



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Intravascular Ultrasound (IVUS)

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Hyperlink to Related Coverage Policies

- Brachytherapy of the Coronary Arteries
- Cardiovascular Magnetic Resonance (CMR)
- Carotid Intima-Media Thickness Measurement
- Computed Tomography Angiography (CTA)
- Drug-Eluting Stents for Ischemic Heart Disease
- Electron Beam Computed Tomography (EBCT) and Multidetector Computed Tomography (MDCT) for Coronary Artery Calcification
- Excimer Laser Coronary Angioplasty
- Magnetic Resonance Angiography (MRA)

INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA covers coronary artery intravascular ultrasound (IVUS) in symptomatic individuals as medically necessary for ANY of the following indications:

- to determine the extent of atherosclerosis in an individual with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild coronary artery disease (CAD) on angiography
- for evaluation of coronary artery obstruction and/or to guide stent placement at a location difficult to image by angiography in an individual with a suspected flow-limiting stenosis or when the angiographic image does not explain the individual's degree of symptoms
- for preinterventional assessment of lesion characteristics and vessel dimensions as a means to select an optimal treatment
- to assess the adequacy of deployment of coronary artery stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent

- to determine the mechanism of coronary artery stent restenosis (i.e., inadequate expansion vs. neointimal proliferation) and/or to guide selection of appropriate therapy (i.e., plaque ablation vs. repeat balloon expansion)
- to assess a suboptimal angiographic result following a percutaneous coronary artery interventions
- to establish the presence and distribution of coronary arterial calcium in individuals for whom adjunctive rotational atherectomy is contemplated
- to determine plaque location and circumferential distribution for guidance of directional coronary artery atherectomy
- for diagnosis and management of coronary artery disease following cardiac transplantation
- to confirm suspected mechanisms of blood flow restriction in individuals with known anomalous coronary artery

CIGNA covers IVUS of a non-coronary vessel, other than carotid (e.g., renal, iliac, femoral, femoropopliteal), as medically necessary for ANY of the following indications:

- assisting in choosing an appropriate treatment device
- guiding a percutaneous intervention
- for immediate post-procedure assessment

CIGNA covers IVUS for vena cava filter placement as medically necessary for EITHER of the following indications:

- in critically ill individuals who are considered transportation risks
- suboptimal angiographic visualization

CIGNA covers IVUS in lieu of angiography when performed to minimize use of iodinated contrast material in individuals with compromised renal function, congestive heart failure or known contrast allergy.

CIGNA does not cover IVUS for ANY of the following indications because each is considered experimental, investigational or unproven:

- carotid stent placement
- monitoring of anti-atherosclerotic therapies
- coronary artery disease (CAD) screening in asymptomatic individuals

CIGNA does not cover IVUS with radiofrequency signal analysis (e.g., integrated backscatter analysis, autoregressive analysis, “virtual histology”) because it is considered experimental, investigational or unproven.

General Background

Grayscale intravascular ultrasonography (IVUS) is an invasive, catheter-based imaging procedure that uses sound waves to see inside the vessels within the body. IVUS provides a standard grayscale sonographic image and is considered conventional IVUS. The most common location imaged by IVUS is the coronary arteries.

There are also novel subtypes of IVUS. Intravascular elastography/palpography measures the mechanical properties of tissue using ultrasound. Ultrasound radiofrequency signal analysis using various mathematical models is being studied for tissue characterization. Types of models/analysis include integrated backscatter analysis, wavelet analysis, autoregressive analysis, and attenuation slope analysis. Through radiofrequency signal analysis, colored maps are created, classifying and color-coding atherosclerotic plaque into tissue types. The color-coding of plaque types via varying radiofrequency signal analyses may be referred to as “virtual histology”.

Proposed Indications

IVUS is most commonly performed in conjunction with conventional coronary angiography for evaluating vessel pathology, atherosclerotic burden, and lesion severity; to determine the size and type of stent required at implantation; for guiding percutaneous coronary interventions (PCIs) (e.g., balloon angioplasty, coronary stent placement, atherectomy); and following PCIs or transplantation. As compared with angiography, IVUS can provide more detail of the vessel architecture, including the cross-sectional composition of the lumen and wall and the presence and composition of plaque. The American College of Cardiology/ American Heart Association (ACC/AHA) Guidelines for PCI state that “the limitations of coronary angiography for diagnostic and interventional procedures can be reduced by the use of adjunctive technology such as intracoronary ultrasound imaging, flow velocity, and pressure. Information obtained from the adjunctive modalities of intravascular imaging and physiology can improve PCI methods and outcomes.” The ACC/AHA also notes that “IVUS is not necessary for all stent procedures; however, the use of IVUS for evaluating results in high-risk procedures (i.e., those patients with multiple stents, impaired TIMI [i.e., flow grades based on results of the Thrombolysis In Myocardial Infarction trial] grade flow or coronary flow reserve, and marginal angiographic appearance) seems warranted” (Smith, et al., 2006). Studies comparing angiography-only guided PCI’s with IVUS-guidance in addition to angiography use IVUS as the “gold” reference standard. Although studies report moderate sensitivity of angiography, comparative studies generally focus on differences in short- and long-term clinical outcomes.

Additional proposed uses include: as an adjunct to peripheral vascular intervention; in certain situations when vena cava filter placement is indicated; as an adjunct to carotid stent placement; to monitor anti-atherosclerotic therapies; and as a screening tool for coronary artery disease (CAD) in asymptomatic populations. Coronary IVUS is not recommended for CAD screening in asymptomatic individuals due to its invasiveness.

Complications

Although IVUS is an invasive imaging modality, reports of major clinical complications are rare despite increasing clinical use. When performed by experienced operators, most major and acute procedural complications associated with IVUS imaging (but not necessarily caused by it) occur during interventional cases. The most frequently encountered complication is coronary spasm, which occurs in approximately 2–3% of patients during interventional and diagnostic procedures and usually responds rapidly to the administration of intracoronary nitroglycerin.

Alternative Technologies

Both external and invasive methods have been proposed to aid in visualizing vessel patency and plaque burden. Noninvasive alternatives to IVUS may include magnetic resonance imaging (MRI), computed tomography (CT), and Doppler ultrasound. Studies support IVUS as the “gold” reference standard when planning, guiding and assessing percutaneous coronary interventions. In a systematic review of 14 studies (340 patients), Springer et al. (2009) reported multislice CT had moderate to good sensitivities and specificities for the visualization of coronary plaques compared with IVUS as the reference standard. Due to limitations of included studies, accuracy rates were not reported. Novel invasive imaging technologies include optical coherence tomography (OCT), which measures the intensity of back-reflected light in a similar way to that by which IVUS measures acoustic waves; intracoronary thermography; and spectroscopy (reflected light is collected and launched into a spectrometer.)

U.S. Food and Drug Administration (FDA)

Both diagnostic ultrasonic transducers and intravascular diagnostic catheters are proved by the FDA as Class II devices. Examples include:

- iLab Ultrasound Imaging System (Boston Scientific Corporation, Fremont, CA, USA)
- Volcano s5/s5i Intravascular Imaging and Pressure System (Volcano Corporation, Rancho Cordova, CA, USA)
- SoundStar 3D Ultrasound Catheter (Biosense Webster, Inc., Diamond Bar, CA, USA)
- Acunav Diagnostic Ultrasound Catheter (Siemens Medical Solutions, USA, Inc., Mountain View, CA, USA)

Some diagnostic ultrasound catheter approved indications include ultrasound examination of intracardiac and great vessel anatomy, coronary intravascular pathology, and evaluation of coronary vessels and peripheral vasculature.

The iLab™ Ultrasound Imaging System “is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.”

The Volcano s5/s5i Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures. The Volcano Virtual Histology™ IVUS (VH-IVUS) analyzes radiofrequency ultrasound signals and provides real-time maps by classifying atherosclerotic plaque into tissue types of fibrous, fibro-fatty, dense calcium, and necrotic-core. VH IVUS is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of radiofrequency ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

Literature Review

Coronary Indications: Numerous studies and textbooks support IVUS as a safe, accurate, and reproducible method of detecting coronary vessel wall structure and disease and visualizing the dynamic changes before, during and after PCI. IVUS can differentiate coronary vessel wall components and types of atherosclerotic plaque which aids in determining what if any treatment is indicated. This is especially helpful when angiography results are ambiguous. Studies demonstrate a positive impact to clinical outcomes because IVUS can be used safely and accurately to defer PCI (Vaz, et al., 2006; Fassa, et al., 2005). IVUS is used for several purposes during PCI including providing information on dynamic changes that occur within the vessel wall after PCI. IVUS is useful for lesions difficult to assess using conventional angiography. IVUS is used to evaluate the mechanisms responsible for ischemia in anomalous origination of a coronary artery from the opposite sinus and other potentially significant coronary artery anomalies. Generally, randomized controlled trials demonstrate statistically significant improvement in clinical outcomes (e.g., short-term, lumen diameter; long-term, major adverse cardiac event rates) when IVUS is used to guide PCI compared with angiography only-guided PCI (Russo, et al., 2009; Gil, et al., 2007; Gaster, et al., 2003; Oemrawsingh, et al., 2003; Fitzgerald, et al., 2000).

Non-Coronary/Non-Carotid Vessels: Similar to coronary use, IVUS may be used as an adjunct to angiography to assist in determining the size and type of stent required at implantation, and for guiding percutaneous transluminal angioplasty and stent placement. Evidence in the published, peer-reviewed scientific literature indicates that compared with IVUS, conventional angiography underestimates lesion severity and restenosis, and is less accurate in evaluating the deployment of stents in patients undergoing renal, iliac, femoral, and femoropopliteal endovascular management. Additionally, studies indicated that the use of IVUS improves long-term clinical outcomes when used during endovascular management (e.g., significantly improved duration of patency when IVUS is used in conjunction with angiography for stent placement compared with angiography-only) (Buckley, et al., 2002; Neglén, et al., 2002; Dangas, et al., 2001; Schwarzenberg, et al., 1998; Arko, et al., 1998; Van Lankeren, et al., 1998; Gerritsen, et al., 1993).

Vena Cava Filter Placement: Imaging of the vena cava is performed to assess the size and patency of the vessel, as well as to identify the proper site for filter placement and to rule out any anatomic abnormalities such as a duplicated vena cava. This is most commonly done with standard intravenous contrast venography and fluoroscopy in an operating or an angiography suite. Retrieval filters can be placed at the bedside using intravascular ultrasound. Patients that may benefit from retrievable filters placed at the bedside include critical, usually multiple-trauma patients who are considered transportation risks. Additionally, IVUS may aid in filter placement when there is suboptimal angiographic visualization (Killingsworth, et al., 2010; Wellons, et al., 2004; Ashley, et al., 2001).

Other: IVUS may be performed as an alternative to angiography when it is necessary to minimize the use of iodinated contrast material from angiography in individuals with compromised renal function, congestive heart failure or known contrast allergy.

Carotid Stenting: The incremental diagnostic value of using IVUS with carotid stenting procedures has not yet been established in the published peer-reviewed literature. Impact on meaningful health outcomes is not definitively known. Bandyk et al. (2009) retrospectively reported on the use of IVUS for assessment of adequate stent deployment and balloon angioplasty in the treatment of internal carotid artery atherosclerotic occlusive

disease. Bandyk et al. identified 220 consecutive carotid procedures performed with (n=110) or without (n=110) IVUS. The two groups were comparable for carotid artery stenting indication, ICA stenosis severity, and atherosclerotic risk factors. The authors reported that IVUS assessment identified more residual stent abnormalities (n=12, 11%) versus performing stenting using angiogram assessment alone (n=2, 1.8 %). The statistical significance of these results was not reported. Clark et al. (2004) prospectively evaluated the safety and utility of IVUS in carotid stenting. In an observational case series, a total of 98 patients (107 arteries) considered high-risk candidates for carotid endarterectomy underwent carotid artery stenting. Clark et al. performed IVUS prior to predilatation in 87 of the 107 vessels. In the remaining 20 vessels (early in the center's carotid experience), the study was performed after predilatation because it was thought that the lesion was too severe or calcified for the IVUS catheter to pass. IVUS measurements of the minimum lumen diameter (MLD) of the distal internal carotid artery (ICA) reference segment were similar to QCA ($p = 0.21$). The ICA stent MLD was significantly smaller by IVUS compared to QCA ($p < 0.001$). IVUS findings, after an optimal angiographic result, necessitated additional treatment in 9% of procedures. Calcium was detected in significantly more arteries with IVUS than angiography (61% vs. 46%; $p < 0.05$). Long-term outcomes were not obtained. Additional large, well-designed trials are needed in order to clearly demonstrate the impact that using IVUS in carotid stenting may have on long-term stent patency and health outcomes.

Antiatherosclerotic Therapies: IVUS is widely-used as a research tool for evaluation of the efficacy of antiatherosclerotic therapies. Many large-scale IVUS progression-regression trials evaluating the efficacy of various possible antiatherosclerotic agents have and continue to be carried out. Although IVUS is providing valuable information in clinical trials, the risk of complications from an invasive imaging procedure outweighs any potential benefit gained from performing IVUS to monitor noninvasive therapy results.

Coronary Artery Disease (CAD) Screening In Asymptomatic Individuals: The risk of complications from an invasive imaging procedure outweighs any potential benefit gained from performing IVUS to screen an asymptomatic individual for CAD.

IVUS With Radiofrequency Signal Analysis ("Virtual Histology"): Reconstructed color-coded tissue maps show a good correlation to corresponding histopathology (Nair, et al., 2002; Nasu, et al., 2006) but large, well-designed clinical trials defining the diagnostic and clinical utility of various IVUS radiofrequency signal analysis methodologies are lacking. Additional studies are needed comparing various IVUS radiofrequency signal analysis methodologies with each other, with standard grayscale IVUS, and with other invasive and noninvasive techniques. Other issues to be resolved regarding "virtual histology" IVUS include accuracy or usefulness in the presence of thrombus, occlusions, bifurcation lesions, lesions with severe angulations, heavily calcified lesions, and metal stents (Nasu, et al., 2008; Kim, et al., 2008; Hong, et al., 2007).

Professional Societies/Organizations

American College of Cardiology: The ACC/American Heart Association (AHA) Guidelines for Percutaneous Coronary Intervention (Smith, et al., 2006) state that "the limitations of coronary angiography for diagnostic and interventional procedures can be reduced by the use of adjunctive technology such as intracoronary ultrasound imaging, flow velocity, and pressure. Information obtained from the adjunctive modalities of intravascular imaging and physiology can improve PCI methods and outcomes." The ACC/AHA also notes that "IVUS is not necessary for all stent procedures; however, the use of IVUS for evaluating results in high-risk procedures (i.e., those patients with multiple stents, impaired TIMI [i.e., flow grades based on results of the Thrombolysis In Myocardial Infarction trial] grade flow or coronary flow reserve, and marginal angiographic appearance) seems warranted."

ACC/AHA makes the following recommendations for the use of coronary IVUS:

- assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent (ACC/AHA Class* IIa)
- determination of the mechanism of stent restenosis (inadequate expansion vs. neointimal proliferation) and to enable selection of appropriate therapy (plaque ablation vs. repeat balloon expansion) (ACC/AHA Class IIa)
- evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis (ACC/AHA Class IIa)
- assessment of a suboptimal angiographic result following PCI (ACC/AHA Class IIa)

- diagnosis and management of coronary disease following cardiac transplantation (Class IIb)
- establish presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated (ACC/AHA Class IIa)
- determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy (ACC/AHA Class IIa)
- determine extent of atherosclerosis in patients with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild CAD on angiography (ACC/AHA Class IIb)
- preinterventional assessment of lesion characteristics and vessel dimensions as a means to select an optimal revascularization device (ACC/AHA Class IIb)
- when angiographic diagnosis is clear and no interventional treatment is planned (ACC/AHA Class III) (Smith, et al., 2006)

*See Appendix A for American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification.

The ACC/AHA 2007 Focused Update of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines (King, et al., 2008) does not readdress recommendations for the use of coronary IVUS.

The ACC/Society for Cardiovascular Angiography and Interventions (SCAI) 2009 Appropriateness Criteria for Coronary Revascularization (Patel, et al., 2009) rate various clinical scenarios as appropriate, uncertain or inappropriate for warranting revascularization. This Appropriateness Criteria does address IVUS findings along with other criteria (e.g., borderline severity (50-60%) stenoses, fractional flow reserve) when determining appropriateness for revascularization in stable ischemic heart disease without prior CABG.

The ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease (Warnes, et al., 2008) address IVUS. Some of the recommendations for "Congenital Coronary Anomalies of Ectopic Arterial Origin" include:

- The evaluation of individuals who have survived unexplained aborted sudden cardiac death or with unexplained life-threatening arrhythmia, coronary ischemic symptoms, or left ventricular dysfunction should include assessment of coronary artery origins and course. Computed tomography or magnetic resonance angiography is useful as the initial screening method (*Class I).
- Delineation of potential mechanisms of flow restriction via IVUS can be beneficial in patients with documented anomalous coronary artery origin from the opposite sinus (Class IIa).

*See Appendix A for American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification.

The ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease (Hirsch, et al., 2005) is divided into Lower Extremity, Renal/Mesenteric, and Abdominal Aortic sections.

- In the Lower Extremity section, under contrast angiography subheading, it states "angiography is, at present, the only universally accepted method for guiding percutaneous peripheral interventional procedures. Adjunctive hemodynamic parameters, such as pressure gradient and duplex velocity measurements, as well as use of supportive imaging modalities, such as intravascular ultrasound, angioscopy, and optical coherence tomography, can be useful and occasionally have been used in lieu of digital subtraction angiography to guide procedures."
- In the Renal Artery Disease section, under the subheading catheter-based interventions are these recommendations: 1. Renal stent placement is indicated for ostial atherosclerotic renal artery stenosis lesions that meet the clinical criteria for intervention (Class I) 2. Balloon angioplasty with bailout stent placement if necessary is recommended for fibromuscular dysplasia lesions (*Class I)
- In the Mesenteric Arterial Disease section, under the subheading of endovascular treatment is this recommendation: Percutaneous interventions (including transcatheter lytic therapy, balloon angioplasty, and stenting) are appropriate in selected patients with acute intestinal ischemia caused by arterial obstructions. Patients so treated may still require laparotomy (Class IIb).

*See Appendix A for American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification.

The American College of Cardiology (ACC) released a Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies to provide a framework for standardization of nomenclature, methods of measurement, and reporting of IVUS results (Mintz, et al., 2001). It does not address clinical indications or patient selection. It notes that there are several problems in lesion and stenosis nomenclature because coronary disease often appears to be more extensive by IVUS than by angiography. It states that in some cases, a vessel segment will contain diffuse atherosclerosis, but no focal narrowings. In other cases, IVUS will reveal a number of discrete focal narrowings and a few more severe stenoses. Appropriate definitions of "lesion" and "reference segment" nomenclature require different methodology than commonly employed in angiography and are therefore clarified in the consensus document.

Summary

The clinical utility of intravascular ultrasound (IVUS) for certain coronary artery indications is supported in the peer-reviewed literature and through other sources such as professional society guidelines. Additionally, IVUS has become a useful and often necessary adjunct in many occlusive disease procedures (e.g., renal, iliac, femoral, femoropopliteal); however, larger, well-designed trials are needed to validate if IVUS can improve outcomes specific to carotid stenting. IVUS may be useful in certain clinical scenarios for vena cava filter placement and as an alternative to angiography when it is necessary to minimize the use of iodinated contrast material from angiography in individuals with compromised renal function, congestive heart failure or known contrast allergy.

Due to the invasive nature of this technology, IVUS is not indicated for monitoring anti-atherosclerotic therapies or for the screening of asymptomatic individuals for coronary artery disease (CAD). Comparative studies identifying what if any additional clinical utility the various types of ultrasound radiofrequency signal analysis (e.g., virtual histology) may provide over standard grayscale IVUS, are lacking.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

| CPT®* Codes | Description |
|----------------|--|
| 37250 | Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel (List separately in addition to code for primary procedure) |
| 37251 | Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure) |
| 75945 | Intravascular ultrasound (non-coronary vessel), radiological supervision and interpretation; initial vessel |
| 75946 | Intravascular ultrasound (non-coronary vessel), radiological supervision and interpretation; each additional non-coronary vessel (List separately in addition to code for primary procedure) |
| 92978 | Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to primary procedure) |
| 92979 | Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to primary procedure) |

| HCPCS Codes | Description |
|----------------|-------------|
|----------------|-------------|

| | |
|-------|------------------------------------|
| C1753 | Catheter, intravascular ultrasound |
|-------|------------------------------------|

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|---|
| 410.00 – 410.92 | Acute myocardial infarction |
| 411.1 | Intermediate coronary syndrome |
| 411.81 | Acute coronary occlusion without myocardial infarction |
| 411.89 | Other acute and subacute form of ischemic heart disease |
| 413.0 | Angina decubitus |
| 413.9 | Other and unspecified angina pectoris |
| 414.00 – 414.07 | Coronary atherosclerosis |
| 414.2 | Chronic total occlusion of coronary artery |
| 414.3 | Coronary atherosclerosis due to lipid rich plaque |
| 414.8 | Other specified forms of chronic ischemic heart disease |
| 428.0-428.9 | Heart failure |
| 440.1 | Atherosclerosis of renal artery |
| 444.22 | Arterial embolism and thrombosis, Lower extremity |
| 444.81 | Arterial embolism and thrombosis, Iliac artery |
| 451.11-451.19 | Phlebitis and thrombophlebitis, Of deep vessels of lower extremities |
| 451.81 | Phlebitis and thrombophlebitis, Iliac vein |
| 453.2 | Other venous embolism and thrombosis, Of inferior vena cava |
| 453.3 | Other venous embolism and thrombosis, Of renal vein |
| 453.40-453.42 | Acute venous embolism and thrombosis of deep vessels of lower extremity |
| 453.50-453.2 | Chronic venous embolism and thrombosis of deep vessels of lower extremity |
| 453.77 | Chronic venous embolism and thrombosis of other thoracic veins |
| 453.87 | Acute venous embolism and thrombosis of other thoracic veins |
| 584-584.9 | Acute kidney failure |
| 585.1-585.9 | Chronic kidney disease (CKD) |
| 586 | Renal failure, unspecified |
| 587 | Renal sclerosis, unspecified |
| 593.81 | Vascular disorders of kidney |
| 747.3 | Anomalies of pulmonary artery |
| 747.40 | Anomaly of great veins, unspecified |
| 996.83 | Complications of transplanted heart |
| V15.08 | Allergy due to radiographic dye |
| V42.1 | Organ or tissue replaced by transplant; heart |

Experimental/Investigational/Unproven/Not Covered:

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|--|
| 433.10-433.11 | Occlusion and stenosis of precerebral arteries, Carotid artery |

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

References

1. Arko F, Mettauer M, McCollough R, Patterson D, Manning L, Lee S, et al. Use of intravascular ultrasound improves long-term clinical outcome in the endovascular management of atherosclerotic aortoiliac occlusive disease. *J Vasc Surg.* 1998 Apr;27(4):614-23.
2. Ashley DW, Gamblin TC, Burch ST, Solis MM. Accurate deployment of vena cava filters: comparison of intravascular ultrasound and contrast venography. *J Trauma.* 2001 Jun;50(6):975-81.
3. Bandyk DF, Armstrong PA. Use of intravascular ultrasound as a "Quality Control" technique during carotid stent-angioplasty: are there risks to its use? *J Cardiovasc Surg (Torino).* 2009 Dec;50(6):727-33.
4. Buckley CJ, Arko FR, Lee S, Mettauer M, Little D, Atkins M, et al. Intravascular ultrasound scanning improves long-term patency of iliac lesions treated with balloon angioplasty and primary stenting. *J Vasc Surg.* 2002 Feb;35(2):316-23.
5. Casella G, Klauss V, Ottani F, Siebert U, Sangiorgio P, Bracchetti D. Impact of intravascular ultrasound guided stenting on long-term clinical outcome: a meta-analysis of available studies comparing intravascular ultrasound-guided and angiographically guided stenting. *Catheter Cardiovasc Interv.* 2003 Jul;59(3):314-21.
6. Clark DJ, Lessio S, O'Donoghue M, Schainfeld R, Rosenfield K. Safety and utility of intravascular ultrasound-guided carotid artery stenting. *Catheter Cardiovasc Interv.* 2004 Nov;63(3):355-62.
7. Dangas G, Laird JR Jr, Mehran R, Lansky AJ, Mintz GS, Leon MB. Intravascular ultrasound-guided renal artery stenting. *J Endovasc Ther.* 2001 Jun;8(3):238-47.
8. Fassa AA, Wagatsuma K, Higano ST, Mathew V, Barsness GW, Lennon RJ, et al. Intravascular ultrasound-guided treatment for angiographically indeterminate left main coronary artery disease: a long-term follow-up study. *J Am Coll Cardiol.* 2005 Jan 18;45(2):204-11.
9. Fitzgerald PJ, Oshima A, Hayase M, Metz JA, Bailey SR, Baim DS, et al. Final results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) study. *Circulation.* 2000 Aug 1;102(5):523-30.
10. Gaster AL, Slothuus Skjoldborg U, Larsen J, Korsholm L, von Birgelen C, Jensen S et al. Continued improvement of clinical outcome and cost effectiveness following intravascular ultrasound guided PCI: insights from a prospective, randomised study. *Heart.* 2003 Sep;89(9):1043-9.
11. Gerritsen GP, Gussenhoven EJ, The SH, Pieterman H, v d Lugt A, Li W, et al. Intravascular ultrasonography before and after intervention: in vivo comparison with angiography. *J Vasc Surg.* 1993 Jul;18(1):31-40.
12. Gil RJ, Pawłowski T, Dudek D, Horszczaruk G, Zmudka K, Investigators of Direct Stenting vs Optimal Angioplasty Trial (DIPOL), et al. Comparison of angiographically guided direct stenting technique with direct stenting and optimal balloon angioplasty guided with intravascular ultrasound. The multicenter, randomized trial results. *Am Heart J.* 2007 Oct;154(4):669-75.
13. Guedes A, Tardif JC. Intravascular ultrasound assessment of atherosclerosis. *Curr Atheroscler Rep.* 2004 May;6(3):219-24.
14. Hirsch AT, Haskal ZJ, Hertzner NR, American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, ACC/AHA Task Force on Practice Guidelines, et al. ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease (lower extremity, renal/mesenteric, and abdominal aortic): a collaborative report from the American Associations for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (writing committee to develop guidelines for the

management of patients with peripheral arterial disease)--summary of recommendations. *J Vasc Interv Radiol.* 2006 Sep;17(9):1383-97; quiz 1398.

15. Hong MK, Mintz GS, Lee CW, Suh J, Kim JH, Park DW, et al. Comparison of virtual histology to intravascular ultrasound of culprit coronary lesions in acute coronary syndrome and target coronary lesions in stable angina pectoris. *Am J Cardiol.* 2007 Sep 15;100(6):953-9.
16. Jakabčičin J, Spaček R, Bystroň M, Kvašňák M, Jager J, Veselka J, et al. Long-term health outcome and mortality evaluation after invasive coronary treatment using drug eluting stents with or without the IVUS guidance. Randomized control trial. HOME DES IVUS. *Catheter Cardiovasc Interv.* 2009 Aug 7. [Epub ahead of print]
17. Jimenez-Quevedo P, Sabate M, Angiolillo DJ, Costa MA, DIABETES Investigators, et al. Vascular effects of sirolimus-eluting versus bare-metal stents in diabetic patients: three-dimensional ultrasound results of the Diabetes and Sirolimus-Eluting Stent (DIABETES) Trial. *J Am Coll Cardiol.* 2006 Jun 6;47(11):2172-9.
18. Killingsworth CD, Taylor SM, Patterson MA, Weinberg JA, McGwin G Jr, Melton SM, et al. Prospective implementation of an algorithm for bedside intravascular ultrasound-guided filter placement in critically ill patients. *J Vasc Surg.* 2010 May;51(5):1215-21. Epub 2010 Mar 11.
19. Kim SW, Mintz GS, Hong YJ, Pakala R, Park KS, Pichard AD, et al. The virtual histology intravascular ultrasound appearance of newly placed drug-eluting stents. *Am J Cardiol.* 2008 Nov 1;102(9):1182-6. Epub 2008 Jun 12.
20. King SB 3rd, Smith SC Jr, Hirshfeld JW Jr, Jacobs AK, Morrison DA, Williams DO, et al. 2007 focused update of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. *J Am Coll Cardiol.* 2008 Jan 15;51(2):172-209.
21. Kushner FG, Hand M, Smith SC Jr, King SB 3rd, Anderson JL, Antman EM, et al. 2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (Updating the 2004 Guideline and 2007 Focused Update) and ACC/AHA/SCAI Guidelines on Percutaneous Coronary Intervention (Updating the 2005 Guideline and 2007 Focused Update) A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2009 Dec 1;54(23):2205-41.
22. Lee JT, Fang TD, White RA. Applications of intravascular ultrasound in the treatment of peripheral occlusive disease. *Semin Vasc Surg.* 2006 Sep;19(3):139-44. Review.
23. Libby P, Bonow R, Mann DL, Zipes DP, editors. Libby: Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 8th ed. Philadelphia, PA: Saunders Elsevier; 2007.
24. Mintz GS, Nissen SE, Anderson WD, Bailey SR, Erbel R, Fitzgerald PJ et al. ACC Clinical Expert Consensus Document on Standards for acquisition, measurement and reporting of intravascular ultrasound studies (IVUS). A report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol.* 2001;37(5):1478-1492.
25. Nair A, Kuban BD, Tuzcu EM, Schoenhagen P, Nissen SE, Vince DG. Coronary plaque classification with intravascular ultrasound radiofrequency data analysis. *Circulation.* 2002 Oct 22;106(17):2200-6.
26. Nasu K, Tsuchikane E, Katoh O, Vince DG, Virmani R, Surmely JF, et al. Accuracy of in vivo coronary plaque morphology assessment: a validation study of in vivo virtual histology compared with in vitro histopathology. *J Am Coll Cardiol.* 2006 Jun 20;47(12):2405-12. Epub 2006 May 30.
27. Nasu K, Tsuchikane E, Katoh O, Vince DG, Margolis PM, Virmani R, et al. Impact of intramural thrombus in coronary arteries on the accuracy of tissue characterization by in vivo intravascular

- ultrasound radiofrequency data analysis. *Am J Cardiol*. 2008 Apr 15;101(8):1079-83. Epub 2008 Feb 11.
28. Neglén P, Raju S. Intravascular ultrasound scan evaluation of the obstructed vein. *J Vasc Surg*. 2002 Apr;35(4):694-700.
 29. Nissen SE, Nicholls SJ, Sipahi I, Libby P, Raichlen JS, ASTEROID Investigators, et al. Effect of very high-intensity statin therapy on regression of coronary atherosclerosis: the ASTEROID trial. *JAMA*. 2006a Apr 5;295(13):1556-65. Epub 2006 Mar 13.
 30. Oemrawsingh PV, Mintz GS, Schlij MJ, Zwinderman AH, Jukema JW, van der Wall EE; TULIP Study. Thrombocyte activity evaluation and effects of Ultrasound guidance in Long Intracoronary stent Placement. Intravascular ultrasound guidance improves angiographic and clinical outcome of stent implantation for long coronary artery stenoses: final results of a randomized comparison with angiographic guidance (TULIP Study). *Circulation*. 2003 Jan 7;107(1):62-7.
 31. Patel MR, American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, et al. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization: a report by the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography. *J Am Coll Cardiol*. 2009 Feb 10;53(6):530-53.
 32. Russo RJ, Silva PD, Teirstein PS, Attubato MJ, Davidson CJ, AVID Investigators, et al. A randomized controlled trial of angiography versus intravascular ultrasound-directed bare-metal coronary stent placement (the AVID Trial). *Circ Cardiovasc Interv*. 2009 Apr;2(2):113-23. Epub 2009 Feb 20.
 33. Schwarzenberg H, Müller-Hülsbeck S, Glüer CC, Wesner F, Heller M. Restenosis of peripheral stents and stent grafts as revealed by intravascular sonography: in vivo comparison with angiography. *AJR Am J Roentgenol*. 1998 May;170(5):1181-5.
 34. Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, American College of Cardiology/American Heart Association Task Force on Practice Guidelines, ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). *J Am Coll Cardiol*. 2006 Jan 3;47(1):e1-121.
 35. Springer I, Dewey M. Comparison of multislice computed tomography with intravascular ultrasound for detection and characterization of coronary artery plaques: a systematic review. *Eur J Radiol*. 2009 Aug;71(2):275-82. Epub 2008 Jun 30.
 36. Tuzcu EM, Kapadia SR, Sachar R, Ziada KM, Crowe TD, Feng J et al. Intravascular ultrasound evidence of angiographically silent progression in coronary atherosclerosis predicts long-term morbidity and mortality after cardiac transplantation. *J Am Coll Cardiol*. 2005 May 3;45(9):1538-42.
 37. U.S. Food and Drug Administration. 510(k) Summary. Eagle Eye Gold IVUS Catheter Volcano VH IVUS System. August 18, 2005. Accessed December 2010. Available at URL address:
http://www.accessdata.fda.gov/cdrh_docs/pdf5/K051337.pdf
http://www.accessdata.fda.gov/cdrh_docs/pdf7/K071554.pdf
www.accessdata.fda.gov/cdrh_docs/pdf8/K082229.pdf

38. U.S. Food and Drug Administration. 510(k) Summary of Safety and Effectiveness. Boston Scientific Corporation iLab™ Ultrasound Imaging System. July 14, 2005. Accessed December 2010. Available at URL address: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K051679.pdf
39. van Lankeren W, Gussenhoven EJ, Pieterman H, van Sambeek MR, van der Lugt A. Comparison of angiography and intravascular ultrasound before and after balloon angioplasty of the femoropopliteal artery. *Cardiovasc Intervent Radiol*. 1998 Sep-Oct;21(5):367-74.
40. Vaz VD, Abizaid AC, Abizaid AA, Feres F, Staico R, Mattos LA, et al. The usefulness of intracoronary ultrasound in the treatment decision-making of patients with ambiguous lesions in the left main coronary artery. *Arq Bras Cardiol*. 2006 Dec;87(6):681-7.
41. Virtual Histology. Volcano Corporation ©2010. Accessed December 2010. Available at URL address: <http://www.vhivus.com/about-vhivus.asp>
42. Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA, et al. ACC/AHA 2008 Guidelines for the Management of Adults With Congenital Heart Disease: Executive Summary A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Adults With Congenital Heart Disease) Developed in Collaboration With the American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2008 Dec 2;52(23):1890-947.
43. Wellons ED, Rosenthal D, Shuler FW, Levitt AB, Matsuura J, Henderson VJ. Real-time intravascular ultrasound-guided placement of a removable inferior vena cava filter. *J Trauma*. 2004 Jul;57(1):20-3; discussion 23-5.

APPENDIX A

American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification used:

Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

Policy History

| Pre-Merger Organizations | Last Review Date | Policy Number | Title |
|-------------------------------------|-----------------------------|--------------------------|---|
| CIGNA HealthCare | 1/15/2008 | 0417 | Coronary Intravascular Ultrasound (IVUS) |

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