

ICD-10 Coding Change Request for Percutaneous Creation of Arterio-Venous Fistulas Using Thermal Resistance Energy

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Presenter

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Additional Codes for Percutaneous Creation of Arterio-Venous Fistulas

- This code request is for additional codes to describe percutaneous creation of an arterio-venous fistula (AVF)
- Hemodialysis requires circulation of blood from the body, through an external dialysis machine, and back to the body
- AVFs are the major form of vascular access in use (alternatives are central line catheters and AV grafts)
 - AVFs are generally preferred to help avoid infections
- Until recently, the only way to create an AVF was through open surgery. New devices have enabled a percutaneous approach

Percutaneous Arterio-Venous Fistulas -- pAVFs

- Creation of a pAVF involves bringing an artery and a vein in the forearm closely together and creating a channel between them
- This approach leaves the two vessels side-by-side, while surgical AVF creation usually involves truncation of one vessel and attaching it to the other
- The percutaneous approach avoids an extensive surgical wound and is less disruptive to neighboring tissues

What is the Ellipsys Vascular Access System?

- The Ellipsys Vascular Access System has two components:
 - A **single catheter device** with specialized tip designed to mechanically capture and compress the walls of an artery and an adjacent vein, then to transmit a very short burst of thermal resistance energy to weld the two vessels together
 - A specialized **external power source**, used to provide the energy to the catheter
- In addition, a needle, guidewire, and sheath are used to puncture the two vessels and position the catheter
- The pAVF is placed under ultrasound guidance; fluoroscopy is not required

The Ellipsys Vascular Access System Is Used In a Two-Step Procedure

1. The physician inserts a crossing needle through the perforating vein and into the proximal radial artery and then uses the Ellipsys catheter to bring the two vessels together mechanically and weld them with a carefully calibrated burst of thermal resistance energy, thus creating an arterio-venous anastomosis. The catheter is then withdrawn
2. The physician immediately performs a balloon angioplasty of the anastomosis and the outflow vein to resolve vessel spasm resulting from the first step and to ensure an adequate flow volume (above 500 mL/min) at the time

Additional Points Relating to the Procedure

- This procedure is done in both inpatient and outpatient settings
- Diagnoses relate to end stage renal disease
 - N18.4 – Chronic kidney disease, stage 4
 - N18.5 – Chronic kidney disease, stage 5
 - N18.6 – End stage renal disease
- The current procedure codes identify specific body parts (radial arteries and lower arm veins). This specification of body parts is adequate – no further identification is necessary or beneficial
 - Current codes are: 031B3ZF – Bypass right radial artery to lower arm vein, percutaneous approach
 - 031C3ZF – Bypass left radial artery to lower arm vein, percutaneous approach
- If CMS approves an NTAP application for pAVF creation with Ellipsys, additional specification will be needed to distinguish pAVF creation using the Ellipsys from pAVF creation using the alternative technology –
 - Such specification should rely not on body parts (both technologies are indicated for use in the radial arteries) but on characteristics of the technology

Catheter Documentation and Use

- The use of the technology should be documented in the medical record for the surgical procedure (i.e., operation report)
 - We believe the specific technology would be identified by its brand name
- The procedure is a stand-alone procedure, though with two steps: creation and balloon angioplasty
- One Ellipsys catheter is used for this procedure; this specialized catheter is necessary for the percutaneous creation step.
 - The only other alternative technology available requires the use of two distinct catheters for each pAVF creation
- The catheter is not implanted and is not permanent

Complications and Adverse Events

- Complications have included inadequate flow through the AVF, vessel spasm, arterial steal syndrome, aneurism formation, stenoses, early fistula thromboses
 - These problems are not unusual in AVF creation, which is followed by a period of maturation before the AVF is ready for use and during which additional procedures may be required
 - pAVF with Ellipsys has generally lower complication rates than have been observed for traditional surgical AVFs
- While investigators have reported adverse events related to procedures in which the Ellipsys was used, Avenu Medical has identified none that are attributable to the device

Questions?

Thanks for your attention.