Stroke or TIA (more than 6 months ago or never)

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Disease Area: Cardiology
Care Path Group: Vascular Disease
Care Path Name: Stroke
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Table of Contents

Important Notices **2**

Care Path Overview **5**

Care Path Clinical Discussion 5

Key Information 6

Care Path Diagnostic Criteria **8**

Disease Classification 8

ICD-10 Codes Associated with Classification 8

Presentation and Etiology 9

Causes and Risk Factors3,2 9

Typical History 9

Typical Physical Exam Findings 9

Typical Diagnostic Evaluation 9

Care Path Services & Medical Necessity Criteria **10**

Non-Invasive Testing 10

Service: Carotid Duplex Ultrasound (Carotid Doppler) 10

General Guidelines 10

Medical Necessity Criteria 10

Indications 10

Non-Indications 10

Site of Service Criteria 11

Procedure Codes (HCPCS/CPT) 11

Service: Computed Tomography Angiography (CTA), Neck 12

General Guidelines 12

Medical Necessity Criteria 12

Indications 12

Non-Indications 12

Site of Service Criteria 12

Procedure Codes (HCPCS/CPT) 13

Service: Magnetic Resonance Angiogram (MRA), Neck 14

General Guidelines 14

Medical Necessity Criteria 14

Indications 14

Non-Indications 14

Site of Service Criteria 14

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Procedure Codes (HCPCS/CPT) 15
Surgical or Interventional Management 16
Service: Carotid Endarterectomy (CEA) for asymptomatic extracranial carotid artery occlusive disease 16
General Guidelines 16
Medical Necessity Criteria 16
Indications 16
Non-Indications 16
Applicable CMS Medicare NCDs & LCDs 16
Site of Service Criteria 16
Procedure Codes (HCPCS/CPT) 17
Service: Carotid Artery Stenting (CAS) and/or Transcarotid artery revascularization (TCAR) 18
General Guidelines 18
Medical Necessity Criteria 18
Indications 18
Non-Indications 18
Site of Service Criteria 18
Procedure Codes (HCPCS/CPT) 18
Surgical Risk Factors 20
References **23**
Clinical Guideline Revision History/Information **26**

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Care Path Overview

Care Path Clinical Discussion

Atherosclerosis is defined as the buildup of plaque (fats, cholesterol and other substances) in the arterial wall. Atherosclerotic plaque frequently leads to narrowing of the affected artery, and this narrowing restricts the flow of arterial blood. Atherosclerotic plaque can also ulcerate leading to distal embolization and/or thrombosis of the affected artery. Atherosclerosis of the carotid arteries increases the risk of stroke.

Carotid revascularization procedures (e.g., carotid endarterectomy and/or carotid angioplasty and stenting) may be clinically indicated to reduce the risk of stroke in patients with asymptomatic or symptomatic carotid artery atherosclerosis.
Carotid artery atherosclerosis typically occurs in the carotid bulb and extends into the proximal internal carotid artery (ICA).14 Carotid artery stenosis is classified as either extracranial or intracranial. Extracranial refers to the carotid arteries outside of the skull, and intracranial refers to arteries inside or at the base of the skull. The policy coverage details in this document apply to patients with extracranial carotid artery occlusive disease.

Asymptomatic carotid artery disease is defined as the presence of atherosclerotic narrowing of the extracranial internal carotid artery in patients with no history of recent ipsilateral carotid territory TIA or ischemic stroke (i.e. within the last 6 months).

Patients with asymptomatic extracranial carotid artery stenosis may be treated with either best medical therapy (i.e. platelet inhibition therapy, statin therapy etc) or carotid intervention.

The information contained herein gives a general overview of the pathway of this specific diagnosis, beginning with the initial presentation, recommended assessments, and treatment options as supported by the medical literature and existing guidelines. It should be noted that the care of patients can be complex. The information below is meant to support clinical decision-making in adult patients. It is not necessarily applicable to every case, as the entire clinical picture (including comorbidities, history, etc.) should be considered.

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Key Information

- Extracranial carotid artery occlusive disease is often asymptomatic and screening for asymptomatic extracranial cerebrovascular disease remains controversial
- Stroke affects nearly 800,000 individuals, with many survivors experiencing persistent difficulty with daily tasks as a direct consequence. More than two-thirds of stroke survivors receive rehabilitation services after hospitalization.[1]
- Physical, occupational, and speech therapy can be beneficial for stroke patients to maximize recovery.[2]
- Carotid revascularization may be beneficial for asymptomatic patients with greater than 70% stenosis of the internal carotid artery.

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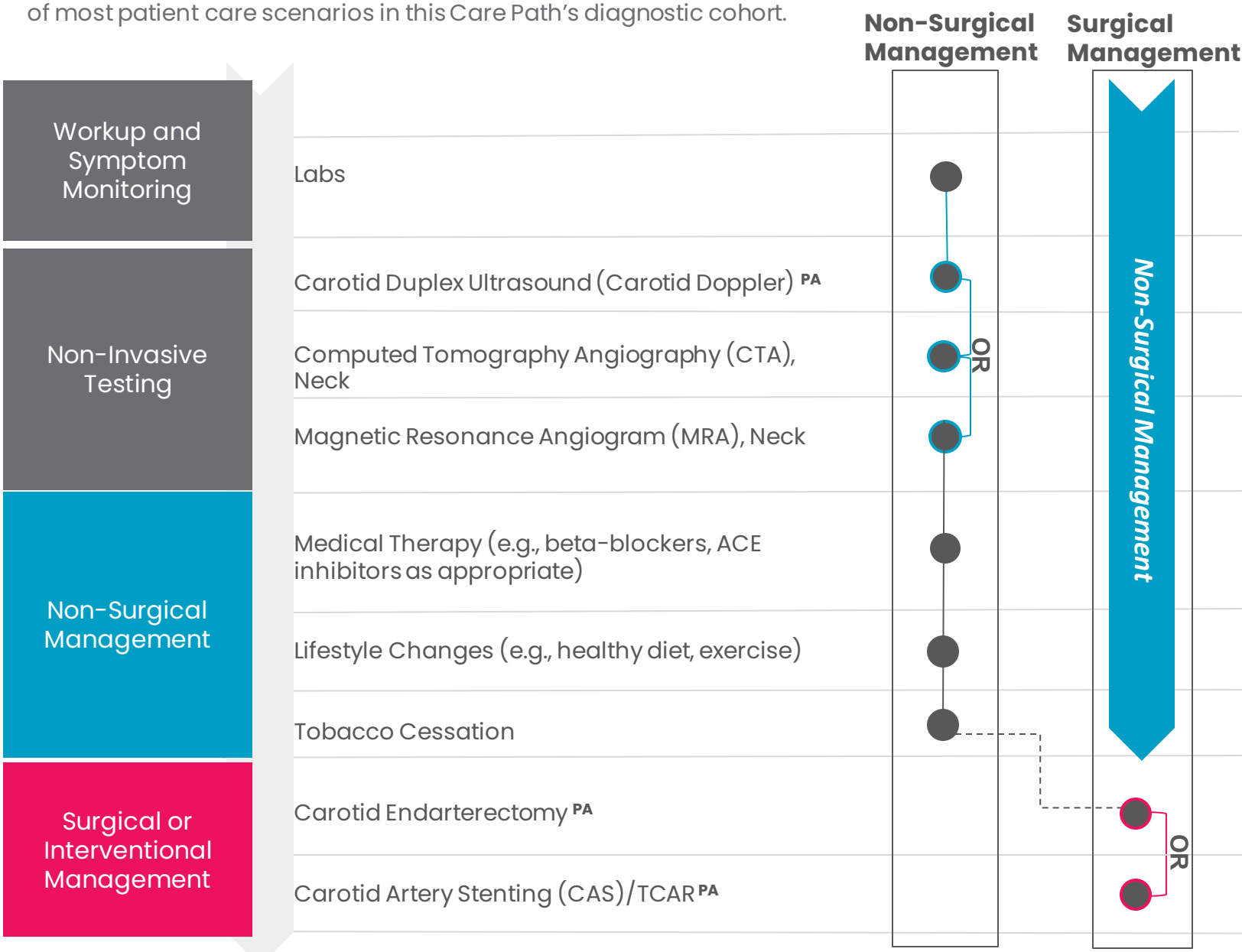
What is a "Cohere Care Path"?

These Care Paths organize the services typically considered most clinically optimal and likely to be automatically approved. These service recommendations also include the suggested sequencing and quantity or frequency determined clinically appropriate and medically necessary for the management of most patient care scenarios in this Care Path's diagnostic cohort.



Key

PA = Service may require prior authorization
★ = Denotes preferred service
AND = Services completed concurrently
OR = Services generally mutually exclusive

= Non-surgical management prior authorization group of services
= Surgical management prior authorization group of services
= Subsequent service
= Management path moves to a different management path

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Care Path Diagnostic Criteria

Disease Classification

Asymptomatic extracranial cerebrovascular disease

ICD-10 Codes Associated with Classification

ICD-10 Code	Code Description/Definition
I65	Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction
I65.0	Occlusion and stenosis of vertebral artery
I65.01	Occlusion and stenosis of right vertebral artery
I65.02	Occlusion and stenosis of left vertebral artery
I65.03	Occlusion and stenosis of bilateral vertebral arteries
I65.09	Occlusion and stenosis of unspecified vertebral artery
I65.1	Occlusion and stenosis of basilar artery
I65.2	Occlusion and stenosis of carotid artery
I65.21	Occlusion and stenosis of right carotid artery
I65.22	Occlusion and stenosis of left carotid artery
I65.23	Occlusion and stenosis of bilateral carotid arteries
I65.29	Occlusion and stenosis of unspecified carotid artery
I65.8	Occlusion and stenosis of other precerebral arteries
I65.9	Occlusion and stenosis of unspecified precerebral artery
I67	Other cerebrovascular diseases
I67.2	Cerebral atherosclerosis
I67.8	Other specified cerebrovascular diseases
I67.89	Other cerebrovascular disease
I67.9	Cerebrovascular disease, unspecified
I68	Cerebrovascular disorders in diseases classified elsewhere
I68.8	Other cerebrovascular disorders in diseases classified

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	elsewhere

Presentation and Etiology

Causes and Risk Factors[3,2]

- Hypertension
- Hyperlipidemia
- Diabetes mellitus
- Sleep apnea
- Obesity
- Tobacco use

Typical History

- Asymptomatic

Typical Physical Exam Findings

- Previous PE evidence of prior carotid intervention
- Carotid bruit or carotid thrill
- Diminished or absent carotid pulse

Typical Diagnostic Evaluation

- Carotid duplex ultrasonography
- CTA
- MRA

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Care Path Services & Medical Necessity Criteria

Non-Invasive Testing

Service: Carotid Duplex Ultrasound (Carotid Doppler)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Subsequent requests may be appropriate for follow-up or if there is a change in clinical status.
- **Recommended Clinical Approach:** Carotid duplex ultrasonography is a non-invasive method of imaging the extracranial carotid and vertebral arteries. The test involves combining 2-dimensional real-time imaging with Doppler flow analysis to evaluate vessels of interest and measure blood flow velocity. Computed tomographic angiography (CTA) and magnetic resonance angiogram (MRA) are options when a carotid duplex is not readily available or when results are equivocal.[4]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Carotid Duplex Ultrasound** is considered appropriate if **ANY** of the following is **TRUE**[5]:

- ◆ Patients with a history of extracranial cerebrovascular disease
- ◆ Patients with a history of a prior carotid revascularization procedure (e.g. carotid stent, carotid endarterectomy or carotid bypass)
- ◆ Patients with a diminished or absent carotid pulse, a carotid bruit or a carotid thrill on physical examination

Non-Indications

➔ **Carotid Duplex Ultrasound** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Non-invasive vascular studies done for screening purposes (i.e., without signs or symptoms of extracranial cerebrovascular disease)[6]

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Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93880	Extracranial arteries; complete bilateral study
93882	Extracranial arteries; unilateral or limited study

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Service: Computed Tomography Angiography (CTA), Neck

General Guidelines

- **Units, Frequency, & Duration:** Cervical computed tomography angiography (CTA) is a noninvasive imaging technology that can be used to evaluate and image vessels in the head and neck.
- **Criteria for Subsequent Requests:** CTA may be indicated for ongoing follow-up of asymptomatic extracranial cerebrovascular disease Subsequent orders can be placed before, during, or after treatment.
- **Recommended Clinical Approach:** CTA may be used as the primary modality for detecting asymptomatic cerebrovascular disease or as an adjunctive tool for characterizing known diseases or assessing changes over time.
- **Exclusions:** This document only includes criteria for CTA of the head/neck. CTA of the head, body, and extremities are excluded and discussed separately.

Medical Necessity Criteria

Indications

➔ **CTA Neck** is considered appropriate if **ANY** of the following are **TRUE**[5]:
- ◆ Carotid duplex scanning is inadequate (or unavailable) for diagnosis and/or follow-up
- ◆ Suspected intracranial cerebrovascular disease
- ◆ Post-procedure follow-up (percutaneous and surgical)[7-19]

Non-Indications

➔ **CTA Neck** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Chronic kidney disease or acute kidney injury (glomerular filtration rate less than 30 mL/min/1.73m2 (or 0.5 mL/sec/1.73m2))
- ◆ Personal/family history of allergic reaction to iodinated contrast media (e.g., anaphylaxis)
- ◆ Current Pregnancy

Site of Service Criteria

Outpatient.

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Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
70498	Computed tomographic angiography (CTA) of neck with contrast material and image postprocessing

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Service: Magnetic Resonance Angiogram (MRA), Neck

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Magnetic resonance angiography (MRA) is a noninvasive imaging technology that can be used to evaluate and image vessels in the head and neck. MRA can be performed with or without gadolinium contrast based on patient characteristics and imaging requirements
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Neck MRA** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Carotid duplex scanning is inadequate (or unavailable) for diagnosis and/or follow-up[20]
- ◆ Patient requires the evaluation of **ANY** of the following:
  - Routine follow-up
  - Post-procedure follow-up (percutaneous and surgical)

Non-Indications

➔ **Neck MRA** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Non-compatible implanted devices.
- ◆ Metallic intraocular foreign bodies.
- ◆ There is a potential for adverse reactions to contrast media.
- ◆ The patient has significant claustrophobia.
- ◆ If the patient has renal insufficiency (eGFR less than 30 mL/min per 1.73 m^2) and if gadolinium contrast is requested, an MRI/MRA may not be considered appropriate.

Site of Service Criteria

Inpatient or outpatient

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Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
70547	Magnetic Resonance Angiography, neck; without contrast material(s)
70548	Magnetic Resonance Angiography, neck; with contrast material(s)
70549	Magnetic Resonance Angiography, neck; without contrast material(s), followed by contrast material(s) and further sequences

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Surgical or Interventional Management

Service: Carotid Endarterectomy (CEA) for asymptomatic extracranial carotid artery occlusive disease

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None
- **Recommended Clinical Approach:** Patients with asymptomatic extracranial carotid artery occlusive disease may be candidates for CEA to reduce the risk of stroke.
- **Exclusions:** Except in extraordinary circumstances, carotid revascularization by CEA is not recommended when atherosclerosis narrows the lumen by less than 50%. CEA is not recommended for patients with chronic total occlusion of the targeted carotid artery.[5]

Medical Necessity Criteria

Indications

➔ **CEA** is considered appropriate if **ANY** of the following is **TRUE**[21-22]:
- ◆ Does the patient have evidence of asymptomatic carotid artery occlusive disease and **ALL** of the following:
  - Greater than or equal to 70% stenosis of a surgically accessible extracranial carotid artery
  - Acceptable surgical risk (less than 3%).
  - Acceptable long-term survival (greater than or equal to 5 years)

Non-Indications

➔ **CEA** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The surgical risk is greater than or equal to 3%.
- ◆ Life expectancy less than 5 years
- ◆ The degree of stenosis is less than 50%.[21]

Applicable CMS Medicare NCDs & LCDs

None.

Site of Service Criteria

Inpatient.

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Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
35301	Carotid thromboendarterectomy by neck incision

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Service: Carotid Artery Stenting (CAS) and/or Transcarotid artery revascularization (TCAR)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Repeat carotid stenting or repeat TCAR represents an unusual clinical scenario which could necessitate a peer to peer review for approval.
- **Recommended Clinical Approach:** CAS has been shown to be an acceptable alternative for the treatment of asymptomatic patients with severe (>70%) stenosis of the extracranial carotid circulation
  Exclusions: Visible thrombus within the lesion detected on preoperative or intraoperative imaging (e.g., ultrasound, angiography), inability to gain vascular access, or active infection.[23]

Medical Necessity Criteria

Indications

➔ **CAS/TCAR** is considered appropriate if **ANY** of the following is **TRUE**[21-22]**:**
- ◆ For asymptomatic patients and **ALL** of the following are **TRUE**:
  - ICA stenosis greater than or equal to 70% by invasive or noninvasive imaging
  - Anticipated rate of periprocedural stroke or death is <3%,
- ◆ In patients with asymptomatic severe stenosis (≥70%) in whom anatomic or medical conditions are present that increase the risk for carotid endarterectomy surgery (e.g., radiation-induced stenosis, carotid restenosis or a surgically inaccessible lesion), it is reasonable to choose CAS or TCAR to reduce the periprocedural complication rate.[24]

Non-Indications

➔ **CAS/TCAR** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Procedure risk is unacceptable

Site of Service Criteria

Inpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition

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37215	Open transcatheter placement of intravascular stent in cervical carotid artery with distal embolic protection
37216	Percutaneous transcatheter placement of intravascular stent in cervical carotid artery
37217	Transcatheter placement of intravascular stent in intrathoracic common carotid artery or innominate artery by retrograde treatment with open exposure of ipsilateral cervical carotid artery
37218	Transcatheter insertion of stent of intrathoracic common carotid artery or innominate artery by open or percutaneous antegrade approach with angioplasty, and radiological supervision and interpretation

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Surgical Risk Factors

Patient Medical Risk Stratification

Patient Risk Score	Patient Characteristic	Min Range	Max Range	Guidance
1- Very Low Risk	No known medical problems			
2- Low Risk	Hypertension		180/110 mm Hg	
2- Low Risk	Asthma	peak flow >80% of predicted or personal best value		
2- Low Risk	Prior history of alcohol abuse			Screen for liver disease and malnutrition
2- Low Risk	Prior history of tobacco use			
3- Intermediate Risk	Asthma	peak flow <80% of predicted or personal best value		
3- Intermediate Risk	Active alcohol abuse			
3- Intermediate Risk	Age	65	75	
3- Intermediate Risk	History of treated, stable coronary artery disease (CAD)			
3- Intermediate Risk	Stable atrial fibrillation			
3- Intermediate Risk	Diabetes mellitus	HbA1C >7%		
3- Intermediate Risk	Morbid obesity	BMI 30	BMI 40	
3- Intermediate Risk	Anemia	hemoglobin <11 (females), <12 (males)		Workup to identify etiology
3- Intermediate Risk	HIV	CD4 <200 cells/mm3		Get clearance from HIV specialist
3- Intermediate Risk	Rheumatologic disease			Preoperative consultation with rheumatologist re: perioperative medication management
3- Intermediate Risk	Peripheral vascular disease or history of peripheral vascular bypass	ankle-brachial pressure		Preoperative consultation with vascular surgeon

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		index (ABPI) <0.9		
3- Intermediate Risk	History of venous thromboembolism (VTE)			
3- Intermediate Risk	Well-controlled obstructive sleep apnea			
3- Intermediate Risk	Malnutrition	transferrin <200 mg/dL albumin <3.5 g/dL prealbumin <22.5 mg/dL total lymphocyte count <1200-1500 cell/mm3 BMI <18		Preoperative consultation with nutritionist
3- Intermediate Risk	Active tobacco Use			Enroll patient in smoking cessation program
3- Intermediate Risk	Known allergy or hypersensitivity to medication needed for procedure			
4- High Risk	Advanced Renal Disease (Creatinine > 2)			
4- High Risk	Diabetes mellitus with complications	HbA1c >8%		
4- High Risk	Age	76	85	
4- High Risk	Oxygen dependent pulmonary disease			
4- High Risk	Sickle cell anemia			
4- High Risk	Obesity	BMI 40		
4- High Risk	Cirrhosis, history of hepatic decompensation or variceal bleeding			
4- High Risk	Impaired cognition; dementia			
4- High Risk	Compensated CHF			
4- High Risk	Cerebrovascular disease			
4- High Risk	Uncontrolled or suspected obstructive sleep apnea (OSA)			
4- High Risk	Renal insufficiency	serum creatinine >1.5 mg/dL or creatinine		

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		clearance <100 mL/min		
4- High Risk	Opioid dependence			
5- Very High Risk	Percutaneous Coronary Intervention (PCI) within 1 month			
5- Very High Risk	Cardiovascular: unstable angina, recent myocardial infarction (60 days), uncontrolled atrial fibrillation or other high-grade abnormal rhythm, severe valvular disease, decompensated heart failure			
5- Very High Risk	Primary pulmonary hypertension			Preoperative consultation with pulmonologist warranted
5- Very High Risk	Cirrhosis or severe liver disease, history of hepatic decompensation or variceal bleeding			
5- Very High Risk	Severe frailty, dependence for ADLs, or history of 3 or more falls in last 6 mos			
5- Very High Risk	Obesity		BMI >50	
5- Very High Risk	Age		>85	
5- Very High Risk	History of VTE with CI to anticoagulation, failure of anticoagulation, cessation of anticoagulation therapy secondary to bleeding			Preoperative consultation with hematologist or internist
5- Very High Risk	Renal failure requiring dialysis			
5- Very High Risk	Immunosuppression			
5- Very High Risk	Chronic Pain			

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