Template Background Paper – Administration of Drug/Therapeutic Agent

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of……

New Technology Application? (Select one) Yes or No. Provide full details regarding NTAP application (intent to submit or date of application submission), if applicable. *Example: Yes. The requestor intends to submit (or has submitted) a New Technology Add-on Payment (NTAP) application for FY 2025 consideration.*

Food & Drug Administration (FDA) Approval? (Select one) Yes or No. Provide full details regarding FDA approval and/or application submission, if applicable. *Examples: Specify if the drug/therapeutic agent received designation as a Qualified Infectious Disease Product (QIDP), Orphan Drug, Regenerative Medicine Advanced Therapy (RMAT), or Breakthrough designation, the date received and for what indication. Provide the target Prescription Drug User Fee Act (PDUFA) date or identify if a Biologics License Application (BLA) was submitted.*

Background: In paragraph form, as shown in the **Sample Background Paper** that follows, provide information regarding the clinical indication for this drug/therapeutic. Describe what condition(s) the drug/therapeutic agent is intended to treat and the population (percentage/case volume) currently affected. Explain what the current treatment/therapy is and why the new therapy is an improvement, if applicable.

Mechanism of Action
In paragraph form, as shown in the **Sample Background Paper** that follows, describe the mechanism of action of the drug/therapeutic.

Inpatient Administration of ……
Describe the procedural steps involved and the routes of administration for the drug/therapeutic.

Example: The proposed dosing for …… is XX mg/kg administered by a health care professional via intravenous infusion over XX minutes.

Requested Implementation Date: (Select one) April 1 or October 1

Current Coding: (*CMS can assist with current coding and coding options once your background paper is received and reviewed)*

Facilities can report the administration of …… using the following code.

XXXXXXX Introduction of other therapeutic substance into XXXXX, percutaneous approach

Sample Background Paper – Administration of Drug/Therapeutic Agent

Administration of ciltacabtagene autoleucel (cilta-cel)

Issue: There are no unique ICD-10-PCS codes to describe the administration of ciltacabtagene autoleucel (cilta-cel), an autologous chimeric-antigen receptor (CAR) T-cell therapy.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? Cilta-cel was granted Breakthrough Therapy designation for the treatment of relapsed or refractory multiple myeloma in December 2019. The requestor will be seeking approval for a Biologics License Application (BLA).

Background: Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells. In 2020, it is estimated that more than 32,000 people were diagnosed and nearly 13,000 died from multiple myeloma in the US. Multiple myeloma is associated with substantial morbidity and mortality and approximately 25% of patients have a median survival of two years or less. Treatment of relapsed and refractory multiple myeloma constitutes a specific unmet medical need. Patients with relapsed and refractory disease are defined as those who, having achieved a minor response or better, relapse and then progress while on therapy, or experience progression within 60 days of their last therapy.

Treatment of relapsed or refractory multiple myeloma is particularly challenging, as additional genetic mutations/alterations are continuously acquired, resulting in double-, triple-, or even multiple-refractoriness to many of the current multiple myeloma treatment options. CAR T-cell-based therapies offer potential advantages over current therapeutic strategies. In general, the growing population of patients whose multiple myeloma is refractory to current treatments provides an opportunity for novel therapies. To date, there are no currently approved CAR T-cell therapies for the treatment of multiple myeloma.

Description of Ciltacabtagene autoleucel (cilta-cel)
Ciltacabtagene autoleucel (cilta-cel) is an autologous CAR T-cell therapy directed against B-cell maturation antigen, BCMA, for the treatment of patients with relapsed or refractory multiple myeloma. BCMA plays a central role in regulating B-cell maturation and differentiation into plasma cells. Cilta-cel is designed to recognize myeloma cells and target their destruction. Its CAR T-cell technology consists of harvesting the patient's own T-cells, programming them to express a chimeric antigen receptor that identifies BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells, and reinfusing these modified cells back into the patient where they bind to the myeloma cells displaying the BCMA antigen. The T-cells become activated and proliferate resulting in the release of pro-inflammatory cytokines and cytotoxic killing of malignant myeloma cells.

Mechanism of Action
Unlike the chimeric antigen receptor design of currently approved CAR T-cell immunotherapies, which are composed of a single-domain antibody (sdAbs), ciltacabtagene autoleucel (cilta-cel) is

composed of two antibody binding domains that allow for high recognition of human BCMA (CD269) and elimination of BCMA expressing myeloma cells. The two distinct BCMA-binding domains confer avidity and distinguish cilta-cel from other BCMA-targeting products. The BCMA-binding domains are linked to the receptor's interior costimulatory (4-1BB) and signaling (CD3ζ) domains through a transmembrane linker (CD8a). These intracellular domains are critical components for T cell growth and anti-tumor activity in the body once CAR T-cells are bound to the BCMA target on multiple myeloma cells.

Inpatient Administration of Ciltacabtagene Autoleucel (cilta-cel)
Ciltacabtagene autoleucel is given as a single intravenous infusion administered through the central or peripheral vein, primarily as a standalone procedure. Once infused into the patient, CAR T-cells are able to identify BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells and target their destruction. The target dose of cilta-cel is 0.75 x 106 CAR-positive viable T-cells per kg body weight (range: 0.5-1.0 x 106 cells/kg).

Requested Implementation Date: October 1

Current Coding: Facilities can report the intravenous administration of ciltacabtagene autoleucel (cilta-cel) with one of the following ICD-10-PCS codes:

XW033C7	Introduction of autologous engineered chimeric antigen receptor T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW043C7	Introduction of autologous engineered chimeric antigen receptor T-cell immunotherapy into central vein, percutaneous approach, new technology group 7