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**Medicare Advantage Policy Manual** **Policy ID:** M-SUR207

# *Percutaneous Transluminal Angioplasty (PTA) and Stenting*

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***IMPORTANT REMINDER***

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.*

*The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.*

## DESCRIPTION

Percutaneous transluminal angioplasty (PTA) "involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of percutaneous transluminal angioplasty (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries." *(National Coverage Determination 20.7)* A stent (wire-mesh tube) may be inserted to keep the vessel open or to block off an aneurysm.

Carotid angioplasty with stenting (CAS) is a treatment for carotid stenosis, intended to prevent future stroke. CAS involves the insertion of a stent (wire-mesh tube) into a narrowed carotid artery, and is proposed as an alternative to medical therapy and a less invasive alternative to carotid endarterectomy (CEA).

PTA has been approached for use in intracranial arteries, but cautiously due to technical difficulties in catheter and stent design and due to the risk of embolism, which can have devastating complications if it occurs in the posterior fossa or brain stem. However, improvement in catheter trackability, allowing catheterization of tortuous veins, and the increased use of stents has created ongoing interest in exploring PTA as a minimally invasive treatment of this difficult-to-treat population.

Intracranial stents are also being used in the treatment of cerebral aneurysms. Stent-assisted coil embolization began as an approach to treat fusiform or wide-neck aneurysms in which other surgical or endovascular treatment strategies may not be feasible. As experience grew, stenting was also used in smaller berry aneurysms as an approach to decrease the rate of retreatment needed in patients who receive coiling

Finally, PTA of the veins has been used as an alternative to open vascular surgery in order to restore blood flow in a narrowed or collapsed veins. Techniques may include balloon angioplasty, laser angioplasty, and stent placement.

**COMMON TERMS AND DEFINITIONS**

- Aneurysm: An aneurysm occurs when part of an artery wall weakens, allowing it to balloon out or widen abnormally. Causes of aneurysms include congenital, vascular disease, injury, or may be unknown.
- Angioplasty: After catheterization of an artery, a balloon is inflated inside the artery to open it up. In angioplasty with stenting, a stent wire-mesh tube is placed inside the artery during the angioplasty to keep it held open after the procedure.
- Arterial thrombosis: A sudden blood clot in an artery, which stops blood flow.
- Arteriovenous (AV) fistula: Surgical connection of a person's artery and vein, usually in the arm to provide blood flow for hemodialysis. Rarely, an AV fistula may be a complication of a procedure or occur naturally.
- Atherosclerosis: The buildup of plaques in the walls of arteries, which can lead to stroke and heart attack when the buildup is found in arteries of the brain, neck, or heart.
- Carotid artery disease: Atherosclerosis with narrowing of the carotid arteries in the *neck*, increasing risk of *stroke*. Treatments used in the management of carotid atherosclerosis include risk factor modifications (such as smoking cessation), lifestyle modifications (such as exercise), medication therapy (anti-platelet drugs, statins, antihypertensives), carotid endarterectomy (CEA) and carotid artery stenting (CAS).
- Carotid Artery Stenting (CAS): A stent is placed by catheter within an atherosclerotic carotid artery. An embolic protection device may be used to minimize debris dislodged during the procedure.
- Carotid Endarterectomy (CEA): An open surgical procedure in which fatty deposits and/or plaques are excised from the atherosclerotic segment of the carotid artery.
- Cerebrovascular accident (CVA, stroke): Bleeding from or blockage due to a blood clot in a blood vessel which supplies blood to the *brain*. The three (3) main types are: ischemic, hemorrhagic, and transient ischemic attack (aka, “mini-stroke”)
- Coronary artery disease (CAD): Atherosclerosis with narrowing of the arteries supplying blood to the *heart* muscle, increasing risk of *heart attack*.

- Myocardial infarction (MI): Also referred to as a “heart attack,” MI is a caused by disruption to blood flow in an artery which supplies blood to the *heart*.
- Percutaneous Coronary Intervention (PCI): PCI may include percutaneous transluminal coronary angioplasty (PTCA), with or without stent insertion, when performed
- Peripheral artery disease (PAD): Narrowing of the arteries in the legs or groin, caused by atherosclerosis.
- Stenosis: Narrowing of the arteries, usually caused by atherosclerosis.

## MEDICARE ADVANTAGE POLICY CRITERIA

| Vessel(s)<br><br>***See Table 1 for arteries and veins*** | **With or Without Stent or Embolic Protection Device (EPD) Placement** | **Criteria Reference** |
|---|---|---|
| **Important Note:** PTA services (with or without stenting) which require prior authorization are found on our "*Medicare Pre-authorization List*" web page. PTA codes not listed on the prior authorization website do not require prior approval. There may be related services not included or addressed within this medical policy. Providers remain responsible for correct coding, billing practices, and medical necessity whether or not there is a policy in place. | | |
| **ARTERIAL PTA AND STENTING:** | | |
| ***Arteriovenous dialysis fistulas/grafts when via an arterial approach*** | With or Without stenting | NCD 20.7, B.1. |
| ***Lower extremities*** *(which include iliac, femoral, and popliteal arteries)* ***for atherosclerotic obstructive lesions*** | With or Without stenting | NCD 20.7, B.1. |
| ***Coronary arteries*** | With or Without stenting | NCD 20.7, B.1.<br><br>**Note**: Apply one (1) interventional procedure code per session to each of the three (3) major coronary arteries and their branches. Report the appropriate "single vessel" code once per session for the most complex intervention, using the appropriate coronary artery modifier (-LC, -LD, or -RC). Report additional major vessel interventions per session using the "each additional vessel" codes, again using the appropriate coronary artery modifier. |

| Vessel(s)<br><br>*See Table 1 for arteries and veins* | With or Without Stent or Embolic Protection Device (EPD) Placement | Criteria Reference |
|---|---|---|
| ***Renal arteries*** | With or Without stenting | NCD 20.7, B.1. |
| ***Upper extremities*** *(which include, innominate, subclavian, axillary, and brachial arteries)*<br><br>*Note, per CMS, the upper extremities do not include head or neck vessels* | With or Without stenting | For atherosclerotic obstructive lesions:<br>✓ NCD 20.7, B.1. |
| ***Carotid artery*** | With or Without stenting<br>*(Carotid angioplasty is rarely performed without stent placement)* | *CMS currently only allows coverage of carotid stenting if the procedure is performed for certain indications outlined under provisions of the NCD.*<br><br>✓ NCD 20.7, B.2.<br>✓ NCD 20.7, B.3.<br>✓ NCD 20.7, B.4.<br><br>**IMPORTANT NOTES** *(Please read to assist with coverage criteria application)*:<br>• *The use of an FDA-approved or cleared embolic protection device is required for coverage. If deployment of the embolic protection device is not technically possible, or is not performed, then the procedure is* ***not*** *covered by Medicare.*<br>• *Medicare approved Category B IDE studies can be found on the Medicare IDE study registry (try using the NCT number, G-number, device or manufacturer name, or other keyword). A small number of CAS-specific Medicare-approved studies and registries* |

| Vessel(s)<br><br>*See Table 1 for arteries and veins* | With or Without Stent or Embolic Protection Device (EPD) Placement | Criteria Reference |
|---|---|---|
| | | *can also be found on the Carotid Artery Stenting (CAS) Investigational Studies web page.*<br>• *FDA-approved post approval studies (PAS) can be found on the FDA PAS database. Any study found here would be eligible for coverage when NCD criteria are otherwise met.*<br>• *For B.4., "High risk for CEA" is defined within the NCD, as are symptoms of carotid artery stenosis. Coverage requirements under this criterion starts with whether or not the patient is symptomatic or asymptomatic, followed by the level of stenosis. Patients with a disabling stroke are excluded from coverage.*<br>o *For high risk for CEA patients **with symptomatic** carotid artery stenosis **≥ 70%,** coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or -cleared embolic protection devices (EBDs). Registry or trial participation is **not** noted within the NCD as being required for these individuals;*<br>o *For other high risk for CEA patients, coverage under the NCD requires participation in either a Medicare-approved Category B IDE study, a Medicare-approved clinical trial, or a CAS post approval study. Only IDE studies and CAS studies are able to be identified by the health plan. See notes below regarding clinical trials subject to NCD 310.1.*<br>• *Coverage is limited to procedures performed using an FDA-approved CAS, stent and FDA-approved or -cleared embolic protection device. FDA-approved devices and their respective indications can be found by searching by device name or by manufacturer in the FDA 510(k) Premarket Notification Database or the De Novo Database and viewing the Summary.* |

| Vessel(s)<br><br>*See Table 1 for arteries and veins* | With or Without Stent or Embolic Protection Device (EPD) Placement | Criteria Reference |
|---|---|---|
| | | • *CAS PTA is reasonable and necessary only if performed in Medicare-approved CAS facilities (see the Medicare-Approved Carotid Artery Stenting Facilities web page, where facilities are listed alphabetically by name)*<br>• *In the event a service is rendered as part of a clinical trial subject to the Medicare clinical trials NCD 310.1, Original Medicare or the local Medicare contractor would have primary financial responsibility for eligible trials. Services rendered in a Medicare-approved clinical trial (under NCD 310.1) are processed by Medicare as the primary payor and the health plan does not know whether these trials are Medicare-approved in advance. It is not expected many CAS PTA with stenting procedures will fall under this provision, but the health plan relies on the Medicare explanation of benefits (EOB) to determine if services may be processed by the plan as the secondary payer.*<br>• Carotid artery PTA with stenting for any indication **not** addressed in one of the above sections, apply the last statement of Section B.4, which states, "… PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device is not reasonable and necessary for all other patients."<br>• Carotid artery PTA without stenting for any indication **not** addressed in one of the above sections, apply NCD 20.7, C. |
| | Without EPD | NCD 20.7, B.4. *("The use of an FDA-approved or cleared embolic protection device is required. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare.")* |

| Vessel(s)<br><br>*See Table 1 for arteries and veins* | With or Without Stent or Embolic Protection Device (EPD) Placement | Criteria Reference |
|---|---|---|
| ***Intracranial arteries*** *(e.g., anterior, middle, and posterior cerebral arteries, vertebral artery [distal], carotid siphon, internal carotid, basilar artery, and ophthalmic artery.)* | With stenting | For cerebral artery stenosis in patients with intracranial atherosclerotic disease<br>✓ NCD 20.7, B.5. *(PTA with stenting of intracranial arteries for cerebral artery stenosis, is not covered except under provisions of the NCD. If the coverage criteria are not met, including the stenosis level requirements, then coverage would not be allowed.)*<br>*Medicare approved Category B IDE studies can be found on the Medicare IDE study registry (try using search term "intracranial" or by using the NCT number, G-number, device or manufacturer name, or other keyword).*<br><br>For other obstructive lesions of the cerebral arteries, as well as PTA with stenting of vertebral arteries:<br>✓ NCD 20.7, C. |
| | Without stenting | All indications:<br>✓ NCD 20.7, C. |
| ***All other arteries for any indication not otherwise addressed*** | Without stenting | Percutaneous approach:<br>✓ Non-covered per NCD 20.7, C.<br><br>Open approach: See next row |
| | With stenting | ➢ NCD 20.7, D. states coverage eligibility is at the individual local contractor discretion for percutaneous transluminal angioplasty (PTA) **with stenting** not addressed by the NCD.<br>➢ The local Medicare contractor Noridian does not address PTA, and there is no active policy by the health plan for several vessels |

| Vessel(s)<br><br>*See Table 1 for arteries and veins* | With or Without Stent or Embolic Protection Device (EPD) Placement | Criteria Reference |
|---|---|---|
| | | (e.g., arteries of the thorax, abdomen and some arteries of the limbs).<br>➢ Therefore, ***PTA with stenting of all other arteries for any indication not otherwise addressed*** may be considered medically necessary for Medicare Advantage (e.g., arteries of the thorax, abdomen or limbs not otherwise specified, such as pulmonary arteries). |
| ***Open transluminal angioplasty procedures (arterial or venous)*** | With or Without stenting | ➢ Some of the relevant CPT codes may be used for either *open* or *percutaneous* approach procedures, but this policy and NCD 20.7 are specific to *percutaneous* transluminal angioplasty procedures. **Open** angioplasty procedures are outside the scope of this policy, but may be considered medically necessary for Medicare Advantage - ***with or without stenting -*** for any indication. |
| **VENOUS PTA AND STENTING:**<br><br>*Medicare coverage guidance is not available in the health plan's service area for venous PTA **with** stenting. NCD 20.7 states coverage eligibility is at the individual local contractor discretion for PTA with stenting not otherwise addressed. Since Noridian does not address venous PTA services with stenting, the health plan's medical policy may be applied for some uses.* | | |
| ***All veins*** *(percutaneous only – for open procedures, see separate row for "Open transluminal angioplasty procedures (arterial or venous)")* | With stenting | For arteriovenous dialysis fistulas and grafts when performed through a venous approach, *with* stenting:<br>✓ NCD 20.7, B.1.<br><br>For all other indications:<br>✓ Percutaneous Angioplasty and Stenting of Veins, Surgery, Policy No. 109 *(see "NOTE" below)* |
| | Without stenting | For any indication not previously addressed: |

| Vessel(s)<br><br>*See Table 1 for arteries and veins* | With or Without Stent or Embolic Protection Device (EPD) Placement | Criteria Reference |
|---|---|---|
| | | ✓ NCD 20.7, C. |

**NOTE:** According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

## Table 1. Arteries and Veins

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### ARTERIES

**LOWER TORSO**
Arcuate Artery (kidney)
Celiac Artery (Celiac Trunk)
Common Hepatic Artery
Common Iliac Artery
External Iliac Artery
Inferior Mesenteric Artery
Internal Iliac Artery
Intestinal Arteries
Left Renal Artery
Proper Hepatic Artery
Right Renal Artery
Splenic Artery
Superior Mesenteric Artery

**HEAD AND NECK**
External and Internal Carotid Arteries
Facial Artery
Vertebral Artery
Cerebral Arteries (anterior, middle, posterior)
Carotid Siphon
Basilar Artery
Ophthalmic Artery

**HEART AND CHEST**
Aorta
Brachiocephalic Trunk (aka, brachiocephalic artery, or innominate artery)
Left and Right Common Carotid Arteries
Left and Right Subclavian Arteries
Pulmonary Trunk and pulmonary arteries
Left Coronary Artery
Right Coronary Artery

**ARM AND HAND**
Axillary Artery
Brachial Artery
Deep Palmar Arterial Arch
Inferior Ulnar Collateral Artery
Palmar Digital Arteries
Radial Artery
Superficial Palmar Arterial Arch
Superior Ulnar Collateral Artery
Ulnar Artery
Arteriovenous (AV) fistulas

**LEG AND FOOT**
Anterior Tibial Artery
Deep Femoral Artery (Profunda Femoris)
Dorsal Digital Arteries of Foot
Dorsal Metatarsal Arteries
Femoral Artery
Fibular (Peroneal) Artery
Lateral Circumflex Femoral Artery
Lateral Inferior Genicular Artery
Lateral Superior Genicular Artery
Medial Inferior Genicular Artery
Medial Superior Genicular Artery
Popliteal Artery
Posterior Tibial Artery

### VEINS

Facial Vein
Left External and Internal Jugular Veins
Retromandibular Vein
Right External and Internal Jugular Vein
Inferior and Superior Vena Cava
Left and Right Inferior Pulmonary Vein
Left and Right Subclavian Vein
Left and Right Superior Pulmonary Vein
Common Iliac Vein
Popliteal Vein

External and Internal Iliac Vein
Hepatic Portal Vein
Hepatic Veins
Inferior and Superior Mesenteric Vein
Intestinal Veins
Right and Left Renal Veins
Posterior Tibial Vein
Small Saphenous Vein

Splenic Vein
Accessory Cephalic Vein
Axillary Vein
Basilic Vein
Brachial Vein
Cephalic Vein
Femoral Vein
Great Saphenous Vein
Lateral Circumflex Femoral Vein

Dorsal Digital Veins of Hand
Dorsal Metacarpal Veins
Dorsal Venous Network of Hand
Intermediate Antebrachial Vein
Anterior Tibial Vein
Deep Femoral Vein (Profunda Femoris)
Dorsal Digital Veins of Foot
Dorsal Metatarsal Veins
Dorsal Venous Arch of Foot

| Table 2. MEDICARE NATIONAL COVERAGE CHRONOLOGY OF EVENTS | | | Back to Criteria |
|---|---|---|---|
| **2001** | **2004** | **2005** | **2006** |
| Medicare issued a national coverage policy restricting coverage for carotid angioplasty and stenting (CAS) to patients participating in a clinical trial with category B investigational device exemption (IDE) designation from the Food and Drug Administration (FDA). | Medicare broadened its coverage policy to include PTA with carotid stent placement when performed consistent with FDA approval of the carotid stent device and in an FDA required post-approval study.<br><br>For unapproved stents and embolic protection devices (EPDs), the prior policy remained in effect and restricted coverage to patients participating in an FDA-approved category B IDE trial of stent placement in the cervical carotid artery. | Effective March 17, 2005, Medicare expanded coverage of PTA of the carotid artery when performed on patients at high risk for CEA who also have symptomatic carotid artery stenosis ≥70% only when performed in a CMS approved facility for CAS with FDA-approved carotid artery stenting systems and embolic protection devices | Effective November 6, 2006, Medicare established coverage for PTA and stenting of intracranial vessels for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with FDA-approved protocols governing Category B IDE clinical trials. All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered. |
| **2007** | **2008** | **2009** | **2012** |
| Medicare reaffirmed their previous decision and confirmed CAS is only covered when used with an EPD. If deployment of the EPD is not technically possible, then coverage would not be allowed. All other sections of the NCD remained unchanged. | CMS reaffirmed its prior coverage decisions and made no change to the NCD regarding coverage of PTA of the renal arteries. However, it did add clarifying language to decidedly explain coverage of PTA with stenting not specifically addressed or discussed in this NCD is at local Medicare contractor discretion. | CMS reaffirmed prior coverage decisions for CAS and EPDs. | In January 2012, CMS convened a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) panel to consider management of carotid atherosclerosis. After MEDCAC panel members voted on specific questions, symptomatic patients not considered at high-risk, the mean scores to the question of whether CAS is the favored |

| Table 2. MEDICARE NATIONAL COVERAGE CHRONOLOGY OF EVENTS | | | Back to Criteria |
|---|---|---|---|
| | Later this same year, Medicare reaffirmed its prior coverage decisions to continue to cover PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis ≥ 50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE trials, and continue national non-coverage for all other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries.<br><br>Finally, in late 2008, Medicare confirmed its coverage decision around PTA and CAS. | | treatment strategy in this population was 1.85 and for CEA 3.6. For asymptomatic patients not considered high-risk, the evidence was judged to have not reached a level of certainty to determine a favored treatment. No changes to national coverage policy were made following this MEDCAC meeting. |

## POLICY GUIDELINES

### REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

For PTA of lower and upper extremities, coronary artery, renal arteries, or arteriovenous dialysis fistulas and grafts:

- Description of the planned treatment, including the location of the target areas and technique to be used;
- Location (i.e., specific vessel) of lesion or obstruction;
- Description of planned treatment, including the type of stent that will be used (if applicable).

For carotid artery PTA with or without stenting:

- Description of the planned treatment, including the location of the target areas and technique to be used;
- The name of the device;
- Facility where services will be rendered;
- The name of the trial, registry, or study;
- The six-digit IDE number that begins with a "G" (e.g., G123456) or FDA-approved post approval study (PAS) number that begins with a "P" (e.g., P040338);
    - For an IDE study approved ***prior to*** January 1, 2015, documentation to support the IDE study was approved by the local MAC must be submitted. A copy of the FDA-approval letter provided to the sponsor or manufacturer of the device is also beneficial and may help to expedite claim processing. The category assignment (Category A or Category B IDE) should be represented on this FDA letter.
    - According to NCD 20.7, carotid artery PTA with or without stent placement is only covered under the terms of the NCD, which includes documentation of trials and studies, applicable registries, and approved facilities. Therefore, this information is required for coverage to be considered for approval.
    - NCT numbers are also useful for individuals participating in trials or registries.

For PTA with or without stenting of veins:

- Description of the planned treatment, including the location of the target areas and technique to be used;
- The name of the device;

- Facility where services will be rendered.

Intracranial artery PTA with or without stents:

- Description of the condition being treated (stenosis, aneurysm, stroke, etc.);
- Location (i.e., specific vessel) of lesion or obstruction;
- Description of planned treatment, including the type of stent that will be used (if applicable).
- Documentation of the Medicare-approved clinical trial as required by the Medicare NCD 20.7 or the six-digit IDE number that begins with a "G" (i.e., G123456);
    - For an IDE study approved ***prior to*** January 1, 2015, documentation to support the IDE study was approved by the local MAC must be submitted. A copy of the FDA-approval letter provided to the sponsor or manufacturer of the device is also beneficial and may help to expedite claim processing. The category assignment (Category A or Category B IDE) should be represented on this FDA letter.
    - According to NCD 20.7, intracranial artery PTA with or without stent placement is only covered when furnished under a Category B IDE clinical trial. Therefore, this information is required for coverage to be considered for approval.

## REGULATORY STATUS

### Carotid angioplasty with stenting (CAS)

The U.S. Food and Drug Administration (FDA) has approved several carotid artery stents and DEP devices from various manufacturers. The FDA has mandated postmarketing studies for these devices. Each FDA-approved carotid stent system is indicated for combined use with a DEP device.

### Intracranial stents

Currently, approval of intracranial stents by the FDA has been through the humanitarian device exemption (HDE) process. This form of FDA approval is available for devices used in the treatment or diagnosis of conditions that affect fewer than 4,000 individuals in the United States per year. An approved HDE authorizes marketing of the humanitarian use device (HUD). However, an HUD may only be used after an internal review board (IRB) approval has been obtained for the use of the device for the FDA approved indication. The labeling for an HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated. "CMS does not have a national policy that addresses coverage of HUDs. Currently, contractors have the discretion to provide coverage for these devices in the absence of a national coverage determination. A HUD is nationally not covered if it falls under the purview of an NCD which nationally non-covers the device or service for which the HUD may be used."[10]

Stents for Intracranial Atherosclerosis

There are currently two devices that have received FDA approval for humanitarian use in the treatment of intracranial atherosclerosis. Their labeled indications are as follows:

- NEUROLINK® System (Guidant) is "indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with greater than or equal to 50% stenosis and that are accessible to the stent system."
- Wingspan™ Stent System with Gateway™ PTA Balloon Catheter (Boston Scientific) is "indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with greater than or equal to 50% stenosis that are accessible to the system." The Wingspan Stent System consists of a highly flexible, microcatheter delivered self-expanding nitinol stent, which may be suitable for lesions in the distal internal carotid and middle cerebral arteries. These arteries are difficult to access with a balloon-mounted stent, such as the NEUROLINK system. In 2008, Boston Scientific Corporation's submitted a request to Medicare reconsider the NCD 20.7 for percutaneous transluminal angioplasty (PTA) with intracranial stent placement. However, after review, CMS reaffirmed their existing coverage decision and did not expand coverage as requested. PTA and stenting of intracranial arteries is only eligible for coverage when furnished in accordance with the FDA-approved protocols governing Category B IDE trials, and non-covered for all other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries.[10]

Stents for Intracranial Aneurysm

*Endovascular Stents for Use with Coils*

The following devices have received FDA approval for humanitarian use with embolic coils in the treatment of unruptured wide-neck intracranial aneurysms:

- The Neuroform™ Microdelivery Stent System (Boston Scientific) (H020002)
- The Enterprise™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular, Inc./DePuy Companies) (H060001)
- The LVIS® or LVIS® Jr. Low-Profile Visualized Intraluminal Support Device (MicroVention®, Inc.) (H130005)

The Solitaire AB retrievable stent (Covidien) has *not* received FDA approval for use in the United States outside the clinical trial setting. According to the Medicare Benefit Policy Manual, Chapter 14, while U.S. Food and Drug Administration (FDA) approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, devices which have not received FDA-approval would not be considered medically reasonable or necessary[7] and stents that have not received FDA approval are non-covered, unless they are used in the context of an FDA-approved investigational (IDE) trial.

*Flow-Diverting Stents*

- In 2011, the Pipeline® Embolization Device (Covidien eV3 Neurovascular), which falls into a new device category called "intracranial aneurysm flow diverters," or flow-diverting stent, received FDA premarket approval for endovascular treatment of large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments in adult patients aged 22 years or older. The Pipeline device is a braided, wire mesh device that is placed within the parent artery of an aneurysm to redirect blood flow away from the aneurysm with the goal of preventing aneurysm rupture and possibly decreasing aneurysm size.

The SILK Reconstruction device (Balt Extrusion) and the Surpass Flow Diverting Stent (Stryker) have *not* received FDA approval for use in the United States. Again, stents that have not received FDA approval are non-covered, unless they are used in the context of an FDA-approved investigational (IDE) trial.

**Venous PTA with stenting**

While there are several types of stents that are approved by the FDA for improvement of outflow for arteriovenous (A-V) access grafts in hemodialysis patients, and for the creation of intrahepatic shunt connections between the portal venous system and hepatic vein [i.e., transjugular intrahepatic portosystemic shunt (TIPS)], there are currently no stents with FDA approval for use in veins for any other indications.

In May 2012, the FDA issued a safety communication concerning the potential for adverse events following endovascular interventions to treat chronic cerebrospinal venous insufficiency (CCSVI) for people with multiple sclerosis (MS).[8] Reports of adverse events included death, stroke, detachment and/or migration of stents, vein damage, thrombosis, cranial nerve damage, and abdominal bleeding. This alert included the caveat that clinical trials of this procedure require FDA approval and an investigational device exemption due to potential for harms.

## CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

Pulmonary Embolectomy, Surgery, Policy No. M-158

## REFERENCES

1. MLN Matters Article "Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty"

2. MLN Matters Article "Clarification of Percutaneous Transluminal Angioplasty (PTA) Billing Requirements Issued in CR 3811"
3. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §160 – PTA for Implanting the Carotid Stent *(See the various subsections of this reference)*
4. Medicare-Approved Carotid Artery Stenting (CAS) Investigational Studies
5. Medicare-Approved IDE Studies
6. Medicare-Approved Carotid Artery Stenting Facilities *(facilities are listed alphabetically by name)*
7. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, §10 - Coverage of Medical Devices
8. Chronic cerebrospinal venous insufficiency treatment in multiple sclerosis patients: FDA safety communication. 2012. [Last Cited 11/09/2020]; Available from: http://wayback.archive-it.org/7993/20170722215753/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm303318.htm
9. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §161 - Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting
10. Medicare Decision Memo for *Intracranial Stenting and Angioplasty* (CAG-00085R5)
11. CMS Manual System Change Request (CR) 5805, dated January 18, 2008
12. Noridian website for Post Market Studies and Post Market Extension Studies

## CODING

**NOTE:**

- PTA codes requiring prior authorization are listed on the "*Medicare Pre-authorization List*" web page. PTA codes not listed on the pre-authorization website do not require prior approval. There may be codes related to PTA that are not included in this medical policy. However, providers are always expected to follow Medicare's medical necessity requirements when rendering treatment to beneficiaries.
- CPT code 37216 is a Medicare Status "N" code, and therefore, is non-covered by Medicare and Medicare Advantage.[1]
- Effective January 1, 2008, all claims submitted for patient care in clinical research studies must use the –Q0 or –Q1 modifiers for routine and investigational clinical services. This includes "studies that are certified under the Medicare Clinical Research Policy, Investigational Device Exemption (IDE) trials, and studies required under a coverage with evidence development (CED) national coverage determination (NCD)."[11]

| Codes | Number | Description |
|---|---|---|
| **CPT** | 36481 | Percutaneous portal vein catheterization by any method |
| | 36901 | Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, |

| | |
|---|---|
| | radiological supervision and interpretation and image documentation and report |
| 36902 | ; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty |
| 36903 | ; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment |
| 36904 | Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s) |
| 36905 | ; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty |
| 36906 | ; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis circuit |
| 36907 | Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty (List separately in addition to code for primary procedure) |
| 36908 | Transcatheter placement of intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment (List separately in addition to code for primary procedure) |
| 36909 | Dialysis circuit permanent vascular embolization or occlusion (including main circuit or any accessory veins), endovascular, including all imaging and radiological supervision and interpretation necessary to complete the intervention (List separately in addition to code for primary procedure) |
| 37215 | Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection |
| 37216 | Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection *(Non-covered by Medicare)* |
| 37217 | Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation |

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|---|---|---|
| | 37238 | Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein |
| | 37239 | ; each additional vein (List separately in addition to code for primary procedure) |
| | 37246 | Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery |
| | 37247 | ; each additional artery (list separately in addition to code for primary procedure) |
| | 37248 | Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein |
| | 37249 | ; each additional vein (List separately in addition to code for primary procedure) |
| | 37799 | Unlisted procedure, vascular surgery |
| | 61630 | Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous |
| | 61635 | Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed |
| **HCPCS** | C2623 | Catheter, transluminal angioplasty, drug-coated, non-laser |

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*