Template Background Paper – Device/Technology/Service or Procedure

Issue: There are currently no unique ICD-10-PCS codes to describe the…..
Examples: insertion/implantation/monitoring/measurement/testing/etc.

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 Device/Technology/Service or Procedure received designation as a Breakthrough Device or, Humanitarian Use Device (HUD), was granted Investigational Device Exemption (IDE) or received 501(k) clearance, the date received and for what indication. Identify when requestor intends to submit (or has submitted) a Premarket Notification 510(k) or Premarket Approval (PMA) application.*

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

Technology
In paragraph form, as shown in the **Sample Background Paper** that follows, describe the device/technology/service/procedure. *Example: Specify the material/properties, components, function, etc.*

Procedure Description
In paragraph form, as shown in the **Sample Background Paper** that follows, 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