LUMA SON®

(sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use VISUALLY DECISIVE

2024 REIMBURSEMENT RESOURCE KIT IDTF INDEPENDENT DIAGNOSTIC TESTING FACILITIES

DISCLAIMERS

The information provided here is general reimbursement information for LUMASON. It is not legal advice, nor is it advice about how to code, complete, or submit any particular claim for payment. Although we supply this information based on our current knowledge, it is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers, and bills for the services that were rendered. This coding and reimbursement information is subject to change without notice. Payers or their local branches may have their own coding and reimbursement requirements and policies. Before filing any claims, providers should verify current requirements and policies with the payer.

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Indications for LUMASON[®] (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

LUMASON[®] (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use is an ultrasound contrast agent indicated for use:

- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult and pediatric patients with suboptimal echocardiograms
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients
- in ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including sulfur hexafluoride lipid microspheres. Most serious reactions occur within 30 minutes of administration.

- · Assess all patients for the presence of any condition that precludes administration
- Always have resuscitation equipment and trained personnel readily available

Contraindications

LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use is contraindicated in patients with known or suspected hypersensitivity to sulfur hexafluoride lipid microsphere or its components, such as polyethylene glycol (PEG).

Warnings

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following administration of ultrasound contrast agents, including LUMASON. Always have cardiopulmonary resuscitation personnel and equipment readily available prior to LUMASON administration and monitor all patients for acute reactions.

Post-marketing **hypersensitivity reactions**, including serious hypersensitivity reactions, have been observed during use or shortly following LUMASON administration. These reactions may occur in patients with no history of prior exposure to sulfur hexafluoride lipid-containing microspheres. LUMASON contains PEG. There may be increased risk of serious reactions including death in patients with prior hypersensitivity reaction(s) to PEG.

Systemic embolization may occur in patients with cardiac shunts. Assess patients with cardiac shunts for embolic phenomena following LUMASON administration.

There is a risk of **ventricular arrhythmia related to high mechanical index** in patients administered LUMASON. LUMASON is not recommended for use at mechanical indices greater than 0.8.

The most common adverse reactions (incidence $\geq 0.5\%$) are headache (1%) and nausea (0.5%).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

Please <u>click here</u> to see full Prescribing Information for LUMASON ultrasound contrast agent, including BOXED WARNING on Serious Cardiopulmonary Reactions.

LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse S.A., Plan-les-Ouates Geneve, Switzerland (LUMASON lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).

LUMASON and SONOVUE are registered trademarks of Bracco Diagnostics Inc. and its affiliated entities.





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INDICATIONS

LUMASON® is the only ultrasound enhancing agent (UEA) with 3 indications¹

Echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult and pediatric patients with suboptimal echocardiograms

Ultrasonography of the liver for the characterization of focal liver lesions in adult and pediatric patients

Ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients



All-inclusive portable kit

20 vials & 20 spike pack



CODING NOMENCLATURE

CPT[®] (Current Procedural Terminology)

Codes used to report the service or procedure performed.

HCPCS (Healthcare Common Procedure Coding System)

Codes used to report the provision of supplies, materials, injections, and certain services and procedures. For example, the HCPCS code for LUMASON ultrasound enhancing agent (UEA) is Q9950.

C-codes

Unique, temporary HCPCS codes created by Medicare and used for HOPPS only. This is often done when no other appropriate code exists. An example of this is the C-code series in echocardiography, which is described on page 10.

Coding Modifiers

Under the Medicare Physician Fee Schedule, LUMASON UEA is separately reimburseable, and therefore the JZ and JW Modifiers are required. The JZ Modifier, mandatory as of July 1, 2023, indicates no drug wastage. The JW Modifier indicates the amount of drugs in a single use vial that has been discarded. Claims that do not report the modifiers as appropriate on or after October 1, 2023 may be returned as unprocessable until claims are properly resubmitted. <u>https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-fags.pdf</u>

ICD-10-CM (International Classification of Disease)

Codes used to describe a patient's signs and symptoms that would represent a medically necessary reason for performing the procedure. ICD-10 codes need to be entered on the claim form. ICD-10 is the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO).

APC (Ambulatory Payment Classification)

In most cases, the unit of payment under the HOPPS is the APC. CMS assigns individual services HCPCS & CPT codes to APCs based on similar clinical characteristics and similar costs. The payment rate and copayment calculated for an APC apply to each service within the APC.

NDC (National Drug Code)

An NDC code provides a unique identifier for a specific drug. The NDC for LUMASON ultrasound enhancing agent is: 0270-7099-16. When billing requires an 11-digit NDC code, please add an additional zero at the beginning of the code.

Medicare Addendum B

These files are updated quarterly and reflect hospital HOPPS payment rates for HCPCS codes and APC codes. <u>www.cms.gov/</u><u>Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates.html</u>.

Medicare Part B ASP (average selling price) file

Quarterly payment files are published for Independent Diagnostic Testing Facilities (IDTFs) and physician offices. This is where the payment value for LUMASON (Q9950) can be found: <u>https://www.cms.gov/medicare/payment/all-fee-service-providers/</u> medicare-part-b-drug-average-sales-price/asp-pricing-files.

Medicare Physician Fee Schedule (MPFS)

Find out physician payment for specific geographic locations in the country for different procedures. This schedule provides: global (G), technical (TC), and professional (26) component payment rates. To find out more information on specific locations visit: www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSLookup/index.html?redirect=/pfslookup.



CODING INFORMATION

Q9950²: LUMASON ultrasound enhancing agent (UEA)

1 vial = 5 mLBilling unit is per mL, not by vial or doses

Medicare Patients: LUMASON UEA is paid separately under MPFS and is separately reimbursed. Please code separately with the echocardiography and radiology procedure codes

Commercially insured patients: The provider must contact their respective insurance providers to include Q9950 and establish a reimbursement value.

Medicaid Patients: Medicaid coverage varies by state, please consult your local Medicaid office to find the policies in your area. Bracco does not participate in the Medicaid rebate program.

Procedure Codes: Echocardiography: 933xx series and C-8921-30 code series.^{2,3} Please see pages 8 and 10 for a complete list.

Please note: C-codes are a unique set of codes established by CMS with the intended purpose of being used exclusively for Medicare patients in the Hospital Outpatient Setting. However, many commercial plans will accept the C-codes in non-hospital facilities as well. Please consult with individual plans to find out the most appropriate way to bill for your patients.





Sample health insurance claim form CMS-1500

Echocardiography with contrast

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1. MEDICARE MEDICAID TRICARE (Medicare#) (Medicaid#) (ID#/DoD#)	CHAMPVA GROUP EECA OTHER 1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
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СТТҮ		
	Ide Area Code) CITY STATE CONDITION RELATED TO: 11. INSURED'S POLICY GROUP OR FECA NUMBER 2010	
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a. OTHER INSURED'S POLICY OR GROUP NUMBE		
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C. RESERVED FOR NUCC USE		
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to process this claim. I also request payment of gov below.	rment benefits after to myself or to the party who accepts assignment services described below.	
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2 03 13 24 03 13 24 3	Og950 JW 3 mL NPI 4 Og950 JW 2 mL NPI 4	
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Nodifier: Zero drug wasted MBER SSN EIN	26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT'S 28. TOTAL CHARGE 29. AMOUNT PAID 30. Rsvd.for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER	YES NO \$ \$ 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # ()	
INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)		
SIGNED DATE	Bracco Diagnostics Inc. cannot guarantee	
NUCC Instruction Manual available at: w	w. procedures at any particular level. For more	
	specific information, please contact your Medicare contractor or the patient's insurer.	
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2024 MEDICARE PHYSICIAN FEE SCHEDULE NATIONAL AVERAGE PAYMENT RATES

Echocardiography CPT® codes² for adult and pediatric patients

CPT code ²	Long-description CPT	Modifier	MPFS National Payment Rate ⁴
		G	\$215.46
93303	Echo transthoracic	тс	\$156.52
		26	\$58.94
		G	\$152.59
93304	Echo transthoracic	TC	\$118.21
		26	\$34.38
		G	\$192.86
93306	Tte w/doppler complete	TC	\$126.72
		26	\$66.14
	Tte w/o doppler complete	G	\$133.92
93307		TC	\$92.34
		26	\$41.59
		G	\$96.92
93308	Tte f-up or Imtd	TC	\$73.02
		26	\$23.90
		G	\$231.17
93312	Echo transesophageal	TC	\$129.34
		26	\$101.83
		G	\$221.68
93314	Echo transesophageal	TC	\$136.54
		26	\$85.14
93315	Echo transesophageal	26	\$120.83
93317	Echo transesophageal	26	\$84.15

CPT code²			MPFS National Payment Rate ⁴
93318	Echo transesophageal intraop	26	\$97.25
93319	3d echo img cgen car anomal	G	\$54.36
		G	\$49.77
93320	Doppler echo exam heart	TC	\$32.74
		26	\$17.03
		G	\$24.56
93321	Doppler echo exam heart	TC	\$17.68
		26	\$6.88
		G	\$22.92
93325	Doppler color flow add-on	TC	\$19.97
		26	\$2.95
		G	\$182.06
93350	Stress tte only	TC	\$115.91
		26	\$66.14
		G	\$227.90
93351	Stress tte complete	TC	\$148.66
		26	\$79.24
93352	Admin ecg contrast agent	G	\$34.05
93356	Myocrd strain img spckl trck	G	\$36.35



Radiology – Liver and Urinary Tract

Ultrasonography of the liver and urinary tract for vesicoureteral reflux ²						
CPT® codeDescriptionMPFS National Payment Rate4						
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non- cardiac); initial lesion	G	\$217.75			
		TC	\$143.09			
		26	\$74.66			
+76979, add-on code	Ultracound torgeted dynamic microhyble concerentic contract characterization (con		\$140.15			
		тс	\$101.18			
	for primary procedure)		\$38.97			

Alternate Coding from the American Medical Association

Ultrasonography of the urinary tract for vesicoureteral reflux ⁵					
CPT [®] code	Modifier	MPFS National Payment Rate ⁴			
51600	Injection procedure for cystography or voiding urethrocystography	G	\$205.96		
74455		G	\$102.16		
	Urethrocystography, voiding, radiological supervision and interpretation	TC	\$87.10		
		26	\$15.06		
74430		G	\$40.60		
	Cystography, minimum of 3 views, radiological supervision and interpretation	TC	\$25.87		
		26	\$14.74		

LUMASON® Ultra	sound Enhancing Agent I Note: LUMASON UEA must be code	d separately
HCPCS code ³	Description	2024 Q1 CMS Average Sales Price*
Q9950	Sulfur hexafluoride lipid microspheres, per mL; there are 5 mL per single-use vial of LUMASON UEA.	\$94.535/vial or \$18.907/mL

*Average Sales Pricing for drugs changes on a quarterly basis under CMS. For the most up-to-date reimbursement rate, please visit https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files



BILLING FOR COMMERCIALLY INSURED PATIENTS

Echocardiography: C-codes

C-codes are a unique set of codes established by CMS with the intended purpose of being used exclusively for Medicare patients in the Hospital Outpatient Setting. However, many commercial plans will accept the C-codes in non-hospital sites as well. Please consult with individual plans to find out the most appropriate way to bill for your patients.

HCPC code ^s	
C892	1 Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete
C892	2 Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study
C892	3 Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color doppler echocardiography
C892	4 Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study
C892	5 Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, real time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report
C892	6 Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
C892	Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis
C8928	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report
C8929	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography
C893(Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision

Echocardiography: Cross Walk Codes Without and With Contrast^{2,3}

CPT®	without contrast with contrast	C-code	СРТ	without contrast with contrast	C-code
93303	<>	C8921	93312	← →	C8925
93304	← →	C8922	93315	← →	C8926
93306	← →	C8929	93318	← →	C8927
93307	← →	C8923	93350	← →	C8928
93308	← →	C8924	93351	← →	C8930



LUMA.SON° (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use VISUALLY DECISIVE

ORDERING INFORMATION



All-inclusive portable kit

Each kit contains:

- One LUMASON[®] vial of 25 mg lipid-type A white lyophilized powder with headspace fill of 60.7 mg of sulfur hexafluoride
- One prefilled syringe containing 5mL of 0.9% Sodium Chloride Injection, USP (Diluent)
- One Mini-Spike

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20-vial pack

Each pack contains:

- Twenty (20) LUMASON[®] vials of 25 mg lipid-type A white lyophilized powder with headspace fill of 60.7 mg of sulfur hexafluoride
- Twenty (20) Mini-Spikes
- Twenty (20) peel-off syringe labels

Product	LUMASON UEA	EA		Product	LUMASON UEA	
SKU	709916			SKU	709707	
NDC	0270–7099–16			NDC	0270–7097–07	
Product Description	KIT LUMASON 5x 25MG FLIPCAP			Product Description	MP LUMASON 20x 2	25MG VIAL/SPIKE US
Product Configuration	Product Configuration Five (5) Vial Kit			Product Configuration	Twenty (20) Vial Pac	k
Novaplus®	SKU 709700	NDC 0270-7099-73		Novaplus®	SKU 709708	NDC 0270-7097-08

Available to purchase direct from Bracco Diagnostics Inc. and through authorized wholesale distributors. Novaplus is a registered trademark of Vizient, Inc.

Customer Service: 1-877-BRACCO 9 (1-877-272-2269)



REIMBURSEMENT HOTLINE

LUMA.SON[®] (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use VISUALLY DECISIVE

How we support you

The Bracco Reimbursement Hotline is here to support you for all your reimbursement needs.

Ask coding and billing questions regarding Bracco Diagnostics products and procedures related to those products.

HCPCS codes for products

CPT[®] and HCPCS codes for procedures

Medicare payments

Monday-Friday: 9:00 AM-6:00 PM Eastern Time

For more information on reimbursement, contact the Bracco Reimbursement Hotline at:





askbracco@reimbursement.bracco.com

Please visit us at www.braccoreimbursement.com for more information

On our website, you may sign up to:

- Receive educational emails
- Access our complimentary reimbursement webinars
- Get the latest updates on:
 - Coding
 - Coverage
 - Payment





REFERENCES

1. LUMASON[®] (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use. <u>Full Prescribing Information</u>. Monroe Twp, NJ: Bracco Diagnostics Inc., August 2021

2. 2024 Professional Edition CPT[®] Current Procedural Terminology. American Medical Association. Chicago, IL; 2023.

3. HCPCS Quarterly Update – January 2024 Alpha-Numeric HCPCS Files. Centers for Medicare & Medicaid Services. Accessed February 15, 2024.<u>https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update</u>

4. Physician fee schedule look-up tool. Centers for Medicare & Medicaid Services. Accessed February 22, 2023. <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup</u>

5. Q&A voiding urosonography. American College of Radiology. Published June 24, 2019. Accessed January 12, 2024. <u>https://www.acr.org/Advocacy-and-Economics/Coding-Source/May-June-2019/QandA-Voiding-Urosonography</u>

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