Chemotherapy: Drugs A-D Policy

Page updated: August 2020

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 E-O* and *Chemotherapy: P-Z* sections in this manual.

Ado-Trastuzumab Emtansine

Ado-trastuzumab emtansine is a Human Epidermal Growth Factor Receptor 2 (HER2)-targeted antibody-drug conjugate which contains the humanized anti-HER2 IgG1, trastuzumab, covalently linked to the microtubule inhibitory drug DM1 (a maytansine derivative) via the stable thioether linker MCC (4-[N- maleimidomethyl] cyclohexane-1-carboxylate). Emtansine refers to the MCC- DM1 complex. Upon binding to sub-domain IV of the HER2 receptor, ado- trastuzumab emtansine undergoes receptor-mediated internalization and subsequent lysosomal degradation, resulting in intracellular release of DM1- containing cytotoxic catabolites. Binding of DM1 to tubulin disrupts microtubule networks in the cell, which results in cell cycle arrest and apoptotic cell death.

Indications

For the treatment of patients with HER2 positive metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. They should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. Documentation must be submitted with the TAR to establish medical necessity.

Dosage

The recommended dose of ado-trastuzumab emtansine is 3.6 mg/kg given as an intravenous infusion every three weeks (21-day cycle) until disease progression or unacceptable toxicity. Ado-trastuzumab emtansine should not be administered at doses greater than 3.6 mg/kg nor should it be substituted for or used with trastuzumab.

Billing

HCPCS code J9354 (injection, ado-trastuzumab emtansine, 1 mg)

Belantamab mafodotin-blmf (BLENREP®)

Belantamab mafodotin-blmf is an antibody-drug conjugate (ADC). The antibody component is an afucosylated IgG1 directed against BCMA, a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is MMAF, a microtubule inhibitor. Upon binding to BCMA, belantamab mafodotin-blmf is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis. Belantamab mafodotin-blmf had antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

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

REMS Program

Belantamab mafodotin-blmf is available only through a restricted program under a Risk Evaluation and Management Strategy (REMS) called the Blenrep REMS because of the risks of ocular toxicity.

Notable requirements of the Blenrep REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training in the Blenrep REMS
- Prescribers must counsel patients receiving belantamab mafodotin-blmf about the risk of ocular toxicity and the need for ophthalmic examinations prior to each dose
- Patients must be enrolled in the Blenrep REMS and comply with monitoring
- Healthcare facilities must be certified with the program and verify that patients are authorized to receive belantamab mafodotin-blmf
- Wholesalers and distributers must only distribute belantamab mafodotin-blmf to certified healthcare facilities

Further information is available at http://www.blenreprems.com and 1-855-209-9188.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J9037 (injection, belantamab mafodontin-blmf, 0.5 mg)

Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.02

Prescribing Restriction(s)

Frequency of billing = 2.5 mg/kg once every 21 days

Belinostat

Belinostat is a histone deacetylase inhibitor and catalyzes the removal of acetyl groups from the lysine residues of histones and some non-histone proteins. In vitro, belinostat caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells with preferential cytotoxicity towards tumor cells compared to normal cells.

Indications

For the treatment of patients 18 years of age and older with relapsed or refractory peripheral T-cell lymphoma.

Authorization

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

Dosage

The recommended dose is 1,000 mg/m^2 once daily on days 1 through 5 of a 21-day cycle.

Billing

HCPCS code J9032 (injection, belinostat, 10 mg)

Brexucabtagene autoleucel (Tecartus™)

Brexucabtagene autoleucel, a CD19 (Cluster of Differentiation 19)-directed genetically modified autologous T cell immunotherapy, binds to CD19-expressing cancer cells and normal B cells. Studies demonstrated that following anti-CD19 CAR T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosages
- Must be administered in a health care facility registered with the Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program
- Patient must be 18 years of age or older
- Patient must have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)
- Patient previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody (for example, rituximab), and a Bruton tyrosine kinase inhibitor (BTKi) (for example, acalabrutinib, ibrutinib, zanubrutinib)
- Patient had disease progression after their last regimen or refractory disease to their most recent therapy
- Patient must have adequate bone marrow, cardiac, pulmonary, renal, and organ functions

- Patient does not have the following:
  - Active or serious infections
  - Prior allogeneic hematopoietic stem cell transplant (HSCT)
  - Detectable cerebrospinal fluid malignant cells or brain metastases
  - History of central nervous system (CNS) lymphoma or CNS disorders
- TECARTUS is not prescribed concurrently with other CAR T-cell immunotherapy (for example, Kymriah, YESCARTA)

Initial Authorization is for three months (1 dose only)

Reauthorization

Continued therapy is not approvable.

REMS Program

TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program. This is due to Cytokine Release Syndrome and Neurologic Toxicities. TECARTUS must be administered in a certified health care facility**.**

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code Q2053, Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Providers are to take the following steps when submitting claims for TECARTUS:

- Submit and receive back an approved *Treatment Authorization Request* (TAR)

- Completion of claim forms:
  - Outpatient claims may be billed by paper claim using *CMS-1500* or electronically using ASC X12N 837P v.5010.
  - Providers must submit one (1) service line on the TAR request, and enter “4” in the Units box
  - On the 837P or *CMS-1500* claim form, provider must submit one claim line to represent one (1) service.
    - ❖ Claims submitted with more than one claim line will be denied
      - Provider must submit an invoice for reimbursement.
      - This process will ensure that the total reimbursement paid for the quantity of four (4) is no more than the paid price on the provider submitted invoice
      - Tecartus must be billed on its own with no other drug or biological
      - For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of 837P and *CMS-1500* claim forms.

Suggested ICD-10-CM Diagnosis Codes

C83.10, C83.11, C83.12, C83.13, C83.14, C83.15, C83.16, C83.17, C83.18, C83.19

Prescribing Restrictions

Frequency of billing equals one dose only. No repeat authorization