Treatment of common iliac or aortoiliac aneurysms with the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), when used also with the GORE® EXCLUDER® AAA Endoprosthesis, is an innovative intervention recently approved by the FDA (PMA P02004s123). Subsequent to FDA approval of any new service and / or technology and release to the marketplace, there are a number of steps to securing coding, coverage, and payment.

We are actively engaged in establishing reimbursement for cases utilizing the IBE. Because this is a new technology, it is important for HCPs to understand the current environment and what can be expected in the future.

**FACILITIES**

**Does the IBE have a HCPCS code?**

No. Implantable devices such as the IBE are not assigned a HCPCS code.

**How does the hospital get reimbursed for IBE cases?**

CMS has determined that the IBE meets all of the criteria for approval of new technology add-on payments for fiscal year (FY) 2017. The maximum new technology add-on payment for a case involving the use of the IBE is $5,250 for FY 2017.

Procedures with the IBE, which also include treatment of a AAA, are typically captured under the DRGs for “Aortic and Heart Assist Procedures” which now reflect a higher reimbursement rate due to the 2015 reclassification.

Procedures which treat isolated iliac aneurysms by IBE with the GORE® EXCLUDER® AAA Endoprosthesis are typically captured under the DRGs for “Other Major Cardiovascular Procedures”.

Please refer to reimbursement guidance obtained from your Sales Associate, or visit goremedical.com.

**How does the hospital report common iliac or aortoiliac aneurysm procedures utilizing the IBE?**

As of October 1, 2016, cases involving the IBE that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure codes:

- 04VC0EZ
- 04VC0FZ
- 04VC3EZ
- 04VC3FZ
- 04VD0EZ
- 04VD0FZ
- 04VD3EZ
- 04VD4FZ
- 04VD3EZ
- 04VD4EZ

For cases that also involve treatment of an aortic aneurysm, report the appropriate associated codes separately.

**PHYSICIANS**

**How will physicians report IBE procedures?**

Currently, the reporting of the procedure for treating common iliac or aortoiliac aneurysms with a bifurcated stent such as the Gore device is by the CPT® Category III Code, 0254T Endovascular repair of iliac artery bifurcation, and 0255T Radiologic S&I (for 0254T) for the radiologic service.

**What is a CPT® Category III Code?**

CPT® Category III Codes were developed by the American Medical Association’s (AMA) CPT® Editorial Panel to expand codes and descriptors to accommodate emerging technology and services in the provision of health care.

CPT® Category I Codes (the typical 5-digit codes) are restricted to clinically recognized and generally accepted services, and not emerging technologies, services, and procedures. CPT® Category III Codes are not required to conform to the CPT® Category I Code requirements but instead are for reporting services or procedures that must have a relevance for research, either ongoing or planned, or the need to be tracked to evaluate the frequency of use.
How are CPT® Category III Codes reimbursed?

As with CPT® Category I Codes, inclusion of a descriptor and its associated code number in CPT® Category Code nomenclature does not represent endorsement by the AMA of any particular diagnostic or therapeutic procedure or service. Additionally, inclusion or exclusion of a procedure or service does not imply any health insurance coverage or reimbursement policy.

When published, CPT® Category III Codes have not been evaluated by the Relative Value Scale Update Committee (RUC), the body responsible for evaluating and assigning Relative Value Units (RVUs) to CPT® procedure codes. Therefore, there are no fee schedules associated with CPT® Category III Codes. Additionally, these codes are generally considered as ‘non-covered’ services by the majority of payers.

Is the reporting of the CPT® Category III Codes a requirement?

Yes. CPT® instructions direct the user to “select the name of the procedure or service that accurately identifies the service performed.” Furthermore, CPT® instructions state that “If a Category III code is available, this code must be reported instead of a Category I unlisted code.”

When will the CPT® Editorial Panel create a CPT® Category I Code, or ‘normal’, code for IBE procedures?

Our Health Economics (HE) team is working with the Society of Vascular Surgeons and others toward the goal of establishing a CPT® Category I Code for aortic aneurysm with associated iliac branch aneurysm procedures. There are a number of timelines and requirements established by the CPT® Editorial Panel related to the transition to a CPT® Category I Code. These include, but are not limited to, FDA approval / clearance, consistency of the procedure with contemporary medical practice, efficacy that is established and supported in part via publication in U.S. peer-reviewed journals, and that the procedure is performed by many physicians in clinical practice.

Once these requirements have been met and evaluated by the CPT® Editorial Panel, a CPT® Category I Code will be assigned. Due to CPT® process timelines, the earliest a CPT® Category I Code will be effective is January 1, 2019.

Once a CPT® Category I Code is assigned, will this mean the procedure will automatically be covered?

A code does not necessarily equal coverage. There are a number of factors payers consider in making coverage determinations, including but not limited to general plan benefit limitations.* It is not unusual for a new-to-market device and its procedure to encounter coverage hurdles. Our HE team will continue to pursue and secure coverage as needed.

Why is it important to submit claims utilizing CPT® Category III Codes?

CPT® Category III Codes are a set of temporary codes for emerging technology, services, and procedures. These codes are intended to be used to track the usage of these services. A critical criteria of the CPT® process for CPT® Category I Code assignment is that “the procedure is performed by many physicians in clinical practice.” The ONLY way to capture this data is through the claims submission process.

What additional support can Gore provide to encourage reporting of the CPT® Category III Code?

We can provide educational support related to claims submission. Examples include appeal support such as conveying Medicare’s process and contact information; template appeal letters (tailored by and with patient-specific clinical information captured by the physician); bibliographic journal article resources. Our HE team is also available for direct support.

Does Gore expect reimbursement issues associated with the CPT® Category III Code?

Yes, it is anticipated that physicians will encounter denials associated with reporting a CPT® Category III Code. It is likely that claims will require additional information. An important step in the process is the claims submission and appeal process afforded physicians and patients. It may be necessary for appeals to be submitted by the physician to affect coverage and payment.

What steps is Gore taking to address coverage issues?

Our HE team will be working closely with all types of payers, including the Centers for Medicare and Medicaid Services (CMS) and Regional Medicare Administrative Contractor (MAC) Medical Directors to ensure continuous dialogue toward establishing coverage, particularly during the CPT® Category III Code phase.

* Gore recommends the prior authorization of services where the plan requires or allows.