



LUMASON[®]

**(sulfur hexafluoride lipid-type A microspheres)
for injectable suspension**

From Bracco Diagnostics Inc.—

A GLOBAL LEADER IN ENHANCED ECHOCARDIOGRAPHY

2016 REIMBURSEMENT INFORMATION

Disclaimers

The information provided above is general reimbursement information. 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.

INDICATIONS AND USAGE:

LUMASON is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

CONTRAINDICATIONS:

LUMASON is contraindicated in patients with:

- known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts,
- history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON.

Do not administer by intra-arterial injection.

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 [see Warnings and Precautions (5.1)]. Most serious reactions occur within 30 minutes of administration [see Warnings and Precautions (5.1)].

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LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by BRACCO Suisse SA, 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).

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I. LUMASON® INDICATIONS

Lumason is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.¹

II. MEDICARE CODING AND PAYMENT OVERVIEW

Table 1: Medicare Coding and Payment Overview – Contrast National Average Reimbursement Rates

Procedure Setting	Reimbursement	Code	2016 Reimbursement Amount
HOPPS (Hospital Outpatient Setting)	Medicare packages payment for contrast imaging agents into the payment for the associated procedure ²	C8929 ³ Other HCPCS codes exist depending on the type of study completed	\$670.96 ³
HOPPS Transitional Pass Through Code for Lumason only	Temporary additional HOPPS payment for innovative medical devices, drugs and biologicals for Medicare beneficiaries ⁴	Q9950 ⁵	\$33.06/mL ⁵ Five mL's per vial ¹
Hospital In-patient	Part of MS-DRG payment ⁶	ICD-10-PCS ⁷	No separate reimbursement for contrast agents ⁶
Physician Office and Free Standing Imaging Centers	Medicare Part B payment ⁸	Q9950 ⁵	ASP + 6% ⁹ Final payment determined by individual carriers

III. USE OF LUMASON IN THE OUTPATIENT HOSPITAL SETTING (HOPPS)

Payment in an outpatient hospital is based on a prospective payment system. The system is based on groups of procedures, medical visits, and ancillary services.⁴

Under the HOPPS system, contrast agents are not separately payable; rather they are packaged into the Ambulatory Payment Categories (APC) for the procedure with which they are utilized.²

Table 2: 2016 APC Rates (National Average Medicare Rates)³

HCP Code	Description	Payment Amount
Contrast Procedures		
C8921	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete	\$670.96
C8922	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study	\$454.05
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	\$454.05
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	\$454.05
C8929	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), included m-mode recording, when performed, completed, with spectral doppler echocardiography, and with color flow doppler echocardiography	\$670.96

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Transitional Pass Through Code Summary

The Centers for Medicare and Medicaid Services (CMS), under the Social Security Act (the Act), provides for temporary additional payments or “transitional pass through payments” for certain innovative medical devices, drugs, and biologicals for Medicare beneficiaries.⁴

Section 1833(t)(6)(B) of the Act, requires that, under the HOPPS, categories of devices will be eligible for transitional pass-through payments for at least two, but not more than three years. Section 1833(t)(6)(B)(ii)(IV) of the Act, requires that CMS will create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.¹⁰

New for January 1, 2016

The C-code C9457 that was implemented October 1, 2015 for reporting the use of Lumason has since been deleted effective January 1, 2016. As of January 1, 2016, one would report Q9950 when using the Lumason contrast agent in conjunction with the appropriate echocardiography with contrast code. Lumason’s pass through payment is \$33.06 per mL.⁵ There are five mL’s in a single Lumason vial.¹

IV. IMAGING WITH LUMASON IN THE INPATIENT HOSPITAL SETTING

Inpatient Coding

ICD-10-PCS procedure codes, which are used only for inpatient billing, indicate the surgical and/or diagnostic procedures performed on the patient. These codes in combination with diagnosis codes may help to determine assignment to a MS-DRG (payment category) under Medicare and other payment systems.⁷

Inpatient Payment

Payment for inpatient hospital services is based on a classification system determined by patient diagnosis known as Medicare Severity Adjusted Diagnosis Related Groups or MS-DRGs. Under MS-DRGs, a hospital is paid at a predetermined, specific rate for each Medicare discharge. Fixed prices are established for hospital services based on the patient diagnosis and are paid regardless of the actual cost the hospital incurs in providing these services.⁶

V. LUMASON IN THE PHYSICIAN OFFICE/IDTF SETTING

When performed in the physicians office or IDTF, Q9950 Injection, sulfur hexafluoride lipid microsphere, would be reported along with the code for the echocardiography procedure. Q9950 indicates the use of Lumason contrast agent.⁵ Payment amounts are based upon manufacturer reported Average Sales Price (ASP) + 6% which is reimbursed at the discretion of the Local Medicare Contractors.⁹

It is recommended that you check with your individual payer for their specific coding, coverage, preauthorization, and payment requirements.

Please refer to the Prescribing Information, including boxed WARNING, inside the pocket of this brochure for complete dosing instructions and additional product information.

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References:

1 Lumason (sulfur hexafluoride lipid type-A microspheres) for injectable suspension full Prescribing Information. Monroe Township, NJ: Bracco Diagnostics Inc., October 2014. **2** <https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/mm8338.pdf> **3** <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending><https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctst.pdf> 2016 OPPS Final Rule Addenda, Addendum B Line 10997 **4** <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctst.pdf> **5** <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending><https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctst.pdf> 2016 OPPS Final Rule Addenda, Addendum B Line 15449 **6** <http://health-information.advanceweb.com/Web-Extras/CCS-Prep/An-Inpatient-Prospective-Payment-System-Refresh-MS-DRGs-2.aspx>. **7** <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/ICD-10Overview.pdf> **8** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Radiology_FactSheet_ICN907164.pdf **9** https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/McrPartBDrugAvgSalesPrice/10_VaccinesPricing.asp **10** <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9205.pdf>

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