



pennsylvania

DEPARTMENT OF HEALTH

Dialysis Vascular and Peripheral Vascular Guidelines issued by the Department of Health for Exception 551.21(d)(1)(3)

Dialysis and Vascular Access* procedures performed in an ambulatory surgical facility/center (ASC) violate Department regulations, specifically §551.21(d), which states the limitations used to identify surgical procedures that may not be performed in an ASC. Therefore, ASCs must request an exception to the cited regulation from the Department. To request a Dialysis and/or a Peripheral Vascular Access Exception, the facility must submit policies and procedures that include Preprocedural and Physician Assessment Criteria, Physician Operator Criteria, Procedure Criteria, Facility Readiness Criteria, and Quality Monitoring Criteria which are detailed below.

Additionally, the Department has determined that vascular procedures that fall within the Department's guidelines and are currently on the Center for Medicare & Medicaid Services' (CMS) Ambulatory Surgical Center (ASC) Reimbursement List will be permitted to be performed in licensed ambulatory surgical facilities with an exception. It is the responsibility of your facility to make sure that the facility records are updated to reflect the procedures that are being performed and to ensure that the facility follows any changes that may occur with the ASC payment rate addendums. This includes ensuring that ASC procedures are updated quarterly in accordance with the ASC payment rates addendums disseminated by CMS. Any changes to your facility's procedures, based on a change in an ASC payment rate addendum, shall be relayed to the Department within ten (10) business days of the facility becoming aware that a procedure will no longer be offered.

The Department requires process and outcome tracking. Facilities are required to use a patient tracking method that includes documentation that a patient meets the five (5) areas outlined below.

*The scope of this guidance covers Dialysis Access and Peripheral Vascular procedures exclusively for the treatment of peripheral arterial disease.

I. Preprocedural and Physician Assessment

The following preprocedural screening must be completed and the criteria must be met for all patients prior to performing these procedures.

Dialysis Vascular	Peripheral Vascular
Weight must not exceed the manufacture’s maximum weight for the procedure table.	Weight must not exceed the manufacture’s maximum weight for the procedure table.
Must be an adult or must be of adult weight and height.	Must be an adult or must be of adult weight and height.
Airway must be adequate for urgent intubation and must have no pertinent history of airway access difficulty.	Airway must be adequate for urgent intubation and must have no pertinent history of airway access difficulty.
If sedation is used (either planned or unanticipated), the patient must be discharged to a responsible person.	If sedation is used (either planned or unanticipated), the patient must be discharged to a responsible person.
The facility’s tracking of benchmarks must be consistent or better those published national standards such as ASDIN, SIR, VQI or reporting into a QCDR as deemed by CMS clinical methodology. The results must be integrated into the peer review and QAPI program.	The facility must participate in a QCDR such as VQI, OEIS National IR Registry (or any other QCDR for peripheral vascular intervention). Results must be incorporated into the facility’s peer review and QAPI program.
The hemoglobin must not be less than 8 gm/dl and must be <u>stable</u> .	For non-renal patients, the hemoglobin must not be less than 10 gm/dl and must be <u>stable</u> . For renal patients, the hemoglobin must not be less than 8 gm/dl and must be <u>stable</u> .
No evidence of heart failure or orthopnea and the patient must be able to lie flat and safely tolerate the procedure.	No evidence of volume overload or orthopnea and the patient must be able to lie flat and safely tolerate the procedure.
No unstable cardiovascular issues. Cardiac rhythm that is a stable rhythm (such as NSR). If there is stable atrial fibrillation or atrial flutter, there must be a preprocedural EKG. If <u>stable</u> , the patient must be at least two weeks post-MI.	No unstable cardiovascular issues. Cardiac rhythm that is a stable rhythm (such as NSR). If there is stable atrial fibrillation or atrial flutter, there must be a preprocedural EKG. If <u>stable</u> , the patient must be at least two weeks post-MI.

Dialysis Vascular	Peripheral Vascular
Patient must be up-to-date on dialysis schedule or have had dialysis within 5 days.	Renal patients must be up-to-date on the dialysis schedule or have had dialysis within 5 days.
<p>No ulceration or infection of the access site, except in cases where the procedure is for the removal of an infected catheter. Surgical site infection is defined as:</p> <ul style="list-style-type: none"> • Positive blood cultures drawn within 72hrs of catheter implantation with no other reasonable source for the bacteremia. • Purulent drainage from the exit or incision (entry) site within 72hrs of catheter implantation 	No ulceration or infection of the access site. No active systemic infections.
N/A	Must have a documented non-invasive vascular study that shows peripheral vascular disease.
Directed History and Physical examination.	Directed History and Physical examination.
Review of current medication list and allergies.	Review of current medication list and allergies.
Review of vital signs, including oxygen saturation.	Review of vital signs, including oxygen saturation.
Evaluation of mental status / ability to cooperate with procedure.	Evaluation of mental status / ability to cooperate with procedure.
All pertinent lab work must be within 30 days of procedure.	Surgeon must obtain and review the following labs within 30 days of the procedure: PT/PTT, INR, BUN/CR, CBC.
<p>All operators must have current board certification in vascular surgery, or current board certification in interventional radiology, or current board certification in nephrology with appropriate society certification to perform maintenance dialysis procedures or otherwise board eligible with appropriate certification. If the operator cannot meet these criteria, please provide evidence to the department that you have formal training or tenured experience equal to or greater than the board certification and fellowship training from the organizations already listed.</p>	<p>All operators must have current board certification in vascular surgery, or current board certification in interventional radiology, or current board certification in cardiology with appropriate society certification to perform peripheral endovascular procedures or otherwise board eligible with appropriate certification.</p> <p>If the operator cannot meet these criteria, please provide evidence to the department that you have formal training or tenured experience equal to or greater than to the board certification and fellowship training from the organizations already listed.</p> <p>An interventional nephrologist would need to have formal training in PAD procedures that meet the standards set by SCAI, IR or Vascular Surgery.</p>

II. Physician Operator Criteria

Physicians performing the procedures must meet the following criteria:

Dialysis Vascular	Peripheral Vascular
<p>All operators must have current board certification in vascular surgery, or current board certification in interventional radiology, or current board certification in nephrology with appropriate society certification to perform maintenance dialysis procedures or otherwise board eligible with appropriate certification. If the operator cannot meet these criteria, please provide evidence to the department that you have formal training or tenured experience equal to or greater than the board certification and fellowship training from the organizations already listed.</p>	<p>All operators must have current board certification in vascular surgery, or current board certification in interventional radiology, or current board certification in cardiology with appropriate society certification to perform peripheral endovascular procedures or otherwise board eligible with appropriate certification.</p> <p>If the operator cannot meet these criteria, please provide evidence to the department that you have formal training or tenured experience equal to or greater than to the board certification and fellowship training from the organizations already listed.</p> <p>An interventional nephrologist would need to have formal training in PAD procedures that meet the standards set by SCAI, IR or Vascular Surgery.</p>

III. Procedure Definitions and Parameters

The following procedures can be performed within the parameters and/or definitions as follows:

Dialysis Vascular	Peripheral Vascular
<p>Hemodialysis Access: creation, revision, maintenance and surgical salvage of percutaneous grafts and fistulas. Creation of AVF/AVG is limited to the upper extremities and as approved by CMS for ASC setting:</p> <ul style="list-style-type: none"> • Catheter placement, exchange and removal, including tunneled catheters. 	<p>Peripheral vascular procedures on the lower extremity as approved by CMS for ASC setting.</p> <p>Planned vascular access size will be limited to sheath size no larger than 8 French sheaths, but larger sheaths can be used for rescue cases.</p>

Dialysis Vascular	Peripheral Vascular
<ul style="list-style-type: none"> • Grafts and Fistulas: maintenance and revision (no new surgical creation placement). • Percutaneous AV creation of AV graft and fistula • Angioplasty and thrombectomy stent placement, both peripheral and central vein angioplasty. • Vessel mapping 	
No open surgical femoral dialysis access (only percutaneous access is permitted).	The common femoral artery must not be the intended site of endovascular therapy but may be the site of access. If femoral artery is the site of access, no access above the inguinal ligament must be used.
Using combined SIR and ASDIN methods to categorize complications, the major complication less than 1%; the minor complication must be less than 5%.	Emergent transfer rate from ASC to hospital for procedure related complications must be less than 1%. Emergent transfer rate related to the procedure must be less than 3% within the first 72 hours.
Attending physician and nurse must be present until discharge of patient.	Attending physician and nurse must be present until discharge of patient.

IV. Facility Readiness Criteria

Dialysis Vascular	Peripheral Vascular
All attending nurses and physicians must have proof of ACLS course completion.	All attending nurses and physicians must have proof of ACLS course completion.
There must be three people who can attend in cases of emergency, the third person does not need to be a nurse or physician or ACLS trained. They must be accessible and physically located in the building until patient discharge.	There must be three people who can attend in cases of emergency, the third person does not need to be a nurse or physician or ACLS trained. They must be accessible and physically located in the building until patient discharge.
All clinical staff that have patient interaction must be Basic Life Support (BLS) certified.	All clinical staff that have patient interaction must be Basic Life Support (BLS) certified.

Dialysis Vascular	Peripheral Vascular
The facility must have a transfer agreement with an acute care hospital that has a board-certified vascular surgeon or a board-certified surgeon who is available during the ASC’s hours of operation and qualified to operate emergently and on-site to address a vascular emergency. Transfer protocols must otherwise have established plans for treatment of complications.	The facility must have a transfer agreement with an acute care hospital that has a board-certified vascular surgeon or a board-certified surgeon who is available during the ASC’s hours of operation and qualified to operate emergently and on-site to address a vascular emergency. Transfer protocols must otherwise have established plans for treatment of complications.
Retention of radiological images sufficient both to demonstrate the medical necessity of procedures and to document results.	Retention of radiological images sufficient both to demonstrate the medical necessity of procedures and to document results.
All devices must be FDA approved or approved for use in an FDA approved study with proper consents.	All devices must be FDA approved or approved for use in an FDA approved study with proper consents.

V. Quality Monitoring Criteria

Facilities that are granted an exception are required to submit data quarterly to the Department. The provider will be required to use a Vascular Access Tracking Spreadsheet, which will be supplied by the Department. The spreadsheet will include the following:

Dialysis Vascular	Peripheral Vascular
Bleeding requiring transfusion within 48hrs of procedure	NA
Arterial complication rate following arteriovenous access procedure.	NA
Arteriovenous graft thrombectomy success rate. Success is defined as being able to run a complete treatment at the next dialysis.	NA
All complication rates are to be broken down into two categories based on the SIR classification system ¹ . SIR major and minor complications are to be further broken down into Grades 1-4	All complication rates are to be broken down into two categories based on the SIR classification system ¹ . SIR major and minor complications are to be further broken down into

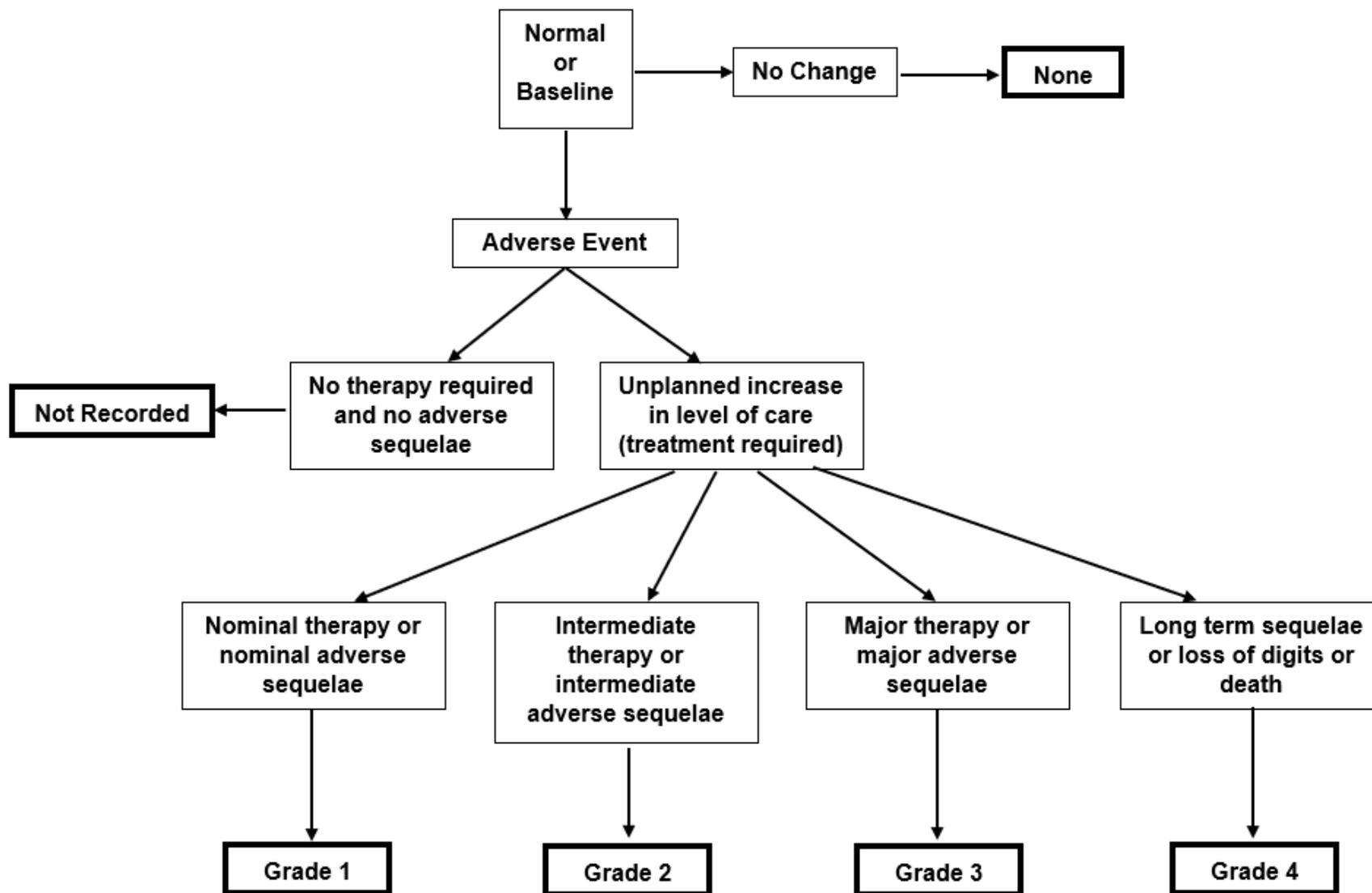
¹ Vedantham,S et al.” Treatment of Lower-Extremity Deep Vein Thrombosis with Use of Endovascular Thrombus Removal ”, J VAS Interventional Radiol 2014: 25:1317-1325 Appendix C.

Patel N Et al.” Percutaneous Management of Acute Lower-extremity Ischemia”, J Vasc Interv Radiol 2013 24:3-15 Appendix C

Dariushnia S Et.al “Percutaneous Image-Guided Management of the Thrombosed or Dysfunctional Dialysis Circuit”,J Vasc Inter Radiol 2016 27:1518-1530.

Dialysis Vascular	Peripheral Vascular
using the ASDIN classification system (see chart at end of document). Must include a list of all complications broken out by type.	Grades 1-4 using the ASDIN classification system (see chart at end of document). Must include a list of all complications broken out by type.
When using fluoroscopy, RPAK values greater than or equal to 1 gray shall be reported to the Department. Documentation that peer review has occurred must be included in the report.	When using fluoroscopy, RPAK values greater than or equal to 1 gray shall be reported to the Department. Documentation that peer review has occurred must be included in the report.
<p>Surgical site infection rate for endovascular procedures. Surgical site infection is defined as:</p> <ul style="list-style-type: none"> • Positive blood cultures drawn within 72hrs of catheter implantation with no other reasonable source for the bacteremia. • Purulent drainage from the exit or incision (entry) site within 72hrs of catheter implantation 	Surgical site infection rate.
N/A	Participation in an approved, audited Endovascular Registry that is QCDR certified by CMS. Provide quality measures comparable to the VQI measures in a report to the Department.
The facility will follow the patient for 72 hours after discharge and report all serious events occurring within that timeframe to PA PSRS.	The facility will follow the patient for 72 hours after discharge and report all serious events occurring within that timeframe to PA PSRS.
Any event resulting in patient death within 30 days following a procedure or administration of anesthesia/sedation by the facility must be report to PA PSRS.	Any event resulting in patient death within 30 days following a procedure or administration of anesthesia/sedation by the facility must be report to PA PSRS.
Total number of procedures broken down by type.	Total number of procedures broken down by type.

ASDIN Classification System



Key Terms

- ACLS - Advanced Cardiac Life Support
- ASC – Ambulatory Surgical Center; and ASF reflect regulatory language from the source documents, but for the purpose of this document they are synonyms.
- ASDIN - American Society of Diagnostic and Interventional Nephology
- AVF - Arteriovenous Fistula
- AVG - Arteriovenous Graph
- BUN - Blood Urea Nitrogen
- CMS - Centers for Medicare and Medicaid Services
- CR – Creatinine
- DAP - Dosimetry Kerma-air product
- IR - Interventional Radiology
- Kerma - Kinetic energy released per unit mass.
- OEIS - Outpatient Endovascular and Interventional Society
- PAD - Peripheral Arterial Disease
- PA PSRS - Pennsylvania Patient Safety Reporting System
- QAPI - Quality Assurance and Performance Improvement
- QCDR - Qualified Clinical Data Registry (deemed by CMS Clinical methodology)
- RPAK – Reference Point Air Kerma**
- SCAI - Society for Cardiovascular Angiography and Intervention
- SIR - Society of Interventional Radiology
- VQI - Vascular Quality Initiative

**May also be known as Air Kerma at the Interventional Reference Point.