Template Background Paper – Device/Technology/Service or Procedure

Issue: Using the following example as a guide, provide full details regarding the ICD-10-PCS request. Also, indicate the requested implementation date for the requested ICD-10-PCS code: **(Select one)** April 1 or October 1.

Example: There is currently no unique ICD-10-PCS code to describe the insertion of a reduction device in the coronary sinus for refractory angina. The requestor is seeking an October 1, 2022 implementation date.

New Technology Application? (Select one) Yes or No.
Using the following examples as a guide, provide full details regarding NTAP application status (intent to submit or application submission), if applicable. Also, indicate the fiscal year (FY) for which the application is being or has been submitted for consideration.

Example: Yes. The requestor intends to submit (or has submitted) a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.
Example: No.

Food & Drug Administration (FDA) Approval? (Select one) Yes or No. 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.

Using the following examples as a guide, provide full details regarding FDA approval and/or application submission, if applicable.

Example: No. 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.
Example: Yes. SeptiCyte® RAPID received FDA 510(k) clearance on November 29, 2021 as a class II medical device as an aid to differentiate sepsis from infection negative systemic inflammation.

Background: In paragraph form, as shown in the Sample Background Paper, and in the example 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.

Example: 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

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

Example: 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

In paragraph form, as shown in the Sample Background Paper, and in the example 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?

Example: 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