Ziv-aflibercept inhibited the growth of xenotransplanted colon tumors in mice.

Indications

In combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) for patients 18 years of age and older with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.

There is no data that suggests activity of FOLFIRI plus ziv-aflibercept in patients who progressed on FOLFIRI plus bevacizumab.

Authorization

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

Dosage

The recommended dose is 4 mg/kg intravenously every two weeks until disease progression or unacceptable toxicity.

Billing

HCPCS code J9400 (injection, Ziv-aflibercept, 1 mg)

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.