2016 Procedures Criteria

PATIENT:	Name	DOB	ID#	GROUP#
	Facility		Service Date	
PROVIDER:	Name		Fax#	Phone#
	Signature		Date	NPI/ID#

ICD-9:
ICD-10:
CPT®:

Subset: Angioplasty and Stent, Carotid[1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]
Requested Service: Angioplasty and Stent, Carotid
Age: Age ≥ 18

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

☐ 10. Asymptomatic carotid stenosis ≥ 60% by imaging

☐ 20. Recurrent carotid stenosis by imaging

☐ 30. Symptomatic carotid stenosis (urgent)

☐ 10. Asymptomatic carotid stenosis ≥ 60% by imaging

There are no questions for the requested service.

☐ 20. Recurrent carotid stenosis by imaging

1. Choose one:[12]

   ☐ A) Asymptomatic restenosis ≥ 80%[13, 14]

   ☐ B) Symptomatic restenosis (urgent)[15, 16]

   ☐ C) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here ***(Outpatient)***
- If option B selected, then go to question 2
- No other options lead to the requested service

2. Choose one:[17]

   ☐ A) Ischemic stroke in carotid distribution by history, physical examination, and imaging[18]

   ☐ B) Transient ischemic attack (TIA) in carotid distribution by history or physical examination[19]

   ☐ C) Other clinical information (add comment)

- If option A or B selected, then go to question 3
- No other options lead to the requested service

3. Carotid findings, Choose all that apply:

- ☐ A) Carotid stenosis ≥ 50%[20]
- ☐ B) No intracranial hemorrhage by imaging
- ☐ C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here ***(Outpatient)***
- No other options lead to the requested service

☐ 30. Symptomatic carotid stenosis (urgent)

1. Choose one:[17]

- ☐ A) Ischemic stroke in carotid distribution by history, physical examination, and imaging[18]
- ☐ B) Transient ischemic attack (TIA) in carotid distribution by history or physical examination[19]
- ☐ C) Other clinical information (add comment)

- If option A or B selected, then go to question 2
- No other options lead to the requested service

2. Carotid findings, Choose all that apply:[21]

- ☐ A) Carotid stenosis ≥ 50%
- ☐ B) No intracranial hemorrhage by imaging
- ☐ C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then go to question 3
- No other options lead to the requested service

3. Carotid endarterectomy (CEA) feasible[22, 23]

- ☐ Yes
- ☐ No

- If option No selected, then the rule is satisfied; you may stop here ***(Outpatient)***
- No other options lead to the requested service

Notes

(1)
I/O Setting: Outpatient

(2)
These criteria address carotid angioplasty with stenting. For criteria covering carotid endarterectomy, see the "Endarterectomy, Carotid Artery" criteria subset.

(3)
Most surgically treatable cerebral vascular disease is atherosclerosis-related and found in the internal carotid artery. Vague central symptoms (e.g., dizziness, lightheadedness, generalized weakness, memory loss) are insufficient indications for revascularization procedures and are not covered in these criteria.

(4)
POL: The Centers for Medicare and Medicaid Services (CMS) requires that carotid artery angioplasty and stenting be performed in a certified center. CMS has developed requirements for minimal standards related to documented medical practitioner training, facility device and support, and monitoring of procedure outcomes. It is a matter of local medical policy whether this procedure needs to be performed in a certified center.

(5)
Medical comorbidities (e.g., New York Heart Association class III or IV heart failure, ejection fraction less than 30%, unstable angina, severe chronic obstructive pulmonary disease) and anatomic risk factors (e.g., unfavorable neck anatomy due to tracheostomy, radical neck surgery, prior radiation treatment, contralateral carotid occlusion) can increase the risk associated with surgery and in these situations, carotid angioplasty and stenting may be preferred (Brott et al., Circulation 2011, 124: 489-532; Ricotta et al., J Vasc Surg 2011, 54: e1-31).

(6)
Revascularization procedures are not indicated for patients who have persistent major neurologic deficit (e.g., hemiplegia causing significant self-care impairment) contralateral to the carotid stenosis (e.g., modified Rankin scale score of less than or equal to two) (Brott et al., Circulation 2011, 124: 489-532).

(7)
The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) compared outcomes of patients with symptomatic and asymptomatic carotid stenosis randomized to carotid artery stenting (CAS) or carotid endarterectomy (CEA). CREST reported that CAS and CEA were both associated with similar rates of periprocedural stroke, myocardial infarction (MI) (including asymptomatic enzyme detection), or death; however, there were differences in end point component results. Stroke occurred in 4.1% of stented patients compared with 2.3% of patients who had CEA, and MI occurred in 1.1% of CAS patients compared with 2.3% of CEA patients. The risk of periprocedural stroke and death was significantly higher for CAS in symptomatic patients (6.0% for CAS and 3.2% for CEA) when MI was not included in the outcome (Brott et al., N Engl J Med 2010, 363: 11-23). Similar results were reported in the International Carotid Investigators Stenting Study (ICSS) and the authors of that study concluded that, for suitable patients, CEA should remain the treatment of choice (Ederle et al., Lancet 2010, 375: 985-97).
The comparative effectiveness of CEA and CAS has been evaluated in multiple meta-analyses which have consistently reported that the periprocedural rate of death and stroke is significantly higher for patients who have CAS versus CEA but that CEA is associated with higher rates of MI and cranial nerve injury. These results include both symptomatic and asymptomatic patients who had a revascularization procedure (Wang et al., Chin Med J (Engl) 2013, 126: 532-5; Arya et al., Vasc Endovascular Surg 2011, 45: 490-8; Bangalore et al., Arch Neurol 2011, 68: 172-84; Economopoulos et al., Stroke 2011, 42: 687-92; Yavin et al., Can J Neurol Sci 2011, 38: 230-5; Ederle et al., Lancet 2010, 375: 985-97). Similar results were reported in a meta-analysis of patients with symptomatic carotid stenosis but the differences in stroke and fatal outcomes were not sustained in the intermediate term (1 to 4 years) (Meier et al., BMJ 2010; 340: c467).

(8)
In post hoc analysis of the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), it was found that patients who experienced a periprocedural stroke reported a significantly negative impact on their quality of life at one year when compared with patients who had a periprocedural myocardial infarction (MI) (Cohen et al., J Am Coll Cardiol 2011, 58: 1557-65). A large data-base study found that the risk of postoperative stroke increased the risk of death in the first year compared with postoperative MI. After five years, the survival curves for postoperative MI and stroke were similar for patients who underwent carotid revascularization (Simons et al., J Vasc Surg 2013, 57: 1581-8).
A recent single-center randomized trial followed patients with asymptomatic and symptomatic carotid stenosis that underwent carotid endarterectomy (CEA) or carotid artery stenting (CAS) for a period of ten years. The study reported similar long-term stroke protection from both CAS and CEA, but the risk of MI remained higher in those who had CEA (Brooks et al., JACC Cardiovasc Interv 2014, 7: 163-8).

(9)
An abundance of evidence suggests that the age of the patient should be considered when selecting a carotid revascularization intervention. The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) reported that the efficacy of carotid artery stenting (CAS) and carotid endarterectomy (CEA) was similar at age 70; however, slightly better outcomes for CAS were seen in patients aged less than 70 and slightly better outcomes for CEA in patients older than 70 (Voeks et al., Stroke 2011, 42: 3484-90; Brott et al., N Engl J Med 2010, 363: 11-23).
These findings were replicated in a pooled analysis of randomized trials; the risk of stroke and death were two-fold in patients greater than 70 years of age undergoing CAS when compared with CEA. CEA had greater short-term safety due to the increased risk of periprocedural stroke with CAS. The risk of myocardial infarction increased with age with CEA but not with CAS (Antoniou et al., J Vasc Surg 2013, 57: 1134-45; Gahremanpour et al., Tex Heart Inst J 2012, 39: 474-87; Bonati and Fraedrich, Eur J Vasc Endovasc Surg 2011, 41: 153-8).

(10)
A subgroup analysis of the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) reported that women who underwent carotid artery stenting (CAS) had a higher periprocedural risk than those who underwent carotid endarterectomy (CEA). There was no reported difference in men (Howard et al., Lancet Neurol 2011, 10: 530-7). A recent study that aimed to develop a clinical rule set to select patients for CEA or CAS found that women less than age 75, in the absence of contralateral occlusion, were identified as low risk for CAS. However, a sensitivity analysis of this group confirmed a trend toward a higher periprocedural rate of stroke or death for CAS when compared to CEA (Touze et al., Stroke 2013, 44: 3394-400). Recent guidelines do not recommend CAS as a treatment option for women for the prevention of stroke (Meschia et al., Stroke 2014, 45: 3754-832). CAS is, therefore, only recommended for women with symptomatic carotid restenosis or who have a history of ipsilateral neck surgery, radiation to the neck, tracheal stoma, history of prior cranial nerve injury, or a lesion extending to the distal second cervical vertebra or to the clavicle (De Rango et al., Neurology 2013, 80: 2258-68).

(11)
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare &Medicaid Services (CMS) National Coverage Determinations, the National Institute of Health and Care Excellence (NICE), and the National Guideline Clearinghouse. Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

(12)
The role of carotid angioplasty and stenting (CAS) for the treatment of asymptomatic restenosis is poorly defined. The American Heart Association/American Stroke Association guideline, the only one to specifically address restenosis, recommends that this procedure may be considered as a treatment option and that the usefulness and efficacy of the procedure is not well established (Brott et al., Circulation 2011, 124: 489-532). A recent systematic review reported a combined death and stroke rate of 3.1% for patients undergoing CAS for restenosis and 3.7% for patients undergoing carotid endarterectomy (Bekelis et al., Br J Surg 2013, 100: 440-7). McKesson clinical consultants agree that CAS can be considered as an option for asymptomatic patients with carotid restenosis greater than 80%.

(13)
Carotid artery stenosis may be identified in patients during an evaluation of vague episodes of dizziness, generalized weakness, syncope or near syncope, blurry vision, or transient visual abnormalities (e.g., floaters). These are nonspecific symptoms and the patient is considered to be asymptomatic. A patient is also considered to be asymptomatic if more than 6 months has passed since their last episode of focal neurologic symptoms.

(14)
The annual rate of stroke for medically treated patients has continued to decline over the past twenty years. Recent studies reported a stroke rate of approximately 1% per year, as compared with a 3.5% per year risk in 1995 (Naylor, Nat Rev Cardiol 2012, 9: 116-24; Markus et al., Lancet Neurol 2010, 9: 663-71). A meta-analysis concluded that best medical therapy (e.g., antiplatelet therapy, antihypertensive medication, statins, improved glycemic control, lifestyle modifications) is optimal for stroke prevention associated with asymptomatic severe carotid stenosis (Abbott, Stroke 2009; 40(10): e573-583).

(15)
Urgent conditions do not require preauthorization. A review to determine the appropriateness of the intervention is generally performed following the intervention.

(16)
Patients who have experienced an acute cerebrovascular event, either a stroke or transient ischemic attack (TIA), due to carotid stenosis within six months are considered to have symptomatic carotid stenosis. Patients who have had a TIA have a 5% chance of having a stroke in the 30 days following their initial event and 25% will have a recurrent neurological event within one year (Mughal et al., Expert Rev Cardiovasc Ther 2011, 9: 1315-30).

(17)
Acute neurologic symptoms that result from an occlusion in the anterior circulation can be either global or focal and include altered level of consciousness, unilateral motor, sensory, or sensorimotor impairment, dysphagia, dysarthria, and visual impairment. Posterior circulation symptoms include vertigo with or without diplopia, loss of balance, ataxia, and unilateral motor weakness (Phan et al., Intern Med J 2013, 43: 353-60).

(18)
Ischemic stroke is defined as an episode of neurologic dysfunction caused by focal cerebral, spinal, or retinal infarction related to atherosclerosis or a thromboembolic process. Timely imaging of the brain is essential for confirmation of the diagnosis and to facilitate treatment planning. Patients who have had an ischemic stroke will have evidence of infarction on imaging (Jauch et al., Stroke 2013, 44: 870-947).

(19)
Transient ischemic attack (TIA) is defined as a transient episode of neurological dysfunction caused by focal cerebral, spinal cord, or retinal ischemia, without evidence of acute brain tissue infarction. Imaging is essential for making the diagnosis, as the focus has shifted from a time-based criterion (symptoms lasting less than 24 hours) to a tissue-based diagnosis. Patients who have had transient symptoms but have evidence of infarction on imaging by definition would be classified as having had an ischemic stroke (Easton et al., Stroke 2009; 40(6): 2276-2293). A meta-analysis found that two-thirds of patients with a confirmed TIA diagnosis had negative diffusion-weighted MRI findings (Brazzelli et al., Ann Neurol 2014, 75: 67-76).

(20)
Carotid angioplasty and stenting is recommended for recurrent stenosis after endarterectomy due to the relative ease of procedure and stability of the plaque. Current guidelines recommend that repeat carotid endarterectomy or stenting can be performed for symptomatic patients (Bekelis et al., Br J Surg 2013, 100: 440-7; Brott et al., Circulation 2011, 124: 489-532).

(21)
The American Heart Association/American Stroke Association Guidelines recommend carotid artery angioplasty and stenting (CAS) as an alternative to carotid endarterectomy for patients with symptomatic carotid stenosis of greater than 70% (50% by catheter angiography) and the periprocedural complication rate for stroke or mortality is less than 6% (Brott et al., Circulation 2011, 124: 489-532). Other guidelines take a more conservative approach and recommended CAS for patients who are high risk for having an carotid endarterectomy (CEA) because of a medical comorbidity (e.g., New York Heart Association class III or IV heart failure, ejection fraction less than 30%, unstable angina, and severe chronic obstructive pulmonary disease), anatomic considerations (e.g., unfavorable neck anatomy due to tracheostomy, radical neck surgery, prior radiation treatment, contralateral carotid occlusion, and surgically inaccessible lesion), or for revascularization of recurrent stenosis (Tendera et al., Eur Heart J 2011, 32: 2851-906; Bryer et al., S Afr Med J 2010, 100: 747-78; Ranta et al., N Z Med J 2010, 123: 58-74; Liapis et al., Eur J Vasc Endovasc Surg 2009; 37(4 Suppl): 1-19). The Society for Vascular Surgery guidelines recommend that for those symptomatic patients with the listed comorbidities, CAS is preferred over CEA when carotid stenosis is greater than or equal to 50% (Ricotta et al., J Vasc Surg 2011, 54: e1-31). These criteria are supported by the recommendations of the Society for Vascular Surgery.

(22)
Medical comorbidities, such as New York Heart Association class III or IV heart failure, ejection fraction less than 30%, unstable angina, and severe chronic obstructive pulmonary disease can increase the risk of carotid endarterectomy (Brott et al., Circulation 2011, 124: 489-532). Anatomic risk factors such as unfavorable neck anatomy due to tracheostomy, radical neck surgery, prior radiation treatment, contralateral carotid occlusion, and surgically inaccessible lesion also increase the risk associated with surgery and in these situations, carotid angioplasty and carotid stenting may be preferred (Brott et al., Circulation 2011, 124: 489-532; Ricotta et al., J Vasc Surg 2011, 54: e1-31; Criado and Gashti, Semin Vasc Surg 2008, 21: 139-42; Narins and Illig, J Vasc Surg 2006, 44: 661-72). Patients with anatomical risk factors have a lower risk of major adverse events than those with physiological risk factors (Massop et al., Catheter Cardiovasc Interv 2009, 73: 129-36).

(23)
Contralateral carotid occlusion increases the perioperative and early postoperative risk of stroke and death in patients undergoing carotid endarterectomy (CEA) but not in those undergoing carotid artery stenting (CAS) (Antoniou et al., J Vasc Surg 2013, 57: 1134-45; Faggioli et al., Eur J Vasc Endovasc Surg 2013, 46: 10-20). Patients with contralateral occlusion who have restenosis or who are female and younger than 75 years of age have a relatively low risk with CAS compared with CEA (Touze et al., Stroke 2013, 44: 3394-400).

ICD-9 (circle all that apply): 00.61, 00.63, 433.10, 433.11, 433.30, 433.31, 435.8, 435.9, Other_____

ICD-10-CM (circle all that apply): G45.1, G45.8, G45.9, I63.139, I63.239, I63.59, I65.29, I65.8, I67.848, Other_____

ICD-10-PCS (circle all that apply): 037H34Z, 037H3DZ, 037H3ZZ, 037H44Z, 037H4DZ, 037H4ZZ, 037J34Z, 037J3DZ, 037J3ZZ, 037J4DZ, 037J4ZZ, 037M34Z, 037M3DZ, 037M3ZZ, 037M44Z, 037M4DZ, 037M4ZZ, 037N34Z, 037N3DZ, 037N3ZZ, 037N4DZ, 037N4ZZ, 03CH3ZZ, 03CJ3ZZ, 03CK3ZZ, 03CL3ZZ, 03CM3ZZ, 03CN3ZZ, Other_____

CPT® (circle all that apply): 35475, 37215, 37216, Other_____