Endovascular Procedures for Intracranial and Extracranial Cerebral Vascular Disease

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary endovascular procedures for intracranial and extracranial cerebral vascular disease.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

PROCEDURES

Endovascular therapy may be used as an alternative or adjunct to conventional management for cerebral aneurysms, carotid artery stenosis, atherosclerotic stenosis, dissections, and/or aneurysms.

These therapies may include one of the following United States (U.S.) Food and Drug Administration (FDA) approved devices:

- Carotid angioplasty with stenting with embolic protection; or
- Percutaneous intracranial balloon angioplasty; or
- Mechanical embolectomy; or
- Intracranial flow diverting device; or
- Percutaneous transluminal angioplasty with or without stenting.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Intracranial Stent Placement

Intracranial stent placement may be considered medically necessary as part of the endovascular treatment of intracranial aneurysms for individuals when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm, e.g., wide-neck aneurysm (greater than or equal to four (4) mm) or sack-to-neck ratio less than two-to-one (2:1).

Intracranial Flow Diverting Stents

Intracranial flow-diverting stents with U.S. FDA approval for the treatment of large or giant wide-necked intracranial aneurysms, with a size of 10 mm or more and a neck diameter of four (4) mm or more or a dome-to-neck ratio less than two (2), in the internal carotid artery from the petrous to the superior hypophyseal segments may be considered medically necessary as part of endovascular treatment of intracranial aneurysms that are not amenable to surgical treatment or standard endovascular therapy.

Intracranial stent placement in the treatment of intracranial aneurysms not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, not covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Percutaneous Intracranial Transluminal Angioplasty

Intracranial percutaneous transluminal angioplasty with or without stenting for the treatment of atherosclerotic cerebrovascular disease is considered experimental/investigational, and, therefore, non-covered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Mechanical Embolectomy

The use of endovascular mechanical embolectomy with an U.S. FDA approved device for the treatment of acute ischemic stroke may be considered medically necessary for individuals who meet ALL of the following criteria:

- Individual is 18 years of age or older; 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; and
- Have evidence of substantial and clinically significant neurological deficits:
  - NIH Stroke Scale (NIHSS) score of 2 or greater; and
- Have 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 (MRI); and
- Have a demonstrated occlusion within the proximal intracranial anterior circulation including ANY of the following:

- Intracranial internal carotid artery; or
- M1 or M2 segments of the middle cerebral artery; or
- A1 or A2 segments of the anterior cerebral artery; or
- Basilar artery.

Endovascular mechanical embolectomy with an FDA approved device for the treatment of acute ischemic stroke not meeting the criteria as indicated in this policy is considered experimental/investigational, and, therefore, not covered because the safety and/or efficacy cannot be established by review of the available published peer-reviewed literature.

Percutaneous Intracranial Cerebrovascular Artery Angioplasty

Percutaneous intracranial cerebrovascular artery angioplasty with or without stenting may be considered medically necessary for the following FDA-approved Humanitarian Device Exemption (HDE) indication:

- For individuals 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 percent stenosis that are accessible to the stent system.

Percutaneous intracranial cerebrovascular artery angioplasty is considered medically necessary for the following FDA-approved HDE indication:

- For improving cerebral artery lumen diameter in individuals who have intracranial atherosclerotic disease that is refractory to medical therapy in intracranial vessels with greater than or equal to 50 percent stenosis that are accessible to the stent system.

The use of percutaneous intracranial cerebrovascular artery angioplasty device for any HDE indications not meeting the criteria as indicated in this policy is considered experimental/investigational and, therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

An HDE may only be used in facilities that have an Institutional Review Board (IRB) to oversee the clinical application of such devices. The IRB must approve the application of the device to ensure that it will be used in accordance with the FDA-approved indication(s). In addition, documentation of IRB approval may be requested by the Company to ensure compliance with the HDE indication(s).

Extracranial Artery Angioplasty/Stenting

Carotid Angioplasty with Associated Stenting (CAS) and Embolic Protection

CAS and embolic protection may be considered medically necessary in individuals with ALL of the following indications:

- 50% to 99% stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] measurement); and
- Symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days, symptom duration less than 24 hours, or non-disabling stroke; and
- Anatomic contraindication for carotid endarterectomy (e.g., prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).

Contraindications:

- Contraindication for CAS and embolic protection may include, but is not limited to, the following:

- Individuals with carotid stenosis who are suitable candidates for carotid endarterectomy; or
- Individuals with carotid artery dissection.

Carotid angioplasty with or without associated stenting and embolic protection not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Endovascular Therapy for Extracranial Vertebral Artery Disease

Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, for the management of extracranial vertebral artery diseases is considered experimental/investigational and therefore noncovered because the safety and effectiveness of this service cannot be established by the available published peer-reviewed literature.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Inpatient

Experimental/investigational (E/I) services are not covered regardless of place of service.

CODING REQUIREMENTS

CPT codes	Description
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.
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).
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.
61640	Balloon dilation of intracranial vasospasm, percutaneous; initial vessel.
61641	Balloon dilation of intracranial vasospasm, percutaneous; each additional vessel in same vascular territory (list separately in addition to code for primary procedure).
61642	Balloon dilation of intracranial vasospasm, percutaneous; each additional vessel in different vascular territory (list separately in addition to code for primary procedure).
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).

75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation.
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection.
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection.
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation.
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.
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 (e.g., middle cerebral artery, posterior inferior cerebellar artery) (list separately in addition to code for primary procedure).

Covered Diagnosis Codes for Procedure Codes: 61623, 61624

I60.00	I60.01	I60.02	I60.10	I60.11	I60.12	I60.2
I60.30	I60.31	I60.32	I60.4	I60.50	I60.51	I60.52
I60.6	I60.7	I60.8	I60.9	I61.0	I61.1	I61.2
I61.3	I61.4	I61.5	I61.6	I61.8	I61.9	I62.00
I62.01	I62.02	I62.03	I62.1	I62.9	I67.1	Q28.2
Q28.3	S06.1X0A	S06.1X1A	S06.1X2A	S06.1X3A	S06.1X4A	S06.1X5A
S06.1X6A	S06.1X7A	S06.1X8A	S06.1X9A	S06.2X0A	S06.2X1A	S06.2X2A
S06.2X3A	S06.2X4A	S06.2X5A	S06.2X6A	S06.2X7A	S06.2X8A	S06.2X9A
S06.300A	S06.301A	S06.302A	S06.303A	S06.304A	S06.305A	S06.306A
S06.307A	S06.308A	S06.309A	S06.810A	S06.811A	S06.812A	S06.813A
S06.814A	S06.815A	S06.816A	S06.817A	S06.818A	S06.819A	S06.820A
S06.821A	S06.822A	S06.823A	S06.824A	S06.825A	S06.826A	S06.827A
S06.828A	S06.829A	S06.890A	S06.891A	S06.892A	S06.893A	S06.894A
S06.895A	S06.896A	S06.897A	S06.898A	S06.899A	S06.9X0A	S06.9X1A
S06.9X2A	S06.9X3A	S06.9X4A	S06.9X5A	S06.9X6A	S06.9X7A	S06.9X8A
S06.9X9A						

Covered Diagnosis Codes for Procedure Codes: **37215, 37216, 37217, 37218**

I63.011	I63.012	I63.013	I63.019	I63.031	I63.032	I63.033
I63.039	I63.111	I63.112	I63.113	I63.119	I63.131	I63.132
I63.133	I63.139	I63.211	I63.212	I63.213	I63.219	I63.231
I63.232	I63.233	I63.239	I63.313	I63.323	I63.333	I63.343
I63.413	I63.423	I63.433	I63.443	I63.513	I63.523	I63.533
I63.543	I63.59	I65.01	I65.02	I65.03	I65.09	I65.21
I65.22	I65.23	I65.29	I65.8			

Covered Diagnosis Codes for Procedure Code: 61645

I63.00	I63.011	I63.012	I63.013	I63.019	I63.02	I63.031
I63.032	I63.033	I63.039	I63.09	I63.10	I63.111	I63.112
I63.119	I63.12	I63.131	I63.132	I63.133	I63.139	I63.19
I63.20	I63.211	I63.212	I63.213	I63.219	I63.22	I63.231
I63.232	I63.233	I63.239	I63.29	I63.311	I63.312	I63.313
I63.319	I63.321	I63.322	I63.323	I63.329	I63.331	I63.332
I63.333	I63.339	I63.341	I63.342	I63.349	I63.431	I63.432
I63.433	I63.439	I63.441	I63.442	I63.443	I63.449	I63.50
I63.511	I63.512	I63.513	I63.519	I63.521	I63.522	I63.523
I63.529	I63.531	I63.532	I63.533	I63.539	I63.541	I63.542
I63.543	I63.549	I63.59	I63.81	I63.89	I63.9	R29.702
R29.703	R29.704	R29.705	R29.706	R29.707	R29.708	R29.709
R29.710	R29.711	R29.712	R29.713	R29.714	R29.715	R29.716
R29.717	R29.718	R29.719	R29.720	R29.721	R29.722	R29.723
R29.724	R29.725	R29.726	R29.727	R29.728	R29.729	R29.730
R29.731	R29.732	R29.733	R29.734	R29.735	R29.736	R29.737
R29.738	R29.739	R29.740	R29.741	R29.742		

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

Society of Vascular and Interventional Neurology – 2016

In 2016, the Society of Vascular and Interventional Neurology published recommendations on comprehensive stroke center requirements and endovascular stroke systems of care. The recommendations were based on 5 multicenter, prospective, randomized, open-label, blinded endpoint 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 tissue plasminogen activator (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 – 2019

In 2018, the American Heart Association and the American Stroke Association (update 2019) published joint guidelines on the early management of patients with acute ischemic stroke. These guidelines included several recommendations relevant to the use of endovascular therapies for acute stroke. Please see table attachment.

The 2 associations also published joint guidelines on the management of patients with unruptured intracranial aneurysms in 2015. These guidelines included the recommendations listed on the table attachment relevant to the use of endovascular therapies for aneurysms. Please see table attachment.

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POLICY UPDATE HISTORY

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