HEALTH ECONOMICS & REIMBURSEMENT

REIMBURSEMENT GUIDE

Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

COVERAGE OVERVIEW

Lower extremity endovascular procedures using Esprit™ BTK System can be performed in the following settings:

- **Facility setting**: Hospital Inpatient, Hospital Outpatient, and Ambulatory Surgical Center (ASC)
- **Non-facility setting:** Physician office/ Office-Based Lab (OBL)

Traditional Medicare has implicit coverage for lower extremity endovascular procedures and does not require prior authorization. Medicare Advantage plans are managed by commercial payers and may require prior authorization. Several commercial plans also require prior authorization; please check with your payers for any requirements.

Additional materials are available for physicians when seeking prior authorization for lower extremity endovascular procedures. The materials can be access on Abbott, Vascular Division Reimbursement website:
Abbott Vascular Reimbursement Resources

CODING AND REIMBURSEMENT

The coding and reimbursement guide listed below is applicable to lower extremity endovascular procedures in the tibial/peroneal arteries using the Esprit™ BTK System. Codes for stenting apply to procedures using Esprit™ BTK System.

HOSPITAL INPATIENT

Effective October 1, 2023 – September 30, 2024.
MS-DRG assignment is based on many factors including documented patient conditions as well as services rendered during an admission. This is not an all-inclusive list of possible MS-DRGs.

MS-DRG	Description	2024 Medicare National Rate[1]
252	Other vascular procedures with MCC	$23,482
253	Other vascular procedures with CC	$17,862
254	Other vascular procedures without CC/MCC	$12,148

MCC: major complications or comorbidities. CC: complications or comorbidities

When Esprit™ BTK System is used in conjunction with atherectomy or thrombectomy in the tibial/peroneal area, the most common MS-DRG assignment is listed below:

MS-DRG	Description	2024 Medicare National Rate[1]
270	Other major cardiovascular services with MCC	$35,406
271	Other major cardiovascular services with CC	$24,199
272	Other major cardiovascular services without CC/MCC	$17,080

HOSPITAL OUTPATIENT

Effective January 1, 2024 – December 31, 2024.

CPT‡ code[2]	APC	Description	2024 Medicare National Rate[3]
37230	5194	Stenting (tibial/peroneal)	$16,725
37231	5194	Stenting & atherectomy (tibial/peroneal)	$16,725
+37234	-	Stenting (tibial/peroneal), additional vessel	No separate payment
+37235	-	Stenting & atherectomy (tibial/peroneal), additional vessel	No separate payment

AMBULATORY SURGICAL CENTER (ASC)

Effective January 1, 2024 – December 31, 2024.

CPT‡ code[2]	Description	2024 Medicare National Rate[4]
37230	Stenting (tibial/peroneal)	$10,735
37231	Stenting & atherectomy (tibial/peroneal)	$11,981
+37234	Stenting (tibial/peroneal), additional vessel	No separate payment
+37235	Stenting & atherectomy (tibial/peroneal), additional vessel	No separate payment

PHYSICIAN

Effective March 9, 2024 – December 31, 2024.

CPT‡ code[2]	Description	2024 Medicare National Rate[5,6]	
		Facility	Non-facility
37230	Stenting (tibial/peroneal)	$671	$8,708
37231	Stenting & atherectomy (tibial/peroneal)	$711	$11,497
+37234	Stenting (tibial/peroneal), additional vessel	$272	$3,551
+37235	Stenting & atherectomy (tibial/peroneal), additional vessel	$356	$3,857

HCPCS C-CODE FOR OUTPATIENT PROCEDURES

Level II HCPCS codes, including C-codes are used in conjunction with the Medicare prospective payment system for outpatient procedures only. Medicare Hospital Outpatient Prospective Payment System (OPPS) requires providers to report device category C-codes on claims to improve the claims data used to annually update the OPPS payment rates.

C-code	Description[7]
C1874	Stent, coated/covered, with delivery system

ADDITIONAL REIMBURSEMENT RESOURCES

Visit the website below for Abbott Reimbursement and Coding page, where you will find reimbursement resources such as coding guides, prior authorization toolkit, and on-demand webinars.
Vascular Resources for Medical Reimbursement | Abbott (cardiovascular.abbott)

For additional information or questions, please contact Abbott Vascular Reimbursement Hotline at **855-569-6430** or AbbottEconomics@abbott.com

IMPORTANT SAFETY INFORMATION

Rx ONLY Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

INDICATIONS
The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm.

CONTRAINDICATIONS
The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is contraindicated for use in:
- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally related compounds or known hypersensitivity to scaffold components poly(L-lactide), poly(D, L-lactide), and platinum.

WARNINGS
- **This device is intended for single use only.** Do not reuse, reprocess, or re-sterilize. Note the product "Use-by" date on the package. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and / or delivery system and / or lead to device failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device and / or delivery system may lead to injury, illness, or death of the patient.
- The Esprit™ BTK System is intended to perform as a system. The scaffold should not be removed for use with other dilatation catheters.
- The Esprit™ BTK System should not be used in conjunction with other non-everolimus drug eluting devices in the same vessel as the Esprit™ BTK Scaffold.
- It is not recommended to use this scaffold to treat lesions located at any joint or other hinge points, such as the knee or ankle. The recommended region for below-the-knee (BTK) treatment with the Esprit™ BTK Scaffold is the infrapopliteal arteries at a location ≥ 10 cm above the proximal margin of the ankle mortise. The Esprit™ BTK Scaffold has not been tested for use outside the recommended implant locations.
- This product should not be used in patients with aneurysms immediately adjacent to the scaffold implantation site.
- Insertion of the Esprit™ BTK System and implantation of the scaffold should be performed only under fluoroscopic observation with radiographic equipment providing high resolution images.
- **Quantitative imaging is strongly recommended to accurately measure and confirm appropriate vessel sizing (reference vessel diameter ≥ 2.5 mm).** If quantitative imaging determines a vessel size < 2.5 mm, do not implant the Esprit™ BTK Scaffold.
- Adequate lesion preparation prior to scaffold implantation is required to ensure safe delivery of the scaffold across the target lesion. It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon.
- **Successful pre-dilatation with residual diameter stenosis of < 30% by visual estimation is required for treatment of the target lesion; < 20% by visual estimation is preferred.**
- Ensure the scaffold is not post-dilated beyond the allowable expansion limits.
- Use of appropriate anticoagulant and / or antiplatelet therapy per standard of care is recommended for use of this scaffold system.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.
- Judicious selection of patients is necessary, since the use of this device carries the associated risk of scaffold thrombosis, vascular complications, and / or bleeding events.

PRECAUTIONS
- Scaffold placement should not be performed in patients with known allergies to contrast agent that cannot be medically managed.
- It is not recommended to treat patients having a lesion with excessive tortuosity proximal to or within the lesion.
- When multiple scaffolds are required, only combinations of Esprit™ BTK Scaffolds must be used. Any potential interaction with other drug-eluting or coated devices has not been evaluated.
- The delivery system is intended for deployment of the scaffold only and should not be used to dilate other locations.
- Implantation of the scaffold should be performed **only** by physicians who have received appropriate training.
- As with all catheter-based procedures, scaffold placement should be performed at facilities where patient can be prepared for necessary intervention and / or surgical removal of the device and vessel repair as per facility protocol.
- Pre-dilatation should be performed with an angioplasty balloon. Cutting or scoring balloons can be used per physician discretion, if the lesion appears to be mildly calcified.
- Failure to pre-dilate the vessel may impair nominal / optimal scaffold delivery.
- Implanting a scaffold may lead to dissection of the vessel distal and / or proximal to the scaffold, requiring additional intervention.

Note: In cases of bailouts, bailout treatment of the target lesion can be done using the Esprit™ BTK Scaffold of the appropriate length. If an appropriate length Esprit™ BTK Scaffold is not available, physicians should use standard of care.
- An unexpanded scaffold may be retracted into the introducer sheath **one time only.** An unexpanded scaffold should not be reintroduced into the artery once it has been pulled back into the introducer sheath.
- Post-dilatation is strongly recommended for optimal scaffold apposition. When performed, post-dilatation should be performed at high pressure (> 16 atm) with a non-compliant balloon up to 0.5 mm larger than the nominal scaffold diameter.
- Use an appropriately sized non-drug coated balloon to pre-dilate the lesion. When treating a long lesion, scaffold the distal portion of the lesion prior to scaffolding the proximal portion of the lesion.
- Ensure that the scaffolded area covers the entire lesion / dissection site and that no gaps exist between scaffolds.
- The extent of the patient's exposure to drug and polymer is directly related to the number of scaffolds implanted. The safety of everolimus, polymer, and polymer breakdown products was evaluated in pre-clinical studies and the biocompatibility assessment of the Esprit™ BTK Scaffold.
- The safety and effectiveness of the Esprit™ BTK Scaffold in patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated-site restenosis in the Esprit™ BTK Scaffold have not been established. Both vascular brachytherapy and the Esprit™ BTK Scaffold alter arterial modeling. The potential combined effect on arterial remodeling by these two treatments is not known.
- The safety and effectiveness of the Esprit™ BTK System have not been established in clinical trials with the use of either mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser atherectomy catheters.
- Formal drug interaction studies have not been performed with the Esprit™ BTK Scaffold because of limited exposure to everolimus eluted from the scaffold.
- Everolimus, the Esprit™ BTK Scaffold's active pharmaceutical ingredient, is an immunosuppressive agent. Therefore, consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglyceride levels, which in some cases required treatment.
- Non-clinical testing has demonstrated the Esprit™ BTK Scaffold is MR Conditional. A person with the Esprit™ BTK Scaffold may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.
    - Static magnetic field strength of 7 Tesla or less
- The Esprit™ BTK Scaffold should not migrate in this MRI environment. MRI at 7 Tesla or less may be performed immediately following the implantation of the Esprit™ BTK Scaffold.

See Important Safety Information referenced within.
Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION (CONTINUED)

POTENTIAL ADVERSE EVENTS
Potential adverse events include, but are not limited to:

Allergic reaction or hypersensitivity to contrast agent, anesthesia, scaffold materials (poly[L-lactide] [PLLA], poly[D, L-lactide] [PDLLA], platinum, or everolimus), and drug reactions to anticoagulation or antiplatelet drugs.

- Vascular access complications which may require transfusion or vessel repair, including: Catheter site reactions • Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage) • Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, and laceration • Embolism (air, tissue, plaque, thrombotic material, or device) • Peripheral ischemia
- Target artery complications which may require additional intervention, including: Total occlusion or abrupt closure • Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture • Embolism (air, tissue, plaque, thrombotic material, or device) • Artery or scaffold thrombosis • Stenosis or restenosis • Vasospasm • Tissue prolapse / plaque shift
- Bleeding (non-access site)
- Additional surgery such as peripheral artery bypass graft surgery or amputation
- Peripheral nerve injury, neuropathy
- Compartment syndrome
- Tissue necrosis, gangrene, ulcer and acute limb ischemia
- Reperfusion injury
- New or worsening pain
- Intervention due to: Damaged scaffolds • Partial scaffold deployment • Scaffold migration / unintentional placement of scaffold
- Other general surgical risks, including: Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias, and blocks) • Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA) • Venous thromboembolism (including pulmonary embolism) • Nausea and vomiting • Hypotension / hypertension • Infection – local and systemic (including post-procedural) • Fever • Blood cell disorders including heparin-induced thrombocytopenia (HIT) and other coagulopathy • Death
- System organ failures: Cardiac Failure • Cardio-respiratory arrest (including pulmonary edema) • Respiratory failure • Renal failure • Shock

The risks described below include the anticipated adverse events referenced in the contraindications, warnings, and precautions sections of the everolimus labels / SmPCs and / or observed at incidences ≥ 10% in clinical trials with oral everolimus for different indications. Refer to the drug SmPCs and labels for more detailed information and less frequent adverse events.

• Abdominal pain • Anemia • Angioedema (increased risk with concomitant angiotensin-converting enzyme [ACE] inhibitor use) • Arterial thrombotic events • Bleeding and coagulopathy (including hemolytic uremic syndrome [HUS], thrombotic thrombocytopenic purpura [TTP], and thrombotic microangiopathy; increased risk with concomitant cyclosporine use) • Constipation • Cough • Diabetes mellitus • Diarrhea • Dyspnea • Embryo-fetal toxicity • Erythema • Erythroderma • Headache • Hepatic artery thrombosis (HAT) • Hepatic disorders (including hepatitis and jaundice) • Hypersensitivity to everolimus active substance, or to other rapamycin derivates • Hypertension

• Infections (bacterial, viral, fungal, or protozoan infections, including infections with opportunistic pathogens). Polyoma virus-associated nephropathy (PVAN), JC virus associated progressive multiple leukoencephalopathy (PML), fatal infections and sepsis have been reported in patients treated with oral everolimus. • Kidney arterial and venous thrombosis • Laboratory test alterations (elevations of serum creatinine, proteinuria, hypokalemia, hyperkalemia; hyperglycemia, dyslipidemia including hypercholesterolemia and hypertriglyceridemia; abnormal liver function tests; decreases in hemoglobin, lymphocytes, neutrophils, and platelets) • Lymphoma and skin cancer • Male infertility • Menstrual irregularities • Nausea • Nephrotoxicity (in combination with cyclosporine) • Non-infectious pneumonitis (including interstitial lung disease) • Oral ulcerations • Pain • Pancreatitis • Pericardial effusion • Peripheral edema • Pleural effusion • Pneumonia • Pyrexia • Rash • Renal failure • Upper respiratory tract infection • Urinary tract infection • Venous thromboembolism • Vomiting • Wound healing complications (including wound infections and lymphocele)

There may be other potential adverse events that are unforeseen at this time.

See Important Safety Information referenced within.
Information contained herein for DISTRIBUTION in the U.S. ONLY.

References:

1. Hospital Inpatient Prospective Payment - Final Rule FY2024 Payment Rates. CMS-1785-F: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page
2. CPT‡ Coding Guidelines. AMA. CPT‡ 2024 Professional Edition. American Medical Association. 2024.
3. Hospital Outpatient Prospective Payment-Notice of Final Rulemaking with Comment Period for CY 2024: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc
4. Ambulatory Surgical Center Payment-Final Rule CY2024 Payment Rates: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc
5. 2024 Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2024 CMS-1784-F: https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f
6. Changes to Physician Fee Schedule – Consolidated Appropriations Act, 2024. Physician Fee Schedule | CMS
7. CMS, 2020 Alpha-Numeric Index HPCPS file. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric- HCPCS-File

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