



2025 Reimbursement Guide:

HOSPITAL OUTPATIENT (OPPS)	PHYSICIAN SERVICES (MFPS)	OFFICE-BASED LAB (OBL)
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Disclaimer

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Introduction to LAVA Liquid Embolic System[®]

U.S. federal law restricts the sale, distribution, and use of this product to physicians or as prescribed by a physician. This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures.

The LAVA Liquid Embolic System (LES) is indicated for embolization of arterial hemorrhage in the peripheral vasculature.

LAVA LES consists of the LAVA LES Kit and the LAVA Mixing Kit.

The LAVA LES Kit comprises a sterile, sealed, serum vial containing the LAVA liquid embolic suspension (LAVA), a sterile, sealed, serum vial containing dimethyl sulfoxide (DMSO), and a sterile, sealed pouch containing DMSO compatible syringes.

LAVA is an injectable, non-adhesive liquid embolic agent comprised of ethylene vinyl alcohol (EVOH) copolymer dissolved in DMSO and suspended micronized tantalum powder to provide contrast for visualization under fluoroscopy.

The LAVA Mixing Kit comprises a sterile, sealed pouch containing a mixing manifold and two sterile, sealed pouches, each containing a single DMSO compatible mixing syringe.

LAVA is delivered through a DMSO compatible delivery microcatheter.

The LAVA LES Kit is available in two product formulations, LAVA-18 (nominal viscosity of 20 cSt), and LAVA-34 (nominal viscosity of 33 cSt). LAVA-18 will travel more distally and penetrate deeper into the vasculature due to its lower viscosity compared to the LAVA-34. Both product formulations precipitate into a spongy, coherent mass or cast upon exposure to blood at the targeted location.

LAVA is delivered by slow controlled injection through a microcatheter into the target peripheral vasculature under fluoroscopic control. The DMSO dissipates into the blood, causing the EVOH copolymer to precipitate while the tantalum remains suspended in situ to form a spongy, coherent embolus. LAVA immediately forms a skin as the polymeric embolus solidifies from the outside to the inside, while traveling more in the lesion. Since LAVA is non-adhesive, the microcatheter can be left in place while slow, controlled injections are performed. Post embolization angiography can be conducted with the delivery microcatheter in place, enabling the physician to make additional injections through the same microcatheter, if necessary.

Diagnostic Indications

ICD-10 CM Diagnosis Codes

Potential Diagnoses

I74.2: Embolism and thrombosis of arteries of the upper extremities

I74.3: Embolism and thrombosis of arteries of the lower extremities

I74.4: Embolism and arteries of extremities, unspecified (peripheral arterial embolism NOS)

I74.9: Embolism and Thrombosis of unspecified artery

CPT/APC Code for LAVA

CPT 37244: Vascular embolization or occlusion, inclusive of all radiological S & I, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation

APC 5193: Medicare APC 5193, Status Code J1, indicates all services and procedures, except services with a status indicator of "F", "G", "H", "L", and "U", reported on the same claim will be packaged into the payment for APC 5193.

NCCI

National Correct Coding Initiative (NCCI) Edits may result in coding conflicts for various treatments and procedures.

Providers should carefully review each quarter's NCCI edit updates. NCCI edits may be downloaded from the CMS website at: <https://www.cms.gov/medicare/coding-billing/ncci-medicare>

Payment Rates

OPPS: CMS finalized a CY 2025 conversion factor (CF) of \$89.169 for hospitals that meet the Hospital OQR reporting requirements, and applying the 2 percent reduction to those that do not with a CF equal to \$87.439.

The codes and national average payment rates shown are reflective of the Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 2025 Final Rule, OPPS Addendum B and ASC Final Addenda. Payment rates do not reflect sequestration reductions.

MPFS: The codes and national average payment rates shown are reflective of the Medicare Physician Fee Schedule as outlined in the Calendar Year 2025 Addendum B using 2025 Final MPFS conversion factor (CF) of \$32.3465.

Medicare providers face other cuts known as sequestration (2% reduction) and statutory "Pay-As-You-Go", or PAYGO (4% reduction), due to laws that control federal spending. Although these specific cuts aren't addressed in the MPFS, they could result in a total cut of almost 9% to overall Medicare payments when added to the CF reduction. Congress has acted each year by passing legislation that reduced or eliminated some of these additional cuts and will need to do so again for 2025 payments.

Reimbursement Support Services

For questions related to reimbursement, please contact the US HEPRA team at USReimbursement@Sirtex.com.

HOSPITAL OUTPATIENT (OPPS)

Embolization or Occlusion for Hemorrhage – Peripheral Vasculature

Service		CMS CY25			
Code	Description	SI	Weight	APC	Rate
37244	Vascular embolization or occlusion, inclusive of all radiological S & I, intra-procedural road mapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	J1	127.18	5193	\$11,340.57

Select Catheter Placement – Arterial System

Service		CMS CY25			
Code	Description	SI	Weight	APC	Rate
36215	Upper extremity cath place, artery; initial	N1	NA	NA	Packaged
36216	Upper extremity cath place, artery, 2nd	N1	NA	NA	Packaged
36217	Upper extremity cath place, artery, 3rd	N1	NA	NA	Packaged
36218*	Upper extremity cath place, in addition to 2nd, 3rd & beyond	N1	NA	NA	Packaged
36245	Lower extremity select cath place, abdominal, initial 1st	N1	NA	NA	Packaged
36246	Lower extremity select cath place, initial 2nd	N1	NA	NA	Packaged
36247	Lower extremity select cath place, initial 3rd or more	N1	NA	NA	Packaged
36248*	Lower extremity select cath place, initial 2nd or more & beyond	N1	NA	NA	Packaged

*CPT Add-on code – Add-on codes are used in conjunction with a primary procedure and are never billed by themselves. Add-on codes are packaged for the hospital however physicians are reimbursed for add-on codes at 100% of allowable payment.

Select Catheter Placement – Venous System

Service		CMS CY25			
Code	Description	SI	Weight	APC	Rate
36011	Select cath place, venous system; 1st	N	NA	NA	Packaged
36012	Select cath place, 2nd or more	N	NA	NA	Packaged

Angiography

Service		CMS CY25			
Code	Description	SI	Weight	APC	Rate
75774	Angiography, selective, RS&I (each add'l vessel)	N	NA	NA	Packaged

PHYSICIAN (MFPS) SERVICES

Embolization or Occlusion for Hemorrhage – Peripheral Vasculature

Service		CMS CY25	
Code	Description	RVUs	Rate
37244	Vascular embolization or occlusion, inclusive of all radiological S & I, intra-procedural road mapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	19.29	\$623.96

Select Catheter Placement – Arterial System

Service		CMS CY25	
Code	Description	RVUs	Rate
36215	Upper extremity cath place, artery; initial	6.28	\$203.14
36216	Upper extremity cath place, artery, 2nd	8.02	\$259.42
36217	Upper extremity cath place, artery, 3rd	9.97	\$322.49
36218*	Upper extremity cath place, in addition to 2nd, 3rd & beyond	1.55	\$50.14
36245	Lower extremity select cath place, abdominal, initial 1st	6.93	\$224.16
36246	Lower extremity select cath place, initial 2nd	7.38	\$238.72
36247	Lower extremity select cath place, initial 3rd or more	8.71	\$281.74
36248*	Lower extremity select cath place, initial 2nd or more & beyond	1.42	\$45.93

*CPT Add-on code – Add-on codes are used in conjunction with a primary procedure and are never billed by themselves. Add-on codes are packaged for the hospital however physicians are reimbursed for add-on codes at 100% of allowable payment.

Select Catheter Placement – Venous System

Service		CMS CY25	
Code	Description	RVUs	Rate
36011	Select cath place, venous system; first	4.58	\$148.15
36012	Select cath place, 2nd or more	5.14	\$166.26

Angiography

Service		CMS CY25	
Code	Description	RVUs	Rate
75774-26	Angiography, selective, RS&I (each add'l vessel)	1.36	\$43.99

OFFICE-BASED LAB (OBL)

Embolization or Occlusion for Hemorrhage – Peripheral Vasculature

Service		CMS CY25	
Code	Description	RVUs	Rate
37244	Vascular embo or occ, inclusive of all radiological S & I, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	185.27	\$5,992.84

Select Catheter Placement – Arterial System

Service		CMS CY25	
Code	Description	RVUs	Rate
36215	Upper extremity cath place, artery; initial	29.81	\$964.25
36216	Upper extremity cath place, artery, 2nd	30.75	\$994.65
36217	Upper extremity cath place, artery, 3rd	53.74	\$1,738.30
36218	Upper extremity cath place, in addition to 2nd, 3rd & beyond	6.13	\$198.28
36245	Lower extremity select cath place, abdominal, initial 1st	35.37	\$1,144.10
36246	Lower extremity select cath place, initial 2nd	23.79	\$769.52
36247	Lower extremity select cath place, initial 3rd or more	40.49	\$1,309.71
36248	Lower extremity select cath place, initial 2nd or more & beyond	3.39	\$109.65

Select Catheter Placement – Venous System

Service		CMS CY25	
Code	Description	RVUs	Rate
36011	Select cath place, venous system; first	22.89	\$740.41
36012	Select cath place, 2nd or more	23.87	\$772.11

Angiography

Service		CMS CY25	
Code	Description	RVUs	Rate
75774**	Angiography, selective, RS&I (each add'l vessel)	2.87	\$92.83

Caution: U.S. federal law restricts the sale, distribution and use of this product to physicians or as prescribed by a physician. This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures. **Indications for Use:** LAVA[®] LES is indicated for embolization of arterial hemorrhage in the peripheral vasculature. **Warnings:** DO NOT use monopolar electrocautery devices for surgical resection of tissue embolized with LAVA due to a possibility of electrical arcing with tantalum metal in the embolic cast. Bipolar devices should be used with caution. Use only DMSO-compatible microcatheters. LAVA LES has been tested for compatibility with Terumo Medical Progreat[®], Boston Scientific Renegade[®], and Merit Medical Maestro[®] microcatheters. Also, use only the DMSO-compatible syringes supplied with the LAVA LES Kit. The use of non-DMSO compatible microcatheters and syringes may result in degradation that can potentially result in unexpected complications such as thromboembolic events. The LAVA LES should be used only by physicians with peripheral vascular training and a thorough knowledge of the pathology to be treated, angiographic techniques, and super-selective embolization. Performing embolization to occlude blood vessels in the peripheral vasculature is a high-risk procedure. If the vessel wall is compromised, LAVA could escape outside the vascular space. It may result in a subacute inflammatory response to the material and tissue damage. Dimethyl sulfoxide (DMSO) can initiate the liberation of histamine which may result in an occasional hypersensitivity reaction. If anaphylactoid symptoms develop, appropriate therapy should be instituted. DO NOT perform a therapeutic embolization when high blood flow precludes safe injection of LAVA. Special attention must be taken to the positioning of the microcatheter tip. The microcatheter tip should be placed to minimize the potential for embolization of non-target vessels or tissues. Mix LAVA per the "LAVA Mixing and Preparation" section of this IFU and inject LAVA immediately after mixing. Failure to prepare and mix LAVA per the "LAVA Mixing and Preparation" section of this IFU may result in inadequate suspension of the tantalum, resulting in inadequate fluoroscopic visualization during delivery. If LAVA injection is delayed, tantalum settling can occur within the syringe resulting in poor visualization during injection. Adequate fluoroscopic visualization must be maintained during LAVA delivery or non-target vessel embolization may result. If visualization is lost at any time during the embolization procedure, halt LAVA delivery until adequate visualization is re-established. Premature solidification of LAVA may occur if the microcatheter luer contacts any amount of saline, blood or contrast. **Potential Complications:** Potential adverse effects (e.g., complications) associated with the use of the device include: Non-target embolization, Ischemia or infarction of the target territory, Allergic reactions to device components, Catheter breakage, Catheter entrapment, Inadvertent embolization of a non-target vessel or territory, Embolization of device components, Access site hematoma or ecchymosis, Access site false aneurysm, Pain at the access site, Arterial dissection, Mural thrombus formation, Vessel perforation, Hemorrhage, Recanalization, Vessel perforation, Arteriovenous fistula, Distal atheroembolism, Infection, Sepsis, Serous drainage, Lymphorrhea, Leg edema, Leg pain, and Back pain. **Precautions:** The safety and effectiveness have not been studied in the following patient populations: Nursing women. Individuals less than 18 years old. Data indicate that DMSO potentiates other concomitantly administered medications. A garlic-like taste may be noted by the patient with the use of the LAVA LES due to the DMSO component. This taste may last several hours. An odor on the breath and skin may be present. Inspect product packaging prior to use. Do not use if the sterile barrier is open or damaged. Use prior to the expiration date. Verify that the microcatheters and accessories used in direct contact with LAVA are clean and compatible with DMSO. DMSO may interact with other embolic agents (e.g., coils). LAVA LES has been tested for compatibility with bare metal (platinum) embolic coils and Cook Medical Nester[®] Embolization Coils. Safety of LAVA at injected volumes greater than 3.5 mL into the patient has not been evaluated. Total volume of LAVA injected should not exceed 3.5 mL. **Difficult removal of microcatheter entrapment may be caused by any of the following:** Angioarchitecture, Vasospasm, Reflux of the embolic agent, and Injection time, to reduce the risk of microcatheter entrapment, carefully select microcatheter placement and manage reflux of LAVA to minimize the factors listed above. **Should microcatheter removal become difficult, the following will assist in microcatheter retrieval:** Carefully pull the microcatheter to assess any resistance to removal. If resistance is felt, remove any "slack" in the microcatheter. Gently apply traction to the microcatheter [approximately 3–4 cm of stretch to the microcatheter]. Hold this traction for a few seconds and release. Assess traction on vasculature to minimize risk of hemorrhage. This process can be repeated intermittently until the microcatheter is retrieved. **Alternate technique for difficult-to-remove microcatheters:** Remove all slack from the microcatheter by putting a few centimeters of traction on the microcatheter to create a slight tension in the microcatheter. Firmly hold the microcatheter and then pull it using a quick wrist snap motion 10–15 centimeters to remove the microcatheter from the LAVA cast. Note: Do not apply more than 20 cm of traction to the microcatheter, to minimize risk of microcatheter separation. **For entrapped microcatheters:** Under some difficult clinical situations, it may be safer to leave the microcatheter in the vascular system. This is accomplished by stretching the microcatheter and cutting the shaft near the entry point of vascular access allowing the microcatheter to remain in the artery. If the microcatheter breaks during removal, distal migration or coiling of the microcatheter may occur. Same-day surgical resection should be considered to minimize the risk of thrombosis. **Contraindications:** LAVA LES is not indicated for use in pregnant women, neonates or individuals with significant liver or kidney function impairment. Safety for these patient groups has not been evaluated. **General Information:** LAVA implantation should only be performed by physicians who have successfully completed training in the use of the product. Serious, including fatal, consequences could result with the use of LAVA without adequate training. Contact BlackSwan Vascular for information on training. **Consult the Instructions for Use (www.sirtex.com/lava/risks_adverse-events) for a complete listing of indications, contraindications, warnings, and precautions.**