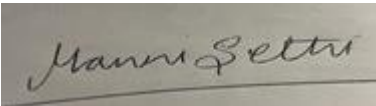


**Prior Authorization Review Panel
MCO Policy Submission**

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: Keystone First Community HealthChoices	Submission Date: 7/1/2024
Policy Number: ccp.1417	Effective Date: 9/2019 Revision Date: June 1, 2024
Policy Name: Intravascular ultrasound	
Type of Submission – Check all that apply: New Policy <input checked="" type="checkbox"/> Revised Policy* Annual Review – No Revisions Statewide PDL	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: See tracked changes below. Reactivated policy	
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: 6/2024

Next review date: 10/2025

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

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Community HealthChoices, 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 Community HealthChoices' 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 Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' 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, 2022a). Intravascular ultrasound does not expose the patient to iodinated contrast or ionizing radiation. The U.S. Food and Drug Administration (202) 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

We added one randomized controlled trial (Ross, 2017), two case series (Arbab-Zadeh, 2002; Higuchi, 2001), and three guidelines to the policy (American College of Radiology, 2022a; Gornik, 2013; National Kidney Foundation Kidney Disease Outcomes Quality Initiative, 2006). The main rationale for applying intravascular ultrasound in assessing hemodialysis access patency is derived from its application in coronary angioplasty. Angiography alone lacks the sensitivity and specificity to detect many coronary lesions. Intravascular ultrasound is considered an adjunctive modality for its ability to improve the diagnostic accuracy of detecting coronary lesions, particularly thrombus and dissection.

The current evidence supporting intravascular ultrasound in assessing hemodialysis access complications is very limited in quantity with a high risk of bias and insufficient to clearly establish its clinical or cost-effectiveness relative to other imaging modalities. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (2006) mentions the potential for intravascular ultrasound to detect abnormalities in fistulae and those not seen with angiography. The Initiative does not recommend intravascular ultrasound for routine use due to its expense, but it may have value as an adjunct in evaluating the efficacy or completeness of the access intervention.

The American College of Radiology (2022a) does not specifically mention intravascular ultrasound but lists -p[=]contraindications to endovascular techniques for thrombosed or dysfunctional dialysis access that would apply to an intravascular ultrasound procedure. An absolute contraindication is active infection of the vascular access site. Relative contraindications include severe hyperkalemia, acidosis, or other life-threatening abnormality of blood chemistry that requires immediate dialysis, known right-to-left shunt, and severe cardiopulmonary disease. One advantage of intravascular ultrasound over other invasive modalities would be its application to patients with severe contrast allergy.

The American College of Radiology (2022b) maintains a practice parameter for use of intravascular contrast media, but does not address specific indications.

The American College of Cardiology Foundation (Gornik, 2013) rated duplex ultrasound as an appropriate test for most clinical scenarios related to upper extremity symptoms or signs of malfunction in the patient with mature dialysis access with arteriovenous fistula or prosthetic graft. The performance of intravascular ultrasound relative to noninvasive methods such as duplex ultrasound is unclear.

Limited evidence suggests intravascular ultrasound is safe and feasible for evaluating hemodialysis access failure in the angiographic suite and dialysis unit (Arbab-Zadeh, 2002; Higuchi, 2001; Ross, 2017). A comparison of angiography and intravascular ultrasound from 21 imaging studies ($n = 17$ participants) on the same day found intravascular ultrasound detected more abnormal vessel segments in arteriovenous grafts than angiography, most notably the presence of thrombus ($P < .001$) (Arbab-Zadeh, 2002). A case series of 40 participants with 63 stenoses in arteriovenous fistulae who had percutaneous transluminal angioplasty found intravascular ultrasound allowed both qualitative and quantitative assessments of arteriovenous fistulae (Higuchi, 2001).

Evidence of the impact of intravascular ultrasound on clinical management is derived from a single-center, randomized controlled study (Ross, 2017) comparing digital subtraction angiography alone (control group) with digital subtraction angiography followed by intravascular ultrasound (test group) in 100 adult participants with failing hemodialysis access grafts considered for endovascular intervention. Addition of intravascular ultrasound to digital subtraction angiography conferred no significant procedural advantages with respect to procedure time ($P = .21$), fluoroscopy time ($P = .23$), or contrast agent volume used ($P = .36$). In an unblinded assessment, intravascular ultrasound changed the treatment plan in 76% (44/58) of participants. The most frequent changes were additional balloon angioplasty (86%), stent implantation (9.1%), and additional thrombectomy (4.5%).

Although intravascular ultrasound demonstrated absolute numerical advantages in some of the primary outcomes, none reached statistical significance, likely due to the underpowered nature of the study (Ross, 2017). At six months, addition of intravascular ultrasound to standard angiography extended the median time to the first re-intervention (graft failure) (60 days versus 30 days in the control group, $P = .16$) in the 59 participants who experienced re-intervention or discontinuation. There were no between group differences with respect to freedom from re-intervention (35% each, $P = .88$) or freedom from arteriovenous graft discontinuation or abandonment (75% in the control group versus 80% in the test group, $P = .45$). After 90 days following the index procedure, participants in the test group returned more frequently (33%) than those in the control group (24%), which the authors could not explain. Adequately powered randomized controlled trials with long-term follow-up are needed to reliably discern clinical benefit as an independent or adjunctive test in this setting.

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we identified no newly published, relevant literature to add to the policy.

In 2022, we added a systematic review of six studies of conventional versus intravascular ultrasound approaches for percutaneous coronary interventions for chronic kidney disease patients. Intravenous ultrasound-guided procedures appear to be safe with comparable efficacy to the conventional approach (Burlacu, 2021). A similar study of 698 patients with chronic kidney disease showed conventional and intravascular ultrasound achieved comparable major cardiovascular event outcomes after 32 months (Shibata, 2022).

In 2023, we added a systematic review ($n = 655$) showing poor patency rates for both venoplasty and stenting for central vein obstruction in patients undergoing hemodialysis; authors endorse further research for the role of intravascular ultrasound use (Andrawos, 2021). We also added a review ($n = 1,766$) that found stent eccentricity (measured using intravascular ultrasound) had no significant impact on risk of one-year restenosis after femoropopliteal endovascular therapy (Mochidome, 2022).

In 2024, we identified no newly published, relevant literature to add to the policy.

References

On May 10, 2024, 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://www.acr.org/-/media/ACR/Files/Practice-Parameters/Dysfunc-DialysisMgmt.pdf?la=en>. Last revised 2022. (a)

American College of Radiology. ACR-SPR practice parameter for the use of intravascular contrast media. <https://www.acr.org/-/media/acr/files/practice-parameters/ivcm.pdf>. Last revised 2022. (b)

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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.