CERENOVUS

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

HEMORRHAGIC STROKE

2020 REIMBURSEMENT GUIDE

Physician and Facility

CONTENTS

PHYSICIAN SERVICES 5
CPT® CODES

HOSPITAL INPATIENT SERVICES 6
Medicare Severity Diagnosis Related Groups (MS-DRGs)

PROCEDURE CODES 7
ICD-10-CM Procedure Codes

DIAGNOSIS CODES 8
ICD-10-CM Diagnosis Codes

COMMON CODING SCENARIOS 9

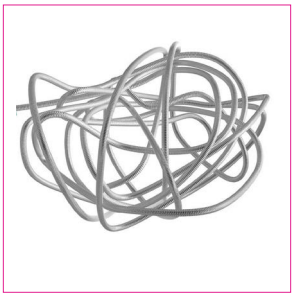
MODIFIERS 11

HUMANITARIAN USE DEVICE (HUD) HUMANITARIAN DEVICE EXEMPTION (HDE) 12

HCPSCS/REVENUE CODES 13

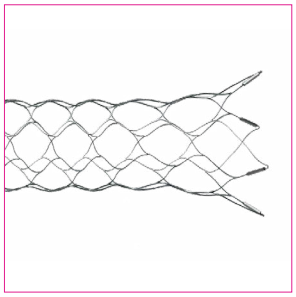
SPECTRA™ FAMILY OF COILS

The CERENOVUS SPECTRA™ Family of Coils is ranked according to softness scale based on key parameters that influence spring constant. Coils are categorized on a scale of 1 to 5. Coils providing structure and stability (rated 1) and ultrasoft coils for dense packing (rated 5) create a full spectrum of softness.



ENTERPRISE® VASCULAR RECONSTRUCTION DEVICE AND DELIVERY SYSTEM

The ENTERPRISE® 2 Vascular Reconstruction Device and Delivery System is intended for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of 3 mm and 4 mm. Wide-neck is defined as having a neck width 4mm or a dome-to-neck ratio < 2.



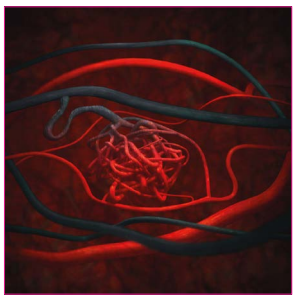
PULSERIDER® ANEURYSM NECK RECONSTRUCTION DEVICE

PULSERIDER® Aneurysm Neck Reconstruction Device is the first commercially available device designed and indicated for the treatment of bifurcated aneurysms at the Basilar Tip or Carotid Terminus.

The PULSERIDER® Device is designed to reduce procedural complexity by removing the need to access distal anatomy.

TRUFILL® N-BCA LIQUID EMBOLIC TREATMENT SYSTEM

TRUFILL® n-BCA Liquid Embolic System is an artificial embolization device, comprised of TRUFILL® n-Butyl Cyanoacrylate (n-BCA), TRUFILL® Ethiodized Oil, and TRUFILL® Tantalum Powder. These components are combined to form a mixture that is injected through a microcatheter to embolize AVMs prior to surgical resection. Although the mixture is liquid during delivery, it hardens to form a solid material on contact with blood at the site of the AVM in the brain.



PHYSICIAN SERVICES

Coding for the interventional neuroradiology services requires accounting for each element of the entire procedure. In some circumstances, component coding is appropriate, and in others comprehensive codes are used. Appropriate insurance payment for the spectrum of physician services billed with the treatment of endovascular aneurysms requires careful documentation in the medical chart and accurate coding of each discrete procedure or consultation.

Below are the components that must be documented in the procedural record and identified for insurance billing purposes. Depending on the procedure, each component may have its own CPT® Procedure code:

- Diagnostic catheterizations
- Diagnostic angiography
- Endovascular occlusion
- Angiographic radiological supervision and interpretation (S&I)
- Follow-up (post-occlusion) angiography

As applicable, document and bill for when appropriate:

- Related evaluation and management (E&M) services also apply as supported by medical necessity

PHYSICIAN SERVICES

The CPT® Code and the Medicare national average payment rates for reference when reporting the treatment of hemorrhagic stroke with CERENOVUS products are outlined below.

CPT® Code	Description	2020 Facility RVUs	2020 Medicare National Average Payment[1]
	Endovascular Occlusion		
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	33.34	$1,203
75894-26	Transcatheter therapy, embolization, any method, radiological supervision and interpretation	2.04	$74
	Temporary Balloon Occlusion		
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	16.56	$598
	Angiography		
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	10.43	$376
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	10.28	$371
+36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery) (List separately in addition to code for primary procedure)	6.98	$252
	Catheterization		
36216	Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family	7.90	$285
36217	Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family	9.52	$344
	Follow-up (post-occlusion) angiography		
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	2.56	$92

HOSPITAL INPATIENT SERVICES

Medicare reimburses inpatient hospital services under the Inpatient Prospective Payment System (IPPS), which bases payment on MS-DRGs (Medicare Severity Diagnosis Related Groups).

The table below lists common MS-DRGs which may be assigned when conducting embolization procedures in the inpatient setting:

MS-DRG	Description	2020 Relative Weight	2020 Medicare National Average Payment[2]
	Ruptured Intracranial Aneurysms		
020	Intracranial vascular procedures with principal diagnosis of hemorrhage with MCC	10.8210	$67,780
021	Intracranial vascular procedures with principal diagnosis of hemorrhage with CC	8.2737	$51,824
022	Intracranial vascular procedures with principal diagnosis of hemorrhage without CC/MCC	4.9318	$30,892
	Non-Ruptured Intracranial Aneurysms		
025	Craniotomy and endovascular intracranial procedures with MCC	4.3945	$27,526
026	Craniotomy and endovascular intracranial procedures with CC	3.0458	$19,078
027	Craniotomy and endovascular intracranial procedures without CC/MCC	2.3967	$15,012

CC=Complications or Comorbidities MCC=Major Complications or Comorbidities

PROCEDURE CODES

Medicare uses The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Procedure Coding System (PCS) codes to identify diagnoses and procedures in the hospital inpatient setting. Hospitals must report the principal diagnosis using the appropriate ICD-10-CM code, as well as any secondary diagnoses — some of which may be considered CCs or MCCs for MS-DRG assignment.

The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." The circumstances of inpatient admission always govern the selection of the principal diagnosis.

For patient admissions involving procedures, hospitals must also report ICD-10-PCS procedure code(s) for the surgical and other procedures as well as ICD-10-CM diagnosis codes.

The following table lists some commonly used ICD-10-PCS codes for embolization procedures:

ICD-10-PCS Code	Description
	Liquid Embolic Treatment
03LG3DZ	Occlusion of Intracranial Artery with Intraluminal Device, Percutaneous Approach
	Embolization Coils
03VG3DZ	Restriction of Intracranial Artery with Intraluminal device, percutaneous approach
	Arteriography
B3160ZZ	Fluoroscopy of Right Internal Carotid Artery using High Osmolar Contrast
B3161ZZ	Fluoroscopy of Right Internal Carotid Artery using Low Osmolar Contrast
B316YZZ	Fluoroscopy of Right Internal Carotid Artery using Other Contrast
B3170ZZ	Fluoroscopy of Left Internal Carotid Artery using High Osmolar Contrast
B3171ZZ	Fluoroscopy of Left Internal Carotid Artery using Low Osmolar Contrast
B317YZZ	Fluoroscopy of Left Internal Carotid Artery using Other Contrast
B3180ZZ	Fluoroscopy of Bilateral Internal Carotid Arteries using High Osmolar Contrast
B3181ZZ	Fluoroscopy of Bilateral Internal Carotid Arteries using Low Osmolar Contrast
B318YZZ	Fluoroscopy of Bilateral Internal Carotid Arteries using Other Contrast
B31D0ZZ	Fluoroscopy of Right Vertebral Artery using High Osmolar Contrast
B31D1ZZ	Fluoroscopy of Right Vertebral Artery using Low Osmolar Contrast
B31DYZZ	Fluoroscopy of Right Vertebral Artery using Other Contrast
B31F0ZZ	Fluoroscopy of Left Vertebral Artery using High Osmolar Contrast
B31F1ZZ	Fluoroscopy of Left Vertebral Artery using Low Osmolar Contrast
B31FYZZ	Fluoroscopy of Left Vertebral Artery using Other Contrast
B31G0ZZ	Fluoroscopy of Bilateral Vertebral Arteries using High Osmolar Contrast
B31G1ZZ	Fluoroscopy of Bilateral Vertebral Arteries using Low Osmolar Contrast
B31GYZZ	Fluoroscopy of Bilateral Vertebral Arteries using Other Contrast
B31R0ZZ	Fluoroscopy of Intracranial Arteries using High Osmolar Contrast
B31R1ZZ	Fluoroscopy of Intracranial Arteries using Low Osmolar Contrast
B31RYZZ	Fluoroscopy of Intracranial Arteries using Other Contrast

ICD-10-PCS Definitions: **Occlusion**: Completely closing an orifice or the lumen of a tubular body part.
Restriction: Partially closing an orifice or the lumen of a tubular body part.

DIAGNOSIS CODES

The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes entered on hospital and physician claims are important in conveying information about the patient's condition to payers. All healthcare providers must report the principal diagnosis using the appropriate ICD-10-CM code, as well as any secondary diagnoses. Payers use this information to evaluate the medical necessity for the episode of care and the appropriateness of the treatment the patient received.

Diagnosis codes should be reported to the highest level of specificity available — a code is invalid if it has not been coded to the full number of digits required for that code.

The table below includes examples only of ICD-10-CM diagnosis codes associated with hemorrhagic stroke.

ICD-10-CM Code	Description
Cerebral Aneurysm/Ruptured	
I60.00	Nontraumatic subarachnoid hemorrhage from unspecified carotid siphon and bifurcation
I60.01	Nontraumatic subarachnoid hemorrhage from right carotid siphon and bifurcation
I60.02	Nontraumatic subarachnoid hemorrhage from left carotid siphon and bifurcation
I60.10	Nontraumatic subarachnoid hemorrhage from unspecified middle cerebral artery
I60.11	Nontraumatic subarachnoid hemorrhage from right middle cerebral artery
I60.12	Nontraumatic subarachnoid hemorrhage from left middle cerebral artery
I60.2	Nontraumatic subarachnoid hemorrhage from anterior communicating artery
I60.30	Nontraumatic subarachnoid hemorrhage from unspecified posterior communicating artery
I60.31	Nontraumatic subarachnoid hemorrhage from right posterior communicating artery
I60.32	Nontraumatic subarachnoid hemorrhage from left posterior communicating artery
I60.4	Nontraumatic subarachnoid hemorrhage from basilar artery
I60.50	Nontraumatic subarachnoid hemorrhage from unspecified vertebral artery
I60.51	Nontraumatic subarachnoid hemorrhage from right vertebral artery
I60.52	Nontraumatic subarachnoid hemorrhage from left vertebral artery
I60.6	Nontraumatic subarachnoid hemorrhage from other intracranial arteries
I60.7	Nontraumatic subarachnoid hemorrhage from unspecified intracranial artery
Cerebral Aneurysm/Non-Ruptured	
I60.9	Nontraumatic subarachnoid hemorrhage, unspecified
Q28.3	Other malformations of cerebral vessels
Arteriovenous Fistula/Ruptured	
I60.8	Other nontraumatic subarachnoid hemorrhage
Arteriovenous Fistula/Non-Ruptured	
I67.1	Cerebral aneurysm, nonruptured
Q28.2	Arteriovenous malformation of cerebral vessels

SCENARIO

WIDE NECK ANEURYSM AT A BIFURCATED INTRACRANIAL CEREBRAL ARTERY (ICA)

Products used: PULSERIDER®, SPECTRA™ Coils, Prowler®/Prowler Select® Microcatheters

PROCEDURE

The patient presents with a wide neck intracranial aneurysm at the vessel bifurcation of the internal carotid cerebral artery, with no additional complications or comorbidities. The neck width is 5mm as confirmed with a previous cerebral diagnostic angiogram. The aneurysm is accessed via common femoral access. Once the aneurysm site has been reached, the aneurysm neck reconstruction device is placed across the aneurysm neck to create a bridge. Various coils are placed into the aneurysm to reduce blood flow to the aneurysm preventing further expansion and rupture. At the conclusion of the procedure, a follow-up angiogram confirms total occlusion of the aneurysm. Patient presents six hours after the onset of an acute ischemic stroke due to thrombosis of a cerebral artery.

PHYSICIAN PAYMENT EXAMPLE

CPT® Code	Description	2020 Medicare National Average Payment[1]
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	$1203
36224-51	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	$376X50%=$188
75894-26	Transcatheter therapy, embolization, any method, radiological supervision and interpretation	$74
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	$92
Total Physician Payment		**$1,557**

*Medicare's multiple procedure reduction applies. Payment will be reduced by 50%.

FACILITY PAYMENT EXAMPLE

ICD-10-CM Diagnosis Code and Description	ICD-10-PCS Procedure Code and Description	MS-DRG and Description	2020 Medicare National Average Payment
I67.1 Cerebral aneurysm, nonruptured	**03VG3DZ** Restriction of Intracranial Artery with Intraluminal Device, Percutaneous Approach	**027** Craniotomy and endovascular intracranial procedures without CC/MCC*	**$15,012**
	B316YZZ Fluoroscopy of Right Internal Carotid Artery using Other Contrast		
Total Hospital Payment			**$15,012**

*CC=Complications or Comorbidities MCC=Major Complications or Comorbidities

SCENARIO

INTRACRANIAL SACCULAR BASILAR ANEURYSM

Products used: Enterprise®25, SPECTRA™ Coils, Prowler®/Prowler Select® Microcatheters

PROCEDURE

A previous diagnostic cerebral angiogram confirmed an intracranial saccular basilar aneurysm (8mm in size). The patient presents without additional complications or comorbidities. Right radial artery access OR femoral access is established and the catheter is advanced through to the right basilar artery. The vascular reconstruction device is deployed and through its interstices, micro-coils of varying dimensions are introduced via a micro-catheter into the aneurysm. At the conclusion of the procedure, a follow-up angiogram confirms total occlusion of the aneurysm.

PHYSICIAN PAYMENT EXAMPLE

CPT® Code	Description	2020 Medicare National Average Payment[1]
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	$1203
36226-51	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	$371X50%=$186
75894-26	Transcatheter therapy, embolization, any method, radiological supervision and interpretation	$74
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	$92
Total Physician Payment		**$1,555**

*Medicare's multiple procedure reduction applies. Payment will be reduced by 50%.

FACILITY PAYMENT EXAMPLE

ICD-10-CM Diagnosis Code and Description	ICD-10-PCS Procedure Code and Description	MS-DRG and Description	2020 Medicare National Average Payment
I67.1 Cerebral aneurysm, nonruptured	**03VG3DZ** Restriction of Intracranial Artery with Intraluminal Device, Percutaneous Approach	**027** Craniotomy and endovascular intracranial procedures without CC/MCC*	**$15,012**
	B316YZZ Fluoroscopy of Right Internal Carotid Artery using Other Contrast		
Total Hospital Payment			**$15,012**

*CC=Complications or Comorbidities MCC=Major Complications or Comorbidities

MODIFIERS

A modifier provides a way to indicate that a service or procedure that has been performed has been altered by some specific circumstance but not changed in its definition of code. Modifiers also enable healthcare professional to effectively respond to payment policy requirements established by other entities. Some modifiers apply to either physician or hospital outpatient claims; some may only be relevant for one or the other. The table below is a list of some of the CPT and HCPCS modifiers which may be common to procedures associated with CERENOVUS products.

Modifier	Description
22	Increased Procedural Service: When the work required to provide a service is substantially greater than typically required, it may be identified by adding modifier 22 to the usual procedure code. Documentation must support the substantial additional work and the reason for the additional work (ie, increased intensity, time, technical difficulty of procedure, severity of patient's condition, physical and mental effort required). **Note: This modifier should not be appended to an E/M service.**
50	Bilateral Procedures: Unless otherwise identified in the listings, bilateral procedures that are performed at the same operative session should be identified by adding modifier 50 to the appropriate five digit code.
51	Multiple Procedures: When multiple procedures, other than E/M services, Physical Medicine and Rehabilitation services or provision of supplies (eg, vaccines), are performed at the same session by the same individual, the primary procedure or service may be reported as listed. The additional procedure(s) or service(s) may be identified by appending modifier 51 to the additional procedure or service code(s). Note: This modifier should not be appended to designated "add-on" codes (see Appendix D of the current CPT Manual).
59	Distinct Procedural Service: Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-E/M services performed on the same day. Modifier 59 is used to identify procedures/services, other than E/M services, that are not normally reported together, but are appropriate under the circumstances. Documentation must support a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual. However, when another already established modifier is appropriate it should be used rather than modifier 59. Only if no more descriptive modifier is available and the use of the modifier 59 best explains the circumstances should modifier 59 be used. Note: Modifier 59 should not be appended to an E/M service. To report a separate and distinct E/M service with a non-E/M service performed on the same date, see modifier 25.
G0	Modifier G0 is valid for all Telehealth distant site codes billed with Place of Service (POS) code 02 or Critical Access Hospitals, CAH method II (revenue codes 096X, 097X, or 098X); or Telehealth originating site facility fee, billed with HCPCS code Q3014.

HUMANITARIAN USE DEVICE (HUD) AND HUMANITARIAN USE DEVICE EXEMPTION (HDE)[3]

Certain types of aneurysms may be treated with devices that are considered to be humanitarian use devices (HUDs). HUDs are devices that help in conditions affecting a small number of persons. The Federal Food, Drug and Cosmetic Act defines a HUD as a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect, or are manifested in, not more than 8,000 individuals in the United States per year.

An approved HDE authorizes marketing of the HUD. However, a HUD may only be used in facilities that have established a local IRB to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific disease. The labeling for a HUD must state the device is a humanitarian use device, and although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

The PULSERIDER™ Aneurysm Neck Reconstruction Device was approved by the FDA, effective June 19, 2017 under a Humanitarian Device Exemption, HDE# H160002 as a Humanitarian Use Device, HUD# 09-0223. The device is intended for use with neurovascular embolic coils in patients ≥ 18 years of age for the treatment of unruptured wide-necked intracranial aneurysms with neck widths ≥ 4mm or dome to neck ratio <2 originating on or near a vessel bifubrication of the basilar tip or carotid terminus with at least a portion of the aneurysm neck overlapping the lumen of the parent artery. The inflow vessels should have diameters from 2.7mm to 4.5mm.

PULSERIDER™ Aneurysm Neck Reconstruction Device: HUMANITARIAN DEVICE (USA ONLY): Authorized by Federal law for use with neurovascular embolic coils in patients ≥ 18 years of age for the treatment of unruptured wide-necked intracranial aneurysms with neck widths ≥ 4 mm or a dome to neck ratio < 2 originating on or near a vessel bifurcation of the basilar tip or carotid terminus with at least a portion of the aneurysm neck overlapping the lumen of the parent artery. The inflow vessels should have diameters from 2.7 mm to 4.5 mm. The effectiveness of this device for this use has not been demonstrated.

The CERENOVUS ENTERPRISE™ Vascular Reconstruction Device was approved by the FDA, effective May 8, 2007 under a Humanitarian Device Exemption, HDE# H060001 as a Humanitarian Use Device, HUD# 04-0147. The device is intended for use with embolic coils for the treatment of wide neck, intra-cranial, saccular of fusiform aneurysms arising from a parent vessel with a diameter of ≥ 3mm and ≤ 4mm. Wideneck is defined as having a neck width ≥ 4mm or a dome-to-neck ratio < 2.

HUMANITARIAN DEVICE (USA ONLY): The CERENOVUS ENTERPRISE™ Vascular Reconstruction Device and Delivery System is authorized by Federal Law for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 2.5 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥4 mm or a dome-to-neck ratio < 2. The effectiveness of this device for this use has not been demonstrated.

Medicare coverage for Humanitarian Use Devices with FDA Humanitarian Device Exemption will vary by Local Medicare Administrative Contractor (MAC). Each MAC will have their own claims processing and pre-approval requirements. For Part A and B claims, providers are reminded to follow Medicare claims processing procedures for HUD's. Providers are encouraged to contact their local MAC for more information.

HCPCS CODES[4]

Many hospitals look to manufacturers for coding advice specific to that manufacturer's products. This is especially true when it comes to "product codes" also known as C Codes. In general, most CERENOVUS products are used in the inpatient hospital setting. C Codes are categorized for use in the outpatient setting only and are not for use in the hospital inpatient setting.

Where there is a need to report a HCPCS device/C code **for internal purposes only** please reference the table of HCPCS device codes below.

HCPCS Code	Description
C1769	Guide wire
C1887	Catheter, guiding (may include infusion/perfusion capability)
C1874	Stent, coated/covered, with delivery system
C2628	Catheter, occlusion

REVENUE CODES

Revenue codes allow hospitals to categorize services provided by revenue center for cost reporting. For Medicare, revenue codes must be included for each service on a CMS 1450 (UB-04) claim form.6 Sample revenue codes that hospital facilities may use to track costs for services associated with neurovascular, nonsurgical procedures are listed in the following table.

Revenue Code	Description
0270	Medical/Surgical Supplies and Devices — General
0271	Medical/Surgical Supplies and Devices — Nonsterile Supply
0272	Medical/Surgical Supplies and Devices — Sterile Supply
0278	Medical/Surgical Supplies and Devices — Other Implants
0323	Radiology - Diagnostic — Arteriography
0360	Operating Room Services — General Classification

NOTES

Not all codes provided are applicable for the recommended uses of CERENOVUS products. The most appropriate code for the patient's clinical presentation must be selected. CPT® copyright 2019 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS / DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

SOURCES

1. Calendar Year 2020 Medicare Physician Fee Schedule, Final Rule [CMS-1715-F]. Federal Register, November 15, 2019. No geographic adjustments have been made to the reported payment rates.

2. Calendar Year 2020 Medicare Inpatient Final Rule, Final Rule [CMS-1716-F]. Federal Register, August 16, 2019. No geographic adjustments have been made to the reported payment rates.

3. On December 13, 2016, Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255) changed the population estimate required to qualify for Humanitarian Use Device (HUD) designation from "fewer than 4,000" and "not more than 8,000." Accordingly, a HUD is now defined as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. The full text of the 21st Century Cures Act is available at: https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf. Source: http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/default.htm

4. On December 13, 2016, Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255) changed the List of Device Category Codes for Present or Previous Pass-Through Payment and Related Definitions. Effective January 1, 2018 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Complet-list-DeviceCats-OPPS.pdf

5. Medicare Claims Processing Manual, Chapter 25 — Completing and Processing the Form CMS-1450 Data Set, §75.4 — Form Locator 42.

DISCLAIMER

The information contained in this document is provided for informational purposes only and represents no statement, promise, or guarantee by CERENOVUS concerning levels of reimbursement, payment, or charge. Similarly, all CPT® (AMA), ICD-10, HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by CERENOVUS that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. We strongly recommend that you consult your payer organization with regard to its reimbursement policies.

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