BlueCross BlueShield of Alabama

Note: For intracranial stent placement see NCD 20.7: Percutaneous Transluminal Angioplasty (PTA)

For therapeutic embolization please see NCD 20.28

For endovascular mechanical embolectomy, see policy criteria below.

Name of Blue Advantage Policy:

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy #: 263
Category: Surgery

Latest Review Date: May 2021
Policy Grade: A

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on and after May 1, 2018:

Blue Advantage will treat **the use of endovascular mechanical embolectomy** with an FDA approved device for the treatment of **acute ischemic stroke** as a **covered benefit** as part of the treatment of acute ischemic stroke for patients who meet **all** of the following criteria:

- Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery); **AND**
- Can receive endovascular mechanical embolectomy:
    - within 12 hours of symptom onset **OR**
    - within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical and imaging criteria which meets the following criteria:

        - 6 to 24 hours related to mismatch between severity of clinical deficit and infarct volume:
            - ≥80 years of age, score ≥10 on the NIHSS, and had an infarct volume <21 mL; **OR**
            - ≤80 years age, score of ≥10 on the NIHSS, and had an infarct volume <31 mL; **OR**
            - ≤80 years of age, had a score ≥20 on the NIHSS, and had an infarct volume of 31 to <51 mL

        OR

        - 6 to 16 hours related to mismatch between severity of clinical deficit and infarct volume:
            - Infarct size of <70 mL; **AND**
            - Ratio of ischemic tissue volume to infarct volume of ≥1.8; **AND**
            - Ischemic penumbra of ≥15 cm^3

    AND

- Have evidence of substantial and clinically significant neurological deficits (i.e. NIHSS score ≥2); **AND**
- Have evidence of salvageable brain tissue in the affected vascular territory; **AND**
- Have no evidence of intracranial hemorrhage or arterial dissection on computed tomography (CT) or magnetic resonance imaging.

Blue Advantage will treat **endovascular mechanical embolectomy** as a **non-covered benefit** and as **investigational** for the treatment of acute ischemic stroke when the above criteria are not met.

Blue Advantage will treat **other endovascular interventions (angioplasty, stenting)** as a **non-covered benefit** and investigational for the treatment of acute ischemic stroke.

Effective for dates of service on or after October 1, 2015 and through April 30, 2018:
Blue Advantage will treat **the use of endovascular mechanical embolectomy** with an FDA approved device for the treatment of **acute ischemic stroke** as a **covered benefit** as part of the treatment of acute ischemic stroke for patients who meet **all** of the following criteria:

- Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery); **AND**
- Can receive endovascular mechanical embolectomy within 12 hours of symptom onset; **AND**
- Have evidence of substantial and clinically significant neurological deficits (i.e. NIHSS score ≥2); **AND**
- Have evidence of salvageable brain tissue in the affected vascular territory; **AND**
- Have no evidence of intracranial hemorrhage or arterial dissection on computed tomography (CT) or magnetic resonance imaging.

Blue Advantage will treat **endovascular mechanical embolectomy** as a **non-covered benefit** and as **investigational** for the treatment of acute ischemic stroke when the above criteria are not

Blue Advantage will treat **other endovascular interventions (angioplasty, stenting)** as a **non-covered benefit** and investigational for the treatment of acute ischemic stroke.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Intracranial arterial disease includes thromboembolic events, vascular stenoses, and aneurysms. Endovascular techniques have been investigated for treatment of intracranial arterial disease. Endovascular therapy is used as an alternative or adjunct to intravenous tissue plasminogen activator (TPA) and supportive care for acute stenosis and as an alternative to risk factor modification for chronic stenosis. For cerebral aneurysms, stent-assisted coiling and the use of flow-diverting stents have been evaluated as an alternative to endovascular coiling in patients whose anatomy is not amenable to simple coiling.

Cerebrovascular diseases include a range of processes affecting the cerebral vascular system, including arterial thromboembolism, arterial stenosis, and arterial aneurysms, all of which can lead to restrictions in cerebral blood flow due to ischemia or hemorrhage. Endovascular techniques, including endovascular mechanical embolectomy; using one of several types of

devices (i.e. stents), and angioplasty with or without stenting, have been investigated for treatment of cerebrovascular diseases.

Acute Stroke
Acute stroke is the third leading cause of death in the U.S., Canada, Europe and Japan and is the leading cause of adult disability in the U.S. Eighty-seven percent of strokes are ischemic and 13% hemorrhagic. Differentiation between the two types of stroke is necessary to determine the appropriate treatment. Ischemic stroke occurs when an artery to the brain is blocked by a blood clot, which forms in the artery (thrombotic), or when another substance (i.e., plaque, fatty material) or a blood clot travels to an artery in the brain causing a blockage (embolism). Recanalization of the vessel, particularly in the first few hours after occlusion, has been shown to reduce rates of disability and death.

Intracranial Arterial Stenosis
It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in two ways: either due to embolism or low flow ischemia in the absence of collateral circulation. Recurrent annual stroke rates are estimated at 4% to 12% per year with atherosclerosis of the intracranial anterior circulation and 2.5% to 15% per year with lesions of the posterior (vertebrobasilar) circulation.

Intracranial Aneurysms
Compared with acute ischemic stroke, cerebral aneurysms have a much lower incidence among the U.S. population, with prevalence between 0.5% and 6% of the population. However, they are associated with significant morbidity and mortality due to subarachnoid hemorrhage resulting from aneurysm rupture.

KEY POINTS:
The most recent update literature review through March 11, 2021.

Summary of Evidence
For individuals who have acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes RCTs comparing endovascular therapy with standard care and systematic reviews of these RCTs. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. From 2013 to 2015, 8 RCTs were published comparing endovascular therapies with noninterventional care for acute stroke in patients with anterior circulation occlusions. Several trials that were ongoing at the time of publication of these eight RCTs were stopped early, and results with the limited enrollment have been published. Trials published from 2014 to 2015 demonstrated a significant benefit regarding reduced disability at 90 days post treatment. The trials that demonstrated a benefit for endovascular therapy either exclusively used stent retriever devices or allowed the treating physician to select a device, mostly a stent retriever device, and had high rates of mechanical embolectomy device use in patients randomized to endovascular therapy. Studies that demonstrated a benefit for endovascular therapy required demonstration of a large vessel, anterior circulation occlusion for enrollment.

In addition, they were characterized by fast time-to-treatment. Two trials published in 2018 demonstrated that it was possible to extend the window for mechanical thrombectomy up to about 24 hours for select patients. To achieve results in real-world settings similar to those in clinical trials, treatment times, clinical protocols, and patient selection criteria should be similar to those in RCTs. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute ischemic stroke due to basilar artery occlusion who receive endovascular mechanical embolectomy, the evidence includes an RCT. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. The RCT was terminated early due to high crossovers and poor recruitment. There was not a statistically significant difference in the proportion of participants with a modified Rankin Scale of 0 to 3 at 90 days or in 90-day mortality rates in the endovascular and standard therapy groups. Additional RCTs are ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic intracranial arterial stenosis who receive intracranial percutaneous transluminal angioplasty with or without stenting, the evidence includes a systematic review and two major RCTs. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. Both available RCTs have demonstrated no significant benefit with endovascular therapy. In particular, the SAMMPRIS trial was stopped early due to harms, because the rate of stroke or death at 30 days post treatment was higher in the endovascular arm, which received percutaneous angioplasty with stenting. Follow-up of SAMMPRIS subjects has demonstrated no long-term benefit from endovascular therapy. Although some nonrandomized studies have suggested a benefit from endovascular therapy, the available evidence from two RCTs does not suggest that intracranial percutaneous transluminal angioplasty with or without stenting improves outcomes for individuals with symptomatic intracranial stenosis. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

For individuals who have intracranial aneurysm(s) who receive endovascular coiling with intracranial stent placement or intracranial placement of a flow-diverting stent, the evidence includes RCTs, several nonrandomized comparative studies, and multiple single-arm studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. The available nonrandomized comparative studies have reported occlusion rates for stent-assisted coiling that are similar to or higher than coiling alone and recurrence rates that may be lower than those may for coiling alone. For stent-assisted coiling with self-expanding stents, some evidence has also shown that adverse event rates are relatively high, and a nonrandomized comparative trial has reported that mortality is higher with stent-assisted coiling than with coiling alone. For placement of flow-diverting stents, a pragmatic RCT and registry study have compared flow diversion with standard management (observation, coil embolization, or parent vessel occlusion) in patients for whom flow diversion was considered a promising treatment. The pragmatic study was stopped early after crossing a predefined safety boundary when 16% of patients treated with flow diversion were dead, dependent at 3 months, or later. Flow diversion was also not as effective as the investigators had hypothesized. A nonrandomized study comparing the flow-diverting stents with endovascular coiling for intracranial aneurysms has demonstrated higher rates of aneurysm obliteration in those treated

with the Pipeline endovascular device than those treated with coiling, with similar rates of good clinical outcomes. The evidence does not provide high certainty whether stent-assisted coiling or placement of a flow-diverting stent improves outcomes for patients with intracranial aneurysms because the risk-benefit ratio cannot be adequately defined. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

Society of Vascular and Interventional Neurology

In 2016, the Society of Vascular and Interventional Neurology (SVIN) published recommendations on comprehensive stroke center requirements and endovascular stroke systems of care. The recommendations were based on five multicenter, prospective, randomized, open-label, blinded end clinical trials that demonstrated the benefits of endovascular therapy with mechanical thrombectomy in acute ischemic strokes with large vessel occlusions. Their recommendation pertinent to this evidence review is:

"Endovascular mechanical thrombectomy, in addition to treatment with IV tPA [intravenous tissue plasminogen activator] in eligible patients, is recommended for anterior circulation large vessel occlusion ischemic strokes in patients presenting within 6 h of symptom onset."

American Heart Association and American Stroke Association

In 2018, the AHA and the American Stroke Association (update 2019) published joint guidelines for the early management of patients with acute ischemic stroke. These guidelines include several recommendations relevant to the use of endovascular therapies for acute stroke:

Table 1. Recommendations on Use of Endovascular Therapies to Manage Acute Stroke

Recommendation	COR	LOE
"Mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and a comprehensive periprocedural care team. Systems should be designed, executed, and monitored to emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures."	I	C
"Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria: "Prestroke mRS score 0 to 1, "Causative occlusion of the internal carotid artery or MCA (M1), "Age ≥18 years, NIHSS score of ≥6, "ASPECTS of ≥6, and "Treatment can be initiated (groin puncture) within 6 hours of symptom	I	A

Recommendation	COR	LOE
onset."		
In selected patients with acute ischemic stroke within 6 to 16 hours of last known normal who have LVO in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria, mechanical thrombectomy is recommended.	I	A
"The technical goal of the thrombectomy procedure should be a reperfusion to a modified TICI 2b/3 angiographic result to maximize the probability of a good functional clinical outcome."	I	A
"As with intravenous alteplase, reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TICI grade 2b/3 should be achieved as early as possible and within the therapeutic window."	I	B-R
"Use of stent retrievers is indicated in preference to the MERCI device." "The use of mechanical thrombectomy devices other than stent retrievers may be reasonable in some circumstances."	I IIb	A B-NR
"The use of proximal balloon guide catheter or a large bore distal access catheter rather than a cervical guide catheter alone in conjunction with stent retrievers may be beneficial. Future studies should examine which systems provide the highest recanalization rates with the lowest risk for nontarget embolization."	IIa	C-LD
In selected patients with AIS within 16 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable.	IIa	B-R
"In carefully selected patients with anterior circulation occlusion who have contraindications to intravenous r-tPA, endovascular therapy with stent retrievers completed within 6 hours of stroke onset is reasonable. There are inadequate data available at this time to determine the clinical efficacy of endovascular therapy with stent retrievers for those patients whose contraindications are time-based or non-time based (e.g., prior stroke, serious head trauma, hemorrhagic coagulopathy, or receiving anticoagulant medications)."	IIa	C
"Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the M2 or M3 portion of the	IIb	B-R

Recommendation	COR	LOE
MCAs."		
"Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the anterior cerebral arteries, vertebral arteries, basilar artery, or posterior cerebral arteries."	IIb	C
"Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have prestroke mRS score of >1, ASPECTS <6, or NIHSS score <6 and causative occlusion of the internal carotid artery or proximal MCA (M1). Additional randomized trial data are needed."	IIb	B-R
In patients under consideration for mechanical thrombectomy, observation after IV alteplase to assess for clinical response should not be performed.	III	B-R
"Use of salvage technical adjuncts including intra-arterial fibrinolysis may be reasonable to achieve these angiographic results"	IIb	C-LD
"Intra-arterial fibrinolysis initiated within 6 hours of stroke onset in carefully selected patients who have contraindications to the use of intravenous alteplase might be considered, but the consequences are unknown."	IIb	C-EO

AIS: acute ischemic stroke; ASPECTS: Alberta Stroke Program Early Computed Tomography Score; COR: class of recommendation; LOE: level of recommendation; LVO: large vessel occlusion; MCA: middle cerebral artery; mRS: modified Rankin Scale; NIHSS: National Institutes of Health Stroke Scale; r-tPA: recombinant tissue plasminogen activator; TICI: Thrombolysis in Cerebral Infarction.

Table 2. Recommendations on Management of Unruptured Intracranial Aneurysms

Recommendation	COR	LOE
"...coil embolization may be superior to surgical clipping with respect to procedural morbidity and mortality, length of stay, and hospital costs, so it may be reasonable to choose endovascular therapy over surgical clipping in the treatment of select unruptured intracranial aneurysms, particularly in cases for which surgical morbidity is high, such as at the basilar apex and in the elderly"	IIb	B
"...coil embolization may be superior to surgical clipping with respect to procedural	IIb	B

morbidity and mortality, length of stay, and hospital costs, so it may be reasonable to choose endovascular therapy over surgical clipping in the treatment of select unruptured intracranial aneurysms, particularly in cases for which surgical morbidity is high, such as at the basilar apex and in the elderly"		
"Endovascular treatment of unruptured intracranial aneurysms is recommended to be performed at high-volume centers."	I	B

COR: class of recommendation; LOE: level of recommendation.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force (USPSTF) recommendations for treatment of intracranial arterial disease were identified. USPSTF recommends against screening for asymptomatic carotid artery stenosis in the general population.

KEY WORDS:
intracranial stenting, flow diverting stent, intracranial angioplasty, Percutaneous Transluminal Angioplasty, mechanical embolectomy, stroke, cerebral aneurysm, revascularization, Intracranial Circulation, Vertebrobasilar Stenosis, Angioplasty, Merci® Retriever, Penumbra System®, Solitaire™, Trevo Pro Retriever™, Neurolink®, Neurolink System, Wingspan Stent System, Pipeline® Embolization Device, Neuroform ™ Microdelivery Stent System, Enterprise™, Low Profile Visualized Intraluminal Support Device, PulseRider, Surpass Streamline Flow Diverter, Surpass, EmboTrap®, EmboTrap® II Revascularization Device, Atlas Stent System

APPROVED BY GOVERNING BODIES:
Several devices for endovascular treatment of intracranial arterial disease have received clearance by FDA either through the 510(k) process or through the humanitarian device exemption (HDE) process. By indication, approved devices are as follows:
A summary of the devices with FDA clearance for the endovascular treatment of acute stroke is provided in Table 6.

Table 3: FDA-Cleared Mechanical Embolectomy Devices for Acute Stroke

Device	510(k) No. for Original Device	Approval Date for Original Device	Indications
Merci® Retriever (Concentric Medical, Mountain View, CA; acquired by Stryker Neurovascular, Kalamazoo, MI, in 2011)	K033736	Aug 2004 (modified device approved May 2006)	Patients with acute ischemic stroke and who are ineligible for or who fail IV tPA therapy

Penumbra System® (Penumbra, Alameda, CA)	K072718	Dec 2007	Patients with acute ischemic stroke secondary to intracranial large-vessel occlusive disease within 8 h of symptom onset
Stent retrievers			
Solitaire™ FR Revascularization Device (Covidien/ev3 Neurovascular, Irvine, CA)	K113455	Mar 2012	Patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA
Trevo® Retriever device (Stryker Neurovascular, Kalamazoo, MI)	K122478	Aug 2012	Patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA
EmboTrap® II Revascularization Device	K173452	May 2018	Patients with ischemic stroke within 8 hours of symptom onset who are ineligible for or who fail IV t-PA

FDA: Food and Drug Administration; IV: intravenous; tPA: tissue plasminogen activator.

Intracranial Stenosis
Two devices have received approval for atherosclerotic disease from the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process. This form of FDA approval is available for devices used to treat conditions with an incidence of 4,000 or less per year; the FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows:

Neurolink System® (Guidant, Santa Clara, CA)
"The Neurolink system 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 ≥50% stenosis and that are accessible to the stent system."

Wingspan™ Stent System (Boston Scientific, Fremont, CA)
"The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease,

refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system."

Intracranial Aneurysms
In 2011, FDA granted premarket approval to the Pipeline® Embolization Device (Covidien/eV3 Neurovascular, Irvine, CA), an intracranial aneurysm flow diverter, for the endovascular treatment of adults (≥22 years of age) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments (P100018). Approval was based on the Pipeline for Uncoilable for Failed Aneurysms Study, a single-arm, open-label feasibility study that included 108 patients aged 30 to 75 years with unruptured large and giant wide-necked aneurysms.

In 2018, Surpass Streamline Flow Diverter (Stryker Neurovascular) was approved by the FDA through the premarket approval PMA process (P170024) for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm. The approval was based on one1-year results of the Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT) study. The SCENT study is continuing follow-up up to five5 years post-procedure as a post-approval study.

The following stents have received FDA approval through the Humanitarian Device Exemption (HDE) program for treatment of intracranial aneurysms.

Neuroform™ Microdelivery Stent System (Stryker, Kalamazoo, MI)
In 2002, based on a series of approximately 30 patients with six-month follow-up, the Neuroform Microdelivery Stent System was approved (HDE) for use with embolic coils for treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping (H020002).

Neuroform™ Atlas Stent System
In 2019, the Neuroform Atlas Stent System (Stryker) was approved by the FDA through the PMA process (P190031) based on the pivotal ATLAS study including 201 patients with up to 12 months of follow-up. The approved indication is "for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients greater or equal to 18 years of age with saccular wide-necked (neck width greater or equal to 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of greater or equal to 2.0 mm and less than or equal to 4.5 mm." Product Code: QCA.

Enterprise™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular Inc., Miami Lakes, FL)
In 2007, based on a series of approximately 30 patients with six-month follow-up, the Enterprise Vascular Reconstruction Device and Delivery System (Cordis Neurovascular, Inc.) was approved (HDE) for use with embolic coils for treatment of wide-neck, intracranial, saccular or fusiform aneurysms (H060001).

The Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr.) (MicroVention, Inc., Tustin, CA)
In July 2014, the Low Profile Visualized Intraluminal Support Device received HDE approval (H130005) for use with embolic coils for the treatment of unruptured, wide neck (neck ≥ 4 mm or dome to neck ratio < 2), intracranial, saccular aneurysms arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 4.5 mm. In 2018, the LVIS™ and LVIS™ Jr. were approved through the PMA process (P170013).

PulseRider Aneurysm Neck Reconstruction Device
In 2017, the PulseRider Aneurysm Neck Reconstruction Device (Pulsar Vascular, Inc.) was approved by the FDA through the HDE process (H160002) for use with neurovascular embolic coils for treatment of unruptured wide-necked intracranial aneurysms with neck width at least 4 mm or dome to neck ratio greater than 2.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:
CPT codes specific for intracranial angioplasty and stent placement:

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

CPT code for occlusion of a vascular malformation performed as part of the treatment of an aneurysm:

61624	Transcatheter permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)

Diagnostic studies of cervico-cerebral arteries codes (e.g., 36221-36228) describe non-selective and selective arterial catheter placement and diagnostic imaging.

CPT code for mechanical embolectomy:

61645	percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)

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POLICY HISTORY:

Adopted for Blue Advantage, February 2007
Available for comment February 6-March 22, 2007
Medical Policy Group, September 2010
Medical Policy Group, September 2011
Medical Policy Group, October 2012
Medical Policy Group, October 2013
Medical Policy Group, April 2015
Medical Policy Group, October 2015
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Medical Policy Group, July 2020
Medical Policy Group, May 2021

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.