Chemotherapy: Drugs T-Z Policy

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 P-Q Policy
- Chemotherapy: Drugs R-S Policy

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 six 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 One (1): days one, four, eight, 15 and 22 of the 28-day cycle.
- Cycles Two and Three (2 and 3): days one, eight, 15 and 22 of each 28-day cycle.
- Cycle Four (4) and beyond: days one and 15 of each 28-day cycle.

Tagraxofusp-erzs (Elzonris)

Tagraxofusp-erzs is a CD123-directed cytoxin composed of recombinant human interleukin-3 (IL-3) and truncated diptheria toxin (DT) fusion protein that inhibits protein synthesis and causes cell detah 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 Limit

Must be two years of age or older.

Billing

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

Prescribing Restrictions

Frequency of billing equals on days one thru five 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 Limit

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 one 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 distributers must only distribute TALVEY to certified pharmacies.

Further information about the TECVAYLI and TALVEY REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

Age Limit

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

Tarlatamab-dlle for Injection (Imdelltra™)

Tarlatamab-dlle is a bispecific T-cell engager that binds to DLL3 expressed on the surface of cells, including tumor cells, and CD3 expressed on the surface of T-cells. Tarlatamab-dlle causes T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells. Tarlatamab-dlle had anti-tumor activity in mouse models of SCLC.

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 J9026 (injection, tarlatamab-dlle, 1 mg).››

Prescribing Restriction(s)

Maximum billing unit(s) equal to 10 mg/10 units.

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 Limit

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 three or four pneumonitis.
- For grade three or four immune-mediated hepatitis.
- For grade four diarrhea or colitis.
- For grade four hypophysitis.
- For any grade of meningitis or encephalitis; or myasthenic syndrome/myasthenia gravis; or Guillain-Barré syndrome.
- For grade for or any grade of recurrent pancreatitis.
- In patients with grade three or four 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 three 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 Limit

Must be 18 years of age or older.

Billing

HCPCS code J9380 (injection, teclistamab-cgyv, 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 tisagenleceucel 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 HCPCS code 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:

‹‹TAR/SAR Submission››

1. Submit and receive back an approved TAR/Service Authorization Request (SAR).
2. ‹‹Providers must submit one service line on the TAR/SAR request and enter “6” in the *Units* box

Claim Submission››

1. Bill using Q2042 (tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).
2. Completion of claim forms:
   - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I
   - ‹‹On the 837I or *UB-04* claim form, provider must submit one claim line to represent one service or six (6) units.››
     - 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

3. 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.

4. 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.

Tislelizumab-jsgr (TEVIMBRA)

Binding of the PD-1 ligands PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Tislelizumab-jsgr binds to PD-1 and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.

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 the following:

- Must be 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.
- Confirmed diagnosis of esophageal squamous cell carcinoma (ESCC).
- Tumor progress during or after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor for advances unresectable/metastatic ESCC.
- Inadequate response, intolerance, or contraindication to nivolumab or pembrolizumab.
- Patient is evaluated for baseline liver enzymes, creatinine, and thyroid function.
- Pregnancy testing and advice on contraception are provided to patient of reproductive potential prior to initiating treatment.

Initial authorization is for 12 months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has an absence of unacceptable toxicities or side effects, including immune-mediated adverse reactions, severe infusion reactions.

Reauthorization is for 12 months.››

‹‹Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9329 (injection, tislelizumab-jsgr, 1mg)

Prescribing Restriction(s)

Frequency of billing is equal to 200 mg / 200 units every three weeks
Maximum billing unit(s) is equal to 200 mg / 200 units››

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 three 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^2 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^2 by intravenous infusion over 30 minutes daily on days one, two and three; followed by cisplatin 50 mg/m^2 by intravenous infusion on day one, 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, C53.0 thru C53.9, C56.1 thru C57.4

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.

Toripalimab (LOQTORZI)

Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Toripalimab-tpzi is a humanized IgG4 monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth.

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 J3263 (injection, toripalimab-tpzi, 1 mg).

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 Limit

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. The HER2 (or c-erbB2) proto-oncogene encodes a transmembrane receptor protein of 185 kDa, which is structurally related to the epidermal growth factor receptor. Herceptin has been shown, in both in vitro assays and in animals, to inhibit the proliferation of human tumor cells that overexpress HER2. Herceptin is a mediator of antibody-dependent cellular cytotoxicity (ADCC). In vitro, Herceptin-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.

Age Limit

Must be 18 years of age or older.

TAR Requirement

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

Required ICD-10-CM 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 codes:

J9355 (injection, trastuzumab, excludes biosimilar, 10 mg).

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

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

‹‹Q5146 (injection, trastuzumab-strf (hercessi), biosimilar, 10 mg).››

Trastuzumab-anns (Kanjinti)

Trastuzumab-anns is a humanized lgG1 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 Limit

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 Limit

Must be 18 years of age 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 Limit

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 Limit

Must be18 years of age 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 two to five 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 Limit

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 four doses every 21 days, followed by 75 mg/75 units per one 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 zero to two.

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 Limit

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^2 administered prior to each chemotherapy regiment.

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 four weeks
- 11.25 mg every 12 weeks
- 22.5 mg every 24 weeks

Required Codes

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

Billing

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

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

Vincristine Sulfate

Vincristine sulfate 1 mg (HCPCS code J9370). The maximum dose is 4 mg; however, a dose in excess of 4 mg is allowed with documentation of body surface area greater than 2.75 m^2.

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^2” in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim or on an attachment.

Billing

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

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

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

Ziv-aflibercept

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

Indications

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

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

Authorization

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

Dosage

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

Billing

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

Legend

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

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