Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

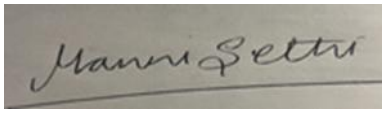
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 7/1/2025
Policy Number: CCP.1417	Effective Date: 9/1/2019 Revision Date: 6/2025
Policy Name: Intravascular ultrasound	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Intravascular ultrasound

Clinical Policy ID: CCP.1417

Recent review date: 6/2025

Next review date: 10/2026

Policy contains: Arteriovenous fistula; arteriovenous graft; hemodialysis; intravascular ultrasound; IVUS.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Intravascular ultrasound for assessment of primary arteriovenous fistula or prosthetic graft access is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Digital subtraction angiography.
- Doppler ultrasound.
- Venography.

Background

Vascular access complications represent a serious obstacle in patients undergoing hemodialysis with consequences to morbidity and mortality (Murphy, 2017). Individuals with end-stage renal disease and central venous catheter access are at higher risk for central venous occlusive disease (McFall, 2018). In long-term arteriovenous fistula or graft access, the leading cause of vascular access failure is thrombosis resulting from vascular stenosis and restricted blood flow.

Endovascular management of primary arteriovenous fistula and prosthetic grafts is an alternative to surgical thrombectomy and revision (American College of Radiology, 2022a). The procedure involves angiographic

evaluation of the vascular access circuit and identification and treatment of hemodynamically significant stenosis (defined as stenosis greater than 50% in diameter). It is usually performed on an outpatient basis.

Prospective surveillance of asymptomatic, hemodynamically significant stenosis combined with correction of the anatomic stenosis by angioplasty, may improve patency rates and decrease the incidence of thrombosis (National Kidney Foundation Kidney Disease Outcomes Quality Initiative, 2006). A number of monitoring and surveillance methods are available to assess arteriovenous patency. They employ measures of intra-access flow, sequential dynamic or static pressures, and recirculation, and each technique has own advantages and limitations. Modalities used to image arteriovenous access include digital subtraction angiography, Doppler ultrasound, and single-plane contrast venography. Magnetic resonance imaging and computed tomography are used less commonly. The choice of technique largely depends on access type, technology, effect of operator, and cost (usually labor) (Murphy, 2017).

Intravascular ultrasound, also known as endovascular ultrasound or intravascular echocardiography, is a catheter-based device that employs an ultrasonic transducer to generate cross-sectional images of endovascular morphology (American College of Radiology, 2023). Intravascular ultrasound does not expose the patient to iodinated contrast or ionizing radiation. The U.S. Food and Drug Administration (2025) describes intravascular ultrasound devices as diagnostic intravascular catheters, regulated as Class 2 devices requiring 510(k) premarket notification. Its primary application is visualization of the coronary arteries in conjunction with catheter angiography or angioplasty and vascular stenting but approved clinical applications to the peripheral vasculature are emerging. As an interventional procedure, it should be performed by angiographers who are trained in interventional vascular techniques.

Findings

Clinical Guidelines

Clinical guidelines provide limited support for intravascular ultrasound in hemodialysis access evaluation. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (2006) acknowledges intravascular ultrasound's potential to detect abnormalities in fistulae not visible with angiography but does not recommend its routine use due to cost concerns, suggesting it may serve as an adjunct in evaluating access intervention efficacy. The American College of Radiology (2022a) does not specifically address intravascular ultrasound but outlines contraindications to endovascular techniques for thrombosed or dysfunctional dialysis access that would apply to intravascular ultrasound procedures, including active infection at the vascular access site as an absolute contraindication and severe hyperkalemia, acidosis, right-to-left shunt, and severe cardiopulmonary disease as relative contraindications. The American College of Cardiology Foundation (Gornik, 2013) rated duplex ultrasound as appropriate for most clinical scenarios related to hemodialysis access dysfunction but did not address intravascular ultrasound's relative performance.

Systematic Reviews

Systematic reviews examining intravascular ultrasound in renal patients demonstrate mixed results across various applications. A 2021 systematic review of patients with central vein obstruction undergoing hemodialysis (n = 655) revealed poor patency rates for both venoplasty and stenting, with the authors endorsing further research into intravascular ultrasound's potential role (Andrawos, 2021). Another systematic review examining minimum- or zero-contrast intravascular ultrasound-guided percutaneous coronary interventions in chronic kidney disease patients found intravascular ultrasound-guided procedures to be safe with comparable efficacy to conventional approaches (Burlacu, 2021). A review of 1,766 patients found that stent eccentricity measured using intravascular ultrasound had no significant impact on the risk of one-year restenosis after femoropopliteal endovascular therapy (Mochidome, 2022). These findings suggest intravascular ultrasound may have

application in specific clinical scenarios but does not demonstrate clear superiority over conventional approaches.

Clinical Trials

Clinical outcome data from individual trials provide limited evidence of intravascular ultrasound's impact on hemodialysis access management. A single-center randomized controlled trial (n = 100) comparing digital subtraction angiography alone versus digital subtraction angiography followed by intravascular ultrasound in patients with failing hemodialysis access grafts found that intravascular ultrasound changed the treatment plan in 76% of participants, with the most frequent changes being additional balloon angioplasty (86%), stent implantation (9.1%), and additional thrombectomy (4.5%). However, intravascular ultrasound conferred no significant procedural advantages regarding procedure time (*P* = .21), fluoroscopy time (*P* = .23), or contrast agent volume (*P* = .36). While intravascular ultrasound showed numerical advantages in extending median time to first re-intervention (60 days versus 30 days, *P* = .16), it did not demonstrate statistically significant improvements in freedom from re-intervention (35% in both groups, *P* = .88) or freedom from arteriovenous graft discontinuation (75% in control versus 80% in intravascular ultrasound group, *P* = .45) (Ross, 2017). A similar study of 698 patients with chronic kidney disease showed conventional and intravascular ultrasound approaches achieved comparable major cardiovascular event outcomes after 32 months (Shibata, 2022).

Diagnostic Capabilities

The diagnostic capabilities of intravascular ultrasound in hemodialysis access evaluation derive primarily from its application in coronary angioplasty, where it improves detection of lesions not adequately visualized by angiography alone. In the hemodialysis access context, limited evidence suggests intravascular ultrasound can detect more abnormal vessel segments than angiography, particularly thrombi (P < .001) (Arbab-Zadeh, 2002), and allows both qualitative and quantitative assessments of arteriovenous fistulae (Higuchi, 2001). However, these diagnostic advantages have not translated into clearly established clinical or cost-effectiveness relative to other imaging modalities.

In 2025, we reorganized the findings section by evidence and thematically. No new relevant literature was found, and no policy changes were warranted.

References

On May 19, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Renal Dialysis” (MeSH), “Ultrasonography, Interventional” (MeSH), “Arteriovenous Shunt, Surgical” (MeSH), “intravascular ultrasound,” “intravascular ultrasonography,” and “arteriovenous graft.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

American College of Radiology. EACR–SIR practice parameter for endovascular management of the thrombosed or dysfunctional dialysis access. https://gravitas.acr.org/PPTS/GetDocumentView?docId=143. Last revised 2022.(a)

American College of Radiology. ACR-SPR practice parameter for the use of intravascular contrast media. https://gravitas.acr.org/PPTS/DownloadPreviewDocument?DocId=142. Last revised 2023.

Andrawos A, Saeed H, Delaney C. A systematic review of venoplasty versus stenting for the treatment of central vein obstruction in ipsilateral hemodialysis access. *J Vasc Surg Venous Lymphat Disord*. 2021;9(5):1302-1311. Doi: 10.1016/j.jvsv.2021.02.014.

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Gornik HL, Gerhard-Herman MD, Misra S, Mohler ER, 3rd, Zierler RE. ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 appropriate use criteria for peripheral vascular ultrasound and physiological testing part II: Testing for venous disease and evaluation of hemodialysis access: A report of the American College of Cardiology Foundation appropriate use criteria task force. *J Am Coll Cardiol.* 2013;62(7):649-665. Doi: 10.1016/j.jacc.2013.05.001.

Higuchi T, Okuda N, Aoki K, et al. Intravascular ultrasound imaging before and after angioplasty for stenosis of arteriovenous fistulae in haemodialysis patients. *Nephrol Dial Transplant*. 2001;16(1):151-155. Doi: 10.1093/ndt/16.1.151.

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Murphy EA, Ross RA, Jones RG, et al. Imaging in vascular access. *Cardiovasc Eng Technol*. 2017;8(3):255-272. Doi: 10.1007/s13239-017-0317-y.

National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines. Clinical practice guidelines and clinical practice recommendations. Hemodialysis adequacy. Peritoneal dialysis adequacy. Vascular access. http://kidneyfoundation.cachefly.net/professionals/KDOQI/guideline_upHD_PD_VA/va_guide4.htm#table8. Published 2006.

Ross JR, Franga DL, Gallichio M, Patel AJ, Ouriel K. Role of intravascular ultrasound imaging during endovascular interventions of failing hemodialysis access grafts. *J Vasc Surg.* 2017;65(5):1383-1389. Doi: 10.1016/j.jvs.2016.10.115.

Shibata K, Wakabayashi K, Ishinaga T, et al. Feasibility, safety, and long-term outcomes of zero-contrast percutaneous coronary intervention in patients with chronic kidney disease. *Circ J*.2022;86(5):787-796. Doi:10.1253/circj.CJ-21-0905.

U.S. Food and Drug Administration. 510(k) premarket notification database searched using product code OBJ. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Policy updates

7/2019: initial review date and clinical policy effective date: 9/2019

6/2020: Policy references updated.
6/2021: Policy references updated.
6/2022: Policy references updated.
6/2023: Policy references updated.
6/2024: Policy references updated.

6/2025: Policy references updated.