

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

VISUALLY DECISIVE

REIMBURSEMENT RESOURCE KIT **HOPPS**

HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM
January 2024

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

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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 www.fda.gov/medwatch 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.





<u>LUMA</u>SON°

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

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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







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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 are described on page 8.

Coding Modifiers

Under HOPPS, LUMASON UEA is not separately reimbursable, and therefore the JZ and JW Modifiers do not apply under this billing system. They are required for independent imaging centers billing under the Medicare Physician Fee Schedule.

ICD-10 (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: 00270-7099-16.

Medicare Addendum B

These files are updated quarterly and reflect hospital HOPPS payment rates for HCPCS codes and APC codes. <u>www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files.</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: www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

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.





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CODING INFORMATION

Q9950²: LUMASON ultrasound enhancing agent (UEA)

1 vial = 5 mL

Billing unit is per mL, not by vial or doses

Medicare Patients: LUMASON UEA is part of a bundled payment under HOPPS and not 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 page 8 and 9 for a complete list.

Please note that C-codes series is for HOPPS only and generally for Medicare patients.





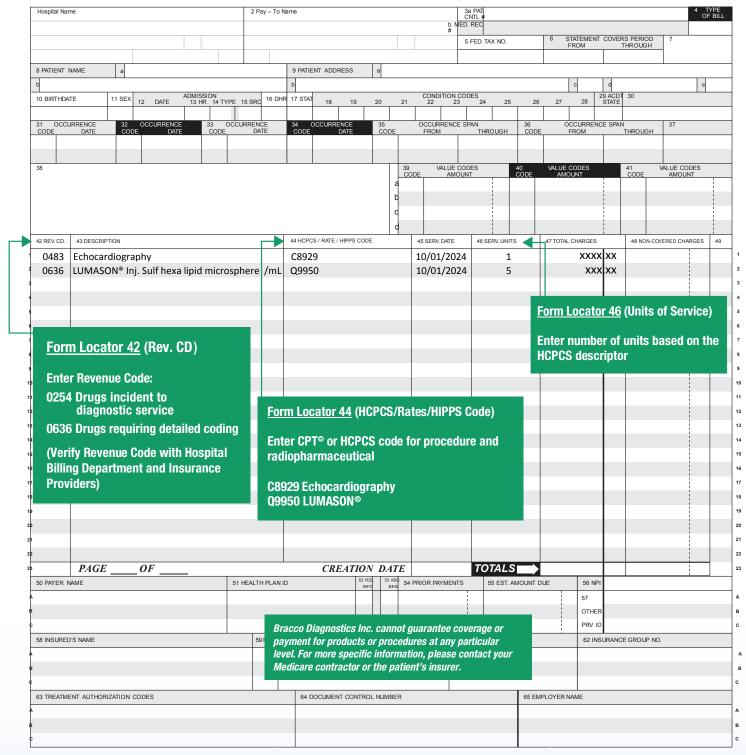


EXAMPLE OF BILLING

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Sample hospital setting billing form UB-04 CMS-1450

Echocardiography with contrast







MEDICARE NATIONAL AVERAGE PAYMENT RATES

Echocardiography: C-codes

HCPCS code ³	Long-description HCPCS	2024 HOPPS National Payment Rate ⁵
C8921	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete	\$763.67
C8922	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study	\$763.67
C8923	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	\$763.67
C8924	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	\$366.80
C8925	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	\$763.67
C8926	Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	\$763.67
C8927	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	\$763.67
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	\$763.67
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	\$763.67
C8930	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	\$763.67

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

CPT®	Without contrast With contrast	C-code
93303	←	C8921
93304	←	C8922
93306	←	C8929
93307	←	C8923
93308	←	C8924

СРТ	Without contrast With contrast	C-code
93312	←	C8925
93315	←	C8926
93318	←──	C8927
93350	←	C8928
93351	←	C8930





MEDICARE NATIONAL AVERAGE PAYMENT RATES FOR HOPPS (cont'd)

Echocardiography CPT® codes² for adult and pediatric patients

Transthoracic echocardiography for congenital cardiac anomalies; complete 9304 Transthoracic echocardiography for congenital cardiac anomalies; follow-up or limited study 526 93306 Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color doppler echocardiography Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only Fransesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report only Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only Echocardiography, transesophageal (TEE) 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	6.17 6.17 3.71 3.71 6.17 6.17 aged 6.17 aged
Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color doppler echocardiography Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report only Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real-time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac \$526	6.17 3.71 3.71 6.17 6.17 aged 6.17 6.17 aged
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p3308 Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study \$233 p3312 Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report \$526 p3313 Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only \$526 p3314 Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only \$526 p3315 Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report only \$526 p3316 Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only \$526 p3317 Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only \$526 p3318 Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real-time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac \$526 p3318 pa318 image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac \$526	3.71 6.17 6.17 aged 6.17 6.17
follow-up or limited study Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); S526	6.17 aged 6.17 6.17 aged
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P3318 Echocardiography, transesophageal (TEE) 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 \$526	
image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac \$526 pumping function and to therapeutic measures on an immediate time basis	3.17
93350 Echocardiography, transthoracic, 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 \$526	3.17
93351 Echocardiography, transthoracic, 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 supervision by a physician or other qualified health care professional \$526	3.17
93352 Use of echocardiographic contrast agent during stress echocardiography (List separately in addition to code for primary procedure) (Do not report 93352 more than once per stress echo cardiogram) (Use 93352 in conjunction with 93350, 93351) Not p	
Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, tavr, transcathether pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, doppler, color flow, and 3d	aged
93320 Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); complete	aged
Add-on code, use 93320 in conjunction with 93303, 93304, 93312, 93314, 93315, 93317, 93350, 93351, C8921, C8922, C8925, C8926, C8928, C8930	
Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); follow-up or limited study (list separately in addition to codes for echocardiographic imaging) Packa	aged
Add-on code, use 93321 in conjunction with 93303, 93304, 93308, 93312, 93314, 93315, 93317, 93350, 93351, C8921, C8922, C8924, C8925, C8928, C8930	
93325 Doppler echocardiography color flow velocity mapping (list separately in addition to codes for echocardiography) Packa	aged
Add-on code, use 93325 in conjunction with 76825, 76826, 76827, 76828, 93303, 93304, 93308, 93312, 93314, 93315, 93317, 93350, 93351, C8921, C8922, C8924, C8925, C8926, C8928, C8930	
+93356 Myocardial strain imaging using speckle tracking derived assessment of myocardial mechanics Packa	aged





MEDICARE NATIONAL AVERAGE PAYMENT RATES FOR HOPPS (cont'd)

Radiology - Liver and Urinary Tract

Ultrasonography of the liver and urinary tract for vesicoureteral reflux²

CPT® code	Description	2024 HOPPS National Payment Rate ⁵
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	\$175.24
+76979, add-on code	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection (List separately in addition to code for primary procedure)	Packaged

Alternate Coding from the American Medical Association

Ultrasonography of the urinary tract for vesicoureteral reflux⁴

CPT® code	Description	2024 HOPPS National Payment Rate ⁵
51600	Injection procedure for cystography or voiding urethrocystography	
74455	Urethrocystography, voiding, radiological supervision and interpretation	\$233.71
74430	Cystography, minimum of 3 views, radiological supervision and interpretation	\$366.80

LUMASON® Ulti	asound Enhancing Agent Note: LUMASON UEA must be coded separately		
HCPCS code ³	Description		
Q9950	Sulfur hexafluoride lipid microspheres, per mL; there are 5 mL per single-use vial of LUMASON UEA.		





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HOSPITAL IN-PATIENT BILLING AND COVERAGE

Hospital in-patient billing: Medicare Severity Adjusted Diagnosis Related Groups (MS-DRG)⁶

ICD-10-PCS procedure codes are used for in-patient billing. They indicate the surgical and/or diagnostic procedures performed on the patient. These codes, in combination with diagnosis codes, help determine the assignment to an MS-DRG payment category under Medicare and other payment systems. Payment in the hospital is determined by the MS-DRG. Under this system, a hospital is paid at a predetermined specific rate for each Medicare discharge. Fixed reimbursement is established for hospital services based on the patient diagnosis and is paid regardless of the actual cost the hospital incurs in providing the services. Ultrasound exams and contrast agents are part of the MS-DRG payment.

Coverage: Medicare National Coverage Decisions (NCD)

Echocardiography is included in the Medicare NCD for ultrasound and is limited. There are Medicare Local Coverage Decisions (LCDs) for echocardiography with contrast.

The echocardiography LCDs can be found on the CMS website at: https://www.cms.gov/medicare-coverage-database/search.aspx.

The Medicare National Coverage Determination (NCD) for ultrasound is non-specific. Abdominal and retroperitoneal ultrasound are covered if medically appropriate.

Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 220.5 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1 Part4.pdf





ORDERING INFORMATION

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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 5 mL of 0.9%
 Sodium Chloride Injection, USP (Diluent)
- One Mini-Spike

Product	LUMASON UEA		
SKU	709916	709916	
NDC	0270-7099-16	0270–7099–16	
Product Description	KIT LUMASON 5x 25MG FLIPCAP		
Product Configuration	Five (5) Vial Kit		
Novaplus®	SKU 709700 NDC 0270-7099-73		



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	
SKU	709707	
NDC	0270–7097–07	
Product Description	MP LUMASON 20x 25MG VIAL/SPIKE US	
Product Configuration	Twenty (20) Vial Pack	
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)





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REIMBURSEMENT HOTLINE

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







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REFERENCES

- 1. LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use. Full Prescribing Information. Monroe Twp, NJ: Bracco Diagnostics Inc., August 2021.
- 2. American Medical Association. 2024 Professional Edition CPT® Current Procedural Terminology. Chicago, IL: American Medical Association; 2023: 416, 546, 563, 792-794.
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