

Template Background Paper – Administration of Drug/Therapeutic Agent

Issue: There are currently no unique ICD-10-PCS codes to describe.....

New Technology Application? (Select one) Yes or No. Provide full details regarding NTAP application (intent to submit or date of application submission), if applicable.

Food & Drug Administration (FDA) Approval? (Select one) Yes or No. Provide full details regarding FDA approval and/or application submission, if applicable.

Background: Provide information regarding the clinical indication for this drug/therapeutic.

- *What diagnoses are associated with or indicated for use of the drug/therapeutic agent?*
- *How is the indication currently treated or managed?*

Mechanism of Action

Describe the mechanism of action of the drug/therapeutic.

- *Describe the drug/therapeutic agent in general terminology for which you are requesting a new or revised procedure code*
 - *What is it?*
 - *What does it do?*
 - *Is it only used for the inpatient setting or is it also used in the outpatient setting?*
- *Have there been any associated complications/sequela/adverse events? If yes, how many and what did they consist of? (E.g. fever, shortness of breath, anaphylaxis, etc.)*

Inpatient Administration of

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

- *What are the procedural steps involved?*
- *What are the routes of administration for the drug?*

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 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 0.75×10^6 CAR-positive viable T-cells per kg body weight (range: $0.5\text{--}1.0 \times 10^6$ 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 |

Template Background Paper – Device/Technology/Service or Procedure

Issue: There are currently no unique ICD-10-PCS codes to describe.....

New Technology Application? (Select one) Yes or No. Provide full details regarding NTAP application (intent to submit or date of application submission), if applicable.

Food & Drug Administration (FDA) Approval? (Select one) Yes or No. Provide full details regarding FDA approval and/or application submission, if applicable.

Background: Provide information regarding the clinical indication for this device/technology/service or procedure.

- *What diagnoses are associated with or indicated for use of the device/technology/service or procedure?*
- *How is the indication currently treated or managed?*

Technology

Describe the device/technology/service/procedure.

- *Describe the device/technology/service or procedure in general terminology for which you are requesting a new or revised procedure code.*
 - *What is it?*
 - *What does it do?*
 - *How is it used?*
- *Have there been any associated complications/sequela/adverse events? If yes, how many and what did they consist of? (E.g. dislodgement, failure, loosening, etc.)*

Procedure Description

Describe how the technology/service/procedure is performed.

- *What are the procedural steps involved?*
- *If the technology is a device or implant, is only one device/implant routinely inserted or can multiple devices/implants be utilized?*
- *If the technology involves a device or implant, is the device considered permanent?*
- *If the procedure involves vessels or specific body parts, is it beneficial or necessary to identify a range of the specific site? (E.g. 2-3 vertebrae, 4+ vessels or stents, etc.)*
- *Is the procedure/technology performed in conjunction with another procedure/technology or is it considered a standalone procedure/technology?*

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 using the following code.

XXXXXXX Insertion of _____ into XXXXX, percutaneous approach

Sample Background Paper – Device/Technology/Service or Procedure

Restriction of Coronary Sinus

Issue: There is currently no unique ICD-10-PCS code to describe the insertion of a reduction device in the coronary sinus for refractory angina.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approved? FDA approval for the Reducer™ System is anticipated for FY 2021. The Reducer Device was granted Breakthrough Medical Device Status by the FDA in October 2018.

Background: Chronic angina pectoris, refractory to medical and interventional therapies, is a common and disabling medical condition, and a major public health problem that affects millions of patients worldwide. The clinical burden of refractory angina (RA) is growing due to an aging population and improved survival from coronary artery disease (CAD). Estimates suggest that in the US up to 1.8 million patients suffer from RA. An increasing number of patients, particularly those with advanced, chronic coronary artery disease, have severe symptoms of angina despite optimal medical therapy. However, RA is common not only in patients who are not good candidates for revascularization, but also in patients following successful revascularization. Persistence or recurrence of angina after PCI or CABG surgery is well recognized and may affect 20–40% of patients during short and medium-term. When further revascularization options are limited, these patients are frequently described as being “no option,” and as having RA. The care of these patients is challenging, and the guidance available from national practice guidelines is limited.

The target population are patients with RA that suffer from chest pain that persists in spite of optimal medical therapy, who have evidence of reversible ischemia, and are not amenable to revascularization.

Technology

The Neovasc Reducer System is a device implanted in the coronary sinus vein using minimally invasive techniques. The Reducer creates a permanent and controlled narrowing of the coronary sinus. It is placed via a balloon catheter with a unique hourglass shaped balloon. By modulating blood flow and pressure in the coronary sinus, the Reducer acts to increase the perfusion of oxygenated blood to certain areas of the heart muscle, thereby reducing the pain and disability caused by the condition. The Neovasc Reducer System is comprised of the Reducer Balloon Catheter and the Reducer device. The Reducer Balloon Catheter is an over the wire catheter with a unique hourglass shaped balloon.

Procedure Description

The Neovasc Reducer procedure begins under ultrasound. A right jugular venous access is obtained and an introducer sheath is inserted over a J-wire. A multipurpose (MP) guiding catheter is inserted into the ostium of the coronary sinus (CS) without a guiding wire. After the tip of the catheter is engaged, the catheter is advanced into the CS either with or without guidewire assistance. A long guidewire (0.35”J-wire or a SupraCore wire) is then advanced within the multipurpose catheter

deep into the great cardiac vein (as distal as possible into the CS), and the diagnostic catheter is removed.

There are two implantation options:

Implantation option 1: If SupraCore wire is used, the Reducer system inside a 9F guiding catheter (GC), is advanced over the SupraCore guidewire into the CS so that the tip of the GC and the Reducer system's tip is distal to the planned implantation target. The GC is withdrawn to the most proximal marker on the Reducer system, exposing the Reducer, which is held in the landing zone previously identified.

Implantation option 2: If a regular long J-wire is used, the diagnostic 6F MP catheter is inserted into the 9F GC and is advanced over the wire deep into the CS. After the MP's tip is located in the great cardiac vein, the MP and the wire are held in place as an anchor and the GC is advanced. The tip of the GC is placed distal to the target landing zone planned for the Reducer. The MP diagnostic catheter is then removed. The Reducer system is inserted and advanced inside the GC and positioned in the planned implantation target. The GC is now withdrawn to the most proximal marker on the Reducer system, exposing the Reducer, which is held in the landing zone previously identified.

Coronary sinus narrowing has been demonstrated to improve perfusion to ischemic territories of the myocardium which lead to relief of angina symptoms in patients with refractory angina. The Reducer therapy has extensive clinical data, including a randomized, double-blind, sham-controlled study published in the New England Journal Medicine. Available literature demonstrates similar results from hundreds of patients across multiple geographies, including one study with 12-year follow-up demonstrating long-term safety and benefit.

Requested Implementation Date: October 1

Current Coding: Facilities can report procedures for insertion of a reduction device in the coronary sinus using the following code.

02H43DZ Insertion of intraluminal device into coronary vein, percutaneous approach