

Endovascular AAA Stent Grafts Inpatient Reimbursement Reference Guide

These suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The provider of services is ultimately responsible for correct coding.

Physician Coding for Inpatient Procedures: Endovascular Repair of the AAA

The following CPT codes will be paid as inpatient procedures ONLY.

Procedure	CPT Code	CPT Code Description	CPT Code for Radiologic S & I
Bilateral open femoral exposure	34812 Modifier options:* -50 (bilateral) -62 (co-surgeons) -80 (asst. surgeon)	Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral	
Catheter placement in aorta from both groins	36200	Introduction of catheter, aorta	
Deploy stent graft (bifurcated and one contralateral limb)	34802 Modifier options:* -62 (co-surgeons) -80 (asst. surgeon)	Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using modular bifurcated prosthesis (one docking limb)—90-day global period Note: All PTA/stenting within target zone of graft is included in this code	75952 Endovascular repair of infrarenal abdominal aortic aneurysm or dissection, radiological supervision and interpretation Modifier options:* -26 (professional component)
Placement of additional proximal or distal extension cuff—initial vessel	34825 Modifier options:* -62 (co-surgeons) -80 (asst. surgeon)	Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, or dissection; initial vessel—90-day global period	75953 Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal aortic or iliac artery aneurysm, pseudoaneurysm, or dissection, radiological supervision and interpretation Modifier options:* -26 (professional component)
Placement of additional proximal or distal extension cuff—each additional vessel	34826 Modifier options:* -62 (co-surgeons) -80 (asst. surgeon)	Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, or dissection; each additional vessel (list separately in addition to code for primary procedure)	75953 Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal aortic or iliac artery aneurysm, pseudoaneurysm, or dissection, radiological supervision and interpretation Modifier options:* -26 (professional component)

Hospital Inpatient Coding: Endovascular Repair of the AAA

Definition	Code	Nomenclature
ICD-9 diagnosis code	441.4	Abdominal aortic aneurysm without mention of rupture
ICD-9 surgical code	39.71	Endovascular implantation of graft in abdominal aorta
Related MS-DRGs	237	Major cardiovascular procedures with MCC or thoracic aortic aneurysm (TAA) repair
	238	Major cardiovascular procedures without MCC
HCPCS (C-Code)	N/A	The procedure associated with this device is approved in the inpatient setting only. C-Codes are reported with device-dependent procedures on outpatient claims; therefore no C-Code applies

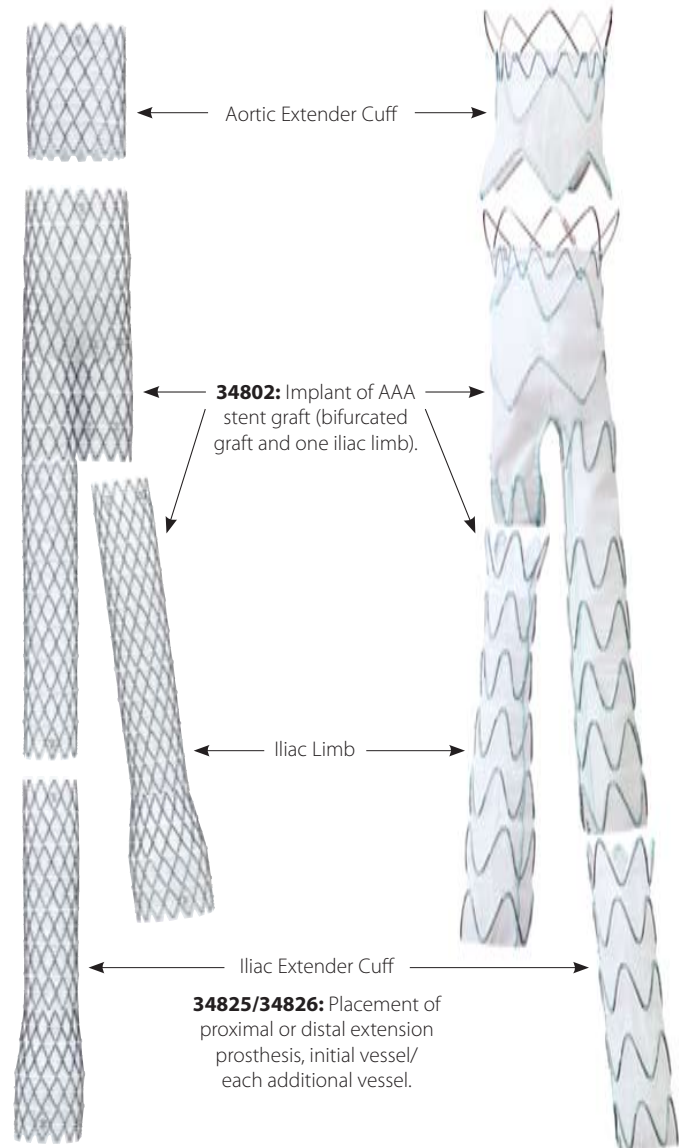
*Other coding modifiers could possibly be used. The options listed here are common ones used with these CPT codes.

Utilizing CPT Codes with the Medtronic AAA Stent Grafts

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AneuRx AAAAdvantage® Stent Graft

TALENT™ Abdominal Stent Graft



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AneuRx AAA Advantage® Stent Graft System

Indications

The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- Adequate iliac/femoral access
- Infrarenal nonaneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10-20% smaller than the labeled device diameter
- Morphology suitable for endovascular repair
- One of the following:
 - Aneurysm diameter of > 5 cm
 - Aneurysm diameter of 4-5 cm which has also increased in size by 0.5 cm in the last 6 months
 - Aneurysm which is twice the diameter of the normal infrarenal aorta.

Contraindications

There are no known contraindications currently associated with this device.

Warnings and Precautions

FDA approval of the AneuRx device on September, 28, 1999 was based upon one-year follow-up data. The clinical information in this Brief Statement has been updated from the information originally submitted to the FDA for approval to include updated clinical information available to Medtronic as of August 1, 2003 (the clinical data freeze date for the 2003 PMA Annual Report).

THE ANEURYSM STENT GRAFT IS INTENDED TO PREVENT RUPTURE OF ABDOMINAL AORTIC ANEURYSMS. HOWEVER, THIS RISK IS NOT COMPLETELY ELIMINATED. BASED ON REPORTS RECEIVED FOR PATIENTS ENROLLED IN ALL PHASES OF THE CLINICAL STUDY, THROUGH AUGUST 1, 2003, RUPTURES HAVE OCCURRED IN 2/1193 (0.167%) PATIENTS DURING THE OPERATIVE PERIOD; IN 3/1193 (0.251%) PATIENTS WITHIN 30 DAYS OF TREATMENT; AND IN 15/1193 (1.257%) PATIENTS GREATER THAN 30 DAYS AFTER TREATMENT. THE ONE-YEAR FREEDOM FROM RUPTURE RATE FOR PATIENTS ENROLLED IN ALL PHASES OF THE CLINICAL STUDY IS 99.5%; THE TWO-YEAR FREEDOM FROM RUPTURE RATE IS 98.6%; THE THREE-YEAR FREEDOM FROM RUPTURE RATE IS 98.5%; THE FOUR-YEAR FREEDOM FROM RUPTURE RATE IS 97.2%; AND THE FIVE-YEAR FREEDOM FROM RUPTURE RATE IS 97.2%.

The long-term safety and effectiveness of this implant have not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

Exercise care in the handling and delivery technique to aid in the prevention of vessel rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of nonaneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

- Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle > 45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle < 45 degrees. The same data indicate that patients with an aortic seal length of < 15 mm and an iliac seal length of < 25 mm may also have a higher likelihood of suboptimal outcomes.
- This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.
- Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.
- The results of the clinical studies indicated that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to surgical Abdominal Aortic Aneurysm (AAA) repair, are likely to have increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues, and mortality).
- The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms have not been evaluated in patients:
 - With aneurysms pending rupture
 - With connective tissue disorder
 - With hypercoagulability
 - With mesenteric artery occlusive disease
 - With ilio-femoral, thoracic, or inflammatory aneurysms

- With juxtarenal AAA
- With pararenal AAA
- With suprarenal or thoracoabdominal aneurysms
- Who are morbidly obese
- Pregnant or nursing
- Less than 18 years old
- With less than one-year life expectancy
- Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

Patient Selection, Treatment and Follow-Up

- Do not use this device in patients having an active systemic infection.
- Do not use this device in patients with sensitivities or allergies to the device materials. The materials include: polyether block amide (PEBA); polyether block amide (PEBA) with tungsten filler; polyether block amide (PEBA) with barium sulfate filler; acrylonitrile-butadiene-styrene (ABS) copolymer; glass-filled acrylonitrile-butadiene-styrene (ABS) copolymer; polyetheretherketone (PEEK); polyvinyl chloride (PVC); stainless steel; ethylene propylene rubber; Nylon; silicone; polycarbonate; cyanoacrylate; nickel/titanium (nitinol); tantalum; and polyester. The AneuRx Stent Graft with Xcelent Delivery System is latex-free.
- The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.
- The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively.
- Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight exceeds 350 lb (150 kg) or whose weight may impede accurate fluoroscopic imaging.
- Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations). During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks, and device integrity.
- Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:
 - Aneurysm growth > 5 mm (with or without leak) since last follow-up
 - Change in aneurysm pulsatility (with or without growth or leak)
 - Persistent endoleak with or without aneurysm growth
 - Stent graft migration resulting in an inadequate seal zone
- The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.
- Non-clinical testing has demonstrated that the AneuRx Stent Graft is MR Conditional. It can be scanned safely under the following conditions:
 - Static magnetic field of 3-Tesla or less
 - Spatial gradient field of 720 Gauss/cm or less
 - Maximum whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

Adverse Events

Death, AAA rupture, bleeding, cardiac failure/infarction, edema, wound healing complications, impotence, pulmonary complications, renal failure, gastrointestinal complications, arterial vascular occlusion, and venous vascular occlusion.

Potential adverse events include: arterial and venous occlusion (includes thrombosis and thromboembolism), arterial trauma/dissection/perforation, bleeding, cardiac failure/infarction, central or peripheral nervous system impairment, coagulopathy, death, edema, endoleak, erosion with fistula or pseudo-aneurysm, gastro-intestinal complications, graft dilatation, graft migration, graft occlusion, impotence, infection, loss of device integrity; stent fractures, graft wear holes, suture breaks, pulmonary/respiratory complications, renal insufficiency/failure, ruptured vessel/aneurysm, and wound healing complications.

Please reference appropriate product Instructions for Use for a more detailed list of indications, warnings, precautions and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

TALENT™ Abdominal Stent Graft

Indications

The Talent™ Abdominal Stent Graft is indicated for the endovascular treatment of abdominal aortic aneurysms with or without iliac involvement having:

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- A proximal aortic neck length of ≥ 10 mm;
- Proximal aortic neck angulation ≤ 60°;
- Distal iliac artery fixation length of ≥ 15 mm;
- An aortic neck diameter of 18–32 mm and iliac artery diameters of 8–22 mm; and
- Vessel morphology suitable for endovascular repair.

Contraindications

The Talent Abdominal Stent Graft is contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients with sensitivities or allergies to the device materials.

Warnings and Precautions

- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- The Talent Abdominal Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device. Specific training expectations are described in the *Instructions for Use*.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- The Talent Abdominal Stent Graft System is not recommended in patients unable to undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in the *Instructions for Use*.
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft.
- Inappropriate patient selection may contribute to poor device performance.
- Exercise care in handling and delivery technique to aid in the prevention of vessel rupture.
- Patients experiencing reduced blood flow through the graft limb and/or leaks may be required to undergo secondary interventions or surgical procedures.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.
- Prior to the procedure, pre-operative planning for access and placement should be performed. See *Instructions for Use*.

- Renal complications may occur:
 - From an excess use of contrast agents.
 - As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.
- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.
- Inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent graft. Other possible causes of migration are deployment of the proximal spring into a thrombus-filled or severely angled vessel wall.
- The safety and effectiveness of the Talent Abdominal Stent Graft System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

MRI Safety and Compatibility

Non-clinical testing has demonstrated that the Talent Abdominal Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

Adverse Events

Potential adverse events include (not arranged in any particular order): Amputation; Anesthetic complications and subsequent attendant problems (e.g., aspiration); Aneurysm enlargement; Aneurysm rupture and death; Aortic damage (including perforation, dissection, bleeding, rupture and death); Arterial or venous thrombosis and/or pseudoaneurysm; Arteriovenous fistula; Bleeding, hematoma or coagulopathy; Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); Claudication (e.g., buttock, lower limb); Death; Edema; Embolization (micro and macro) with transient or permanent ischemia or infarction; Endoleak; Fever and localized inflammation; Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection); Hepatic failure; Impotence; Infection of the aneurysm, device access site, including abscess formation, transient fever and pain; Lymphatic complications and subsequent attendant problems (e.g., lymph fistula); Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis); Occlusion of device or native vessel; Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation); Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure); Surgical conversion to open repair; Vascular access site complications (including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection); Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death); Vessel damage; Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis); Stent graft complications: improper component placement, incomplete component deployment, component migration, suture break, occlusion, infection, stent fracture, graft twisting and/or kinking, insertion and removal difficulties, graft material wear, dilatation, erosion, puncture, and perigraft flow.

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

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