



Carotid Stent Data Dictionary

**Blue Cross Blue Shield of Michigan
Carotid Registry
Data Collection Definitions**

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Qualifying Case Criteria

Qualifying Procedures:

- CAS or TCAR of the common carotid artery (CCA), internal carotid artery (ICA), carotid bifurcation and carotid bulb
- Carotid artery ballooning only
 - Enter this case as a CAS and enter No for the stent questions
- CAS where the sheath was inserted; even if the wire or device did not cross the index lesion

CAS procedures that do not qualify:

- CAS of the external carotid artery (ECA)
- CAS of the intracranial regions of the internal carotid artery (ICA)
 - Petrous segment
 - Cavernous segment
 - Supraclinoid segment
- A qualifying CAS where the sheath was unable to be inserted
- Stenting of tandem lesions
 - Cases in which an extracranial internal carotid occlusive or stenotic lesion accompanied

Physician

Data Abstraction Instructions:

Choose the attending physician from the drop down list, or create a physician identification if not already listed.

Selections:

- Choose physician

Required:

Yes

Fellow ID/Second Operator

Data Abstraction Instructions:

Use the drop down box to choose a physician. If not available in drop down, enter the fellow's or second operator's information to create a physician ID.

Selections:

- Choose Physician

Supporting Definitions:

This is an optional field if your site chooses to track its fellows or second operators.

Required:

No

Procedure Date & Start Time

Data Abstraction Instructions:

Enter the date of the current procedure (mm/dd/yyyy) and enter the time the procedure was initiated. (Military time)

Selections:

- Enter Date & Time

Supporting Definitions:

The time the procedure started is defined as the time which local anesthetic was first administered for vascular access, or the time of the first attempt at vascular access for the peripheral intervention (use whichever is earlier), or incision time for open vascular surgery procedures. Indicate the time (hours:minutes) using military 24-hour clock, beginning at midnight (0000 hours). If an arterial sheath is already in place, use the time of the introduction of a catheter or the time the sheath was exchanged.

Required:

Yes

Procedure End Date & Time

Data Abstraction Instructions:

Enter the date and time the procedure ends.

Selections:

- Enter Date & Time

Supporting Definitions:

The time the procedure ended is defined as the time the primary operator leaves the room for peripheral interventions. End time for open surgical procedures is defined as the time when all instrument and sponge counts are completed; all dressings and drains are secured; and the physicians/surgeons have completed all procedure-related activities on the patient. Should the patient expire in the procedure area, indicate the time the patient was pronounced. Indicate the time (hours:minutes) using military 24-hour clock, beginning at midnight (0000 hours).

Required:

Yes

Status of Procedure

Data Abstraction Instructions:

Indicate status of the procedure using the following categories.

Elective = the procedure could be deferred without increased risk of compromised vascular outcome. This should include the planned or scheduled procedures.

Urgent = required operation within 72 hours, but > 12 hours of admission.

Emergent = required operation within 12 hours of admission to prevent limb loss.

Selections:

- Elective
- Urgent
- Emergent

Required:

Yes

Labs

Pre Procedure Creatinine

Data Abstraction Instructions:

Use the last value between 30 days prior to arrival and current procedure. If there is no value, mark not drawn.

Selections:

- Drawn
 - Enter value
- Not drawn

Supporting Definitions:

When multiple lab values are available pre-procedure, enter the value closest to the procedure start time. If a patient has multiple procedures within a hospitalization, the pre-procedure labs should be abstracted after the previous procedure; if no labs are drawn from the end of the previous procedure to the start of the current procedure, enter "Not drawn".

Required:

Yes

Suffix:

mg/dl

Minimum:

0.1

Maximum:

15

Soft Minimum:

0.3

Pre Procedure Hemoglobin (Hgb)

Data Abstraction Instructions:

Use the last value between 30 days prior to arrival and current procedure. If there is no value, mark not drawn.

Selections:

- Drawn
 - Enter value
- Not drawn

Supporting Definitions:

When multiple lab values are available pre-procedure, enter the value closest to the procedure start time. If a patient has multiple procedures within a hospitalization, the pre-procedure labs should be abstracted after the previous procedure; if no labs are drawn from the end of the previous procedure to the start of the current procedure, enter "Not drawn".

Required:

Yes

Suffix:

g/dl

Minimum:

2

Maximum:

20

Soft Minimum:

5

Soft Maximum:

18

Pre Procedure BNP

Data Abstraction Instructions:

Indicate if a BNP value was obtained within the 30 days prior to the procedure. If more than one value exists, use the one closest to the procedure start time.

Selections:

Pre Procedure BNP

- Yes
 - Value _____ pg/mL
- No

Required:

Yes

Pre Procedure Troponin

Data Abstraction Instructions:

Indicate if a Troponin I, Troponin T, Troponin I HS (High Sensitivity) or Troponin T HS value was obtained within the 30 days prior to the procedure. If more than one value exists, use the value closest to the procedure start time.

Selections:

Pre Procedure Troponin

- Yes
 - Pre procedure troponin I
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - Pre procedure troponin T
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - Pre procedure troponin I HS
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - Pre procedure troponin T HS
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
- Not Drawn

Supporting Definitions:

When multiple lab values are available pre-procedure, enter the value closest to the procedure start time. If a patient has multiple procedures within a hospitalization, the pre-procedure labs should be abstracted after the previous procedure; if no labs are drawn from the end of the previous procedure to the start of the current procedure, enter "Not drawn".

Required:

Yes

Suffix:

ng/dL, ng/mL, ng/L, pg/mL

Post Procedure Peak Creatinine

Data Abstraction Instructions:

Record the highest level recorded from end of procedure to next procedure or discharge, whichever occurs first. For extended hospitalizations, greater than 30 days, use the highest creatinine prior to day 30 after the procedure.

Selections:

- Drawn
 - Enter value
- Not drawn

Supporting Definitions:

The next procedure is any procedure utilizing contrast, or any open surgical procedure. If the "next procedure" is a complication from the entered procedure, continue to abstract the peak creatinine beyond it.

If only one value is available post procedure through discharge, that value will be used for both the post procedure peak creatinine **and** the discharge value.

Required:

Yes

Suffix:

mg/dl

Minimum:

0.1

Maximum:

15

Soft Minimum:

0.3

Post Procedure Nadir Hemoglobin

Data Abstraction Instructions:

Record the lowest level recorded from end of procedure to next procedure or discharge, whichever occurs first.

Selections:

- Drawn
 - Enter value
- Not drawn

Supporting Definitions:

The next procedure is any procedure utilizing contrast, or any open surgical procedure. If the "next procedure" is a complication from the entered procedure, continue to abstract the peak creatinine beyond it.

If only one value is available post procedure through discharge, that value will be used for both the post procedure nadir hemoglobin **and** the discharge value.

Required:

Yes

Suffix:

g/dl

Minimum:

2

Maximum:

20

Soft Minimum:

5

Soft Maximum:

Patient History

Significant Valve Disease

Data Abstraction Instructions:

Indicate whether the patient has had a previous surgical replacement and/or repair of a cardiac valve by any approach prior to arrival at this facility. This includes percutaneous valve procedures and valvuloplasty. Also indicate if patient has mitral valve regurgitation of at least grade 2 or greater, mitral valve area < 1.5 cm², aortic valve regurgitation of at least grade 2 or greater, or aortic valve area < 1.0 cm².

Selections:

- Yes
 - MI/MR
 - MS
 - AI
 - AS
- No

Supporting Definitions:

This may include physician documentation of moderate or severe valve disease.

Required:

Yes

Mechanical Aortic or Mitral Valve

Data Abstraction Instructions:

Indicate if the patient has a history of open surgical or percutaneous valve replacement with a mechanical mitral or aortic valve. If the patient has received a biological (e.g. tissue) valve, had surgical valve repair (without valve replacement), or undergone percutaneous valve modification (including valvuloplasty, mitral annular remodeling, or mitral valve clipping/suturing), without mechanical valve replacement, code "No".

Selections:

- Yes
- No

Required:

Yes

Angina CCS Class III or IV w/in 6 weeks

Data Abstraction Instructions:

Indicate if the patient experienced anginal symptoms equivalent to the Canadian Cardiovascular Society (CCS) Classification System Class III or IV within 6 weeks prior to the procedure.

CCS Class III or Class IV are defined as:

Class III = Marked limitation of ordinary activity; for example, angina occurs walking one or two blocks on the level or climbing one flight of stairs in normal conditions and at a normal pace.

Class IV = Inability to carry on any physical activity without discomfort - angina syndrome may be present at rest.

Selections:

- Yes
- No

Required:

Yes

Peripheral Arterial Disease (PAD)

Data Abstraction Instructions:

Indicate if the patient has a history of peripheral arterial disease prior to the current procedure. Peripheral arterial disease is characterized by any of the following:

- Claudication, either with exertion or at rest
- Amputation for arterial vascular insufficiency
- Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities
- Documented aortic aneurysm
- Positive noninvasive test (e.g., ankle brachial index less than 0.8)

Selections:

- Yes
- No

Required:Yes

Home O2 Therapy

Data Abstraction Instructions:

Indicate if, prior to the current procedure, the patient has been receiving home oxygen therapy for treatment of chronic lung disease.

Selections:

- Yes
- No

Required:Yes

Major Surgery Planned w/in Next 8 Wks

Data Abstraction Instructions:

Indicate if the patient is receiving carotid revascularization in preparation for a major surgical procedure. Indicate "Yes" only if the surgical procedure will take place within eight weeks following the carotid revascularization.

Selections:

- Yes
- No

Required:Yes

Type of Major Surgery

Data Abstraction Instructions:

Indicate the type of major surgical procedure scheduled within eight weeks after the current admission. If more than one major surgery is scheduled, choose the type of surgery that is scheduled to be completed first.

Selections:

- Cardiac
- Vascular
- Other

Required:Yes

Previous Neck Radiation

Data Abstraction Instructions:

Indicate if the patient had previous x-ray therapy to the neck prior to the current procedure.

Selections:

- Yes
- No

Required:

Yes

Prior neck surgery (other than CEA)

Data Abstraction Instructions:

Indicate if the patient had a previous extensive (i.e., radical) neck dissection (other than carotid endarterectomy [CEA]) prior to the current admission or prior to the current procedure.

Selections:

- Yes
- No

Required:

Yes

Tracheostomy Present

Data Abstraction Instructions:

Indicate if the patient has an open tracheostomy, at the time of the current procedure.

Selections:

- Yes
- No

Required:

Yes

Previous Laryngeal Nerve Palsy

Data Abstraction Instructions:

Indicate if the patient has a history of laryngeal nerve palsy, defined as paralysis of the larynx caused by damage to the recurrent laryngeal nerve or its parent nerve, the vagus nerve, prior to the current procedure. Indicate the location of the laryngeal nerve palsy, either right or left.

Yes - Right = Laryngeal Nerve Palsy located on right side of the neck.

Yes - Left = Laryngeal Nerve Palsy located on left side of the neck.

No = No Laryngeal Nerbe Palsy.

Selections:

- Yes
 - Right
 - Left
- No

Required:

Yes

Cardiac History

Two or More Major Coronary Arteries with Stenosis \geq 70% (LAD, LCX, RCA)

Data Abstraction Instructions:

Indicate if the patient currently has two or more major coronary arteries stenosis greater than or equal to 70% prior to the current procedure. Major Coronary Arteries are defined as Left Anterior Descending (LAD), Left Circumflex Artery (LCX) and Right Coronary Artery (RCA). This does not include collaterals. Indicate only if the patient currently has coronary arteries with stenosis. If the arteries were Intervened upon, or the patient had a CABG, to repair the blocked arteries, it does not qualify.

Selections:

- Yes
- No

Required:

Yes

Left Main Coronary Artery Stenosis \geq 50%

Data Abstraction Instructions:

Indicate if the patient currently has a Left Main Coronary Artery stenosis greater than or equal to 50% prior to the current procedure. Indicate only if the patient currently has left main stenosis. If the artery was intervened upon, or if the patient has had a CABG, to repair the blocked artery, it does not qualify.

Selections:

- Yes
- No

Required:

Yes

MI w/in 6 weeks

Data Abstraction Instructions:

Indicate if the patient had a myocardial infarction (MI) within 6 weeks prior to the index procedure as evidenced by the following:

- Acute myocardial infarction (\leq 7 days) manifested as a rise and fall of cardiac biomarkers (preferable troponin) with at least one of the values above the range of normal for your laboratory [above the 99th percentile of the upper reference limit (URL)] together with evidence of myocardial ischemia with at least one of the following:
 - ischemic symptoms;
 - ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch block),
 - Development of pathological Q waves in the ECG;
 - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
- Prior myocardial infarction ($>$ 7 days) manifested by
 - A myocardial infarction meeting the criteria of an acute MI, as documented in the medical record, or by either of the following:
 - Development of new pathological Q waves with or without symptoms.
 - Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause.

Selections:

- Yes
- No

Required:

Yes

NYHA Functional Class III or IV w/in 6 weeks

Data Abstraction Instructions:

Indicate if the patient's highest New York Heart Association (NYHA) cardiac functional class has been Class III or IV anytime within 6 weeks prior to the current procedure. Patients with NYHA Class III and Class IV have anginal or heart failure symptoms, at rest, and/or resulting in marked limitation of physical activity. Class III and Class IV are formally defined as:

Class III = Patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest. However, less than ordinary physical activity (e.g., walking one to two level blocks or climbing one flight of stairs) causes fatigue, palpitations, dyspnea, or anginal pain.

Class IV = Patient has dyspnea at rest that increases with any physical activity. Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Enter No for patients without cardiac disease or patients with NYHA Class I or II.

Selections:

- Yes
- No

Required:

Yes

Permanent Pacemaker or ICD

Data Abstraction Instructions:

Indicate if the patient has a permanent pacemaker or implantable cardioverter defibrillator (ICD) placed prior to the current procedure.

Selections:

- Yes
- No

Required:

Yes

Cardiac Stress Test (CAS)

Data Abstraction Instructions:

Indicate if a Cardiac Stress Test was performed within prior 6 months. If performed, indicate if the study was normal or abnormal.

Selections:

- Yes
 - Normal
 - Abnormal
- No

Required:

Yes

EKG (CAS)

Data Abstraction Instructions:

Indicate if an EKG was performed within prior 6 months. If performed, indicate if the study was normal or abnormal.

Selections:

- Yes
 - Normal
 - Abnormal
- No

Required:

Yes

Neurological History and Risk Factors

Dementia or Alzheimer's Disease

Data Abstraction Instructions:

Indicate if the patient has a history of dementia or Alzheimer's Disease, with global deterioration of intellectual or cognitive function as indicated in the medical record

Selections:

- Yes
- No

Required:

Yes

History of Seizure or Known Seizure Disorder

Data Abstraction Instructions:

Indicate if the patient has a history of a seizure disorder as indicated in the medical record, or characterized by at least two unprovoked seizures that occurred at different times (excluding febrile seizures) prior to the current procedure.

Selections:

- Yes
- No

Required:

Yes

Previous Carotid Intervention

Data Abstraction Instructions:

Indicate if the patient had a previous carotid endarterectomy or carotid artery angioplasty or carotid stent procedure. The event may have occurred either prior to this admission, or during this admission prior to the current procedure. If there was more than one procedure (i.e. more than one carotid artery stent procedure on the right carotid artery), code the most recent occurrence for each intervention.

Selections:

- Yes
- No

Required:

Yes

Previous Right CEA Timeframe

Data Abstraction Instructions:

Indicate the timeframe of the most recent carotid endarterectomy (CEA) for the right side, prior to the current procedure

Selections:

- Yes
 - <= to 30 days ago
 - 31 to 180 days ago
 - >= to 181 days ago
- No

Required:

Yes

Previous Right CAS Timeframe

Data Abstraction Instructions:

Indicate the timeframe of the most recent carotid angioplasty and/or stent procedure for the right side, prior to the current procedure

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Previous Left CEA Timeframe

Data Abstraction Instructions:

Indicate the timeframe of the most recent carotid endarterectomy (CEA) for the left side, prior to the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Previous Left CAS Timeframe

Data Abstraction Instructions:

Indicate the timeframe of the most recent carotid angioplasty and/or stent procedure for the left side, prior to the current procedure

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Neurologic Event(s) prior to procedure

Data Abstraction Instructions:

Indicate if the patient experienced a neurologic event at any time prior to the current procedure. Neurologic events are defined as TIA (transient ischemic attack), ischemic stroke, or intracranial hemorrhage/hemorrhagic stroke, and are further described as:

- Transient Ischemic Attacks (TIA) are characterized by the following: A focal neurologic abnormality of sudden onset and brief duration (i.e., lasting <24 hours) that reflects a dysfunction (presumed to be ischemic in origin) in the cerebral distribution of the affected artery. They are evidenced by neurological symptoms involving right or left retinal, right or left hemispheric, vertebrobasilar, and/or unknown territories.
- Ischemic Strokes are caused by a “blockage of a blood vessel” resulting in residual symptoms lasting greater than 24 hours, and leading to impaired functional outcomes. They are evidenced by loss of neurological function involving right or left retinal, right or left hemispheric, vertebrobasilar, and/or unknown territories.
- Intracranial Hemorrhage or Hemorrhagic Strokes are caused by “bursting or leaking of blood vessels” in the brain and may lead to impaired functional outcomes. They are evidenced by intraparenchymal (e.g., hemorrhagic conversion of prior stroke) intracranial hemorrhage, subarachnoid intracranial hemorrhage, and/or subdural intracranial hemorrhage.

Symptoms of transient ischemic attack or ischemic stroke in specific territories can include the following:

1. Ischemia in the retinal territory can be manifested as:

- Transient monocular blindness (e.g., amaurosis fugax, defined as a transient episode of blindness or partial blindness, affecting one eye only).

2. Ischemia in the hemispheric territory supplied by the carotid artery can be manifested as:

- language impairment
- speech impairment or dysphasia
- hemi-neglect
- and/or, the symptoms noted in #4 (a through e) below

3. Ischemia in the vertebrobasilar territory can be manifested as:

- vertigo (spinning sensation)
- cranial nerve abnormalities (an example is dysconjugate gaze, in which eyes are no longer yoked together)
- “crossed” neurological symptoms, indicated by focal neurological deficits involving both sides of the body (example: sensory loss on the right and motor weakness on the left)
- and/or, the symptoms noted in #4 (a through e) below

4. Symptoms of ischemia that can be manifested in either the carotid hemispheric territory and/or Vertebrobasilar territory include:

- motor weakness
- sensory loss
- slurred speech (“dysarthria”)
- visual field cut (more common in the vertebrobasilar territory)
- clumsiness or incoordination (more common in the vertebrobasilar territory)

Note: The specific territory of the prior event should be confirmed by a physician and prior imaging studies may be of assistance to confirm the territory involved.

Selections:

- Yes
- No

Required:

Yes

TIA – Right Retinal

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a Transient Ischemic Attack (TIA) involving the right retinal territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - <= to 30 days ago
 - 31 to 180 days ago
 - >= to 181 days ago
- No

Required:

Yes

TIA – Left Retinal

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a Transient Ischemic Attack (TIA) involving the left retinal territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure

Selections:

- Yes
 - <= to 30 days ago

31 to 180 days ago
>= to 181 days ago

- No

Required:Yes

TIA – Right Hemispheric

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a Transient Ischemic Attack (TIA) involving the right hemispheric territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - <= to 30 days ago
 - 31 to 180 days ago
 - >= to 181 days ago
- No

Required:Yes

TIA – Left Hemispheric

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a Transient Ischemic Attack (TIA) involving the left hemispheric territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - <= to 30 days ago
 - 31 to 180 days ago
 - >= to 181 days ago
- No

Required:Yes

TIA – Vertebrobasilar

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a Transient Ischemic Attack (TIA) involving the vertebrobasilar territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - <= to 30 days ago
 - 31 to 180 days ago
 - >= to 181 days ago
- No

Required:Yes

TIA – Unknown

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a Transient Ischemic Attack (TIA) involving an unknown territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Ischemic Stroke – Right Retinal

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a completed ischemic stroke involving the right retinal territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Ischemic Stroke – Left Retinal

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a completed ischemic stroke involving the left retinal territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Ischemic Stroke – Right Hemispheric

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a completed ischemic stroke involving the right hemispheric territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Ischemic Stroke – Left Hemispheric

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a completed ischemic stroke involving the left hemispheric territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:Yes

Ischemic Stroke – Vertebrobasilar

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a completed ischemic stroke involving the vertebrobasilar territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:Yes

Ischemic Stroke – Unknown

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a completed ischemic stroke involving an unknown territory. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:Yes

Intracranial Hemorrhage or Hemorrhagic Stroke - Intraparenchymal

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced an intraparenchymal (e.g. hemorrhagic conversion of prior stroke) intracranial hemorrhage. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Intracranial Hemorrhage or Hemorrhagic Stroke - Subarachnoid

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a subarachnoid hemorrhage. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Intracranial Hemorrhage or Hemorrhagic Stroke – Subdural

Data Abstraction Instructions:

Indicate the timeframe if the patient experienced a subdural hemorrhage. If there was more than one, code the most recent occurrence prior to admission or the current procedure.

Selections:

- Yes
 - </= to 30 days ago
 - 31 to 180 days ago
 - >/= to 181 days ago
- No

Required:

Yes

Acute Evolving Stroke

Data Abstraction Instructions:

Indicate if the patient has experienced an acute evolving stroke with ischemia which is ongoing and progressing at the time of the procedure. Acute evolving stroke includes all of the following:

- Any sudden development of neurological deficits attributable to cerebral ischemia and/or infarction.
- Onset of symptoms occurring within prior three days and ongoing at time of procedure.
- The event is marked by progressively worsening symptoms.
- Note: Possible symptoms include, but are not limited to the following: numbness or weakness of the face or body; difficulty speaking or understanding; blurred or decreased vision; dizziness; or loss of balance and coordination.

Selections:

- Yes
- No

Required:

Yes

Transient monocular blindness

Data Abstraction Instructions:

Indicate if the patient experienced transient monocular blindness, termed amaurosis fugax, pre procedure.

Selections:

- Yes
- No

Supporting Definitions:

Amaurosis fugax can be caused from an embolus from the carotid artery, causing a temporary reduction in retinal artery, ophthalmic artery, or ciliary artery blood flow, leading to a decrease in retinal circulation which, in turn, causes retinal hypoxia and transient blindness. Amaurosis fugax may present as a type of TIA, during which an embolus unilaterally obstructs the lumen of the retinal or ophthalmic artery, causing a decrease in blood flow to the ipsilateral retina. Also, a severely atherosclerotic carotid artery may cause amaurosis fugax due to its stenosis of blood flow, leading to ischemia when the retina is exposed to bright light.

Required:

Yes

Pre-Procedure Carotid Studies (w/in past 6 months)

Carotid Duplex Ultrasound (PRE)

Data Abstraction Instructions:

Indicate if a carotid duplex ultrasound was performed prior to the current procedure. If yes, enter the most recent values.

Selections:

- Yes
- No

Required:

Yes

Peak Systolic Velocity - Right (PRE)

Data Abstraction Instructions:

Indicate the patient's right peak systolic velocity (PSV) for the internal carotid artery (ICA) in centimeters per second (cm/sec).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

cm/sec

Minimum:

0

Maximum:

999

Peak Systolic Velocity - Left (PRE)

Data Abstraction Instructions:

Indicate the patient's left peak systolic velocity (PSV) for the internal carotid artery (ICA) in centimeters per second (cm/sec).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

cm/sec

Minimum:

0

Maximum:

999

End Diastolic Velocity - Right (PRE)

Data Abstraction Instructions:

Indicate the patient's right end diastolic velocity (EDV) for the internal carotid artery (ICA) in centimeters per second (cm/sec).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

cm/sec

Minimum:

0

Maximum:

700

End Diastolic Velocity - Left (PRE)

Data Abstraction Instructions:

Indicate the patient's left end diastolic velocity (EDV) for the internal carotid artery (ICA) in centimeters per second (cm/sec).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

cm/sec

Minimum:

0

Maximum:

700

ICA/CCA Ratio - Right (PRE)

Data Abstraction Instructions:

Indicate the ratio of the peak systolic velocity in the right internal carotid artery (ICA) to the peak systolic velocity in the distal right common carotid artery (CCA).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

ICA/CCA Ratio - Left (PRE)

Data Abstraction Instructions:

Indicate the ratio of the peak systolic velocity in the left internal carotid artery (ICA) to the peak systolic velocity in the distal left common carotid artery (CCA).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

MR Angiography Performed

Data Abstraction Instructions:

Indicate if a magnetic resonance (MR) angiogram was performed prior to the current procedure.

Selections:

- Yes
- No

Required:

Yes

MRA CCA Highest % Stenosis - Right

Data Abstraction Instructions:

Indicate, for the MR Angiography, the highest percent (%) stenosis for the right common carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

MRA CCA Highest % Stenosis - Left

Data Abstraction Instructions:

Indicate, for the MR Angiography, the highest percent (%) stenosis for the left common carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

MRA ICA Highest % Stenosis - Right

Data Abstraction Instructions:

Indicate, for MR Angiography, the highest percent (%) stenosis for the right internal carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

MRA ICA Highest % Stenosis - Left

Data Abstraction Instructions:

Indicate, for MR Angiography, the highest percent (%) stenosis for the left internal carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

CT Angiography Performed

Data Abstraction Instructions:

Indicate if a computed tomography (CT) angiogram was performed

Selections:

- Yes
- No

Required:

Yes

CTA CCA Highest % Stenosis - Right

Data Abstraction Instructions:

Indicate, for CT Angiography, the highest percent (%) stenosis for the right common carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:
100

CTA CCA Highest % Stenosis - Left

Data Abstraction Instructions:

Indicate, for CT Angiography, the highest percent (%) stenosis for the left common carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

CTA ICA Highest % Stenosis - Right

Data Abstraction Instructions:

Indicate, for CT Angiography, the highest percent (%) stenosis for the right internal carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

CTA ICA Highest % Stenosis - Left

Data Abstraction Instructions:

Indicate, for CT Angiography, the highest percent (%) stenosis for the left internal carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

Carotid Angiography Performed

Data Abstraction Instructions:

Indicate if a diagnostic carotid angiogram was performed prior to the current procedure.

Selections:

- Yes
- No

Required:

Yes

Carotid Angio CCA Highest % Stenosis - Right

Data Abstraction Instructions:

Indicate, for the Carotid Angiography, the highest percent (%) stenosis for the right common carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter Value
- Not Documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

Carotid Angio CCA Highest % Stenosis - Left

Data Abstraction Instructions:

Indicate, for Carotid Angiography, the highest percent (%) stenosis for the left common carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

Carotid Angio ICA Highest % Stenosis - Right

Data Abstraction Instructions:

Indicate, for the Carotid Angiography, the highest percent (%) stenosis for the right internal carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter Value
- Not Documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

Carotid Angio ICA Highest % Stenosis - Left

Data Abstraction Instructions:

Indicate, for the Carotid Angiography, the highest percent (%) stenosis for the left internal carotid artery. If the vessel is totally occluded, enter 100%. If no stenosis is present, enter 0%. If a range is given, enter the highest value.

Selections:

- Documented
 - Enter Value
- Not Documented

Required:

No

Suffix:

%

Minimum:

0

Maximum:

100

Procedure Information

Target Carotid Vessel

Data Abstraction Instructions:

Indicate whether the target vessel is the right or left carotid artery for the current procedure.

Selections:

- Right
- Left

Required:

Yes

TCAR

Data Abstraction Instructions:

Indicate if the procedure is a Trans Carotid Artery Revascularization (TCAR).

Selections:

- Yes
- No

Required:

Yes

Anesthesia (CAS)

Data Abstraction Instructions:

Indicate if the patient received general, local, or MAC anesthesia during the current procedure.

Selections:

- Local
- General
- MAC

Required:

Yes

Procedure Indications and Anatomic Variables

Urgent Cardiac Surgery w/in 30 days

Data Abstraction Instructions:

Indicate if the patient is having the carotid revascularization procedure because of the need for cardiac surgery within 30 days of the current procedure. Cardiac Surgery is defined as bypass, valve, ICD patches and transplant surgery.

Selections:

- Yes
- No

Required:

Yes

Concurrent with CABG

Data Abstraction Instructions:

Indicate if the CEA/CAS was performed in the same OR time as a CABG.

Selections:

- Yes
- No

Required:

Yes

Target Lesion Symptomatic w/in Past 6 Months

Data Abstraction Instructions:

Indicate if the patient has had neurologic symptoms in the past six months related to the target lesion. Conditions qualifying patients as symptomatic:

- Transient Ischemic Attack (TIA): distinct focal neurologic dysfunction persisting less than 24 hours;
- Non-disabling stroke: Modified Rankin Scale < 3 with symptoms for 24 hours or more;
- Transient monocular blindness: amaurosis fugax

Selections:

- Yes
- No

Required:

Yes

Syncope

Data Abstraction Instructions:

Indicate if the patient experienced syncope as an indication for the procedure. If you enter Yes for Syncope, then enter No for Target Lesion Symptomatic within Past 6 Months.

Selections:

- Yes
- No

Required:

Yes

Restenosis in Target Vessel After Prior CAS

Data Abstraction Instructions:

Note if the indication for the current procedure is restenosis in the target carotid artery which was previously treated with an angioplasty and/or stent. Carotid artery restenosis is defined as greater than 50% diameter stenosis at or adjacent to the site previously treated with balloon angioplasty or stent.

Selections:

- Yes
- No

Required:Yes

Restenosis in Target Vessel After Prior CEA

Data Abstraction Instructions:

Note if the indication for the current procedure is restenosis in the target carotid artery which was previously treated with a carotid artery endarterectomy. Restenosis is defined as the reoccurrence of stenosis within or adjacent to a prior endarterectomy site, evidenced by greater than 50% diameter stenosis.

Selections:

- Yes
- No

Required:Yes

Contralateral Carotid Artery Occlusion

Data Abstraction Instructions:

Indicate if there is known 100% occlusion of the patient's contralateral carotid artery.

Selections:

- Yes
- No

Required:Yes

Fibromuscular Dysplasia of Carotid Artery

Data Abstraction Instructions:

Indicate if the patient has a history of known fibromuscular dysplasia of the ipsilateral carotid artery prior to admission or prior to the current procedure.

Selections:

- Yes
- No

Required:Yes

Spontaneous Carotid Artery Dissection

Data Abstraction Instructions:

Indicate if the patient has had a spontaneous carotid artery dissection prior to the current procedure.

Selections:

- Yes
- No

Required:Yes

Pre-procedure Smoking Cessation

Data Abstraction Instructions:

Indicate if the patient received physician-delivered advice, a prescription for nicotine replacement, and/or a referral for smoking cessation services before admission to the hospital. These interventions would be implemented to prepare the patient for the current procedure. Select all that apply.

Selections:

- Yes
 - Physician delivered advice
 - Patient refused
 - Nicotine replacement therapy (NRT)
 - Patient refused
 - Referral to smoking counseling services
 - Patient refused
 - Local counseling service
 - Michigan Quitline
 - Other counseling service
- No

Supporting Definitions:

Yes = Enter Yes for Pre Procedure Smoking Cessation if Yes was entered for Current Smoker under Patient History ' Comorbidity, and one of the three steps was implemented before admission to the hospital.

Physician delivered advice = A surgeon, advanced practice personnel (PA, NP), or resident has a conversation with the patient and recommends the patient stop smoking. A recommendation to stop smoking offered by a nurse, respiratory therapist or student does not count as physician-delivered advice.

If there is documentation that the provider recommended smoking cessation and the patient refused, enter Physician delivered advice AND Patient refused. There must be adequate documentation to support this claim.

Nicotine replacement therapy (NRT) = The provider ordered NRT before admission to the hospital. NRT may include a nicotine patch, gum, lozenge, or other pharmacologic assistance (Varenicline or Bupropion).

If a patient refuses NRT, and there is provider documentation that NRT was offered and documentation that the patient refused, enter NRT AND Patient refused.

Referral to smoking counseling services = The provider documents they referred the patient to a smoking counseling service. Smoking counseling services may include a smoking counseling service, a smoking cessation program, a smoking cessation class, the Michigan Tobacco Quitline, or a national smoking cessation service. The provider must recommend a smoking counseling service to the patient. The standard message to stop smoking on the AVS or discharge summary template is not sufficient.

If a physician, mid-level provider, or resident does an assessment and then refers the patient to a respiratory therapist or a dedicated smoking cessation nurse to provide smoking cessation education, you can choose Referral to smoking counseling services.

If there is documentation that the provider recommended smoking counseling services and the patient refused, enter Referral to smoking counseling services, AND Patient refused. There must be adequate documentation to support this claim.

Patient Refused = The provider documented that the patient refused the corresponding intervention.

Local counseling service = The provider refers the patient to the hospital's smoking counseling service or a community-based smoking counseling service. Enter Referral to smoking counseling services AND Local counseling service.

Michigan Quitline = The provider refers the patient to the Michigan Tobacco Quitline. Enter Referral to smoking counseling services AND Referral to Michigan Quitline.

Other counseling service = The provider refers the patient to a Federal or National smoking cessation service. Enter Referral to smoking counseling services AND Other counseling service.

No = Enter No for Smoking Cessation at Discharge if No was entered for Ever Smoked or current Smoker under Patient History / Comorbidity. Enter No if the patient is a current smoker; however, none of the three steps were implemented before admission to the hospital.

Required:

Yes

Lesion Difficult to Access Surgically

Data Abstraction Instructions:

Indicate if the lesion is difficult to access surgically for CEA. Lesions that are difficult to access include those which are quite high in the neck (e.g. at or above the level of C2), and those that are within the proximal 1/2 or 1/3 of the common carotid artery, at or below the clavicle rendering endarterectomy either difficult or impossible.

Selections:

- Yes
- No

Required:

Yes

Lesion Location

Data Abstraction Instructions:

Indicate if the patient has high cervical internal carotid artery lesions or common carotid artery lesions below the clavicle.

Selections:

- High Cervical
- Low Intrathoracic

Required:

Yes

Aortic Arch Type

Data Abstraction Instructions:

Indicate the patient's aortic arch type configuration. The three types of aortic arch are based on the relationship of the innominate artery to the aortic arch. The more inferior the origin of the target artery (i.e., Type II or III aortic arch), the greater the difficulty in gaining access to the carotid artery.

Type I = The Type I aortic arch is characterized by origin of all three great vessels in the same horizontal plane as the outer curvature of the aortic arch.

Type II = In the Type II aortic arch, the innominate artery originates between the horizontal planes of the outer and inner curvatures of the aortic arch.

Type III = In the Type III aortic arch, the innominate artery originates below the horizontal plane of the inner curvature of the aortic arch.

Unknown = The aortic arch type is not documented.

Selections:

- Type I
- Type II
- Type III
- Unknown

Required:

Yes

Bovine Arch

Data Abstraction Instructions:

Indicate if the patient's aortic arch is bovine, in which the right brachiocephalic and left carotid arteries share a common trunk from the aortic arch.

Selections:

- Yes
- No

Required:

Yes

Contrast Volume

Data Abstraction Instructions:

Indicate the volume of iodinated contrast injected during the procedure in milliliters (mL).

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

ml

Minimum:

0

Maximum:

500

Procedural Arterial Access Site

Data Abstraction Instructions:

Enter the primary arterial access site utilized to perform the carotid artery stenting (CAS) procedure.

Femoral = Percutaneous puncture or cutdown (incision with a surgical blade) of the femoral artery.

Brachial/Radial/Axillary = Percutaneous puncture or cutdown (incision with a surgical blade) of the brachial, radial or axillary artery.

Direct Carotid Puncture = Percutaneous puncture of the carotid artery.

Carotid Cutdown = Cutdown (incision with a surgical blade) of the carotid artery.

Other = Percutaneous entry or cutdown (incision with a surgical blade) to a site that is not the femoral, brachial, radial, axillary, or carotid artery.

Selections:

- Femoral
- Brachial/Radial/Axillary
- Direct Carotid Puncture
- Carotid Cutdown
- Other

Required:

Yes

Vascular Closure Type (CAS)

Data Abstraction Instructions:

Enter the arterial closure methods used regardless of whether they provided hemostasis. Select every type of vascular closure used per access if more than one closure type was used. Each type will only be counted once. E.g., two access sites, two perclose devices; select perclose box.

Manual = no device or a mechanical type was used, e.g., manual pressure was held by the staff pulling the sheath.

Selections:

- Manual
- Perclose
- Angioseal
- Mynx
- Starclose
- Exoseal
- Surgical
- Celt
- Radial compression band

Required:

Yes

Lesions and Devices

Target Lesion Location

Data Abstraction Instructions:

Indicate the target lesion location for this procedure.

Isolated CCA = Target lesion location is a lesion isolated to the common carotid artery and does not extend to or involve the carotid bifurcation.

Isolated ICA = Target lesion location is a lesion isolated to the internal carotid artery and does not extend to or involve the carotid bifurcation.

Bifurcation = Target lesion location is any lesion that involves the carotid bifurcation. For example, a high grade stenosis in the ICA or CCA adjacent to the bifurcation wherein the plaque extends to involve the bifurcation is considered a bifurcation lesion.

Selections:

- Isolated CCA
- Isolated ICA
- Bifurcation

Required:

Yes

Visible Thrombus Present

Data Abstraction Instructions:

Indicate if the target lesion contains thrombus as assessed by baseline angiography and implied by presence of filling defect.

Selections:

- Yes
- No

Required:

Yes

Ulceration

Data Abstraction Instructions:

Indicate if the target lesion is ulcerated as assessed by baseline angiography.

Selections:

- Yes
- No

Required:

Yes

Calcification

Data Abstraction Instructions:

Indicate the degree of calcification in the target lesion as assessed by fluoroscopic inspection.

None = No calcification present on fluoroscopic inspection.

Mild to Moderate = Mild to moderate calcification present on fluoroscopic inspection, but not qualifying as densely or concentrically calcified.

Dense and Concentric = Heavy, concentric calcification completely encasing the vessel present on fluoroscopic inspection.

Selections:

- None
- Mild to Moderate
- Dense and Concentric

Required:

Yes

Lesion Length (CAS)

Data Abstraction Instructions:

Indicate the length of the target lesion in millimeters (mm) as assessed by baseline angiography or dictated by the physician. If no value available, use the stent length.

Selections:

- Documented
 - Enter value in mm
- Not documented

Required:

Yes

Suffix:

mm

Soft Minimum:

5

Soft Maximum:

100

Pre procedure % Stenosis

Data Abstraction Instructions:

Indicate the percent stenosis pre-procedure, calculated as follows:

1. When the tightest stenosis is in the Internal Carotid Artery or at the carotid bifurcation, use NASCET methodology. Percent Diameter Stenosis is calculated as:
 - $(1 - \text{minimum luminal diameter at the lesion site} / \text{diameter of non-tapering segment of distal ICA}) * 100$.
 - "Non-tapering site" is where the walls of the ICA become parallel.
2. Do not use NASCET if the distal lumen collapses from a low-flow situation. In such cases, enter 99%, as the stenosis may be graded as a near occlusion.
3. For stenosis localized to the Common Carotid Artery, Percent Diameter Stenosis is calculated as:
 - $(1 - \text{minimum luminal diameter} / \text{diameter of the adjacent normal segment of the Common Carotid artery}) * 100$
4. If no other value available, use the physician dictated percent stenosis.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

Second Lesion Pre procedure % Stenosis

Data Abstraction Instructions:

Indicate if there was a second lesion on the operative side as dictated in the medical record. If yes, the percent stenosis of a second lesion, whether intervened upon, or not.

Selections:

- Yes
 - Enter value
- No

Required:

Yes

Lesion Treatment Incomplete or Aborted

Data Abstraction Instructions:

Indicate if the lesion treatment was incomplete or aborted.

Selections:

- Yes
- No

Required:

Yes

Reasons Treatment Aborted

Data Abstraction Instructions:

Indicate the reasons the lesion treatment was incomplete or aborted.

Selections:

- Failure to gain vascular access
- Failure to confirm significant stenosis
- Unable to place guiding catheter/sheath
- Unable to cross guide wire
- Unable to cross balloon
- Unable to deploy EPD
- Unable to deliver stent
- Unable to deploy stent
- Difficult to access due to tortuosity
- Hypotension
- Hypertension
- Arrhythmia
- Cardiac ischemia
- Other

Required:

Yes

Embolc Protection Attempted

Data Abstraction Instructions:

Indicate if the operator attempted to use an embolic protection device (EPD). The flow reversal system used for TCAR has the EPD filter built into the system.

Selections:

- Yes
- No

Required:

Yes

Predilation Prior to Embolic Protection Device Deployment

Data Abstraction Instructions:

Indicate whether predilation was attempted prior to the deployment of the embolic protection device. The flow reversal system used for TCAR has the EPD filter built into the system.

Selections:

- Yes
- No

Required:Yes

Embolic Protection Successfully Deployed

Data Abstraction Instructions:

Indicate if the embolic protection device was successfully deployed for each device attempted. The flow reversal system used for TCAR has the EPD filter built into the system.

Selections:

- Yes
- No

Required:Yes

Embolic Protection Manufacturer

Data Abstraction Instructions:

Indicate the manufacturer of the embolic protection device.

Selections:

Select the manufacturer name from list.

Required:Yes

Embolic Protection Model Name

Data Abstraction Instructions:

Indicate the brand or model of the embolic protection device.

Selections:

Select brand or model name from list.

Required:Yes

Stent(s) Implanted

Data Abstraction Instructions:

Indicate if at least one stent was implanted.

Selections:

- Yes
- No

Required:Yes

Predilation Prior to Attempted Stent Implant

Data Abstraction Instructions:

Indicate whether balloon dilation was performed on the target lesion after placement of the embolic protection device, but before delivery of the stent. Do not include predilation prior to deployment of the embolic protection device.

Selections:

- Yes
- No

Required:

Yes

Stent Tapered

Data Abstraction Instructions:

Indicate if the stent device was tapered.

Selections:

- Yes
- No

Required:

Yes

Stent Diameter

Data Abstraction Instructions:

Indicate the diameter of the stent. If a tapered stent was used, indicate the smallest diameter of the tapered stent in millimeters (mm).

Selections:

- Yes
 - Enter value in mm
- No

Required:

Yes

Suffix:

mm

Minimum:

5

Maximum:

20

Stent Length

Data Abstraction Instructions:

Indicate the length of the stent in millimeters (mm).

Selections:

- Yes
 - Enter value in mm
- No

Required:

Yes

Suffix:

mm

Minimum:

15

Maximum:

100

Malposition

Data Abstraction Instructions:

Indicate if the stent was deployed in a location or position other than that for which it was intended.

Selections:

- Yes
- No

Required:

Yes

Stent Manufacturer

Data Abstraction Instructions:

Indicate the manufacturer of the stent.

Selections:

Select name of manufacturer from list.

Required:

Yes

Stent Manufacturer Model Name

Data Abstraction Instructions:

Indicate the brand or model name of the stent.

Selections:

Select the brand name or model name from the list.

Required:

Yes

Ballooning/Post Dilation Performed

Data Abstraction Instructions:

Indicate if the carotid artery was ballooned or postdilation was performed after the stent was implanted.

Selections:

- Yes
- No

Required:

Yes

Balloon Diameter

Data Abstraction Instructions:

Indicate the diameter of the largest balloon used in millimeters (mm).

Selections:

- Documented
 - Enter value in mm
- Not documented

Required:

Yes

Suffix:

mm

Minimum:

0

Maximum:
20

Maximum Inflation Pressure

Data Abstraction Instructions:

Indicate the maximum inflation pressure of the largest balloon used in atmospheres (atm).

Selections:

- Documented
 - Enter value in atm
- Not documented

Required:

Yes

Suffix:

atm

Minimum:

0

Maximum:

50

Final Minimum Luminal Diameter

Data Abstraction Instructions:

Indicate the final residual lumen diameter in millimeters (mm). If the final minimum luminal diameter is not documented, enter the stent diameter.

Selections:

- Documented
 - Enter value in mm
- Not documented

Required:

Yes

Suffix:

mm

Minimum:

0

Maximum:

20

Final % Stenosis

Data Abstraction Instructions:

Indicate the percent stenosis post procedure, calculated as follows:

1. For Internal Carotid artery site, use NASCET methodology. Percent Diameter Stenosis is calculated as:
 - $(1 - \text{minimum residual luminal diameter within the treated site/diameter of nontapering segment of distal ICA}) * 100$
 - "Nontapering site" is where the walls of the ICA become parallel.
2. For lesion and interventional site localized to the Common Carotid artery, Percent Diameter Stenosis is calculated as:
 - $(1 - \text{minimum residual luminal diameter/diameter of the adjacent normal segment of the Common Carotid artery}) * 100$
3. If no other value available, use the physician dictated percent stenosis.

Selections:

- Documented
 - Enter value
- Not documented

Required:

Yes

Suffix:

%

Minimum:

0

Maximum:

100

Outcomes

Vascular Access Complications

Data Abstraction Instructions:

Indicate vascular complications at the access site requiring transfusion/prolonged hospital stay/causing a drop in hemoglobin 3.0 gm/dl, or any access site complications requiring surgery repair.

Retroperitoneal hematoma = bleeding into the anatomical space located behind the abdominal or peritoneal cavity.

Pseudoaneurysm = the occurrence of a disruption and dilation of the arterial wall without identification of the arterial wall layers at the site of the catheter entry demonstrated by arteriography or ultrasound.

Hematoma at access site = blood loss at the site of arterial or venous access due to perforation of a traversed artery or vein that causes at one or more of the following:

- transfusion
- prolonged hospital stay
- drop in hemoglobin > 3.0 gm/dl

Bleeding at access site = Blood loss associated with decreased Hgb (greater than or equal to 3.0 gm/dl) and/or causes an increased length of hospital stay. Without other obvious source (GI, GU, operative, or hemolysis) that is attributable to intraprocedural blood loss (e.g. during equipment changes) should be considered bleeding at the access site even if no hematoma is palpable or documented on imaging studies.

AV fistula = A connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and most often characterized by a continuous bruit.

Acute thrombosis = Total obstruction of the artery by thrombus most commonly at the site of access.

Surgical repair of the vascular access site = such as surgical closures, exploration of the arteriotomy site, balloon angioplasty or covered stent (JOMED GraftMaster) placement to deal the arterial tear.

Other = a vascular access complication that is not in this list.

Selections:

- Yes (Choose all that apply)
 - Retroperitoneal hematoma
 - Pseudo-aneurysm
 - Hematoma at access site
 - Bleeding at access site
 - AV fistula
 - Acute thrombosis
 - Surgical repair of the vascular access site
 - Other
- No

Required:

Yes

Filter Spasm

Data Abstraction Instructions:

Indicate if spasm or haziness noted at site of filter deployment.

Selections:

- Yes
- No

Required:

Yes

Slow Flow

Data Abstraction Instructions:

Indicate if slow flow occurred during the procedure.

Selections:

- Yes
 - After stent deployment
 - After post dilation
 - Aspiration was performed
 - Aspirate had visible debris
 - Patient had neurological changes during slow flow
- No

Required:

Yes

New Stroke

Data Abstraction Instructions:

Indicate if the patient experienced a new ischemic stroke during or after the current procedure and before discharge. If yes, specify all new events and resolution status.

Selections:

- Yes
- No

Required:

Yes

New Right Hemispheric or Retinal Neurologic Event Occurred (Stroke)

Data Abstraction Instructions:

Indicate if a new right hemispheric or retinal stroke developed during or after the current procedure.

Selections:

- Yes
- No

Required:

Yes

New Right Hemispheric or Retinal Neurologic Event Resolved (Stroke)

Data Abstraction Instructions:

Indicate if the new right hemispheric or retinal stroke resolved prior to discharge.

Selections:

- Yes
- No

Required:

Yes

New Left Hemispheric or Retinal Neurologic Event Occurred (Stroke)

Data Abstraction Instructions:

Indicate if a new left hemispheric or retinal stroke developed during or after the current procedure.

Selections:

- Yes
- No

Required:

Yes

New Left Hemispheric or Retinal Neurologic Event Resolved (Stroke)

Data Abstraction Instructions:

Indicate if the new left hemispheric or retinal stroke resolved prior to discharge.

Selections:

- Yes
- No

Required:

Yes

New Vertebrobasilar Event Occurred (Stroke)

Data Abstraction Instructions:

Indicate if a new vertebrobasilar stroke developed during or after the current procedure.

Selections:

- Yes
- No

Required:

Yes

New Vertebrobasilar Event Resolved (Stroke)

Data Abstraction Instructions:

Indicate if the new vertebrobasilar stroke resolved prior to discharge.

Selections:

- Yes
- No

Required:

Yes

New Unknown Event Occurred (Stroke)

Data Abstraction Instructions:

Indicate if a new stroke developed in an unspecified or unknown location during or after the current procedure.

Selections:

- Yes
- No

Required:

Yes

New Unknown Event Resolved (Stroke)

Data Abstraction Instructions:

Indicate if the unknown stroke resolved prior to discharge.

Selections:

- Yes
- No

Required:

Yes

New TIA

Data Abstraction Instructions:

Indicate if the patient experienced a new TIA during or after the current procedure and before discharge. If yes, specify the territory of all new events.

Selections:

- Yes
- No

Required:

Yes

New Right Hemispheric or Retinal Neurologic Event Occurred (TIA)

Data Abstraction Instructions:

Indicate if a new right hemispheric or retinal TIA developed during or after the current procedure.

Selections:

- Yes
- No

Required:

Yes

New Left Hemispheric or Retinal Neurologic Event Occurred (TIA)

Data Abstraction Instructions:

Indicate if a new left hemispheric or retinal TIA developed during or after the current procedure.

Selections:

- Yes
- No

Required:

Yes

New Vertebrobasilar Event Occurred (TIA)

Data Abstraction Instructions:

Indicate if a new vertebrobasilar TIA developed during or after the current procedure.

Selections:

- Yes
- No

Required:
Yes

New Unknown Event Occurred (TIA)

Data Abstraction Instructions:

Indicate if a new TIA developed in an unspecified or unknown location during or after the current procedure.

Selections:

- Yes
- No

Required:
Yes

Death

Data Abstraction Instructions:

Indicate if the patient died during or post procedure, prior to discharge.

For purposes of this registry the start of the procedure is defined as the time the physician obtained vascular access. Any adverse events that occur before (i.e. in the holding room) are not attributed to the procedure. The procedure is complete when the patient leaves the procedure room.

Selections:

- Yes
 - During procedure
 - Post procedure
- No

Required:
Yes

Cause of Death

Data Abstraction Instructions:

Indicate the cause of death.

Selections:

- Neurologic: Due to a new or progressive neurologic event.
- Cardiac: Due to a fatal arrhythmia, MI or heart failure.
- Pulmonary: Due to pulmonary complication.
- Vascular: Due to major blood loss or other vascular complication.
- Infection: Due to infection.
- Renal Failure: Due to renal failure.
- Other: Due to other cause.

Required:
Yes

Myocardial Injury

Data Abstraction Instructions:

Indicate if the patient suffered any type of myocardial injury post procedure, including a troponin leak, demand ischemia, NSTEMI or STEMI. If so, indicate the date of the first elevated troponin value as well as the peak troponin value. **The peak troponin value should be obtained within 30 days of the procedure.**

Selections:

- Yes
 - Enter date of first occurrence of Myocardial Injury post procedure _____
 - Enter type of injury:
 - Troponin leak
 - Demand ischemia
 - NSTEMI
 - STEMI
 - Not documented
- No

Supporting Definitions:

Utilize progress notes and consults to help in the determination of the type of myocardial injury. If no determination is made, select "Not documented".

If only a single abnormal troponin value was found in absence of other criteria for myocardial injury, then record as No.

Troponin: Troponin rise alone should be reported if there was a rise in cardiac biomarker values [preferably cardiac troponin (cTn)] with at least one value above the 99th percentile upper reference limit (URL) in absence of the qualifying criteria for myocardial infarction or sudden death as listed in the clinical MI definition below. This elevation may be classified as a troponin leak or demand ischemia. Note, ""rise"" in troponin would imply that the troponin can be elevated at baseline (either pre-op or post-op baseline), but not rise above whatever the patient's baseline level is. The lack of rising troponin above the baseline number would indicate that there was no additional myocardial injury.

A myocardial infarction is evidenced by any of the following:

1. A rise and fall of cardiac biomarkers (preferably troponin) with at least one of the values in the abnormal range for that laboratory [typically above the 99th percentile of the upper reference limit (URL) for normal subjects] together with at least one of the following manifestations of myocardial ischemia:
2. Ischemic symptoms such as angina or acute shortness of breath.
3. ECG changes indicative of new ischemia (new ST-T changes, new left bundle branch block, or loss of R wave voltage).
4. Development of pathological Q waves in 2 or more contiguous leads in the ECG (or equivalent finding for true posterior MI).
5. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
6. Documentation in the medical record of the diagnosis of acute myocardial infarction based on the cardiac biomarker pattern in the absence of any items enumerated in a-d due to conditions that may mask their appearance (e.g., peri-operative infarct when the patient cannot report ischemic symptoms; baseline left bundle branch block or ventricular pacing).
7. ECG changes associated with prior myocardial infarction can include the following (with or without prior symptoms):
 - Any Q wave in leads V2-V3 \geq 0.02 seconds or QS complex in leads V2 and V3.
 - Q-wave \geq 0.03 seconds and \geq 0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V6; V4-V6; I, III, and aVF).
 - R-wave \geq 0.04 seconds in V1-V2 and R/S \geq 1 with a concordant positive T-wave in the absence of a conduction defect.
8. Imaging evidence of a region with new loss of viable myocardium at rest in the absence of a non-ischemic cause. This can manifest as:
9. Echocardiographic, CT, MR, ventriculographic or nuclear imaging evidence of left ventricular thinning or scarring and a failure to contract appropriately (i.e., hypokinesis, akinesis, or dyskinesis).
10. Fixed (non-reversible) perfusion defects on nuclear radioisotope imaging (e.g., MIBI, thallium).
11. Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB, but death occurred before cardiac biomarkers were obtained, or before cardiac biomarker values would be increased.

Source:

Thygesen K, Alpert JS, White HD, et al. (Circulation 2007). Universal Definition of Myocardial Infarction. ESC/ACCF/AHA/WHF expert consensus document. *AHA Journals*, 140(13), 2634-53. <https://ahajournals.org/journal/circ>

Required:

Yes

Peak post-operative troponin value**Data Abstraction Instructions:**

Indicate the peak value and type of troponin drawn within 30 days post procedure.

Selections:

Peak post-operative troponin

- ◆ Yes
 - troponin I
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - troponin T
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - troponin I HS
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - troponin T HS
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
- ◆ Not Drawn

Required:

Yes

Suffix:

ng/dL, ng/mL, ng/L, pg/mL