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## Chemotherapy: Drugs P-Z Policy

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Page updated: July 2023

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 Policy* and *Chemotherapy: Drugs E-O Policy* 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**

«All FDA-approved indications»

### **Dosage**

«FDA-approved dosages»

### **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**

HCPCS code J9267 (injection, paclitaxel, 1 mg)

## **«Paclitaxel Protein-Bound Particles (Abraxane)»**

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**

«All FDA-approved indications»

### **Dosage**

«FDA-approved dosages

### **TAR Requirement**

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

### **Billing**

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

### **«Required ICD-10-CM Diagnosis Codes»**

C25.0 thru C25.3

C34.00 thru C34.92

C25.7 thru C25.9

C50.011 thru C50.929

## **«Paclitaxel Protein-Bound Particles (American Agent and Teva)»**

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) is a microtubule inhibitor that promotes the assembly of microtubules from tubulin dimers 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. Paclitaxel induces abnormal arrays or “bundles” of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

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

### **TAR Criteria**

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 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 six months**

#### Continuation of Therapy

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

### **Reauthorization is for 12 months.**

### **Age Limits**

«No age limit (Teva).

Must be 18 years of age or older (American Regent).»

### **Billing**

HCPCS codes:

«J9258 (injection, paclitaxel protein-bound particles [teva] not therapeutically equivalent to J9264, 1 mg)»

J9259 (injection, paclitaxel protein-bound particles [American Regent] not therapeutically equivalent to J9264, 1 mg)

### **Suggested ICD-10-CM Diagnosis Codes**

C25.0 thru C25.3

C25.7 thru C25.9

C34.00 thru C34.92

C50.011 thru C50.929

## **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 (Neulasta®)**

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.

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirements**

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

### **Billing**

HCPCS code J2506 (injection, pegfilgrastim, excludes biosimilar, 0.5 mg).  
One (1) unit equals 0.5 mg

### **Suggested ICD-10-CM Diagnosis Codes**

D70.1, T45.1X5S, T45.1X5D, T45.1X5A, T45.1X5, T45.1X, T45.1

### **Prescribing Restriction(s)**

Maximum billing unit(s) equals 6 mg/12 units

## **Pegfilgrastim-apgf (Nyvepria™)**

Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

### **Indications**

All FDA-approved indications

### **Dosages**

FDA-approved dosages

**TAR Requirement**

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

**Billing**

HCPCS code Q5122 (injection, pegfilgrastim-apgf, biosimilar, [nyvepria], 0.5 mg)

**Prescribing Restrictions**

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

**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 equals 6 mg/12 units per chemotherapy cycle

Maximum billing units equals mg/12 units

## **Pegfilgrastim-cbqv**

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

### **Indications**

Pegfilgrastim-cbqv 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 45 kg or more, a single 6 mg SQ injection is administered once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. Pegfilgrastim-cbqv 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 45 kg, two SQ injection doses are administered one week apart based on the patient's body weight:

- Less than 10 kg: 0.1 mg/kg
- 10 to 20 kg: 1.5 mg
- 21 to 30 kg: 2.5 mg
- 31 to 44 kg: 4 mg

### **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 Q5111 (Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg)  
One (1) unit of Q5111 equals 0.5 mg of pegfilgrastim-cbqv

## 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 equals 0.5 mg of pegfilgrastim-jmdb

## «Pembrolizumab (KEYTRUDA®)»

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

«All FDA-approved indications.

## Dosage

FDA-approved dosages.

## Authorization

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

## Billing

HCPCS code J9271 (injection, pembrolizumab, 1 mg).

## **«Pemetrexed (Pemfexy™ and Pemrydi RTU)»**

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**

«Pemetrexed is considered medically necessary when the following criteria are met:

#### Universal Criteria»

- I. Must be used for FDA labelled indications and dosing regimens.
- II. Patient must be 18 years of age or older
- III. «Patient must have a diagnosis of malignant pleural mesothelioma or locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC) (A or B below)
  - A. Malignant pleural mesothelioma»
    - 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 therapy
  - and

- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; and
- Patient’s disease presentation is unresectable; or

**B. «Locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC)»**

- Patient has a diagnosis of locally advanced or metastatic non-squamous 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.
- Pemetrexed is not approvable for the treatment of patients with squamous cell non-small cell lung cancer.

**Initial approval is for six 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
- «Patient does not have unacceptable toxicity such as severe hypersensitivity reactions, myelosuppression, renal, skin and gastrointestinal toxicity, etc.»

**Reauthorization is for 12 months.**

**Age Limits**

Must be 18 years of age or older.

**Billing**

HCPCS codes:

J9304 (injection, pemetrexed [pemfexy], 10 mg) (Pemfexy™)

«J9324 (injection, pemetrexed [pemrydi rtu], 10 mg)»

## Suggested ICD-10-CM Diagnosis Codes

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

## Prescribing Restrictions

Frequency of billing equals 500 mg/m<sup>2</sup> on day one of each 21-day cycle.

## Pemetrexed (Alimta<sup>®</sup>, Teva, Accord, Hospira, Sandoz and Bluepoint)

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 codes:

- J9305 (Injection, pemetrexed, not otherwise specified 10 mg) [Alimta<sup>®</sup>]
- J9314 (Injection, pemetrexed [Teva] not therapeutically equivalent to J9305, 10 mg)
- J9294 (Injection, pemetrexed [Hospira] not therapeutically equivalent to J9305, 10 mg)
- J9296 (Injection, pemetrexed [Accord] not therapeutically equivalent to J9305, 10 mg)
- J9297 (Injection, pemetrexed [Sandoz] not therapeutically equivalent to J9305, 10 mg)

- J9322 (Injection, pemetrexed [BluePoint] not therapeutically equivalent to J9305, 10 mg)
- J9323 (Injection, pemetrexed ditromethamine, 10 mg)

## **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 equals 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**

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

**Age Limits**

Must be 18 years of age or older.

**Billing**

HCPCS code J9309 (injection, polatuzumab vedotin-piiq, 1 mg).

**«Required ICD-10 CM Diagnosis Codes»**

C83.30 thru C83.39

**Prescribing Restrictions**

«Frequency of billing equals 1.8 mg/kg every 21 days for six cycles.»

## **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/m<sup>2</sup> administered as an intravenous push over 3 to 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 m<sup>2</sup>.

### **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 to 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 (CYRAMZA®)**

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**

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 J9308 (injection, ramucirumab, 5 mg)

## **«Retifanlimab-dlwr (ZYNYZ™)**

Retifanlimab is a humanized IgG<sub>4</sub> monoclonal antibody which is a programmed death receptor-1 (PD-1) blocking antibody. Retifanlimab binds to the PD-1 receptor, blocking interaction with its ligands, PD-L1 and PD-L2, and potentiating T-cell activity. PD-L1 and PD-L2 binding to the PD-1 receptor on T-cells inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors; therefore, signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors.

### **Indications**

All FDA-approved indications.»

## «Dosage

FDA-approved dosages.

## TAR Requirement

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

## TAR Criteria

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 must have a diagnosis of Merkel cell carcinoma (MCC) with metastatic disease or recurrent, advanced locoregional disease not amenable to surgery or radiation.
- Patient has not received systemic therapy for MCC, including chemotherapy and prior PD-1 or PD-L1-directed therapy (for example, avelumab, pembrolizumab, atezolizumab, cemiplimab, dostarlimab, durvalumab, nivolumab, etc.)
- Patient does not have clinically significant pulmonary, cardiac, gastrointestinal or autoimmune disorders.
- Patient does not have active bacterial, fungal, or viral infections, including hepatitis A, B, and C.
- Provider will evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment.
- Patient is not pregnant or breastfeeding.

**Initial authorization is for 6 months.**

### Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response such as stabilization of disease or decrease in tumor size or spread.
- Patient has absence of disease progression or unacceptable toxicity such as immune-mediated adverse reactions, infusion-related reactions, complications of Allogeneic hematopoietic stem-cell transplantation (HSCT), etc.

**Reauthorization is for 12 months.»**

## Age Limits

Must be 18 years of age or older.

## Billing

HCPCS code J9345 (injection, retifanlimab-dlwr, 1 mg).

## Suggested ICD-10-CM Diagnosis Codes

C4A0, C4A4, C4A8, C4A9, C4A10, C4A20, C4A21, C4A22, C4A30, C4A31, C4A39, C4A51, C4A52, C4A59, C4A60, C4A61, C4A62, C4A70, C4A71, C4A72, C4A111, C4A112, C4A121, C4A122

## Prescribing Restrictions

Frequency of billing equals 500 mg/500 units every four weeks.

Maximum billing units equals 500 mg/500 units.

## 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 R Policy* section in the appropriate Part 2 Medi-Cal manual.»

## Age Limits

Must be 18 years of age 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

HCPCS code J9312 (injection, rituximab, 10 mg)

One (1) unit of J9312 equals 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 Limits

Must be 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 equals 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**

HPCS 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 equals 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-HT<sub>3</sub> 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 equals 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 equals 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/m<sup>2</sup> 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 equals 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 equals one infusion

## **Sirolimus Protein-Bound Particles (albumin-bound) (Fyarro™)**

Sirolimus in FYARRO is an inhibitor of mechanistic target of rapamycin kinase (mTOR, previously known as mammalian target of rapamycin). mTOR, a serine threonine kinase, is downstream of the PI3K/AKT pathway, controls key cellular processes such as cell survival, growth and proliferation, and is commonly dysregulated in several human cancers. In cells, sirolimus binds to the immunophilin, FK Binding Protein-12 (FKBP-12), to generate an immunosuppressive complex. The sirolimus-FKBP-12 complex binds to and inhibits activation of the mechanistic target of rapamycin complex 1 (mTORC1). Inhibition of mTOR by sirolimus has been shown to reduce cell proliferation, angiogenesis, and glucose uptake in in vitro and in vivo studies. In a nonclinical study in athymic mice bearing human tumor xenografts, intravenous administration of FYARRO resulted in higher tumor accumulation of sirolimus, inhibition of an mTOR target in the tumor, and tumor growth inhibition compared to administration of an oral formulation of sirolimus at the same weekly total dose.

## Indications

All FDA-approved indications

## Dosage

FDA-approved dosages

## TAR Requirements

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

## Age Limit

Must be 18 years of age or older

## Billing

HCPCS code J9331 (injection, sirolimus protein-bound particles, 1 mg)



## Prescribing Restriction(s)

Frequency of billing equals 100 mg/m<sup>2</sup> administered on Days one and eight of each 21-day cycle

## Sodium Thiosulfate (Pedmark®)

Cisplatin-induced ototoxicity is caused by irreversible damage to hair cells in the cochlea hypothesized to be due to a combination of reactive oxygen species (ROS) production and direct alkylation of DNA leading to cell death. Sodium thiosulfate interacts directly with cisplatin to produce an inactive platinum species. In addition, sodium thiosulfate can enter cells through the sodium sulfate cotransporter 2 and cause intracellular effects such as the increase in antioxidant glutathione levels and inhibition of intracellular oxidative stress. Both activities may contribute to the ability of sodium thiosulfate to reduce the risk of ototoxicity.

Concurrent incubation of sodium thiosulfate with cisplatin decreased the in vitro cytotoxicity of cisplatin to tumor cells; delaying the addition of sodium thiosulfate to these cultures prevented the protective effect.

## Indications

All FDA-approved indications

## Dosage

FDA-approved dosages

## TAR Requirement

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

## TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be at least 1 month of age to 18 years of age.
- It must be prescribed by or in consultation with an oncologist.
- Patient has a diagnosis of localized, non-metastatic solid tumors.
- Drug is being used for prophylaxis of ototoxicity.
- Patient will receive a chemotherapy treatment regimen that includes a cumulative cisplatin dose that is at least 200 mg/m<sup>2</sup> with individual cisplatin doses to be infused over 6 hours or less but at least 10 hours before the next cisplatin infusion.

- Must document baseline serum sodium and potassium and as clinically indicated.
  - Baseline serum sodium must be less than 145 mmol/L
- Patient has no previous hypersensitivity to sodium thiosulfate or other thiol agents (for example, amifostine trihydrate, N-acetylcysteine, MESNA, or captopril).

**Initial authorization is for 6 months.**

#### Continued Therapy

- Patient continues to meet initial approval criteria.
- Documentation of positive clinical response.
- Serum sodium is not greater than 145 mmol/L.

**Reauthorization is for 12 months.**

#### **Age Limits**

Must be at least one month of age to 18 years of age.

#### **Billing**

«HCPCS code: J0208 (injection, sodium thiosulfate [pedmark], 100 mg).»

#### **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 equals 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 equals on days 1 thru 5 of every 21-day cycle

Maximum billing units equals 2,730 mcg equals 273 units

## **Talimogene Laherparepvec (IMLYGIC®)**

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**

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.

## **Required 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)

## **«Talquetamab-tgvs (TALVEY™)**

Talquetamab-tgvs is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and G protein-coupled receptor class C group five member D (GPRC5D) expressed on the surface of multiple myeloma cells and non-malignant plasma cells, as well as healthy tissues such as epithelial cells in keratinized tissues of the skin and tongue.

In vitro, talquetamab-tgvs activated T-cells caused the release of proinflammatory cytokines and resulted in the lysis of multiple myeloma cells. Talquetamab-tgvs had anti-tumor activity in mouse models of multiple myeloma.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

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

### **TECVAYLI and TALVEY REMS**

TALVEY is available only through a restricted program under a REMS called the TECVAYLI and TALVEY REMS because of the risks of CRS and neurologic toxicity, including ICANS [see Warnings and Precautions (5.1, 5.2)]. Notable requirements of the TECVAYLI and TALVEY REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Prescribers must counsel patients receiving TALVEY about the risk of CRS and neurologic toxicity, including ICANS and provide patients with Patient Wallet Card.
- Pharmacies and healthcare settings that dispense TALVEY must be certified with the TECVAYLI and TALVEY REMS program and must verify prescribers are certified through the TECVAYLI and TALVEY REMS program.
- Wholesalers and distributors must only distribute TALVEY to certified pharmacies.

Further information about the TECVAYLI and TALVEY REMS program is available at [www.TEC-TALREMS.com](http://www.TEC-TALREMS.com) or by telephone at 1-855-810-8064.

### **Age Limits**

Must be 18 years of age or older.>>

## Billing

«HCPCS code J3055 (injection, talquetamab-tgvs, 0.25 mg).»

## Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.02

## **Tebentafusp-tebn (Kimmtrak®)**

Tebentafusp-tebn is a bispecific gp100 peptide-HLA-A\*02:01 directed T cell receptor CD3 T cell engager. The TCR arm binds to a gp100 peptide presented by human leukocyte antigen-A\*02:01 (HLAA\*02:01) on the cell surface of uveal melanoma tumor cells.

In vitro, tebentafusp-tebn bound to HLA-A\*02:01-positive uveal melanoma cells and activated polyclonal T cells to release inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumor cells.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

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

## TAR Criteria

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

- Must be used for FDA indications and dosages.
- Patient must be 18 years of age or older.
- Patient must have a histologically or cytologically confirmed metastatic uveal melanoma (mUM).
- Patient meets one of the following criteria for prior treatment:
  - No prior systemic therapy in the metastatic or advanced setting including chemotherapy, immunotherapy, or targeted therapy
  - No prior regional, liver-directed therapy including chemotherapy, radiotherapy, or embolization
  - Prior neoadjuvant or adjuvant therapy is allowed provided administered in the curative setting in patients with localized disease

- Patient is human leukocyte antigen (HLA)-A\*02:01 positive by central assay.
- Patient has Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1.
- Female patients of reproductive potential to use effective contraception.
- Patient does not have the following:
  - Systemic or untreated CNS metastases
  - History of severe hypersensitivity reactions to other iologic drugs or monoclonal antibodies
  - Clinically significant cardiac or impaired cardiac function
  - Active infections or inflammations.
- Documentation of ALT, AST, and total bilirubin at baseline and periodically during treatment.

Initial Authorization is for six months.

### **Continued therapy**

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

**Reauthorization is for 12 months.**

### **Age Limits**

Must be 18 years of age or older.

### **Billing**

HCPCS code J9274 (injection, tebentafusp-tebn, 1 mcg)

### **Required ICD-10 Diagnosis Codes**

C69.31, C69.32, C69.41, C69.42, C69.61, C69.62, Z85.840

### **Prescribing Restriction(s)**

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

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



## **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)

## **Teclistamab-cqyv (TECVAYLI™)**

Teclistamab-cqyv is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells.

In vitro, teclistamab-cqyv activated T-cells, caused the release of various proinflammatory cytokines, and resulted in the lysis of multiple myeloma 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 18 years of age or older.

### **Billing**

HCPCS code J9380 (injection, teclistamab-cqyv, 0.5 mg)

### **Suggested ICD-10-CM Diagnosis Codes**

C90.00, C90.02

### **TECVAYLI REMS**

The purpose of the TECVAYLI REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity (ICANS) by educating prescribers on the importance of monitoring patients for signs and symptoms of CRS and neurologic toxicity, including ICANS.

- Prescribers must be certified in the TECVAYLI REMS to treat patients with TECVAYLI.
- Pharmacies and Healthcare Settings must be certified in the TECVAYLI REMS to dispense TECVAYLI to patients.

### **Availability**

Available through a single in-network specialty distributor, CVS.

## **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 equals 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 T Policy* section in the Part 2 manual for details.»

## **Tisagenlecleucel (Kymriah™)**

KYMRIAH is a CD19 (Cluster of Differentiation 19)-directed genetically modified autologous T cell immunotherapy which involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells. The CAR is comprised of a murine single-chain antibody fragment which recognizes CD19 and is fused to intracellular signaling domains from 4-1BB (CD137) and CD3 zeta. The CD3 zeta component is critical for initiating T-cell activation and antitumor activity, while 4-1BB enhances the expansion and persistence of Kymriah. Upon binding to CD19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of the Kymriah cells.

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirement**

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

### **TAR Criteria**

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.
- Must be prescribed by or in consultation with an oncologist or a hematologist.
- The provider facility is certified by the Kymriah REMS (Risk Evaluation Management Strategy) Program for tisagenlecleucel administration.
- Outpatient administration is restricted to Hospital Outpatient Services only.
- The physician's legible, complete, and signed treatment plan/order for tisagenlecleucel.

Initial authorization is for three months (one dose only).

### **Reauthorization**

Reauthorization is not approvable.

## Kymriah REMS Requirements

- All hospitals and their associated clinics must be certified and enrolled in the Kymriah REMS to be able to infuse Kymriah.
- All relevant staff involved in the prescribing, dispensing, or administering of Kymriah are trained on Kymriah REMS requirements and must successfully complete the Kymriah REMS Knowledge Assessment.

## 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 equals a single infusion of up to 600 million autologous anti-CD19 CAR-positive viable T cells.

Administration code: CPT code 96413 (Chemotherapy administration, intravenous infusion; up to 1 hour, single or initial substance/drug).

### Important Instructions for Billing

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

1. Submit and receive back an approved TAR/Service Authorization Request (SAR).
2. Bill using Q2042 (tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).
3. Completion of claim forms:
  - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I
  - Providers must submit one service line on the TAR/SAR request and enter “6” in the *Units* box
  - On the 837I or *UB-04* claim form, provider must submit one claim line to represent one service
    - ❖ Claims submitted with more than one claim line will be denied
  - Providers must submit an invoice for reimbursement
  - This process will ensure that the total reimbursement paid for the quantity of six (6) is no more than the paid price on the provider submitted invoice
  - Kymriah must be billed on its own with no other drug or biological
4. For instructions regarding physician claim form completion, refer to the [Forms](#) page on the [Medi-Cal Providers website](#), for completion of 837I and *UB-04* claim forms. Providers may also refer to the [UB-04 Completion: Outpatient Services](#) section of the Provider Manual.

5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 96413.

## 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)

## Prescribing Restrictions

Frequency of billing is once in a lifetime.

## Tisotumab vedotin-tftv (Tivdak™)

Tisotumab vedotin-tftv is a tissue factor (TF)-directed antibody drug conjugate (ADC). The antibody is a human IgG1 directed against cell surface TF. TF is the primary initiator of the extrinsic blood coagulation cascade. The small molecule, MMAE, is a microtubule-disrupting agent, attached to the antibody via a protease-cleavable linker. Nonclinical data suggests that the anticancer activity of tisotumab vedotin-tftv is due to the binding of the ADC to TF expressing cancer cells, followed by internalization of the ADC-TF complex, and release of MMAE via proteolytic cleavage. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death. In vitro, tisotumab vedotin-tftv also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity.

## Indications

All FDA-approved indications

## Dosage

FDA-approved dosages

## TAR Requirement

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

## Age Limit

Must be 18 years of age or older.

## Billing

HCPCS code J9273 (injection, tisotumab vedotin-tftv, 1 mg)

## Prescribing Restriction(s)

Frequency of billing equals 2 mg/kg (up to a maximum of 200 mg/200 units) every 3 weeks

## 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/m<sup>2</sup> by intravenous infusion over 30 minutes daily for five consecutive days, starting on day one 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/m<sup>2</sup> by intravenous infusion over 30 minutes daily on days one, two and three; followed by cisplatin 50 mg/m<sup>2</sup> 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 equals 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 (YONDELIS®)

Trabectedin is an alkylating drug that binds guanine residues in the inor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death.

## 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 J9352 (injection, trabectedin, 0.1 mg).

## Required Codes

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

## 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

Must be 18 years of age 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 equals 10 mg of trastuzumab

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

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

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

One (1) unit of Q5114 equals 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 equals Every 21 days

Maximum billing units equals 1,820 mg equals 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 equals 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 equals every 21 days

Maximum billing units equals 1,820 mg equals 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 equals 10 mg of trastuzumab and hyaluronidase-oysk

**Tremelimumab-actl (Imjudo®)**

Cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) is a negative regulator of T-cell activity. Tremelimumab-actl is a monoclonal antibody that binds to CTLA-4 and blocks the interaction with its ligands CD80 and CD86, releasing CTLA-4-mediated inhibition of T-cell activation. In synergistic mouse tumor models, blocking CTLA-4 activity resulted in decreased tumor growth and increased proliferation of T cells in tumors.

**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 J9347 (injection, tremelimumab-actl, 1 mg)»

## Prescribing Restrictions

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)

## **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 six 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 equals 240 mg/m<sup>2</sup> 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

HPCS 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 m<sup>2</sup>.

## **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/m<sup>2</sup> 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 m<sup>2</sup>” 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.

<b>Symbol</b>	<b>Description</b>
«	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.