CMS WILL NO LONGER BE PROVIDING PAPER COPIES OF HANDOUTS FOR THE MEETING. ELECTRONIC COPIES OF ALL MEETING MATERIALS WILL BE POSTED ON THE CMS WEBSITE PRIOR TO THE MEETING AT HTTPS://WWW.CMS.HHS.GOV/ICD9PROVIDERDIAGNOSTICCODES/03_MEETINGS.ASP

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Agenda

ICD-10 Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-10-PCS Topics
September 22, 2015

Pat Brooks, CMS – Co-Chairperson

Webcast and Dial-In Information

- The meeting will begin promptly at 9am ET and will be webcast.
- Toll-free dial-in access is available for participants who cannot join the webcast: Phone: 1-877-267-1577; Meeting ID: 998 963 192. We encourage you to join early, as the number of phone lines is limited.
- If participating via the webcast or dialing in you do NOT need to register on-line for the meeting.

This meeting is being webcast via CMS at http://www.cms.gov/live/. By your attendance, you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may disclose about you during the meeting. Please do not disclose personal health information.

Note: Proposals for diagnosis code topics are scheduled for September 23, 2015 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address:
http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

Introductions and Overview	Pat Brooks

ICD-10-PCS Topics:

1. Branched and Fenestrated Endograft Repair of Aneurysms Pages 12-16	Mady Hue Matthew J. Sideman, MD Vascular Surgeon University of Texas Health Science Center San Antonio, TX Chair of Coding Committee Society of Vascular Surgery RUC Advisor for SVS
2. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement Pages 17-19	Mady Hue Dr. Samir Kapadia Professor of Medicine, Director, Cardiac Catheterization Laboratory Cleveland Clinic
3. Intracardiac Pacemaker Pages 20-23	Chioma Obi Timothy Shinn, M.D. FACC Michigan Heart St. Joseph Mercy Health System
4. Endovascular Repair of Abdominal Aortic Aneurysms via Entire Sac-Sealing Pages 24-27	Chioma Obi Jeffrey Carpenter, M.D. Professor and Chairman Department of Surgery Cooper Medical School
5. Addenda and Key Updates Page 28	Rhonda Butler, 3M

Registering for the meeting:

Registration for the March 9-10, 2016 ICD-10 Coordination and Maintenance Committee meeting opens on February 1, 2016**. If participating by Livestream webcast or dialing in you do not need to register online.**

Information on registering online to attend the meeting can be found at:
http://www.cms.hhs.gov/apps/events/

For questions about the registration process, please contact Chioma Obi at 410-786-6050 or chioma.obi@cms.hhs.gov.

Continuing Education Credits:

Continuing education credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation in CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Calls, Meetings and Webcasts.

Continuing Education Information for American Academy of Professional Coders (AAPC)

If you have attended or are planning to attend a CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Call, you should be aware that CMS does not provide certificates of attendance for these calls. Instead, the AAPC will accept your e-mailed confirmation and call description as proof of participation. Please retain a copy of your e-mailed confirmation for these calls as the AAPC will request them for any conference call you entered into your CEU Tracker if you are chosen for CEU verification. Members are awarded one (1) CEU per hour of participation.

Continuing Education Information for American Health Information Management Association (AHIMA)

AHIMA credential-holders may claim 1 CEU per 60 minutes of attendance at an educational program. Maintain documentation about the program for verification purposes in the event of an audit. A program does not need to be pre-approved by AHIMA, nor does a CEU certificate need to be provided, in order to claim AHIMA CEU credit. For detailed information about AHIMA's CEU requirements, see the Recertification Guide on AHIMA's web site.

Please note: The statements above are standard language provided to CMS by the AAPC and the AHIMA. If you have any questions concerning either statement, please contact the respective organization, not CMS.

ICD-10 TIMELINE

A timeline of important dates in the ICD-10 process is described below:

September 22 –23, 2015	ICD-10 Coordination and Maintenance Committee meeting. Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 11, 2015.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
October 2015	Webcast of the September 22–23, 2015 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Summary report of the Diagnosis part of the September 22–23, 2015 ICD-10 Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm
October 1, 2015	ICD-10-CM/PCS codes go into effect along with ICD-10 MS-DRGs
October 1, 2015	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum from previous years are available on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd/icd10cm.htm Due to the partial code freeze there are no updates to ICD-10-CM for October 1, 2015. Procedure addendum – https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html
October 16, 2015	**Deadline for receipt of public comments on proposed new codes if any discussed at the September 22-23, 2015 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2016.**

November 2015	Any new ICD-10 codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2016 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html
November 13, 2015	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 22-23, 2015 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2016.**
January 15, 2016	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses by this date.**
February 2016	Tentative agenda for the Procedure part of the March 9, 2016 ICD-10 Coordination and Maintenance Committee meeting posted on CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the March 10, 2016 ICD-10 Coordination and Maintenance Committee meeting posted on NCHS webpage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm Federal Register notice of March 9–10, 2016 ICD-10 Coordination and Maintenance Committee Meeting will be published.
February 1, 2016	**On-line registration opens for the March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
March 2016	Because of increased security requirements, **those wishing to attend the March 9–10, 2016** ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by February 29, 2016; failure to do so may result in lack of access to the meeting**.

March 9 – 10, 2016	ICD-10 Coordination and Maintenance Committee meeting.
April 1, 2016	Any new ICD-10 codes to capture new diseases or technology on April 1, 2016, will be implemented.
April 8, 2016	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2016**.
April 2016	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the complete and finalized FY 2017 ICD-10-CM diagnosis and ICD-10-PCS procedure codes. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
April 2016	Webcast of the March 9-10, 2016 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html
	Summary report of the Diagnosis part of the March 10, 2016 ICD-10 Coordination and Maintenance Committee meeting report will be posted on the NCHS webpage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm
June 2016	Final addendum posted on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd/icd10cm.htm Procedure addendum - http://cms.hhs.gov/Medicare/Coding/ICD10/index.html
July 15, 2016	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee**

	meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.
August 1, 2016	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2016. This rule can be accessed at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
August 2016	Tentative agenda for the Procedure part of the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the September 13 –14, 2016 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at - http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm Federal Register notice for the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 5, 2016	**On-line registration opens for the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
September 2, 2016	Because of increased security requirements, those wishing to attend the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by September 2, 2016; failure to do so may result in lack of access to the meeting.**
September 13 –14, 2016	ICD-10 Coordination and Maintenance Committee meeting.

	Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 2, 2016.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
October 2016	Webcast of the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html Summary report of the Diagnosis part of the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm
October 1, 2016	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum available on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd/icd10cm.htm Procedure addendum – http://www.cms.gov/Medicare/Coding/ICD10/
October 16, 2016	**Deadline for receipt of public comments on proposed new codes discussed at the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2017.**
November 2016	Any new ICD-10 codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2017 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm http://www.cms.gov/Medicare/Coding/ICD10/
November 13, 2016	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2017.**

Introductions and Overview

- ICD-10 Coordination & Maintenance (C&M) Committee is a public forum on ICD-10-CM & ICD-10-PCS code updates
- CMS & CDC Co-chair the meetings
  - CMS has lead on procedure issues
  - CDC has lead on diagnosis issues
- Coding proposals presented and public given opportunity to comment

Code Proposals

- No final decisions made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment at meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - October 16, 2015 for new technology code requests for April 1, 2016 implementation (there were no such requests at this meeting)
  - November 13, 2015 for codes to be implemented on October 1, 2016
- Procedure comments to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchs@cdc.gov

Partial Code Freeze

- We have been under a partial code freeze
  - ICD-10 will be implemented for services provided on or after October 1, 2015
  - Only ICD-10 codes for new technologies will be implemented on October 1, 2015
  - The partial code freeze ends on October 1, 2016

Proposed and Final Rules

- April 2015 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2015 C&M meeting
- August 1, 2015 – Final rule with links to final codes to be implemented on October 1, 2015
  - Includes any additional codes approved from March 2015 C&M meeting

Addendum

- June 2015 – Final code updates and addendum posted
  - FY 2016 ICD-10-CM (Diagnosis) and ICD-10-PCS (procedure) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2016 ICD-10-CM (Diagnosis) http://www.cdc.gov/nchs/icd/icd10cm.htm
- June 2016 – FY 2017 final code updates and addendum to be posted

GEM and Reimbursement Files

- FY 2016 ICD-10-CM and ICD-10-PCS GEMs and Reimbursement mappings posted at http://www.cms.gov/Medicare/Coding/ICD10/index.html
- Annual GEM updates will be posted by August

March 9-10, 2016 C&M Code Requests

- January 15, 2016– Deadline for submitting topics for March 9-10, 2016 C&M meeting
  - Procedure requests to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
  - Diagnosis requests to Donna Pickett, CDC nchsicd9@cdc.gov

Public Participation

- For this meeting the public may participate in three ways:
  - Attend public C&M meeting
  - Listen to proceedings through free conference lines
  - Participate through a free livestream webcast
- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - October 16, 2015 for new technology codes requests for April 1, 2016 implementation (there were no such requests at this meeting)
  - November 13, 2015 for codes to be implemented on October 1, 2016
- Procedure comments to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchsicd9@cdc.gov

Partial Code Freeze for ICD-9-CM and ICD-10

The ICD-9-CM Coordination and Maintenance Committee implemented a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10. The partial freeze is scheduled to end one year after the implementation of ICD-10. There was considerable support for this partial freeze. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services issued a final rule on August 4, 2014 that changed the compliance date for ICD-10 from October 1, 2014 to October 1, 2015. The final rule also requires HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015. Links to the final rule are provided at http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html.

Partial Code Freeze Ends

- The last regular, annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014 there were only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108-173.
- On October 1, 2015, there will be only limited code updates to ICD-10 code sets to capture new technologies as required by section 503(a) of Pub. L. 108-173. There will be no updates to ICD-9-CM, as it will no longer be used for reporting.
- On October 1, 2016 (one year after implementation of ICD-10), regular updates to ICD-10 will begin.

Branched and Fenestrated Endograft Repair of Aneurysms

Issue: Within ICD-10-PCS, there are not unique device values to describe branched and/or fenestrated endograft repair for aneurysms that occur in the abdominal or thoracic aorta. In addition, branched endograft devices designed to treat aneurysms of the common iliac arteries are currently in clinical trials. Should new ICD-10-PCS device values be created to identify these types of aneurysm repair?

New Technology Application? No.

Background: Endografts, also known as stent grafts, are used for repair of aortic and aorto- iliac aneurysms. The devices are inserted via an endovascular approach, usually through the femoral artery, and line the diseased segment of the aorta to exclude the aneurysm from the blood flow. The endovascular procedure is an alternative to the invasive open procedure in which the aneurysmal segment of the aorta is completely excised and replaced with a graft.

The simplest aortic endografts are essentially straight tubes, used to repair an isolated aneurysm. However, most aneurysm repair also involves adjacent vessels. More commonly, endografts are bifurcated with distal limbs (sometimes called "docking limbs") that reach into the right and left common iliac arteries below the aortic bifurcation. Extensions of an endograft can also be placed further down within the common iliac, internal iliac or external iliac arteries. Additional aortic cuffs may be placed within the aorta as well.

Initially, standard endografts were only used to treat aneurysms in the infra-renal abdominal aorta. There were issues treating juxta-renal and supra-renal abdominal aortic aneurysms impinging on or covering the origins of the renal arteries with the endograft preventing blood flow to the kidneys. Branched and fenestrated aortic endografts were developed to address the issue by preserving blood flow to the renal arteries and other vessels that branch off the aorta when repair of an aortic aneurysm compromised blood flow to the renal arteries or other branching vessels.

Branched endografts have nubs or branches that extend towards the arteries branching off the aorta. Covered stents can then be placed within the nubs, extending from the nub into the branch vessels themselves. This ensures that the branch vessels are not blocked off when the grafts are deployed to repair the aneurysm.

There is a distinction between bifurcated endografts and branched endografts. Bifurcated endografts are placed at the aortic bifurcation and have distal limbs that reach into the left and right common iliac arteries. In contrast, branched endografts are used primarily for side arteries branching off the aorta. Depending on the nature of the aneurysm, the surgeon may choose an endograft that is both branched for the side arteries and bifurcated for the aortic bifurcation.

Fenestrations are openings or windows in the material covering the endograft. The fenestrations are placed in the endograft to allow for precise alignment with the origins of the arteries branching off the aorta. Typically, a covered stent is then placed from the aorta through the fenestration and into the branch artery. Scallops are a variation on fenestrations in which a U-

shaped cut-out is made in the proximal end of an endograft. This allows the sides of the endograft to be placed higher up in the diseased segment of the aorta, while the scallop keeps the endograft from blocking the branch vessel.

It should be noted that use of a covered stent with branched or fenestrated endografts does not clinically equate with dilation of a vessel. Angioplasty is performed to re-open an occluded vessel and restore blood flow. In contrast, when performed with endovascular aneurysm repair (EVAR), the objective of placing the stent in the branch vessel is to ensure that blood flow to the end organ is preserved.

Fenestrated endografts, which were initially FDA approved in 2012, are currently used in the repair of aneurysms in the region of the abdominal aorta. Fenestrated endografts have openings in the fabric of the endograft, which allow flow into the visceral arteries. There are four key branch arteries in the abdominal aorta where blood flow must be preserved: the left renal artery, the right renal artery, the superior mesenteric artery and the celiac trunk (which gives rise to the common hepatic, left gastric and splenic arteries). Note that in patients with variant anatomy, there may be more than four main branch arteries. These vessels are collectively referred to as the visceral arteries. Depending on the nature of the aneurysm, fenestrated endografts can also be bifurcated for use near the aortic bifurcation.

The abdominal aorta is the segment below the diaphragm. Development of branched or fenestrated aortic endografts is also underway for the thoracic aorta, the segment that runs from just above the aortic valve to the diaphragm. The thoracic aortic arch gives rise to three critical branches: the left subclavian artery, the left common carotid artery, and the innominate or brachiocephalic artery (which gives rise to the right common carotid and right subclavian arteries). Patients with variant anatomy may have more than three branch arteries in the arch. These arteries are also called the precerebral arteries and they supply the brain, making it essential to preserve blood flow.

Some endografts cross anatomic boundaries into other segments of the aorta or other arteries. This occurs when the aneurysm itself extends into an adjacent site, for example when the aneurysm involves the abdominal aorta as well as the common iliac arteries below the bifurcation, or when the aneurysm involves both the thoracic aorta and abdominal aorta. Crossing anatomic boundaries also occurs as a procedural component in sealing off the aneurysm. All endografts require a "landing zone", a stretch of healthy vessel without involvement of the aneurysm into which the endograft must extend to form a proper seal and preclude endoleaks. For example, an abdominal aortic endograft may have a proximal landing zone in the thoracic aorta or it may have a distal landing zone in the common iliac artery.

Upon successful completion of on-going clinical trials, endovascular repair of the entire aorta from just above the aortic valve through to the distal aortic bifurcation will be possible.

Current Coding: The following ICD-10-PCS codes are used to report branched and/or fenestrated endograft repair for aneurysms that occur in the abdominal or thoracic aorta, as well as the common iliac arteries. These codes do not allow differentiation between standard endovascular repair and endovascular repair of those aneurysms with a branched or fenestrated graft.

Note: A proposal was made at the September 2012 Coordination and Maintenance Committee meeting for the 02 code tables to revise existing Body Part value W Thoracic Aorta to W-Thoracic Aorta, Descending and create a new Body Part value X for Thoracic Aorta, Ascending/Arch.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
REVISE from W Thoracic Aorta **REVISE to W** Thoracic Aorta, Descending **ADD X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Section	**0**	Medical and Surgical
Body System	**4**	Lower Arteries
Operation	**V**	Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device	**J** Temporary **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Artery, Right **D** Common Iliac Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not add a new device value to tables 02V, Restriction of Heart and Great Vessels and 04V, Restriction of the Lower Arteries. Continue to use existing codes as shown above.

Option 2. Add the device value E, Intraluminal Device, Branched or Fenestrated, to the root operation Restriction, tables 02V and 04V, for the Thoracic Aorta, Abdominal Aorta, and Common Iliac Artery body part values. Also add the qualifier Bifurcation to the existing second row in table 04V for the Abdominal Aorta body part to identify endograft procedures at the aortic bifurcation whose distal limbs extend into the common iliac arteries. Separate codes to identify the placement of stents into branch arteries could be assigned pending discussion.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
REVISE from W Thoracic Aorta **REVISE to W** Thoracic Aorta, Descending **ADD X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **ADD E** Intraluminal Device, Branched or Fenestrated **Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device **ADD E** Intraluminal Device, Branched or Fenestrated	**ADD 6**Bifurcation **J** Temporary **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Artery, Right **D** Common Iliac Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **ADD E** Intraluminal Device, Branched or Fenestrated **Z** No Device	**Z** No Qualifier

Option 3. Add the device values E and F Intraluminal Device, Branched or Fenestrated, with the number of arteries, to the root operation Restriction, tables 02V and 04V, for the Thoracic Aorta, Abdominal Aorta, and Common Iliac Artery body part values. Also add the qualifier Bifurcation to the existing second row in table 04V for the Abdominal Aorta body part to identify endograft procedures at the aortic bifurcation whose distal limbs extend into the common iliac arteries. No additional codes would be assigned for stenting of the branch arteries with use of a branched or fenestrated graft device.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
REVISE from W Thoracic Aorta **REVISE to W** Thoracic Aorta, Descending **ADD X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **ADD E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **ADD F** Intraluminal Device, Branched or Fenestrated, Three or More Arteries **Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device	**ADD 6** Bifurcation **J** Temporary **Z** No Qualifier
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **ADD F** Intraluminal Device, Branched or Fenestrated, Three or More Arteries	**ADD 6**Bifurcation **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Artery, Right **D** Common Iliac Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **ADD E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **Z** No Device	**Z** No Qualifier

CMS Recommendation: CMS recommends Option 3 effective October 1, 2016.

Interim Coding Advice: Continue to code endovascular repair of aneurysms occurring in the abdominal or thoracic aorta, as well as the common iliac arteries that use fenestrated or branched device procedures with the appropriate ICD-10-PCS codes from table 02V (Restriction of Heart and Great Vessels) and table 04V (Restriction of Lower Arteries). Also assign separate codes for stenting of the branch arteries to table 04H (Insertion of Lower Arteries) or table 047 (Dilation of Lower Arteries) as noted below.

Table 04H (Insertion of Lower Arteries) – report the appropriate codes from this table to identify stents that are inserted into branch arteries when the medical record documentation indicates that the arteries are normal or there is no documentation of any stenosis or stricture in the arteries

Table 047 (Dilation of Lower Arteries) - report the appropriate codes from this table to identify stents that are inserted into branch arteries when the medical record documentation indicates that there is stenosis or stricture in the branch arteries

Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement

Issue: There is currently not a unique ICD-10-PCS procedure code to identify the use of a cerebral embolic protection system during transcatheter aortic valve replacement. Should a new code be created?

New Technology Application? Yes. A New Technology Add-On Payment application for the Claret Medical™ Sentinel™ Cerebral Protection System will be submitted for FY 2017.

Food and Drug Administration (FDA) Approval: Pending. The Claret Medical™ Sentinel™ Cerebral Protection System (CPS) is currently the subject of a prospective, randomized controlled IDE study (G130276) in the US. FDA clearance of the 510(k) is expected in the second quarter of 2016.

Background: Stroke remains a major complication for transcatheter aortic valve replacement (TAVR) procedures, occurring in at least 2-5% of procedures, and has been reported to increase mortality in these patients by 3-fold. Diffusion-weighted magnetic resonance imaging (DW-MRI) can detect and evaluate the quality, quantity and fate of cerebral embolism with subsequent acute ischemic cerebral lesions within the brain hemispheres, brain stem, and cerebellum. This method has been validated for use in evaluating the number and volume of ischemic lesions in acute stroke for a number of years. DW-MRI serves as a surrogate endpoint for clinical and subclinical ischemic stroke and has been used frequently to quantify thromboembolism associated with TAVR, showing that upwards of 80% or more of patients have new cerebral lesions post-procedure. Even initially silent cerebral lesions found on DW-MRI have been shown to increase the risk of future stroke >3-fold, as well as to increase risk of dementia and other cognitive impairments.

During TAVR procedures, embolic debris can be liberated due to device manipulations in the aortic arch, or due to replacement valve deployment. Studies have shown that the histopathology of embolic debris captured during TAVR procedures consists of acute and organizing thrombus, as well as, valve and aortic wall tissue, myocardium, and calcified material derived most likely from either the native aortic valve leaflets or the aortic wall.

The Claret Medical™ Sentinel™ Cerebral Protection System is a percutaneously delivered embolic protection device, designed to protect the brain from injury caused by embolic debris dislodged during endovascular procedures. The device includes two conically-shaped polyurethane filters with 140 micron holes mounted onto nitinol self-expanding wire frames. The system is delivered through a 6-French sheath placed in the right radial artery, the Proximal Filter is deployed in the brachiocephalic artery, and the Distal Filter is delivered to the left common carotid artery at the beginning of the TAVR procedure. At the completion of the TAVR procedure, the filters and captured debris are withdrawn into the catheter and removed from the patient.

A recent randomized TAVR study (CLEAN-TAVI trial) using the Claret Medical Montage™ Cerebral Protection System* demonstrated embolic debris captured in 88% of patients in which a Claret filter system was used, and a significant reduction (>50%) in the number and volume

of new cerebral lesions at 2 and 7 days after TAVR in the filter group as compared to the unprotected controls, as determined by DW-MRI subtraction imaging. In addition, the filter group showed a lower ataxia rate than the control group (9% vs 24%) at 2 days, indicating the potential to reduce neurologic complications.

The CLEAN-TAVI randomized trial showed no significant safety differences between filter and control arms for 30-day procedural outcomes according to VARC-2** definitions, including a lack of reported device-related procedural strokes, the current clinical experience and data suggests that the use of such a device could be highly beneficial for patients undergoing TAVR to reduce the potential of cerebral damage, the likelihood of immediate and late neurological and/or cognitive impairments, and other disabling and costly events and conditions.

Claret Medical cerebral protection systems have had CE mark approval since 2011 (Montage™ since 2011 and its replacement, Sentinel™, since 2013) and have been used in Europe to protect over 1,500 patients. The Claret Medical™ Sentinel™ Cerebral Protection System is the Claret CPS currently being sold in Europe and is the subject of investigation in the prospective, randomized controlled SENTINEL IDE trial in the U.S., which is currently enrolling patients.

The currently approved eligible TAVR population in the U.S. is comprised of high and extreme risk elderly patients with severe co-morbidities and a very short predicted life span (average age of 85). As the TAVR procedure expands to younger, and intermediate and low risk patients in the near future, the potential for the beneficial impact of embolic protection will become even greater.

* Montage is the prior iteration of Sentinel. It is identical in functionality, but differs in handle aesthetics and ergonomics, and catheter manufacturability.

** "Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document", published in European Heart Journal (2012) 33, 2403–2418.

Current Coding: There is no ICD-10-PCS code for cerebral embolic protection devices used during TAVR procedures. Code the TAVR procedure with the appropriate values from table 02R, Replacement of Heart and Great Vessels.

Section	**0**	Medical and Surgical
Body System	**2**	Heart and Great Vessels
Operation	**R**	Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve	**3** Percutaneous	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**H** Transapical **Z** No Qualifier

Coding Options:
Option 1. Do not create a new ICD-10-PCS code. Continue to code the TAVR procedure as stated above in current coding.

Option 2. Create a new code in section X, New Technology, to identify percutaneous, prophylactic filtering using the dual, independent filtration technique, during a TAVR procedure. A separate code for the valve replacement procedure would also be reported with this option.

Section	**X**	New Technology
Body System	**2**	Cardiovascular System
Operation	**0**	Assistance: Taking over a portion of a physiological function by extracorporeal means

Body Part	*Approach*	*Device/Substance/Technology*	*Qualifier*
5 Brachiocephalic and Left Common Carotid Arteries	**3** Percutaneous	**ADD 1** Cerebral Embolic Filtration, Dual Independent Technique	**2** New Technology Group 2

Option 3. Create a new code in the Extracorporeal Assistance and Performance section (section 5) by adding a new row containing value 6, Circulatory, Intracranial for the body system character and values 2 and 3, Embolic Protection, Dual and Single Filter for the qualifier characters. A separate code for the valve replacement procedure would also be reported with this option.

Section	**5**	Extracorporeal Assistance and Performance
Body System	**A**	Physiological Systems
Operation	**0**	Assistance: Taking over a portion of a physiological function by extracorporeal means

Body System	*Duration*	*Function*	*Qualifier*
6 Circulatory, Intracranial	**2** Continuous	**0** Filtration	**2** Embolic Protection, Dual Filter **3** Embolic Protection, Single Filter

CMS recommendation: CMS is interested in hearing from the audience as this is a new technology application.

Interim Coding Advice: Continue to code for the TAVR procedure only and do not add a code for the use of the Claret Medical™ Sentinel™ Cerebral Protection System.

Intracardiac Pacemaker

Issue: Currently there is not a unique ICD-10-PCS procedure code to describe the insertion of an intracardiac pacemaker, commonly referred to as "leadless pacemaker", as well as its removal or revision.

New Technology Application: No. St. Jude Medical (Nanostim) and Medtronic (Micra) have not submitted a new technology application at this time but may decide to apply later.

FDA Approval: Nanostim (St. Jude Medical) and Micra (Medtronic) applications for the insertion of an intracardiac pacemaker are currently under review and anticipated FDA approvals are expected mid-year 2016 and the second half of 2016 respectively.

Background: Pacemakers treat slow heart rates, such as bradycardia, sick sinus syndrome, and atrioventricular heart blocks. Conventional pacemaker devices require two components: a generator and one or more leads. The generator creates the electrical pulse and the electrode on the lead delivers it to the heart tissue. The generator is placed in a subcutaneous pocket, typically on the upper chest. The lead or leads are advanced transvenously into one or more heart chambers and then tunneled below the skin to connect to the generator.

Upon FDA approval, intracardiac pacemakers will be the first and only pacemaker in which the components are combined into a single device implanted directly within the heart, without any subcutaneous pocket or tunneling. The intracardiac pacemaker is currently used for single-chamber pacing of the right ventricle. Using a specialized delivery catheter, the device is inserted into a peripheral vessel, typically the femoral vein, and advanced into the selected heart chamber. This eliminates the need for a separate generator in a subcutaneous pocket as well as tunneling of the lead, which can be the source of complications such as pocket infection, skin erosion, and lead fracture. The manufacturers emphasized that intracardiac pacemakers do not defibrillate, they are capable of pacing only.

The intracardiac pacemaker is powered by a sealed battery. When the battery eventually reaches end-of-life, a new device must be implanted. The old device can either be removed percutaneously or it can be permanently turned off and abandoned in place. Also, it may sometimes happen that an existing intracardiac pacemaker becomes dislodged within the heart chamber and must be repositioned. Finally, like all pacemakers, an intracardiac pacemaker must also be programmed and then periodically interrogated and/or re-programmed.

It is anticipated that dual-chamber pacing will be available in the future, with one device implanted in the right ventricle and a second device implanted in the right atrium.

Current Coding: Code using the device value D, Intraluminal Device and the root operations Insertion, Removal or Revision (Tables 02H, 02P, and 02W, respectively) as appropriate for intracardiac pacemaker procedures. Code pacemaker interrogations using table 4B0.

Section **0** Medical and Surgical
Body System **2** Heart and Great Vessels
Operation **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Coronary Vein **6** Atrium, Right **7** Atrium, Left **K** Ventricle, Right **L** Ventricle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead	**Z** No Qualifier

Section **0** Medical and Surgical
Body System **2** Heart and Great Vessels
Operation **P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Cardiac Lead **Q** Implantable Heart Assist System **R** External Heart Assist System	**Z** No Qualifier
A Heart	**X** External	**2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **M** Cardiac Lead	**Z** No Qualifier

Section **0** Medical and Surgical
Body System **2** Heart and Great Vessels
Operation **W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Cardiac Lead **Q** Implantable Heart Assist System **R** External Heart Assist System	**Z** No Qualifier

Section **4** Measurement and Monitoring
Body System **B** Physiological Devices
Operation **0** Measurement: Determining the level of a physiological or physical function at a point in time

Body Part	*Approach*	*Function/Device*	*Qualifier*
2 Cardiac	**X** External	**S** Pacemaker **T** Defibrillator	**Z** No Qualifier

Coding Options:

Option 1. Do not create new codes for insertion, removal and revision of an intracardiac pacemaker. Continue to code as above under current coding.

Option 2. Create new device value N Intracardiac Pacemaker for the related body part values that currently exist in tables 02H, 02P and 02W for the device value Cardiac Lead.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**H** Insertion: Putting in a non-biological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Coronary Vein **6** Atrium, Right **7** Atrium, Left **K** Ventricle, Right **L** Ventricle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead **ADD N** Intracardiac Pacemaker	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extra luminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Non-autologous Tissue Substitute **M** Cardiac Lead **ADD N** Intracardiac Pacemaker **Q** Implantable Heart Assist System **R** External Heart Assist System	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extra luminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Non-autologous Tissue Substitute **M** Cardiac Lead **ADD N** Intracardiac Pacemaker **Q** Implantable Heart Assist System **R** External Heart Assist System	**Z** No Qualifier

Option 3. Create new section X codes for the root operations Insertion, Removal and Revision, with device value N Intracardiac Pacemaker, body part value Ventricle, Right and approach Percutaneous.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**H** Insertion: Putting in a non-biological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
K Ventricle, Right	**3** Percutaneous	**ADD N** Intracardiac Pacemaker	**2** New Technology Group 2

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**P** Removal: Taking out or off a device from a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
K Ventricle, Right	**3** Percutaneous	**ADD N** Intracardiac Pacemaker	**2** New Technology Group 2

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
K Ventricle, Right	**3** Percutaneous	**ADD N** Intracardiac Pacemaker	**2** New Technology Group 2

CMS Recommendation: CMS recommends option 2 create new device value N Intracardiac Pacemaker for the related body part values that currently exist in tables 02H, 02P and 02W for the device value Cardiac Lead.

Interim Coding: As above under current coding.

Endovascular Repair of Abdominal Aortic Aneurysms via Entire Sac-Sealing

Issue: Currently there is not an ICD-10-PCS procedure code to describe the use of "entire sac sealing" abdominal aortic aneurysm repair procedures from other endovascular abdominal aortic aneurysm repair procedures. Should a new code be created?

New Technology Application: Yes. Endologix plans to submit an application for a New Technology Add-on Payment next year in FY 2017 for FY 2018 consideration.

FDA Approval: Endologix, Inc.'s application for the Nellix® Endovascular Aneurysm Sealing System (EVAS) is currently under review and anticipated FDA approval is in the second half of 2016, likely October.

Background: Endovascular aneurysm repair (EVAR) of the abdominal aorta may be performed percutaneously, or via two small incisions made in the groin to expose the femoral arteries. A synthetic graft expanded by stents is fed through these arteries with delivery catheters and guide wires until the graft is positioned correctly at the top and bottom of the defective portion of the aorta. The delivery sheath is then withdrawn to expose the EVAR graft. Either balloon-expansion, self-expansion from stent spring force, or thermal memory set, allows the graft to open to its full diameter and for barbs or other fixing devices to attach to the artery wall and hold the graft firmly in place. This channels the blood flow through the graft removing pressure from the weakened aortic wall.

Before the introduction of EVAR, aortic aneurysms were treated by open surgical repair, a lengthy, major operation done under general anesthesia with an inherent mortality rate. EVAR is now the gold standard for repair of aortic aneurysms. However, it has been associated with endoleaks, device migration and is somewhat limited by restrictions related to unfavorable anatomy.

Endovascular aneurysm sealing (EVAS) is an alternative to conventional endovascular aneurysm repair (EVAR). It was developed to address issues with endoleaks, device migration and other challenges seen with EVAR. In addition, use of EVAR is somewhat limited by restrictions related to unfavorable neck anatomy. Further, because the distal landing zone for EVAR devices is usually the common iliac artery and abdominal aortic aneurysms often extend into the common iliac artery, there are implications for procedural and clinical outcomes.

EVAS utilizes the technology of entire sac sealing. In contrast to conventional EVAR endografts, EVAS stabilizes and completely seals the aneurysm sac by means of polymer-filled bags encasing the endografts. This simultaneously creates a secure pathway for the blood flow through the aorta to the distal limbs, while also destroying the aneurysm sac itself rather than simply excluding it. Obliterating the aneurysm sac is the essential concept upon which the EVAS procedure is based. Filling the entire treatment zone with polymer from the proximal segment of the aorta across the aneurysm sac to the distal segment can eliminate potential endoleak space as well as provide secure fixation by using the sac itself to anchor the graft and prevent migration.

A seal is also accomplished because the liquid polymer takes the shape of the aneurysm's seal zones, regardless of neck morphology.

Procedurally, two stent grafts (endografts) are advanced via femoral access and placed in kissing fashion in the infrarenal aorta. The distal ends of the stent grafts are positioned in the common iliac arteries bilaterally, thus spanning the aneurysm. Each stent graft is surrounded by an "endobag". The endobags are initially filled with saline to completely fill the contours and seal the aneurysm, as verified by angiography. The saline in the endobags is then removed by aspiration and, under pressure monitoring, replaced by injection of a comparable volume of polymer into the endobags. Sealing is again verified by angiography. After filling, the polymer cures (hardens) in approximately 3 to 5 minutes. As needed, a secondary fill can be performed with additional polymer. The cured polymer forms a cast of the lumen of the aorta and common iliac arteries, maintaining the endograft position and obliterating the sac.

It should be noted that EVAS seals the side branches of the aorta. Because of this, physicians may choose to use EVAS with separate stents to the visceral branch arteries in a "snorkel" or "chimney" configuration. For a snorkel or chimney, a separate stent is placed next to the EVAS endograft, between the endograft and the wall of the aorta. The stent's distal end is positioned within the branch vessel and the stent's proximal end is positioned slightly above the upper end of the aortic endograft. This allows the stent to receive blood from the aorta above the endograft and then channel it into the branch vessel to preserve blood flow to the end organs. The polymer-filled endobags serve to fix the additional stent or stents in place.

The Nellix Global Registry post-market registry data, which constitutes a set of real-world patient populations, demonstrated that entire sac sealing results in a very low, overall composite endoleak rate of as low as 0.7% at up to one year.

It is anticipated that EVAS will also be used in the ascending and descending portions of the thoracic aorta in the near future. In addition, to eliminate the need for snorkels and chimneys, it is expected that a Nellix® EVAS device with fenestrations will be developed.

Current Coding: There is no ICD-10-PCS procedure code to distinguish the use of "entire sac sealing" endovascular abdominal aortic aneurysm repair procedures from other endovascular abdominal aortic aneurysm repair procedures. The appropriate codes from table 04V would be assigned.

Section	**0**	Medical and Surgical
Body System	**4**	Lower Arteries
Operation	**V**	Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device	**J** Temporary **Z** No Qualifier

Coding options:

Option 1. Do not create a new code. Continue to use existing codes from table above.

Option 2. Add a new device value, G Intraluminal Device, Entire Sac-Sealing to table 04V Restriction of Lower Arteries. This option allows identification of the sealing beyond the aortic bifurcation in the common iliac arteries and also reflects the proposal to add the qualifier value 6, Bifurcation. For chimney and snorkel configurations, separate codes to identify the placement of stents into branching visceral arteries could be assigned pending discussion.

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device **ADD G** Intraluminal Device, Sac-Sealing	**ADD 6** Bifurcation **J** Temporary **Z** No Qualifier
1 Celiac Artery **2** Gastric Artery **3** Hepatic Artery **4** Splenic Artery **5** Superior Mesenteric Artery **6** Colic Artery, Right **7** Colic Artery, Left **8** Colic Artery, Middle **9** Renal Artery, Right **A** Renal Artery, Left **B** Inferior Mesenteric Artery **C** Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left **H** External Iliac Artery, Right **J** External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left **V** Foot Artery, Right **W** Foot Artery, Left **Y** Lower Artery	**0** Open **3** Percutaneous **4** Percutaneous endoscopic	**C** Extraluminal Device **D** Intraluminal Device **ADD G** Intraluminal Device, Entire Sac-Sealing **Z** No Device	**Z** No Qualifier

Option 3. Add a new code for EVAS to Section X, New Technology, under Body System 2 (Cardiovascular System). This option allows the ability to identify this technology separately regardless of whether or not a New Technology application is submitted.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Abdominal Aorta	**5** Percutaneous Intraluminal	**ADD G** Intraluminal Device, Entire Sac-Sealing	**2** New Technology Group 2

CMS Recommendation: CMS is recommending option 1: do not create a new code at this time. It is CMS' position that it is too early to fully evaluate and consider this request for a new code that is also the subject of a future New Technology Add-on Payment application with an anticipated filing date that is not until November 2016 (FY 2017) for October 1, 2017 (FY 2018) consideration. Also, as noted above in the background section, it is anticipated that the Nellix® EVAS will be used in the thoracic aorta in the near future. According to the requester it is also expected that a Nellix® EVAS device with fenestrations will be developed which would eliminate the need for snorkels and chimneys. Therefore, we recommend that this proposal be brought back for further discussion at a future ICD-10 Coordination and Maintenance Committee meeting when more information is available regarding this technology.

Interim Coding: Continue to code endovascular aneurysm repair (EVAR) of the abdominal aorta with the appropriate values from Table 04V, Restriction of Lower Arteries.

Addenda

Body Part Definitions (Body Part Key) Addenda

Section 0		Medical and Surgical
Axis 4		Body Part
Row		
Term		Pharynx
Includes	Add	Base of Tongue
Includes	Add	Tongue, base of

Device Definitions (Device Key) Addenda

Axis 6		Device
Row		
Term		Nonautologous Tissue Substitute
Includes	Add	Cook Biodesign(R) Fistula Plug(s)
Includes	Add	Cook Biodesign(R) Hernia Graft(s)
Includes	Add	Cook Biodesign(R) Layered Graft(s)
Includes	Add	Cook Zenapro(tm) Layered Graft(s)

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	Delete	03JY4ZZ
	Delete	04JY4ZZ
	Add	see Inspection, Great Vessel 02JY
	Add	see Inspection, Artery, Upper 03JY
	Add	see Inspection, Artery, Lower 04JY