

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

# 2017 LUMASON® ULTRASOUND CONTRAST AGENT REIMBURSEMENT RESOURCE KIT

Updated March 20, 2017

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### Significant restructuring of APC<sup>2</sup>

In 2017, the APC structure used in radiology, echocardiography, and ultrasound services was consolidated from 17 codes to only 7 codes. A detailed description of changes in procedure APC coding from 2016 to 2017 can be found on **pages 4** and **5**.

### Summary of 2017 imaging APCs<sup>3</sup>

Final CY 2017 Imaging APCs	APC	2017 payment levels
Level 1 Imaging without Contrast	5521	\$59.86
Level 2 Imaging without Contrast	5522	\$112.73
Level 3 Imaging without Contrast	5523	\$225.91
Level 4 Imaging without Contrast	5524	\$449.68
Level 1 Imaging with Contrast	5571	\$265.02
Level 2 Imaging with Contrast	5572	\$426.52
Level 3 Imaging with Contrast	5573	\$656.91

APC=Ambulatory Payment Classification;

HOPPS=Hospital Outpatient Prospective Payment System.

### INDICATIONS AND USAGE<sup>1</sup>

LUMASON 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 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

### **CONTRAINDICATIONS**<sup>1</sup>

LUMASON is contraindicated in patients with:

• history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

### 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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- Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

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# WHAT'S NEW IN 2017? HOPPS (cont'd)

### <u>LUMA</u>SON®

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

### 2016 APCs vs 2017 APCs<sup>4</sup>

HCPCS/ CPT® codes	Short descriptor	APC 2016	APC 2016 description	New APC 2017	APC 2017 description
Echocardio	graphy				
93303	Echo transthoracic	5534	Ultrasound & related services level 4	5524	Level 4 Imaging without contrast
93304	Echo transthoracic	5533	Ultrasound & related services level 3	5524	Level 4 Imaging without contrast
93306	TTE w/doppler complete	5533	Ultrasound & related services Level 3	5524	Level 4 Imaging without contrast
93307	TTE w/o doppler complete	5533	Ultrasound & related services Level 3	5524	Level 4 Imaging without contrast
93308	TTE f-up or Imtd	5532	Ultrasound & related services Level 2	5523	Level 3 Imaging without contrast
93312	Echo transesophageal	5534	Ultrasound & related services Level 4	5524	Level 4 Imaging without contrast
93313	Echo transesophageal	5534	Ultrasound & related services Level 4	5524	Level 4 Imaging without contrast
93315	Echo transesophageal	5534	Ultrasound & related services Level 4	5524	Level 4 Imaging without contrast
93316	Echo transesophageal	5534	Ultrasound & related services Level 4	5524	Level 4 Imaging without contrast
93318	Echo transesophageal intraop	5534	Ultrasound & related services Level 4	5524	Level 4 Imaging without contrast
93350	Stress TTE only	5533	Ultrasound & related services Level 3	5524	Level 4 Imaging without contrast
93351	Stress TTE complete	5533	Ultrasound & related services Level 3	5524	Level 4 Imaging without contrast
C8921	TTE w or w/o fol w/cont, com	5562	Ultrasound & related services Level 3	5573	Level 3 Imaging with contrast
C8922	TTE w or w/o fol w/cont, f/u	5561	Echo with contrast- level 1	5573	Level 3 Imaging with contrast
C8923	2d TTE w or w/o fol w/con, co	5561	Echo with contrast- level 1	5573	Level 3 Imaging with contrast
C8924	2d TTE w or w/o fol w/con, fu	5561	Echo with contrast- level 1	5572	Level 2 Imaging with contrast
C8925	2d TEE w or w/o fol w/con, in	5562	Echo with contrast- level 2	5573	Level 3 Imaging with contrast
C8926	TEE w or w/o fol w/cont, cong	5562	Echo with contrast- level 2	5573	Level 3 Imaging with contrast
C8927	TEE w or w/o fol w/cont, mon	5562	Echo with contrast -level 2	5573	Level 3 Imaging with contrast
C8928	TTE w or w/o fol w/con, stres	5562	Echo with contrast- level 2	5573	Level 3 Imaging with contrast
C8929	TTE w or w/o fol wcon, doppler	5562	Echo with contrast- level 2	5573	Level 3 Imaging with contrast
C8930	TTE w or w/o contr, cont ecg	5562	Echo with contrast- level 2	5573	Level 3 Imaging with contrast

CPT=Current Procedural Terminology;

HCPCS=Healthcare Common Procedure Coding System.

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### 2016 APCs vs 2017 APCs (cont'd)<sup>4</sup>

HCPCS/ CPT® codes	Short descriptor	APC 2016	APC 2016 description	New APC 2017	APC 2017 description
Ultrasonog	raphy of the liver				
C9744	Ultrasound of abdomen with contrast - new Oct. 1, 2016 <sup>5</sup>	5571	Level 1 CT with contrast & CT angiography	5571	Level 1 Imaging with contrast
76700	Ultrasound of abdomen complete	5532	Ultrasound & related services level 2	5522	Level 2 Imaging without contrast
76705	Ultrasound of abdomen limited	5532	Ultrasound & related services level 2	5522	Level 2 Imaging without contrast
Ultrasonog	raphy of the urinary tract				
C9744	Ultrasound of abdomen with contrast - updated March 3, 2017 <sup>5</sup>	5571	Level 1 CT with contrast & CT angiography	5571	Level 1 Imaging with contrast
76770	Ultrasound retroperitoneal, complete	5532	Ultrasound & related services level 2	5522	Level 2 Imaging without contrast
76775	Ultrasound, retroperitoneal, limited	5532	Ultrasound & related services level 2	5522	Level 2 Imaging without contrast

### *New HCPCS C-code for ultrasound, abdominal with contrast—Code C9744<sup>5</sup>*

On March 3, 2017, CMS Transmittal 3728 provided a more complete definition: "as a reminder to hospital providers, HCPCS code C9744 (Ultrasound, abdominal, with contrast) may be used to describe use of a contrast agent in ultrasonography of the liver, kidneys and/or bladder." For more information, visit: <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3728CP.pdf">www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3728CP.pdf</a>.

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# LUMASON Pass-Through Payment—HOPPS

### LUMASON has Pass-Through payment status

Payment in an outpatient hospital clinic is based on a prospective payment system. The system is based on groups of procedures, medical visits, and ancillary services. Under the HOPPS system, contrast agents are not separately payable; rather, they are packaged into the APCs for the procedure with which they are utilized.

However, there is an exception in the case of LUMASON, because of its Pass-Through payment status. A Pass-Through payment status means that a temporary additional HOPPS payment is made for innovative devices, drugs, and biologicals for Medicare beneficiaries. It is not subject to coinsurance or packaging rules. LUMASON Pass-Through payment value is updated guarterly: go to Medicare Addendum B—code Q9950 for the current reimbursement: https://www.cms. gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-CN.html.

It is important to code Q9950 and all the mL used and discarded for a total of 5 mL to benefit from the Pass-Through payment along with the specific procedure performed, and effective January 1, 2017, Medicare requires the use of the JW *modifier* to indicate the amount of discarded drug/product from a single-use vial. For more information: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.

To find out which APC is applicable to the procedure code, please refer to the 2016 APCs vs 2017 APCs chart under the What's new in 2017? HOPPS section of this quide.



UMASON

use or intravesical use

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

### Each mL of LUMASON is billable

# Lumason

sulfur hexafluor microspheres) lyo injectable suspent hexafluoride/ 25 me For intravenous use aff njection, USP. (Diluent) Date & time of reconstitu Discard Unused Portion al Distributed by Bracco Diag

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### **LUMASON**<sup>®</sup> (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

### Sample hospital setting billing form UB-04 CMS-1450 Echocardiography with LUMASON

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NUBC<sup>\*</sup>National United Billing Committee LIC921325

Bracco Diagnostics Inc. cannot guarantee coverage or payment for products or procedures at any particular level. For more specific information please contact your Medicare contractor or the patient's insurer.

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history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### **IMPORTANT SAFETY INFORMATION<sup>1</sup>**

### 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)]. • Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].

- Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].1 Please see full Prescribing Information including boxed WARNING at http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhancedultrasound/lumason/prescribing-information.

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.



Committed to Science, Committed to You."

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

# LUMASON is the only ultrasound contrast agent with 3 indications and Pass-Through payment status<sup>1</sup>

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

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

# NEW—On Dec. 22, 2016, LUMASON received FDA approval for:

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

### INDICATIONS AND USAGE<sup>1</sup>

LUMASON 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 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

### **CONTRAINDICATIONS<sup>1</sup>**

LUMASON is contraindicated in patients with:

• history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

### 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)]. • Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].

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The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].<sup>1</sup> Please see full Prescribing Information including boxed **WARNING** at <a href="http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information">http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information</a>.



### Using the correct codes is the first step to support correct reimbursement

Procedures must be coded correctly in order to obtain appropriate reimbursement from both CMS and commercial payers. The following describes the types of codes that may be applied when submitting claims for echocardiography, ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients, or ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients.

### **CPT**<sup>®</sup>

Codes used to report the service or procedure performed.

### **HCPCS**

Codes used to report the provision of supplies, materials, injections, and certain services and procedures. For example, the HCPCS code for LUMASON 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 11, and the new C-code for ultrasound of the abdomen with contrast: C9744.

### 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.

### APC

This is the payment system of HOPPS. A summary chart of the changes in 2017 with the new APCs is included on **pages 4** and **5** of this guide.

### NDC (National Drug Code)

An NDC code provides a unique identifier for a specific drug. The NDC for LUMASON is: 0270-7099-16.

### **Medicare Addendum B**

These files are updated quarterly and reflect hospital HOPPS payment rates for HCPCS codes and APC codes. This is also where the Pass-Through code for LUMASON (Q9950) can be found: <a href="https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates.html">www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates.html</a>.

### Medicare Part B ASP (average selling price) file

Quarterly payment files are published for independent diagnostic testing facilities (IDTFs) or physician offices. This is where the payment value for LUMASON (Q9950) can be found at: <u>www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/</u><u>McrPartBDrugAvgSalesPrice/2017ASPFiles.html</u>.

### 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. See **MEDICARE NATIONAL AVERAGE PAYMENTS FOR PHYSICIAN OFFICE & IDTFs** chart for echocardiography and ultrasound procedures covered on **page 14** of this guide. To find out more information on specific locations visit: <u>www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSLookup/index.html?redirect=/pfslookup</u>.

### **INDICATIONS AND USAGE<sup>1</sup>**

LUMASON 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 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

### CONTRAINDICATIONS<sup>1</sup>

LUMASON is contraindicated in patients with:

• history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

### 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)].

• Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].

• Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].<sup>1</sup> Please see full Prescribing Information including boxed **WARNING** at <a href="http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information">http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information</a>.



### **CPT® & HCPCS codes**

The following chart displays codes for procedures using LUMASON.

CPT®/HCPCS codes	Description
Q9950	Sulfur hexafluoride lipid microspheres, per mL; there are 5 mL per single-use vial of LUMASON. The Pass-Through payment for LUMASON is effective until December 31, 2017. The ASP or payment rate for the Pass-Through payment is updated on a quarterly basis in the Medicare Addendum B. LUMASON is paid separately in the physician office/IDTF; refer to the Medicare Part B drug ASP file for the current payment value. Links are provided to find the quarterly update on <b>page 9</b> of this guide. Starting Jan. 1, 2017, CMS is requiring the use of the <i>JW modifier</i> to indicate the number of mL or units discarded for single-use vial drugs. Visit <u>www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates.html</u> for more information. Note that LUMASON, HCPCS code Q9950, is always separately coded along with the appropriate procedure performed as defined below
Echocardiography procedure codes <sup>4,6</sup>	
	See chart Echocardiography: Cross Walk Codes Without and With Contrast on page 13 of this guide
933xx series and C-8921-30 series	Note that the C-codes series is for HOPPS only
	Some commercial payers may accept C-codes. Providers need to check with their contracts
Ultrasonography of the liver <sup>4,6</sup>	
C9744	Ultrasound, abdominal, with contrast, for HOPPS only, some commercial payers may accept the C-code
76700	Ultrasound, abdominal w/real time documentation, complete
76705	Ultrasound, abdominal w/real time documentation, limited
Ultrasonography of urinary tract for ve	sicoureteral reflux <sup>4-6</sup>
C9744	Ultrasound, abdominal, with contrast, for HOPPS only, some commercial payers may accept the C-code
76770	Ultrasound, retroperitoneal, real time with image documentation, complete
76775	Ultrasound, retroperitoneal, real time with image documentation, limited
Other codes that may apply based on s	etting and payer <sup>7</sup>
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single, or initial susbstance/drug. Not billable by the physician. Not appropriate with modifiers -26 or TC. Applicable if the physician provider bills from a place of service (11)

### **INDICATIONS AND USAGE<sup>1</sup>**

LUMASON 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 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

### **CONTRAINDICATIONS1**

LUMASON is contraindicated in patients with:

• history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

### 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)].

- Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
- Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].<sup>1</sup> Please see full Prescribing Information including boxed **WARNING** at <a href="http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information">http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information</a>.



LUMA SON®

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

### **Medicare National Payment Rates for HOPPS**

### Medicare National Payment Rates: echocardiography HCPCS C-code series for Medicare—HOPPS<sup>4</sup>

HCPCS code	Long-description HCPCS	2017 HOPPS National Payment Rate - HCPCS
C8921	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete	\$656.91
C8922	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study	\$656.91
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	\$656.91
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	\$426.52
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	\$656.91
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	\$656.91
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	\$656.91
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	\$656.91
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	\$656.91
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	\$656.91

### INDICATIONS AND USAGE<sup>1</sup>

LUMASON 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 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

### **CONTRAINDICATIONS**<sup>1</sup>

LUMASON is contraindicated in patients with:

• history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

### 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)].

- Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
- Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].<sup>1</sup> Please see full Prescribing Information including boxed **WARNING** at <a href="http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information">http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information</a>.



### LUMASON®

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

### Medicare National Payment Rates for HOPPS (cont'd)

Medicare National Payment Rates: echocardiography CPT<sup>®</sup> codes for non-Medicare and commercial payers—HOPPS<sup>4</sup>

CPT® code	Long-description CPT®	2017 HOPPS National Payment Rate - CPT®
93303	Transthoracic echocardiography for congenital cardiac anomalies; complete	\$449.68
93304	Transthoracic echocardiography for congenital cardiac anomalies; follow-up or limited study	\$449.68
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	\$449.68
93307	Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color doppler echocardiography	\$449.68
93308	Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study	\$225.91
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report	\$449.68
93313	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only	\$449.68
93314	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only	packaged
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	\$449.68
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only	\$449.68
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only	packaged
93318	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	\$449.68
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;	\$449.68
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	\$449.68
93352	Use of echocardiographic contrast agent during stress echocardiography (list separately in addition to code for primary procedure)	not paid under OPPS
93355	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	packaged
93320	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); complete	packaged
	Add-on code, use 93320 in conjunction with 93303, 93304, 93312, 93314, 93315, 93317, 93350, 93351, C8921, C8922, C8925, C8926, C8928, C8930	
93321	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)	packaged
	Add-on code, use 93321 in conjunction with 93303, 93304, 93308, 93312, 93314, 93315, 93317, 93350,93351, C8921, C8922, C8924, C8925, C8926, C8928, C8930	
93325	Doppler echocardiography color flow velocity mapping (list separately in addition to codes for echocardiography)	packaged
	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	

### **INDICATIONS AND USAGE<sup>1</sup>**

LUMASON 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 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

### **CONTRAINDICATIONS<sup>1</sup>**

- LUMASON is contraindicated in patients with:
  - history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### **IMPORTANT SAFETY INFORMATION<sup>1</sup>**

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)]. Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
 Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].1 Please see full Prescribing Information including boxed WARNING at http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhancedultrasound/lumason/prescribing-information.

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Committed to Science, Committed to You.™

### LUMASON®

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### **Medicare National Payment Rates for HOPPS**

### Ultrasonography of the liver: Medicare National Payment Rates HOPPS<sup>4</sup>

CPT® code	Long-description CPT®	2017 HOPPS National Payment Rate - CPT®
C9744	Ultrasound, abdominal, with contrast, for HOPPS only, some commercial payers may accept the C-code	\$265.02
76700	Ultrasound, abdominal, w/real-time documentation, complete	\$112.73
76705	Ultrasound, abdominal w/real-time documentation, limited	\$112.73

### Ultrasonography of the urinary tract: Medicare National Payment Rates HOPPS<sup>4,5</sup>

CPT® code	Long-description CPT®	2017 HOPPS National Payment Rate - CPT®
C9744	Ultrasound, abdominal, with contrast, for HOPPS only, some commercial payers may accept the C-code	\$265.02
76770	Ultrasound, retroperitoneal, real time with image documentation, complete	\$112.73
76775	Ultrasound, retroperitoneal, real time with image documentation, limited	\$112.73

### Echocardiography: Cross Walk Codes Without and With Contrast<sup>4,6</sup>

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

### INDICATIONS AND USAGE<sup>1</sup>

LUMASON 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 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

### **CONTRAINDICATIONS<sup>1</sup>**

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### IMPORTANT SAFETY INFORMATION<sup>1</sup>

### 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)]. • Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].

• Always have resuscitation equipment and trained personnel readily available *[see Warnings and Precautions (4)]*.

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].<sup>1</sup> Please see full Prescribing Information including boxed **WARNING** at <a href="http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information">http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information</a>.



### **LUMASON**<sup>®</sup>

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

### Medicare National Average Payments for physician office & IDTFs<sup>8</sup>

### Echocardiography

Lenocardiography					
CPT®		Short descriptor	Payment		
93303	TC	TTE limited congenital	\$175.14		
93303	26	TTE limited congenital	\$64.96		
93303	G	TTE limited congenital	\$240.10		
93304	TC	TTE limited	\$120.23		
93304	26	TTE limited	\$37.32		
93304	G	TTE limited	\$157.55		
93306	TC	TTE comp, Dop, CF	\$166.52		
93306	26	TTE comp, Dop, CF	\$64.96		
93306	G	TTE comp, Dop, CF	\$231.48		
93307	TC	TTE comp, w/o Dop, CF	\$85.77		
93307	26	TTE comp, w/o Dop, CF	\$45.94		
93307	G	TTE comp, w/o Dop, CF	\$131.71		
93308	TC	TTE F/U or limited	\$100.49		
93308	26	TTE F/U or limited	\$26.20		
93308	G	TTE F/U or limited	\$126.69		
93312	TC	TEE place acq,int, rep.	\$138.17		
93312	26	TEE place acq,int, rep.	\$111.61		
93312	G	TEE place acq,int, rep.	\$249.79		
93314	TC	TEE acq, inter, report	\$146.78		
93314	26	TEE acq, inter, report	\$93.31		
93314	G	TEE acq, inter, report	\$240.10		

CPT®		Short descriptor	Payment
93315	26	TEE cong. acq, inter, report	\$131.93
93317	26	TEE acq, inter, report only	\$95.46
93318	26	TEE monitoring	\$107.31
93320	TC	Doppler echo	\$36.25
93320	26	Doppler echo	\$18.66
93320	G	Doppler echo	\$54.91
93321	TC	Doppler echo F/U or limited	\$20.10
93321	26	Doppler echo F/U or limited	\$7.54
93321	G	Doppler echo F/U or limited	\$27.63
93325	TC	Doppler color flow add-on	\$22.61
93325	26	Doppler color flow add-on	\$3.23
93325	G	Doppler color flow add-on	\$25.84
93350	TC	Stress TTE only	\$171.55
93350	26	Stress TTE only	\$72.50
93350	G	Stress TTE only	\$244.04
93351	TC	Stress TTE with exercise	\$188.06
93351	26	Stress TTE with exercise	\$86.85
93351	G	Stress TTE with exercise	\$274.91
93352	G	Use of contrast at stress	\$34.45

### Ultrasonography of the liver<sup>8</sup>

<b>CPT</b> ®		Short descriptor	Payment	СРТ®		Short descriptor
76700	TC	Ultrasound of abdomen, complete	\$83.62	76770	TC	Ultrasound, retrope
76700	26	Ultrasound of abdomen, complete	\$41.27	76770	26	Ultrasound, retrope
76700	G	Ultrasound of abdomen, complete	\$124.89	76770	G	Ultrasound, retrope
76705	TC	Ultrasound of abdomen, limited	\$63.16	76775	TC	Ultrasound, retrope
76705	26	Ultrasound of abdomen, limited	\$30.15	76775	26	Ultrasound, retrope
76705	G	Ultrasound of abdomen, limited	\$93.31	76775	G	Ultrasound, retrope

VUR=vesicoureteral reflux.

### **INDICATIONS AND USAGE<sup>1</sup>**

LUMASON 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 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

### **CONTRAINDICATIONS<sup>1</sup>**

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• history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### **IMPORTANT SAFETY INFORMATION<sup>1</sup>**

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)].

Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].1 Please see full Prescribing Information including boxed WARNING at http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhancedultrasound/lumason/prescribing-information.

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.



### Ultrasonography of the urinary tract – VUR<sup>8</sup>

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СРТ®		Short descriptor	Payment
76770	TC	Ultrasound, retroperitoneal complete	\$77.88
76770	26	Ultrasound, retroperitoneal, complete	\$37.68
76770	G	Ultrasound, retroperitoneal, complete	\$115.56
76775	TC	Ultrasound, retroperitoneal, limited	\$30.15
76775	26	Ultrasound, retroperitoneal, limited	\$29.43
76775	G	Ultrasound, retroperitoneal, limited	\$59.58

# **PHYSICIAN OFFICE & IDTF BILLING**

### LUMA SON<sup>®</sup> (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

### LUMASON is paid separately by Medicare Part B

When an echocardiogram or other type of ultrasound exam is performed in the physician's office or IDTF, LUMASON (Q9950) is paid separately by Medicare Part B and is reported along with the appropriate CPT<sup>®</sup> procedure code. LUMASON (Q9950) contrast agent payment amounts are based on ASP (average selling price + 6%) and are reimbursed at the discretion of the Local Medicare Contractors (MAC). Payment rates are adjusted quarterly; please refer to the Medicare Part B ASP file at: <a href="http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2017ASPFiles.html">www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2017ASPFiles.html</a>.

LUMASON is a single-use vial. Medicare allows reimbursement for the amount injected and the amount discarded for single-use vials.

Effective January 1, 2017, the *JW modifier* is required on the claim form. The *JW modifier* documents the amount of a single-use vial that is discarded. LUMASON contains a total of 5 mL. For more information: <a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf">www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf</a>.

The Medicare National Average payment rates for global (G), technical (TC), and professional (26) for the procedures are listed in **MEDICARE NATIONAL AVERAGE PAYMENTS FOR PHYSICIAN OFFICE & IDTF** chart in the **CODING** section of this guide.

Commercial payers usually reimburse contrasts agents separately in the physician office and IDTF setting. Providers need to verify their contracts to confirm coding, coverage, and payment amounts.

### INDICATIONS AND USAGE<sup>1</sup>

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### IMPORTANT SAFETY INFORMATION<sup>1</sup>

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### LUMA SON®

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

### Sample physician billing global non-hospital outpatient setting CMS-1500 Echocardiography with LUMASON

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NUCC Instruction Manual available at: www.nucc.org

Bracco Diagnostics Inc. cannot guarantee coverage or payment for products or procedures at any particular level. For more specific information please contact your Medicare contractor or the patient's insurer.

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## **HOSPITAL IN-PATIENT BILLING AND COVERAGE**

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

### Hospital in-patient billing: Medicare Severity Adjusted Diagnosis Related Groups (MS-DRG)<sup>9</sup>

ICD-10 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 a 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: <a href="http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx">www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx</a>.

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 <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\_Part4.pdf</u>

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# **REIMBURSEMENT HOTLINE**

# LUMA SON®

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

### 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<sup>®</sup> and HCPCS codes for procedures

Medicare payments



For more information on reimbursement, contact the Bracco Reimbursement Hotline at: Askbracco@reimbursement.bracco.com

### Or call: 1-800-349-1388 Monday-Friday: 9:00 ам-6:00 рм Eastern Time

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., December 2016. 2. Slavitt AM, Burwell SM. Federal Register, Vol. 81, No 219. Monday, November 14, 2016. Rules and Regulations. CMS-1655-FC and IFC. Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Payment systems final rules 2017. Washington, DC: Centers for Medicare & Medicaid Services, Department of Health and Human Services. www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf. Published November 14, 2016. Accessed January 31, 2017. 3. Centers for Medicare & Medicaid Services. Hospital Outpatient Prospective Payment—Correction Notice. Centers for Medicare & Medicaid Services Web site. www.cms.gov/Medicare/Medicare/Eee-for-Service-Payment/ HospitalOutpatientPPS/Hospital-Outpatient-Regulations and Notices: Addendum B; January 2017. Centers for Medicare & Medicaid Services Web site. www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates-Items/2017-January-Addendum-B.html. Accessed January 31, 2017. 5. CMS Manual System. Pub 100-04 Medicare Claims Processing. Transmittal 3728. Department of Health & Human Services (DHHS). Centers for Medicare & Medicaid Services (CMS). March 3, 2017. Change Request 10005. April 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS). https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3728CP.pdf. 6. American Medical Association. 2017 Professional Edition CPT® current procedural terminology. Chicago, IL: American Medical Association; 2017. 456-457, 618-621. 7. American College of Radiology. Web site. www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PESlookup/index.html. Accessed January 31, 2017. 9. Centers for Medicare & Medicaid Services. Physician Fee Schedule Look-UP Tool. Centers for Medicare Claims Procedural terminology. Chicago, IL: Am

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# **LUMASON ORDERING INFORMATION**

LUMASON<sup>®</sup>

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

### Ordering information

NDC#	0270-7099-16
Product description	LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use, 25 mg/vial
Packaging	5 kits per box
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### Customer Service: 1-877-BRACCO 9 (1-877-272-2269)

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### 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.

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 is a registered trademark of Bracco Diagnostics Inc.

Bracco Diagnostics Inc. 259 Prospect Plains Road, Building H Monroe Township, NJ 08831 USA Phone: 609-514-2200 Toll Free: 1-877-272-2269 (U.S. only) Fax: 609-514-2446

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