Contractor Name
Wisconsin Physicians Service (WPS)

Contractor Number
00951, 00952, 00953, 00954

Contractor Type
Carrier

LCD Database ID Number

LCD Version Number

LCD Title
Dialysis Shunt Maintenance

Contractor's Determination Number
CV-027

AMA CPT/ ADA CDT Copyright Statement

CMS National Coverage Policy

CMS Internet Only Manuals
102 - 11, § 80
102 - 11, § 80.2
102 - 11, § 130.1
104 - 4, 8 § 140.1-140.2

Program Memorandum: AB-00-44; AB-00-55; B-01-28; AB-01-129; AB-01-129.1

Formerly:
Medicare Carriers Manual: 2230-2230.5, 2231.4; 4272-4275.2; 15060.1
Coverage Issue Manual, Section 50-32 allows coverage for a (PTA) of arterio-venous dialysis fistulae and grafts.

Primary Geographic Jurisdiction
Wisconsin, Illinois, Michigan, Minnesota

Oversight Region
Region V

CMS Consortium
Midwest

Original Determination Effective Date
Wisconsin: 12/01/97; 12/01/99
Illinois: 07/15/1997

Michigan: 04/15/1997
Minnesota: 12/15/2003

Revision Effective Date
Wisconsin: 12/15/2003
Illinois: 12/15/2003
Michigan: 12/15/2003
Minnesota: N/A

Indications and Limitations of Coverage and/or Medical Necessity

LCD Description
Arteriovenous fistula (cannula, shunt) declotting or interventions to restore and/or maintain functional patency may encompass a number of open surgical or percutaneous procedures. A fistula may either demonstrate compromised flow presaging occlusion, or it may have recently thrombosed. The objective is to restore appropriate flow, preserve the fistula's functional integrity, and avoid the need to create a new fistula.

Definitions:

Arteriovenous (AV) fistula: An abnormal communication between an artery and a vein; in this instance, a surgically created communication to facilitate chronic hemodialysis. The interposed conduit may be autogenous vessel or synthetic material. (Brescia-Cimino, polytetrafluoroethylene [PEFE], straight or loop, etc.).

Percutaneous transluminal angioplasty (PTA): An invasive procedure which, when successful, culminates in the enlargement of a vascular lumen. Typically, a balloon-tipped catheter is introduced into the stenosed vessel. Inflation of the balloon at the site of vascular narrowing can result in sustained luminal enlargement.

Thrombolysis: Pharmacologic and/or mechanical dissolution of a thrombus or blood clot.
Infusion: Continuous intravenous administration of a medication containing solution lasting longer than thirty (30) minutes. Bolus injections are not considered infusions, regardless of the time required to inject the solution.

Shunt: An arteriovenous conduit

Percutaneous interventions to enhance or re-establish patency of a hemodialysis AV fistula have proven useful in extending the life of the fistula, reducing the need for open repair, reconstruction or replacement. The longevity and quality of life of the ESRD patient are positively impacted
Percutaneous AV fistula declotting, maintenance or re-establishment of appropriate and adequate flow may encompass the following procedures:
- Access by introduction of either needle or vascular sheath into the AV shunt (e.g., 36145)
- Mechanical and/or pharmacologic maneuvers to promote dissolution, fragmentation and/or removal of obstructing thrombotic materials e.g., 36860, 36861).

PTA may be necessary if, after removal of thrombotic material, flow remains inadequate and examination and/or angiography demonstrates residual, hemodynamically significant, impediment to flow that is caused by other than thrombotic material. Residual hemodynamically significant flow impairment may be demonstrated within the AV fistula, at either anastomotic junction or more remotely in the artery or vein providing the fistula's inflow and outflow (e.g., 35475, 35476).

Therapeutically directed angiography (e.g., 75710, 75790). These need not all be performed on every dysfunctional shunt. Each may, under unique circumstances, be considered reasonable and medically necessary

Open surgical therapy for thrombosed dialysis cannulae or hemodynamically significant flow impediment utilizes direct access to the conduit and contiguous vessels. Mechanical fragmentation and surgical removal of occlusive thrombotic material is effected under direct visualization. Adjunctive thrombolytic pharmacotherapy may be employed. Residual vascular stenoses or obstructive lesions are removed and corrected using standard vascular surgical techniques (e.g., 36832, 36834). Angiography is adjunctively employed, when appropriate and medically necessary, to assess the functional integrity of afferent and efferent vessels remote from the surgical field

Indications and Limitations of Coverage and/or Medical Necessity
Evaluation of shunt function:

1. Typically, the clinical examination provides adequate information to determine whether there is hemodynamically significant dialysis shunt dysfunction. The following clinical findings are considered diagnostically specific and appropriate indications to initiate therapies to re-establish physiologically appropriate flow in the dialysis fistula

    a. Venous outflow impediment:
        i. Elevated venous pressure in the graft
        ii. Elevated venous/arterial ratio (static venous pressure ratio - above 40%)
        iii. Prolonged bleeding following needle removal
        iv. Inefficient dialysis
        v. Recirculation percentage greater than 10-15%
        vi. Development of pseudoaneurysms
        vii. Swelling of the extremity
        viii. Large collateral venous channels
        ix. Loss of "machine-like" bruit, i.e., short sharp bruit
        x. Abnormal physical findings, specifically pulsatile graft or loss of thrill

    b. Arterial inflow impediment:
        i. Low pressure in graft even when outflow is manually occluded
        ii. Ischemic changes of the extremity (steal syndrome)
        iii. Diminished intra-access flow

    c. Extremity Arterial Venous Studies (CPT-4 Code 93990)
    - Additional duplex studies of this area are not covered in addition to this code.

    d. The consistent monitoring of dialysis access is an essential element in the quality of care provided to the patient on dialysis. This routine evaluation and monitoring is considered valuable but is included in the composite rate paid to the dialysis facility by Part A and or the monthly capitation payment paid to the physician.

    e. See policy CV033 for more information on non-invasive vascular testing as well as information on initial autogenous graft placement assessment.

Treatment of shunt malfunction

1. PTA of the dialysis conduit and/or afferent and efferent vessels is not necessary for all shunt dysfunction situations. Coverage will be considered if there is documentation supporting the

presence of residual, hemodynamically significant flow restriction after any previous interventions. There must be clear documentation of the site and extent of any hemodynamically significant, stenosis. This documentation may be subjected to medical necessity review.

2. Subject to FDA approval of specific devices, stents are covered if used as a last resort to salvage a graft or fistula. Placement of an intravascular stent (e.g. 37205-37206) and the associated supervision and interpretation (75960) may be appropriate in selected clinical scenarios. The following clinical scenarios are examples where a stent may be considered for payment:
    - There is a PTA induced rupture,
    - For graft salvage,
    - For central veins stenosis or occlusion,
    - Surgical revision is not a viable option,
    - There is contraindication to surgery,
    - There are limited residual access sites,
    - There are surgically inaccessible lesions.

    See Policy CV 028 for coverage of non-coronary vascular stents.

Limitations

1. The dispersing, maceration, and removal of thrombotic material are an integral part of cannula/shunt/fistula declotting or revision (36860, 36861, 36831, 36832, 36833 and 36870). It is not to be interpreted, or coded, as thrombectomy.

2. Intermittent boluses of anticoagulant or thrombolytic agents are integral to and included in the percutaneous thrombectomy of a dialysis access (36870) and are not separately coded. However, if a thrombus is present outside the graft and requires separately identifiable thrombolytic therapy, this portion of the procedure would be separately coded using 37201 and 75896 plus the appropriate catheterization code(s). This therapy typically involves additional selection of the vessel involved, negotiation of an infusion catheter into the thrombus and prolonged infusion of drug to dissolve the clot.

3. In the absence of clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, it is seldom reasonable and necessary to perform diagnostic angiography or sonographic confirmatory studies as part of the decision to treat (i.e., 75710, 75790, 75820. It is included in the monthly composite rate paid to the physician.

    *Declotting by thrombolytic agent of implanted vascular access device or catheter (*36593). This code reports declotting of completely implanted devices and catheters. This code is not to be used for routine flushing of vascular access devices with saline or heparin.
    This procedure necessitates the use of a thrombolytic agent (e.g., Urokinase) that is introduced through a syringe and then slowly instilled into the device or catheter. (Generally considered to be a single bolus of thrombolytic agent.)

4. If the central catheter is checked with fluoroscopy alone (not a port check but injection into central veins), either with injection of contrast or without, a fluoro code (76000) would be appropriate.
    The injection of contrast material is not separately reportable and is inherent to the RS&I study.

5. Non-covered Conditions:

a. Total occlusion of graft due to thrombus of more than one year in duration (for percutaneous interventions).
b. Medical record (e.g., procedure report) that does not verify that the services described by the submitted CPT codes were provided and/or medically necessary.
c. Services that are screening in nature (that are not providing clinically relevant information).
d. The placement of stent(s) in a vessel(s) for which there has been no objective symptoms or limitation of function is considered to be preventive, and therefore not covered by Medicare.

Benefit Category:
Physicians' Services

Coverage Topic
Category Undefined

CPT/HCPCS Codes

35473	Transluminal balloon angioplasty, percutaneous, iliac
35474	Transluminal balloon angioplasty, percutaneous; femoral popliteal
35475	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
35476	Transluminal balloon angioplasty, percutaneous, venous
35903	Excision of infected graft extremity
36005	Injection procedure for extremity venography (including introduction of needle or catheter)
36010	Introduction of catheter, superior vena cava
36120	Introduction of needle or intracatheter, retrograde brachial artery
36140	Introduction of needle or intracatheter, extremity artery
36145	Introduction of needle or intracatheter; arteriovenous shunt created for dialysis (cannula, fistula, or graft)
36215	Selective catheter placement arterial system each first order thoracic or brachiocephalic branch within a vascular family
36216	Selective catheter placement arterial system; initial second order thoracic or brachiocephalic branch within a vascular family
36217	Selective catheter placement arterial system initial third order or more selective thoracis or brachiocephalic branch within a vascular family
36218	Selective catheter placement arterial system; additional second order, third order and beyond, thoracic or brachiocephalic branch within a vascular family (list in addition to code for initial or second or third order vessels as appropriate.
36245	Selective catheter placement arterial system; each first order abdominal or pelvic or lower extremity artery branch within a vascular family
36246	Selective catheter placement arterial system, second order abdominal, pelvic, or lower extremity artery branch within a vascular family
36247	Selective catheter placement arterial system; initial third order or more selective abdominal, pelvic or lower extremity artery branch within a vascular family
*36593	Declotting by thrombolytic agent of implanted vascular access device or catheter
36831	Thrombectomy, open arteriovenous fistula without revision, autologous or non-autologous dialysis graft, (separate procedure)
36832	Revision, open, arteriovenous fistula, without thrombectomy, autogenous or non-autogenous dialysis graft (separate procedure).
36833	Revision, open, arteriovenous fistula with thrombectomy, autogenous or non-autogenous

	dialysis graft (separate procedure)
75820	Venography, extremity, unilateral, Radiological supervision and interpretation
75822	Venography, extremity, bilateral, radiological supervision and interpretation
75825	Venography, caval, inferior with serialography, radiological supervision and interpretation
75827	Venography, caval, superior with serialography, radiological supervision and interpretation
75896	Transcatheter therapy, infusion any method (e.g. thrombolysis other than coronary) radiological supervision and interpretation
75962	Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation
75964	Transluminal balloon angioplasty, each additional peripheral artery, radiological supervision and interpretation (list separately in addition to code for primary procedure)
75978	Transluminal balloon angioplasty, venous (e.g. subclavian stenosis), radiological supervision and interpretation
76000	Fluoroscopy (separate procedure), up to one hour physician time
J0350	Injection, ANISTREPLASE, per 30 units
J2993	Injection, RETEPLASE, 18.1 mg
J2997	Injection, ALTEPLASE RECOMBINANT, 1 mg

Does the CPT 30% Rule Apply
No

ICD-9 Codes that Support Medical Necessity
Note: ICD-9 codes must be coded to the highest level of specificity.

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Diagnoses that DO NOT Support Medical Necessity

Documentation Requirements
Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Angiographic/ultrasound report studies may be required to document the need for angioplasty of arterial and venous vessels at the same setting.

The operative report and medical record must document the services reported and be made available to Medicare upon request

Utilization Guidelines

1. For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare's possible denial of payment. A waiver of liability should be signed when a provider/supplier does not want to accept financial responsibility for the service.
2. Services performed for percutaneous interventions to treat total occlusion of graft due to thrombus of more than one year in duration will be denied as not reasonable and medically necessary.

3. Angioplasty of vessels not documented to be significantly stenosed by angiography or ultrasound will be denied.
4. Dilatation of both limbs of the fistula will be denied unless significant obstruction is documented in both limbs.
5. Dilation of the graft anastomotic site will be considered either arterial or venous but not both.
6. Procedure codes 35475 and 35476 performed on the same day will be denied without documentation of anatomically separate lesions. Code 35475 may be reported for angioplasty of an inflow lesion that is proximal to the graft while 35476 may be reported for PTA of the venous anastomosis and/or venous outflow. 35475 and 35476 should not be reported on the same day for the graft alone since it is considered a single vessel for the purposes in this policy.
7. Services performed with excessive frequency will be denied as not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and reasons for additional services are not justified by documentation.

Sources of Information and Basis for Decision

Other Carrier policies including Empire
DOQI Clinical Practice Guidelines
Standard of Practice, Quality Improvement Guidelines for Percutaneous Management of the Thrombosed or Dysfunctional Dialysis Access, The society of Cardiovascular & Interventional Radiology as reported in JVIR, April 1999. http://www.scvir.org/clinical
Percutaneous intervention to Support Failing Hemodialysis Fistulas and Grafts, Kidney Blood Press Res 1997;20:145-147 by Dierk Vorwerk, M.D.
Percutaneous Intervention for Permanent Hemodialysis Access: A Review, by Richard J. Gray, MD, SCVIR, May-June 1997
Reporting Standards for Percutaneous Intervention in dialysis Access, special communication by R. J. Gray MD, D. Sacks, MD, L. G. Martin MD, and the member of Technology Assessment Committee, November-December 1999 JVIR.
Intervention Based on Monthly Monitoring Decreases Hemodialysis Access Thrombosis, Jeffrey J. Sands, Patti A. Jabyac, Carol L. Miranda and Brian Kapsick, ASAIO Journal 1999; 45:147-150.
Patency of Wallstents Placed across the Venous Anastomosis of Hemodialysis Grafts after Percutaneous Recanalization by R. Patel, MD, S. Peck MD, S. Cooper, MD, D. Epstein, MD, C. T. Sofocleous, MD, I. Schur, MD, A. Falk, MD, November 1998
Treatment of Hemodialysis-related Central Venous Stenosis or Occlusion: Results of Primary Wallstnet Placement and Follow-up in 50 patients., by P. Haage, Md, D. Vorwerk, MD, W. Piroth, MD, K. Schuermann, MD, R. Guenther, MD , July 1999.
Endovascular Stent Placement for Angioplasty-induced Venous Rupture Related to the Treatment of Hemodialysis Grafts by A. Welber, MD, MS, I. Schur, MD, C. Sofocleous, MD, S. Cooper, MD R. Patel, MD, S. Peack, MD, SCVIR 1999.
Surgical Care of the Arteriovenous Graft: Issues for the Interventionalist by Gary. A. Gelbfish, MD, FACS, Techniques in Vascular and Interventional Radiologyk, Vol 2, No 4, (December), 1999: pp 179-185
Assessing the Adequacy of Vascular Access and Its Relationship to Patient Outcome, By Steve J. Schwab, MD in American Journal of Kidney Diseases, Vol 24, No 2 (August), 1994: pp 316-320.

Advisory Committee Meeting Notes

Meeting Date:
Wisconsin: 05/16/2003
Illinois: 05/28/2003

Michigan: 05/07/2003
Minnesota: 05/08/2003

Start Date of Comment Period
Wisconsin: 05/28/2003; 05/30/97
Illinois: 05/28/2003; 10/09/1996
Michigan: 05/28/2003; 10/09/1996
Minnesota: 05/28/2003

End Date of Comment Period
07/15/2003

Start Date of Notice Period
(Published)
Wisconsin: 11/01/97; Article 11/01/99; 11/01/2003;04/01/2005; *01/01/2008
Illinois: NA; 04/01/2001; 05/01/2002-added CPT code 90939; 11/01/2003;04/01/2005; *01/01/2008
Michigan: NA; 04/01/2001; 05/01/2002-added CPT code 90939; 11/01/2003; 04/01/2005; *01/01/2008
Minnesota: 11/01/2003; 04/01/2005; *01/01/2008

Revision History Number/Explanation
Wisconsin: 10/01/1999, one; 01/01/2002-two; 12/15/2003, three; 03/01/2005 (converted to LCD), four; *01/01/2008 (HCPCS update, Code 36593 replaced code 36550)
Illinois: 01/15/1998, one; 01/01/2002-two; 12/15/2003, three; 03/01/2005 (converted to LCD), four; *01/01/2008 (HCPCS update, Code 36593 replaced code 36550)
Michigan: 01/15/1998, one; 01/01/2002-two; 12/15/2003, three; 03/01/2005 (converted to LCD), four; *01/01/2008 (HCPCS update, Code 36593 replaced code 36550)
Minnesota: 12/15/2003, one; 03/01/2005 (converted to LCD), two; *01/01/2008 (HCPCS update, Code 36593 replaced code 36550)

Last Reviewed On
12/15/2004

Notes
* - An asterisk indicates a revision to that section of the policy.
There is a coding document associated with this policy.

Does this LCD contain a "Least Costly Alternative" Provision?
No