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| Subject: | Angiographic Evaluation and Endovascular Intervention for Dialysis Access Circuit Dysfunction | Publish Date: | 12/28/2022 |
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| Status: | Revised | | |

Description

This document addresses angiographic evaluation for dialysis access circuit dysfunction and treatment for stenotic or thrombosed arterio-venous grafts (AVG) or fistulas (AVF). This document does not address angiographic evaluation as a treatment for venous thoracic outlet syndrome, superior vena cava syndrome, Budd-Chiari syndrome, congenital cardiac defects, lower extremity venous congestion, or improving venous flow in individuals with multiple sclerosis and chronic cerebrospinal venous insufficiency (CCSVI).

Note: Please see the following related document for additional information:

- CG-SURG-106 Venous Angioplasty with or without Stent Placement or Venous Stenting Alone

Clinical Indications

Medically Necessary:

- A. Angiographic evaluation for arterio-venous graft (AVG) dysfunction is considered **medically necessary** when two or more of the following abnormalities are present and persistent:
1. Abnormalities of clinical monitoring suggestive of stenosis (for example, abnormal physical findings such as an absent thrill, discontinuous bruit, or edema in the extremity distal to the graft; problems noted during the dialysis session, such as difficulty with cannulation, aspiration of clots, inability to achieve the target dialysis blood flow, or prolonged bleeding from the needle puncture sites; or an unexplained decrease in the delivered dialysis dose [Kt/V] on a constant hemodialysis prescription); **or**
 2. Decreasing intragraft blood flow (less than 600mL/min); **or**
 3. Venous segment static pressure ratio greater than 0.5; **or**
 4. Arterial segment static pressure ratio greater than 0.75.
- B. Angiographic evaluation for arterio-venous fistula (AVF) dysfunction is considered **medically necessary** when two or more of the following abnormalities are present and persistent:
1. Abnormalities of clinical monitoring suggestive of stenosis (for example, abnormal physical findings such as persistent arm swelling, collateral veins, and altered features of the pulse or thrill, problems noted during the dialysis session, such as prolonged bleeding after needle withdrawal, or unexplained persistent decrease in Kt/V); **or**
 2. Access flow rate less than 500 mL/min; **or**
 3. Venous segment static pressure ratio greater than 0.5.
- C. Endovascular intervention (with or without stent placement) is considered **medically necessary** as a treatment for stenotic or thrombosed AVG or AVF when the following criteria are met:
1. Stenosis without thrombosis when:

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- a. Hemodynamically significant stenosis causes a greater than 50% reduction in normal vessel; **and**
 - b. Stenosis is associated with two or more of the clinical or physiological abnormalities noted above (Criterion A for AVG and Criterion B for AVF); **or**
2. Stenosis is associated with thrombosis.

Not Medically Necessary:

Angiographic evaluation for AVF or AVG dysfunction is considered **not medically necessary** when the above criteria are not met and for all other indications.

Endovascular intervention is considered **not medically necessary** when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

- 36901 Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report
- 36902 Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty
- 36903 Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow, including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and

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| 36905 | radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment |
| 36906 | Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty |
| 36907 | Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment |
| 36908 | Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty |
| 36908 | Transcatheter placement of intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment |
| HCPCS | |
| C7513 | Dialysis circuit, introduction of needle(s) and/or catheter(s), with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, with transluminal balloon angioplasty of central dialysis segment, performed through dialysis circuit, including all required imaging, radiological supervision and interpretation, image documentation and report |
| C7514 | Dialysis circuit, introduction of needle(s) and/or catheter(s), with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, with all angioplasty in the central dialysis segment, and transcatheter placement of intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all required imaging, radiological supervision and interpretation, image documentation and report |
| C7515 | Dialysis circuit, introduction of needle(s) and/or catheter(s), with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, with dialysis circuit permanent endovascular embolization or occlusion of main circuit or any accessory veins, |

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C7530 including all required imaging, radiological supervision and interpretation, image documentation and report
 Dialysis circuit, introduction of needle(s) and/or catheter(s), with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty and all angioplasty in the central dialysis segment, with transcatheter placement of intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging, radiological supervision and interpretation, documentation and report

ICD-10 Procedure

05790D1-057A4ZZ Dilation of brachial vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05790D1, 05790DZ, 05790Z1, 05790ZZ, 05793D1, 05793DZ, 05793Z1, 05793ZZ, 05794D1, 05794DZ, 05794Z1, 05794ZZ, 057A0D1, 057A0DZ, 057A0Z1, 057A0ZZ, 057A3D1, 057A3DZ, 057A3Z1, 057A3ZZ, 057A4D1, 057A4DZ, 057A4Z1, 057A4ZZ]

057B0D1-057C4ZZ Dilation of basilic vein [right or left, by approach and with or without device or drug-coated balloon, includes 057B0D1, 057B0DZ, 057B0Z1, 057B0ZZ, 057B3D1, 057B3DZ, 057B3Z1, 057B3ZZ, 057B4D1, 057B4DZ, 057B4Z1, 057B4ZZ, 057C0D1, 057C0DZ, 057C0Z1, 057C0ZZ, 057C3D1, 057C3DZ, 057C3Z1, 057C3ZZ, 057C4D1, 057C4DZ, 057C4Z1, 057C4ZZ]

057D0D1-057F4ZZ Dilation of cephalic vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 057D0D1, 057D0DZ, 057D0Z1, 057D0ZZ, 057D3D1, 057D3DZ, 057D3Z1, 057D3ZZ, 057D4D1, 057D4DZ, 057D4Z1, 057D4ZZ, 057F0D1, 057F0DZ, 057F0Z1, 057F0ZZ, 057F3D1, 057F3DZ, 057F3Z1, 057F3ZZ, 057F4D1, 057F4DZ, 057F4Z1, 057F4ZZ]

ICD-10 Diagnosis

All dialysis related situations, including the following diagnoses:
 N18.6 End stage renal disease
 N18.9 Chronic kidney disease, unspecified
 T82.590A-T82.591S Other mechanical complication of surgically created arteriovenous fistula, arteriovenous shunt
 T82.7XXA-T82.7XXS Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts
 T82.818A-T82.818S Embolism due to vascular prosthetic devices, implants and grafts
 T82.858A-T82.858S Stenosis of other vascular prosthetic devices, implants and grafts
 T82.868A-T82.868S Thrombosis due to vascular prosthetic devices, implants and grafts
 Z49.31 Encounter for adequacy testing for hemodialysis
 Z99.2 Dependence on renal dialysis

When services are Not Medically Necessary:

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For the procedure and diagnosis codes listed above related to dialysis access dysfunction when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

The maintenance of stenotic or thrombosed AVG or AVF for hemodialysis access has been a challenging undertaking for many years. Treatments for dysfunctional hemodialysis access include surgical thrombectomy and revision, and angiographic evaluation. Angiographic evaluation, also known as endovascular management, is the preferred initial treatment for dysfunctional hemodialysis access and yields better clinical outcomes compared to surgical treatment (ACR-SIR, 2017). It can be performed as angiography alone or with stent placement. An individual should be referred for angiographic evaluation when there are persistent abnormalities of surveillance (for example, flow measurements and static pressures), and clinical monitoring (for example, in AVGs: an absent thrill, discontinuous bruit, or edema in the extremity distal to the graft, problems noted during the dialysis session, such as difficulty with cannulation, aspiration of clots, inability to achieve the target dialysis blood flow, or prolonged bleeding from the needle puncture sites, or an unexplained decrease in the delivered dialysis dose [Kt/V] on a constant hemodialysis prescription; and in AVFs: persistent arm swelling, collateral veins, and altered features of the pulse or thrill, problems noted during the dialysis session, such as prolonged bleeding after needle withdrawal, or unexplained persistent decrease in Kt/V [for example, > 0.2 units]).

In 2007, Bakken and colleagues published a retrospective review of a database of consecutive hemodialysis individuals who underwent endovascular treatment for central venous stenosis. Primary angioplasty (PTA) (n=47) and primary stenting (PTS) (n=26) outcomes were assessed. The evaluators found that the initial endovascular treatment for stenosis had a technical success of 82% in the PTA group and 96% in the PTS group (p=0.08); however, residual stenosis occurred significantly more in the PTA group (53%) than the PTS group (7%; p<0.001). The data also showed that “primary patency was equivalent between groups by Kaplan-Meier analysis, with 30-day rates of 76% for both groups and 12-month rates of 29% for PTA and 21% for PTS (p=0.48)” (Bakken, 2007). While endovascular therapy with PTA or PTS for central venous stenosis in hemodialysis individuals is safe with low rates of technical failure, long-term clinical utility is poor.

Nael and colleagues reported on a retrospective review in 2009 that evaluated long-term outcomes of endovascular treatment of hemodialysis individuals with threatened upper extremity dialysis access (n=600). Out of the initial 600 individuals evaluated, 69 individuals (11%) were identified as having central veno-occlusive disease. In the 92 venous segments with stenosis, transverse angioplasty was performed in 88 segments and stenting was performed in 6 segments. The data showed an initial technical success rate of 90%, and primary patency rates of hemodialysis access of 81%, 46%, and 22% at 1, 6, and 12 months, respectively. This review showed endovascular treatment of hemodialysis individuals with central veno-occlusive disease was safe and had low technical failure, but long-term success was low. Larger randomized controlled trials are needed for further evaluation.

In a prospective, multicenter trial, Haskal and colleagues (2010) assessed stenting versus balloon angioplasty as endovascular treatment of venous anastomotic stenosis in failing hemodialysis grafts. Individuals were randomly assigned to either undergo balloon angioplasty alone (n=93) or balloon angioplasty plus placement of stent graft (SG) (n=97). At 6 months post-treatment, the authors found that “the incidence of patency of the treatment area was significantly greater in the SG group than in the balloon-angioplasty group (51% vs. 23%, p<0.001), as was the incidence of patency of the access circuit (38% vs. 20%, p=0.008)” (Haskal, 2010). It was also noted that the need

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for repeat interventions at 6 months was significantly less in the SG group compared with the balloon angioplasty group (32% vs. 16%, $p=0.03$). While this study showed better outcomes for clinical utility in stenting versus balloon angioplasty alone, the 6-month follow-up period was short and needs to be validated by studies with longer follow-up periods.

In 2015, Fu and colleagues released a meta-analysis that compared primary patency rates of stent placement versus angioplasty for dialysis vascular access stenosis. The literature search yielded 10 studies with a total of 860 individuals that met inclusion criteria, which were a measure of primary patency, secondary patency, or access dysfunction. There were four randomized studies, two nonrandomized studies, and four observational studies. The analysis of the studies showed significantly higher primary patency in individuals treated with stents than those treated with angioplasty (pooled relative risk [RR]=0.79; 95% confidence interval [CI]: 0.65-0.96). However, the results of this analysis are limited due to significant heterogeneity caused by varying types of access (AVF, AVG), lesions sites, and types of stents used in the included studies.

Also in 2015, Nassar and colleagues published an observational study that evaluated 520 cases (465 individuals) of thrombosed AVF treated by endovascular intervention. The study was comprised of two cohorts: retrospective cases ($n=404$) and prospectively studied cases ($n=116$). Thrombectomy clinical success was found in 91.9% of cases, and primary patency was 80.7%, 60.1%, 40.1%, 17.7%, and 0.06% at 30, 90, 180, 360, and 720 days, respectively. In addition, the authors found that “the lower arm AVFs had both a primary patency and an assisted primary patency that were significantly better than the upper arm cases ($p=0.006$ and 0.002 , respectively)” (Nassar, 2015). A limitation to this study was combining retrospective and prospective data for overall study results.

Haskal and colleagues (2016) reported on a prospective, randomized controlled trial that compared stent grafts (SG) and PTA for the treatment of AVG anastomotic stenosis of $\geq 50\%$. The 28-site study enrolled 270 individuals with 191 (71%) completing it (lost to follow-up: PTA=1, SG=1; withdrew consent: PTA=1, SG=1; death: PTA=36, SG=38). Individuals were randomized into either the SG group ($n=97$) or the PTA group ($n=94$). Primary outcomes were access circuit primary patency (ACPP), index of patency function (IPF), and adverse events of the SG group compared with the PTA group. The evaluators found procedural success to be 81.2% in the SG group compared to 75% for the PTA group. Long-term outcomes at 24 months post-procedure showed significant findings: ACPP was SG 9.5% versus PTA 5.5% ($p=0.01$), and IPF was SG 7.1 months/intervention \pm 7.0 versus PTA 5.3 months/intervention \pm 5.2. The data showed no significant differences in adverse events ($p>0.05$). The PTA group required reintervention due to restenosis for 82.6% of individuals versus 63% of individuals in the SG group ($p<0.001$). Additional large systematic reviews and meta-analyses have been performed that compared SG with plain balloon PTA. Success rates and patency outcomes have reflected superior more durable outcomes from use of SG than PTA alone (Karnabatidis, 2013; Kouvelos, 2018; Marmagkiolis, 2019).

The National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Vascular Access was updated in 2019 with a detailed review of the published evidence and a refocused approach based on an individualized P-L-A-N for each person, called the Patient Life-Plan first, followed by his or her corresponding access needs. Critical review of new more rigorous evidence has resulted in a de-emphasis on the need for AV access surveillance but a greater emphasis on the need for improved practitioner training and application of vascular access monitoring. The following is excerpted:

In clinical practice, many centers use surveillance techniques with the intention to detect early dysfunction in AVF and AVG with the premise that early identification and correction of stenosis

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may prevent clinically significant dysfunction, such as a thrombotic event. However, in clinical practice, it is difficult to predict which stenosis (anatomic abnormality) will progress into a clinically significant functional abnormality, such as an occlusive thrombosis. Intervening on stenosis that are clinically asymptomatic may lead to unnecessary interventions, and, subsequently, more interventions to maintain patency, which does not appear to be improved with pre-emptive intervention. Thus, given the evidence available from the literature, our recommendations are to intervene only on AVFs and AVGs that have clinically relevant dysfunction when detected on routine clinical monitoring (e.g. abnormal physical examination findings, low Kt/V without other cause, persistently inadequate blood flow rates to provide prescribed dialysis without other cause than the AV access, high venous pressure during dialysis, etc.). We do not recommend interventions in AVG and AVFs that do not have clinically significant dysfunction.

The updated NKF guideline provides the following recommendations:

Endovascular Intervention to Improve Patency:

- KDOQI does not recommend pre-emptive angioplasty of AVFs with stenosis, not associated with clinical indicators, to improve access patency. (Conditional Recommendation, Moderate Quality of Evidence);
- KDOQI does not recommend pre-emptive angioplasty of AVGs with stenosis, not associated with clinical indicators, to improve access patency. (Conditional Recommendation, Moderate Quality of Evidence)

Surgical Intervention to Improve Patency:

- There is inadequate evidence for KDOQI to make a recommendation on pre-emptive surgical interventions in AVFs with stenosis, *not associated with clinical indicators*, to improve access patency.
- KDOQI considers it reasonable for patients with consistently persistent clinical indicators and underlying AV access stenosis to undergo pre-emptive angioplasty of their AV access to reduce the risk of thrombosis and AV access loss. (Expert Opinion)

Angioplasty:

- KDOQI considers it reasonable to use balloon angioplasty (with high pressure as needed) as primary treatment of AVF and AVG stenotic lesions that are both clinically and angiographically significant. (Expert Opinion)

Note: Angiographically present stenosis without accompanying clinical signs and symptoms is inadequate to treat/intervene upon. For stenosis not associated with a clinical indicator, the data on AV access patency outcomes following intervention the evidence is unclear for treatment of AVF and the data for AVG does not demonstrate improved patency with surveillance and subsequent pre-emptive intervention, compared with routine clinical examination.

- There is inadequate evidence for KDOQI to make a recommendation regarding the use of specialized balloons (drug coated or cutting) versus standard high-pressure balloons in the primary treatment of AVF and AVG stenosis.

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In the updated guideline, surveillance is considered supplementary to routine monitoring of vascular access for dialysis with measurements (for example, change in access flow [Qa] or venous pressures).

Surveillance to Facilitate Patency

- There is inadequate evidence for KDOQI to make a recommendation on routine AVF surveillance by measuring access blood flow, pressure monitoring, or imaging for stenosis, that is additional to routine clinical monitoring, to improve access patency.

Note: In other words, monitoring of vascular access is primary, while surveillance findings are supplementary, and action should not be based solely on surveillance findings.

- KDOQI does not suggest routine AVG surveillance by measuring access blood flow, pressure monitoring, or imaging for stenosis, that is additional to regular clinical monitoring, to improve AVG patency. (Conditional Recommendation, Low Quality of Evidence)
- KDOQI considers it reasonable that when clinical monitoring suspects clinically significant AV access lesion (eg, stenosis), further timely and confirmatory evaluation should proceed, including imaging of the dialysis access circuit. (Expert Opinion)
- KDOQI considers it reasonable that when further confirmatory imaging studies reveal a culprit lesion responsible for clinical signs and symptoms, the clinically significant lesion is promptly treated. (Expert Opinion)

Note: A clinically significant lesion is one that contributes to clinical signs and symptoms without other cause (with or without a change in surveillance measurements, such as change in blood flow [Qa] or venous pressures) (Lok, 2020).

Stents

- KDOQI suggests the appropriate use of self-expanding stent-grafts in preference to angioplasty alone to treat clinically significant graft-vein anastomotic stenosis in AVG when the goal is overall better 6-month postintervention outcomes after carefully considering the patient's ESKD Life-Plan.* (Conditional Recommendation, Moderate Quality of Evidence)

Note: Appropriate use avoids cannulation segments.

Note: Overall better 6-month outcomes refer to reduced recurrent AVG restenosis ± improved patency.

- KDOQI considers it reasonable to first consider the consequences of placement of a stent-graft on future AV access options according to the patient's ESKD Life-Plan,* with consultation with the vascular access team if necessary, prior to its placement. (Expert Opinion)
- KDOQI suggests that the use of an appropriately placed stent-graft is preferred to angioplasty alone for the treatment of in-stent restenosis in AVG and AVF for overall better 6-month postintervention outcomes. (Conditional Recommendation, Moderate Quality of Evidence)

Note: Appropriate use avoids cannulation segments.

- KDOQI considers it reasonable to avoid the use of bare metal stents for the treatment of clinically and/or angiographically significant AVG and AVF stenotic lesions. (Expert Opinion)

General Treatment of Clinically Significant Stenosis or Thrombosed AV Access

- KDOQI considers it reasonable to use a careful individualized approach to the treatment of failing or thrombosed AVF and AVG (surgical or endovascular), based on the operator's best
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clinical judgment and expertise and considering the patient's ESKD Life-Plan.* (Expert Opinion)

***Note:** The End Stage Kidney Disease (ESKD) Life-Plan is a strategy for living with ESKD, ideally made together by the patient and a coordinated chronic kidney disease (CKD) management team. For the purposes of dialysis access, this team should include, but is not limited to, the following professionals and supportive members: nephrologist, surgeon, radiologist, nurse, patient family member, or other supporter. The ESKD Life-Plan is a strategy that should start in the predialysis period and encompasses a continuum-of-care model for CKD to ESKD. This chain of careful, continual consideration of modalities and dialysis access lifelines as it pertains to the individual patient's circumstances, needs, and preferences is the essence of the ESKD Life-Plan (Lok, 2020).

In 2017, the American College of Radiology and the Society of Interventional Radiology issued a practice parameter for endovascular management of the thrombosed or dysfunctional dialysis access. The following was recommended for endovascular management of the thrombosed or dysfunctional hemodialysis access (EMDA):

Indications for EMDA include, but are not limited to:

- Stenoses without thrombosis occurring in a hemodialysis graft or fistula if the stenosis is >50% reduction in luminal diameter and is considered functionally significant (see definitions above). The percent stenosis reported can vary considerably depending on the reference chosen, that is, the smaller graft or vein upstream to the lesion (relative to direction of blood flow) versus a larger vein downstream (relative to direction of blood flow). Percent stenosis may also be affected by the presence or absence of blood flow in the access at the time of measurement.
- Stenosis associated with thrombosis. Thrombosis is associated with underlying venous stenosis in >85% of cases.
- Central vein stenosis >50% lumen reduction, when the vascular access is hemodynamically compromised and clinical parameters such as arm swelling or frequently failing access are present. Endovascular intervention with transluminal angioplasty is the preferred treatment of central vein stenosis
- Autogenous fistulae that have failed to mature after 4 to 6 weeks. Treatments include:
 - Balloon angioplasty of the inflow artery, arteriovenous anastomosis, juxta-anastomotic segment, or outflow segments to increase blood flow to the native vein. Multiple areas of stenoses may exist in nonmaturing fistulae.
 - Interruption of venous tributaries that divert blood flow from the primary venous segment improves blood flow and thereby promotes maturation of the fistula.

Indications for endoluminal stent placement:

- Several studies have demonstrated acceptable patencies for stent deployment following unsuccessful balloon angioplasty, especially for central vein lesions. However, several prospective, randomized trials have failed to show a benefit of bare stents over percutaneous transluminal angioplasty alone in the treatment of perianastomotic stenoses. Current indications for endoluminal stent placement include:

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- Persistence of a significant venous stenosis that has failed balloon angioplasty and surgical access is difficult, surgery is contraindicated, or there are limited remaining access sites
- A significant central vein stenosis that has either failed balloon angioplasty or recurred within a 3- month period following an initially successful balloon angioplasty
- Rupture of an outflow vein following balloon angioplasty that cannot be controlled with balloon tamponade

Contraindications:

- The decision to treat a hemodialysis access with endovascular techniques is always made in light of the patient's clinical condition, the number of alternative access sites available, and the expertise of the treating physician.
 - Absolute Contraindications
 - Active infection of the vascular access
 - Relative Contraindications
 - Severe contrast allergy
 - Severe hyperkalemia, acidosis, or other life-threatening abnormality of blood chemistry that requires immediate dialysis
 - Known right-to-left shunt
 - Severe cardiopulmonary disease

Definitions

Angiography (also referred to as percutaneous transluminal angioplasty [PTA]): A therapeutic revascularization procedure that often follows the initial diagnostic imaging procedure. A small balloon is percutaneously placed at the site of the blockage and then inflated in order to reopen the vessel. Frequently a stent is also placed in the vessel to maintain the patency for blood flow.

AV access flow dysfunction: Refers to clinically significant abnormalities in AV access (AVF or AVG) flow or patency due to underlying stenosis, thrombosis, or related pathology. This is in distinction to other types of AV access complications. A clinically significant lesion is one that contributes to clinical signs and symptoms without other cause (with or without a change in surveillance measurements, such as change in blood flow [Qa] or venous pressures) (Lok, 2020).

Dialysis access circuit: Is defined as the continuum from the heart and the arterial inflow through the AV access to the venous outflow back to the heart.

Fistula: Autologous arteriovenous fistula is referred to as a native fistula. A mature fistula is referred to by the NKF as, "One that can provide prescribed dialysis consistently with 2 needles for more than two-thirds of dialysis sessions within 4 consecutive weeks." (Lok, 2020)

Stenosis: A narrowing in a blood vessel such as an artery. Stenosis within the AV access is thought to be reflected by reductions in AV access flow and alterations in AV access circuit pressures.

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Surveillance: The periodic evaluation of the vascular access by using device-based methods or tests that involve special instrumentation beyond clinical examination and for which an abnormal test result suggests the presence of thrombotic flow-related complications/dysfunction (Lok, 2020).

Thrombosis: The presence of blood clots in the blood vessels. Thrombotic flow-related complications or dysfunction are complications specifically related to the risk of, or occurrence of, thrombosis that leads to a clinically important reduction in intra-access flow that threatens the required access patency to achieve prescribed dialysis and/or results in clinical signs and symptoms (stenosis or thrombosis) (Lok, 2020).

Unassisted fistula (or unassisted AVF): An arteriovenous fistula that matures and is usable for dialysis without the need for endovascular or surgical interventions, such as angioplasty. A preplanned vessel superficialization is acceptable and not considered an additional intervention (Lok, 2020).

References**Peer Reviewed Publications:**

1. Bakken AM, Protack CD, Saad WE et al. Long-term outcomes of primary angioplasty and primary stenting of central venous stenosis in hemodialysis patients. *J Vasc Surg.* 2007; 45(4):776-783.
2. Chan PG, Goh GS. Safety and efficacy of the AngioJet device in the treatment of thrombosed arteriovenous fistula and grafts: A systematic review. *J Vasc Access.* 2018; 19(3):243-251.
3. Dukkipati R, Lee L, Atray N, et al. Outcomes of cephalic arch stenosis with and without stent placement after percutaneous balloon angioplasty in hemodialysis patients. *Semin Dial.* 2015; 28(1):E7-E10.
4. Fu N, Joachim E, Yevzlin AS, et al. A meta-analysis of stent placement vs. angioplasty for dialysis vascular access stenosis. *Semin Dial.* 2015; 28(3):311-317.
5. Garcia-Medina J, Maldonado-Carceles A, Garcia-Alfonso J, et al. Stent graft deployment in hemodialysis fistula: Patency rates in partially thrombosed aneurysm and residual thrombi. *Clinical Kidney Journal.* 2020; sfz193:1-6.
6. Haskal ZJ, Saad TF, Hoggard JG, et al. Prospective, randomized, concurrently-controlled study of a stent graft versus balloon angioplasty for treatment of arteriovenous access graft stenosis: 2-year results of the RENOVA study. *J Vasc Interv Radiol.* 2016; 27(8):1105-1114.e3.
7. Haskal ZJ, Trerotola S, Dolmatch B, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. *N Engl J Med.* 2010; 362(6):494-503.
8. Karnabatidis D, Kitrou P, Spiliopoulos S, et al. Stent-grafts versus angioplasty and/or bare metal stents for failing arteriovenous grafts: a cross-over longitudinal study. *J Nephrol.* 2013; 26(2):389-395.
9. Kouvelos GN, Spanos K, Antoniou GA, et al. Balloon angioplasty versus stenting for the treatment of failing arteriovenous grafts: A meta-analysis. *Eur J Vasc Endovasc Surg.* 2018; 55(2):249-256.
10. Marmagkiolis K, Iliescu C, Mallikarjuna M, et al. Primary patency with stenting versus balloon angioplasty for arteriovenous graft failure: A systematic review and meta-analysis. *J Invasive Cardiol.* 2019; 31(12):E356-E361.
11. Nael K, Kee ST, Solomon H, and Katz SG. Endovascular management of central thoracic veno-occlusive diseases in hemodialysis patients: a single institutional experience in 69 consecutive patients. *J Vasc Interv Radiol.* 2009; 20(1):46-51.
12. Nassar GM, Rhee E, Khan AJ, et al. Percutaneous thrombectomy of AVF: immediate success and long-term patency rates. *Semin Dial.* 2015; 28(2):E15-22.

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13. Polkinghorne KR, Lau KK, Saunder A, Atkins RC, et al. Does monthly native arteriovenous fistula blood-flow surveillance detect significant stenosis—a randomized controlled trial. *Nephrol Dial Transplant*. 2006; 21(9):2498-2506.
14. Shemesh D, Goldin I, Zaghal I, et al. Angioplasty with stent graft versus bare stent for recurrent cephalic arch stenosis in autogenous arteriovenous access for hemodialysis: A prospective randomized clinical trial. *J Vasc Surg*. 2008; 48(6):1524-1531, 1531.e1-e2.
15. Simoni E, Blitz L, Lookstein R. Outcomes of AngioJet® thrombectomy in hemodialysis vascular access grafts and fistulas: Pearl I Registry. *J Vasc Access*. 2013; 14(1):72-76.
16. Sivananthan G, Menashe L, Halin NJ. Cephalic arch stenosis in dialysis patients: Review of clinical relevance, anatomy, current theories on etiology and management. *J Vasc Access*. 2014; 15(3):157-162.
17. Vasanthamohan L, Gopee-Ramanan P, Athreya S. The management of cephalic arch stenosis in arteriovenous fistulas for hemodialysis: A systematic review. *Cardiovasc Intervent Radiol*. 2015; 38(5):1179-1185.

Government Agency, Medical Society, and Other Authoritative Publications:

1. ACR-SIR Practice Parameter for Endovascular Management of the Thrombosed or Dysfunctional Dialysis Access. Revised 2017. Available at: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Dysfunctional-DialysisMgmt.pdf?la=en>. Accessed on April 4, 2022.
2. Lok CE, Huber TS, Lee T, et al; National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. *Am J Kidney Dis*. 2020; 75(4)(suppl 2):S1-S164. Available at: <https://www.ajkd.org/action/showPdf?pii=S0272-6386%2819%2931137-0>. Accessed on April 4, 2022.
3. National Kidney Foundation Clinical Practice Guidelines and Clinical Practice Recommendations. 2006 updates. Clinical Practice Guidelines for Vascular Access. Guideline 6. Treatment of arteriovenous graft complications. Available at: https://www.kidney.org/sites/default/files/docs/12-50-0210_jag_dep_guidelines_va_oct06_sectionc_ofc.pdf. Accessed on April 4, 2022.

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 Angioplasty
 Endovascular Management
 Fistula
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 Percutaneous Transluminal Angioplasty
 Stent

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

| Status | Date | Action |
|--------|------------|--------------------------------------------------------------------------------------------|
| | 12/28/2022 | Updated Coding section with 01/01/2023 HCPCS changes; added C7513, C7514, C7515 and C7530. |

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|----------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Revised | 05/12/2022 | Medical Policy & Technology Assessment Committee (MPTAC) review. An example range for the Kt/V was removed from the MN criteria for the angiographic evaluation of AVF dysfunction for clarification. References were updated. |
| Revised | 05/13/2021 | MPTAC review. Administrative edits were made to the Clinical Indications section for clarification. Updated Discussion, Definitions and References sections. Reformatted Coding section. |
| Reviewed | 05/14/2020 | MPTAC review. Updated References section. |
| Revised | 06/06/2019 | MPTAC review. In Clinical Indications section, revised Medically Necessary criteria for angiographic evaluation for AVG and AVF dysfunction. Updated Discussion/General Information and References sections. |
| New | 01/24/2019 | MPTAC review. Initial document development. |

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