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## Chemotherapy: Drugs P-Q Policy

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Page updated: May 2024

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* manual section. Additional policy information for chemotherapy drug services can be found in manual sections:

- Chemotherapy: Drugs A Policy
- Chemotherapy: Drugs B Policy
- Chemotherapy: Drugs C Policy
- Chemotherapy: Drugs D Policy
- Chemotherapy: Drugs E-H Policy
- Chemotherapy: Drugs I-L Policy
- Chemotherapy: Drugs M Policy
- Chemotherapy: Drugs N-O Policy
- Chemotherapy: Drugs R-S Policy
- Chemotherapy: Drugs T-Z Policy

## **Paclitaxel**

Paclitaxel is a natural product with antitumor activity and is obtained via a semi-synthetic process from *Taxus 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**

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 Limit**

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 Limit**

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, (udenycya), 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 Limit**

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.

- 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**

- Must be used for FDA labelled indications and dosing regimens.
- Patient must be 18 years of age or older.
- 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 Limit**

Must be 18 years of age or older.

**Billing**

HCPCS codes:

«J9292 (injection, pemetrexed (avyxa), not therapeutically equivalent to J9305, 10 mg).»

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 folypolyglutamate 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 Limit**

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 Limit**

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 three to five 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 eight 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**

HCPSC code J9307 (injection, pralatrexate, 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.