

Ultrasound Enhancing Agents: Clinical Logistics



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Storage/Accessibility

Mini-fridge



Cabinet



Medstations



Administration Policy to Consider

Storage/Accessibility

Personnel

- IV Start: Sonographer / Nurse / Fellow / Physician
- UEA Administration: Sonographer / Nurse / Fellow / Physician
- Agitated Saline Administration: Sonographer / Nurse / Fellow / Physician

Process for Order

- Fellow or attending cardiologist approves / provides order

Administration Privileges

Consent and/or Education

- Patient education with respect to risks associated with reaction
- Outpatients vs. Inpatients

COMPETENCY CHECKLIST						
Purpose: These are the standards of the technical competencies necessary for performance and/or clinical practice. They supplement continuing education programs and the quality improvement program.						
To meet competency standard the employee must demonstrate proficiency in performing the technical procedures safely as evidenced by department specific criteria.						
Standards Met By:						
A. Demonstration		D. Skills Lab		G. Other		
B. Direct Observation/Checklist		E. Self Study/Test				
C. Video Review		F. Data Management				
NAME:			JOB TITLE:			
CORE COMPETENCIES	DATE	STANDARD MET BY	SUPERVISORS INITIALS	STANDARD MET	STANDARD NOT MET	COMMENTS
• Provides knowledge of mission statement.						
• Performs proper customer service techniques (ie: phone etiquette).						
• Visibly wears I.D. Badge at all times.						
• Demonstrates ability to communicate with others (oral and written).						
• Describes Total Quality Initiative program.						
• Works effectively in a team atmosphere.						
• Demonstrates ability to make logical decisions and seek assistance if necessary.						
• Demonstrates knowledge of the Code of Ethics.						
• Insures all levels of Confidentiality are maintained.						
CORE SAFETY COMPETENCIES						
• Performs specific roles/responsibilities during emergencies.						
• Demonstrates knowledge of fire system, fire extinguishers and evacuation policy.						

Comprehensive UEA training for all Sonographers!!

Laboratory Policy & Procedure



Cardiac Non Invasive Services- Echocardiography Lab

PROTOCOL FOR CONTRAST ADMINISTRATION

SUBJECT: Utilization of microbubble contrast agents for left ventricular opacification and endocardial border delineation (LVO EBD).

PURPOSE: To optimize the assessment of left ventricular function in patients with a suboptimal acoustic window, or to provide an accurate and reproducible quantitative LV ejection fraction. Other benefits of contrast agents include delineation of intracavitary masses (e.g. thrombi or tumors), apical abnormalities (apical HCM, non-compaction, aneurysm or pseudoaneurysm) and enhancement of Doppler signals in the systemic circulation (pulmonary venous inflow, aortic flow signal).

PROCEDURE:

I. Equipment/Supplies

- Peripheral intravenous.
- Syringe pump with microbore tubing.
- Echo machine with digital acquisition system and integrated contrast echo software.
- Intravenous setup (angiocatheters, tubing, etc.)
- 30 mL saline bag (or equivalent), Optispike/Inlepen(or needles)
- Microbubble contrast agent (Opison, Definity).
- Blood pressure, O₂ sat monitor (if required – see below)

II. Personnel

- A sonographer can perform the studies independently.
- Medical supervision will be provided directly or indirectly by a Cardiology Fellow or Echocardiography Attending Physician.
- The rationale for the use of contrast and the protocol will be explained to the patient by the sonographer, fellow or attending (as appropriate). The patient will be informed that there is a 1:15,000 risk of severe allergic reaction to the contrast agents. For Definity, there is a 1:200 risk of back pain reaction. The absence of contraindications to contrast will be confirmed verbally. An order for the contrast agent will be entered into EPIC and co-signed by the echo attending (for outpatients at the time of this writing, a paper order will be filled out and scanned into EPIC).

III. Contraindications to ultrasound contrast agents

- Known allergy to Definity or Opison
- Pregnant or lactating female
- Severe pulmonary hypertension (peak RVSP > 60 mmHg)
- Allergy to blood or blood products (for Opison)
- Known significant intracardiac R-L shunt

IV. Requirements for monitoring

Patients with known or suspected acute coronary syndromes, acute myocardial infarction, decompensated heart failure, and those with severe respiratory compromise should be monitored (intermittent BP and O₂ saturations) for up to 30 min after administration of either Opison or Definity

Protocol for administration of ultrasound contrast agents

- Preparation of ultrasound contrast agents
 - For Opison, gently agitate the vial to resuspend the microbubbles in the vial
 - For Definity, activate the agent in a Vialmix for 45 s
 - Withdraw 27 mL (for Opison) or 28.5 mL (for Definity) of 0.9% NS into a 35 mL syringe
 - Using an Optispike, withdraw the contents of a vial of Opison (3 mL) or Definity (1.5 mL) into the saline syringe. Leave 0.5 mL of airspace within the syringe to help keep the microbubbles suspended. Gently rotate the syringe to mix the contrast agent in the syringe.
 - Attach microbore tubing to the syringe and flush through with the diluted contrast agent
- Infusion of diluted contrast agents
 - Insert the syringe into a syringe pump.
 - For most patients, and infusion rate of approximately 90 mL/h will provide good LVO EBD
 - Adjust infusion rate to obtain adequate enhancement, while minimizing far-field attenuation

Bibliography: Mulvagh SL, Rakowski H, Vannan MA, Abdelmoneim SS, Becher H, Bierig SM, Burns PN, Castello R, Coon PD, Hagen ME, Jollis JG, Kimball TR, Kitzman DW, Kronzon I, Labovitz AJ, Lang RM, Mathew J, Moir WS, Nagueh SF, Pearlman AS, Perez JE, Porter TR, Rosenbloom J, Strachan GM, Thanigaraj S, Wei K, Woo A, Yu EH, Zoghbi WA. American Society of Echocardiography. American Society of Echocardiography Consensus Statement on the Clinical Applications of Ultrasonic Contrast Agents in Echocardiography. *J Am Soc Echocardiogr* 2008;21:1179-1201

Related forms and Procedures:

Supersedes:

Originator/Author: Kevin Wei, MD

Approved by:

Medical Director Diana Rinkovich, MD

Department Director Kristin Ellison, MBA



GUIDELINES AND STANDARDS

Guidelines for the Cardiac Sonographer in the Performance of Contrast Echocardiography: A Focused Update from the American Society of Echocardiography

Thomas R. Porter, MD, FASE (Chair), Sahar Abdelmoneim, MD, J. Todd Belcik, BS, RCS, RDCS, FASE, Marti L. McCulloch, MBA, RDCS, FASE, Sharon L. Mulvagh, MD, FASE, Joan J. Olson, BS, RDCS, RVT, FASE, Charlene Porcelli, BS, RDCS, RDMS, FASE, Jeane M. Tsutsui, MD, and Kevin Wei, MD, FASE, *Omaha, Nebraska; Rochester, Minnesota; Portland, Oregon; Houston, Texas; Charleston, South Carolina; São Paulo, Brazil*

(J Am Soc Echocardiogr 2014;27:797-810.)

Keywords: Echocardiography, Sonographer, Contrast, Imaging

(APPENDIX) Best Practices for Administration

- Oregon Health & Science University
- Medical University of South Carolina
- Houston Methodist Hospital
- Mayo Clinic, Rochester
- University of Nebraska Medical Center

GUIDELINES AND STANDARDS

Clinical Applications of Ultrasonic Enhancing Agents in Echocardiography: 2018 American Society of Echocardiography Guidelines Update

Thomas R. Porter, MD, FASE (Chair), Sharon L. Mulvagh, MD, FASE (Co-Chair), Sahar S. Abdelmoneim, MBBCH, MSc, MS, FASE, Harald Becher, MD, PhD, J. Todd Belcik, BS, ACS, RDCS, FASE, Michelle Bierig, MPH, ACS, RDCS, FASE, Jonathan Choy, MD, MBA, FASE, Nicola Gaibazzi, MD, PhD, Linda D. Gillam, MD, MPH, FASE, Rajesh Janardhanan, MD, MRCP, FASE, Shelby Kutty, MD, PhD, MHCM, FASE, Howard Leong-Poi, MD, FASE, Jonathan R. Lindner, MD, FASE, Michael L. Main, MD, FASE, Wilson Mathias, Jr., MD, Margaret M. Park, BS, ACS, RDCS, RVT, FASE, Roxy Senior, MD, DM, and Flordeliza Villanueva, MD, *Omaha, Nebraska; Rochester, Minnesota; Edmonton, Alberta, Canada; Portland, Oregon; Fort Myers, Florida; Parma, Italy; Morristown, New Jersey; Tucson, Arizona; Toronto, Ontario, Canada; Kansas City, Missouri; São Paulo, Brazil; Cleveland, Ohio; London, United Kingdom; and Pittsburgh, Pennsylvania*

This document is endorsed by the following American Society of Echocardiography International Alliance Partners: the Argentinian Federation of Cardiology, the British Society of Echocardiography, the Canadian Society of Echocardiography, the Chinese Society of Echocardiography, the Echocardiography Section of the Cuban Society of Cardiology, the Indian Academy of Echocardiography, the Indian Association of Cardiovascular Thoracic Anaesthesiologists, the Iranian Society of Echocardiography, the Japanese Society of Echocardiography, the Korean Society of Echocardiography, the Saudi Arabian Society of Echocardiography, and the Vietnamese Society of Echocardiography.

Keywords: Echocardiography, Contrast, Guidelines, Imaging

Informed Consent



Generally, NOT required

Inpatient – admission informed consent

- Why UEA is being administered/indicated
- Confirming NO contraindications (such as known hypersensitivity to gas, shell components, and PEG)
- Use terms such as “ultrasound enhancing agent” to “enhance your ultrasound images”
- Be cautious on prompting patients of AE

Outpatient – minority of labs do require

***Off label use **REQUIRES** written consent

Verbal consent is considered adequate, and written consent is not required

UEA Clinical Supplies

IV Insertion kit

- Alcohol prep
- Tourniquet
- Adhesive tape
- 2 x 2 gauze pads
- Tegaderm film



18, 20, or 22g IV catheter
 Prefilled 0.9% NaCl flushes
 Syringe(s) – 10 ml, 20 ml, 35 ml
 50 ml bag 0.9% NaCl solution
 Venting pin (Opti-Spike, Mini-Spike)
 16g needles (*if not using venting pin*)
 Extension tubing

- Bolus - Macrobore (8")
- Infusion - Microbore (60"/1.2 ml priming volume)



Administration

Bolus Injection

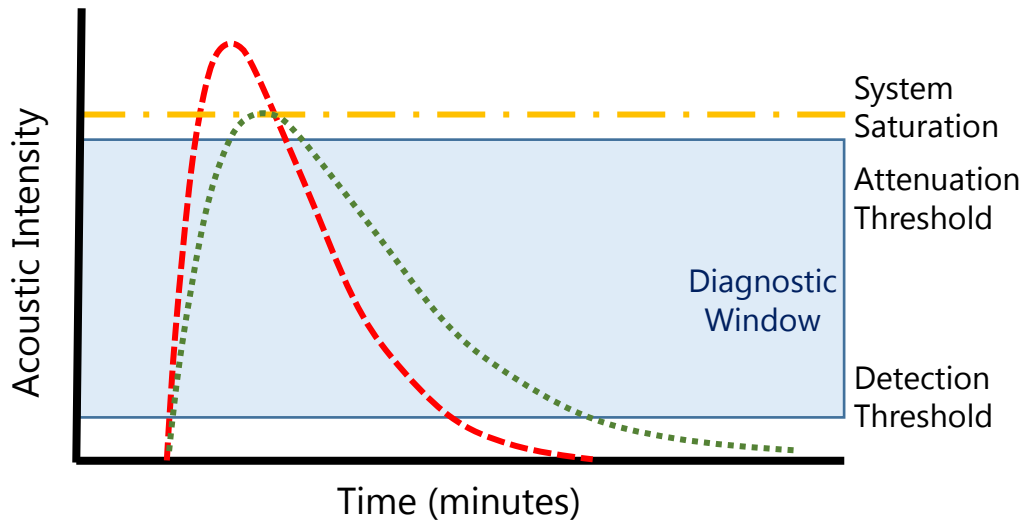


Continuous Infusion



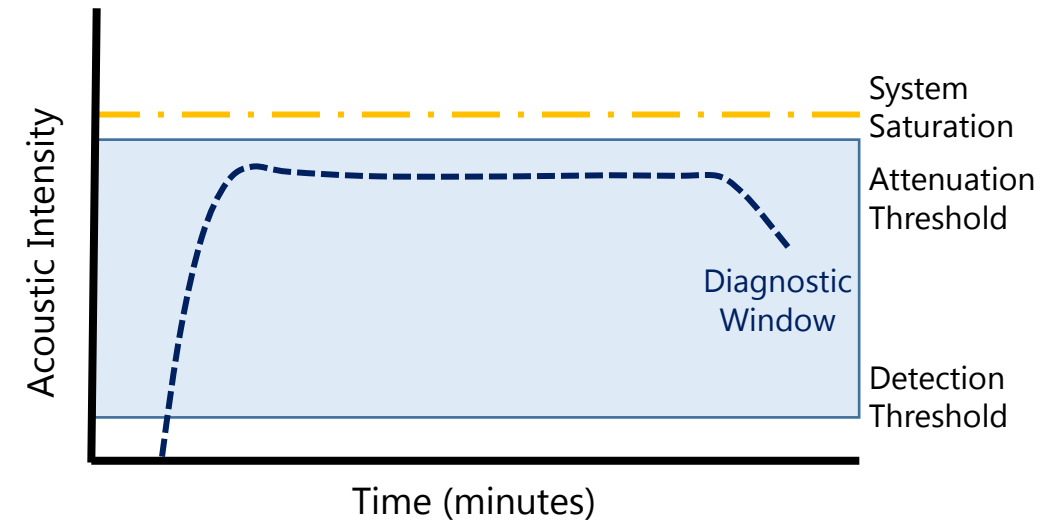
Bolus

- Less equipment = less cost (+)
- Shorter preparation time (+)
- Faster time to complete opacification (+ / -)
- Short duration (rapid decay) (- / +)
- High probability of attenuation artifact (-)
- Small repetitive boluses (+)



Infusion (continuous)

- Longer preparation time (-)
- Homogeneity of opacification (+)
- Minimal attenuation artifact (+)
- Ability to titrate/adjust dose (+)
- Dilution of contrast agent (+)
- Extended length of duration (+)



Adverse Reactions

- Be vigilant/acutely aware of possible adverse event (1:10,000)
- Knowledge of Lab Policy & Procedure
- “Allergy” Safety box

- | | |
|----------------------|------------------|
| • EpiPen/Epinephrine | • Syringes |
| • Benedryl | • Needles |
| • Albuterol inhaler | • Adhesive Tape |
| • Atropine | • Angiocaths |
| • Solumedrol | • Extension Set |
| • Glucagon | • Injection Cap |
| • Lasix | • Alcohol pads |
| • Nasal cannula | • 2x2 gauze pads |
| • NRB mask | |



- Distinguish between CARPA and true anaphylactoid reactions
- Most CARPA reactions are transient (15 min)
- Report AE/SAE's to Manufacturer and/or FDA MedWatch

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

CAPRA Symptoms/Treatment



Respiratory

- Asthma/bronchospasm, chest pain, coughing, cyanosis, dyspnea, tachypnea, wheezing

Treatment

- Inhaled beta-agonist: Albuterol

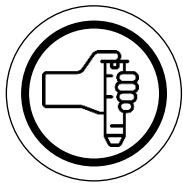


Skin

- erythema, pruritis, rash, urticaria

Treatment

- Antihistamines
- H2-blockers



Anaphylactic

- Angioedema, confusion, hypoxemia, hypotension/shock, death

Treatment

- IM epinephrine
- EpiPen

Billing/Reimbursement

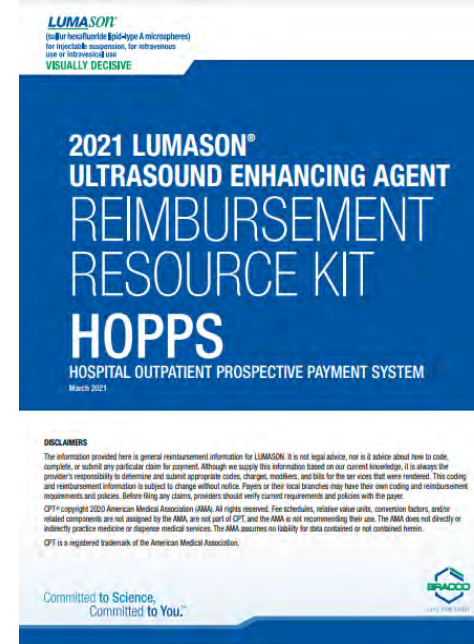



DEFINITY
Perflutren Lipid Microspheres

Medicare
Reimbursement Information
2021

Please see Indications and Important Safety Information on page 11 and the Full Prescribing Information, including boxed **WARNING** regarding serious cardiopulmonary reactions on pages 14-16.

Lantheus
Medical Imaging



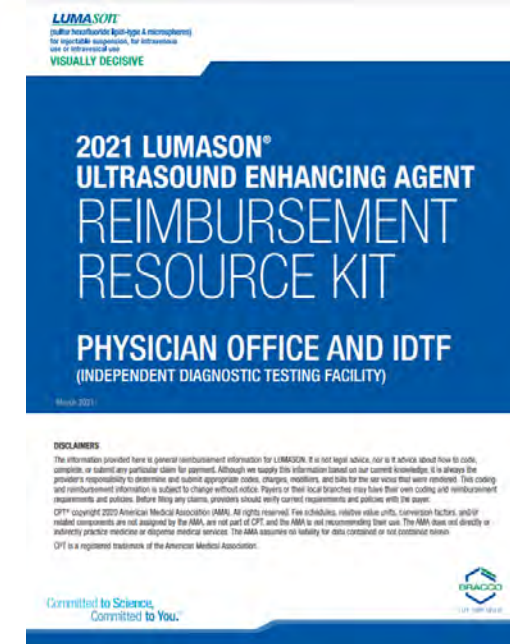
LUMASON
(Octafluoropropane lipid-type A microspheres)
for injectable suspension, for intravenous use or intraperitoneal use
VISUALLY DECISIVE

**2021 LUMASON®
ULTRASOUND ENHANCING AGENT
REIMBURSEMENT
RESOURCE KIT
HOPPS**
HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM
March 2021

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(Octafluoropropane lipid-type A microspheres)
for injectable suspension, for intravenous use or intraperitoneal use
VISUALLY DECISIVE

**2021 LUMASON®
ULTRASOUND ENHANCING AGENT
REIMBURSEMENT
RESOURCE KIT
PHYSICIAN OFFICE AND IDTF**
(INDEPENDENT DIAGNOSTIC TESTING FACILITY)
March 2021

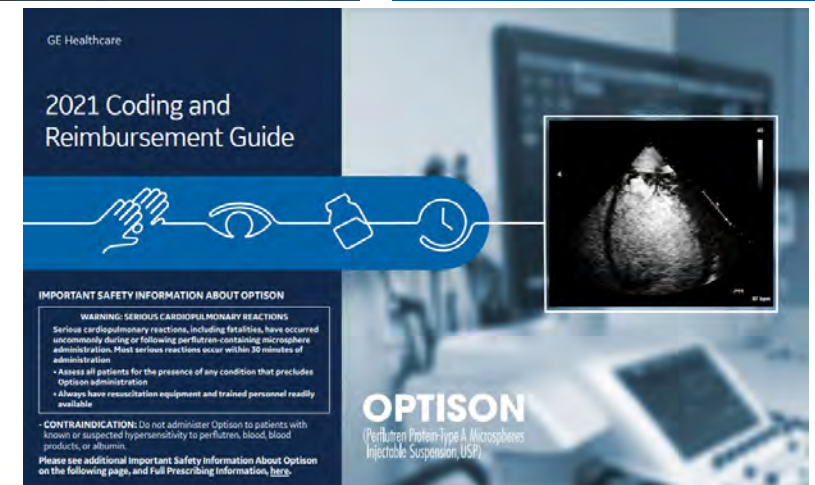
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Q Codes:

- Optison: Q9956 Injection, octafluoropropane microspheres, per mL (3 mL)
- Definity: Q9957 Injection, perflutren lipid microspheres, per mL (2 mL)
- Lumason: Q9950 LUMASON ultrasound enhancing agent, per mL (5 mL)



GE Healthcare

2021 Coding and Reimbursement Guide

OPTISON
(Perflutren Protein-Type A Microspheres)
Injectable Suspension, USP

IMPORTANT SAFETY INFORMATION ABOUT OPTISON

WARNING: SERIOUS CARDIOPULMONARY REACTIONS
Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following Definity-containing microsphere administration. Most serious reactions occur within 30 minutes of administration.

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

CONTRAINDICATION: Do not administer Optison to patients with known or suspected hypersensitivity to perflutren, blood, blood products, or albumin.

Please see additional Important Safety Information About Optison on the following page, and Full Prescribing Information, here.

Reimbursement – CPT Codes

Physician Office / IDTF

		Final 2021 Professional Payment	Final 2021 Technical Payment	Final 2021 Global Payment
Ultrasound Microbubble CPT codes				
76978	Ultrasound, microbubble contrast, initial lesion	\$79.90	\$243.88	\$323.78
76979 add on code	Ultrasound, microbubble contrast, each additional lesion w/ separate injection	\$41.87	\$178.99	\$220.85
Transthoracic Echocardiography (TTE) CPT				
93303	TTE, congenital complete	\$65.32	\$172.15	\$237.47
93304	TTE, congenital limited	\$36.98	\$129.79	\$166.77
93306	TTE, complete	\$70.83	\$137.12	\$207.94
93307	TTE limited	\$45.36	\$101.53	\$146.89
Transesophageal Echocardiography (TEE) CPT				
93312	TEE probe placement, image acquisition, interpretation and report	\$109.21	\$143.05	\$252.25
93315	TEE Congenital, probe placement, image acquisition, interpretation and report	\$128.74	\$-	\$-
Stress Echocardiography CPT				
93350	Stress TTE with interpretation and report	\$70.83	\$125.95	\$196.78
93351	Stress TTE complete	\$84.43	\$158.74	\$243.18
93352	Admin ECG contrast agent	\$-	\$-	\$34.19
0439T	Contrast perfusion	Carrier Priced	Carrier Priced	Carrier Priced
Contrast Agents*				
Q9950 - Lumason	Injection sulfur hexafluoride lipid microspheres, mil (1 mil dosage)	N/A	N/A	\$18.23
Q9956 - Optison	Injection, perflutren lipid microspheres, mil (1 mil dosage)	N/A	N/A	\$31.37
Q9957 - Definity	Injection, perflutren lipid microspheres, mil (1 mil dosage)	N/A	N/A	\$47.06

*Fee Schedule for January – March 2021 noted above. Average Sales Price (ASP) updated quarterly.
Source - <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files>
Source - CMS CY2021 Final Medicare Physician Fee Schedule - <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

Hospital Outpatient Prospective Payment System (HOPPS)

Note: Hospital Outpatient Departments bill Medicare C-codes for Contrast Echocardiography. Commercial payers may accept C-codes; if not, refer to CPT 933XX codes.		Final 2021 Payment	Final 2021 APC	Final 2021 APC Descriptor
Ultrasound Microbubble APCs				
76978	Ultrasound, microbubble contrast, initial lesion	\$182.22	5571	Level Imaging with Contrast
76979 add on code	Ultrasound, microbubble contrast, each additional lesion w/ separate injection	\$-	N/A	Packaged
Contrast Echocardiography APCs				
C8921	TTE with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete	\$715.18	5573	Level 3 Imaging with Contrast
C8922	TTE with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study	\$715.18	5573	Level 3 Imaging with Contrast
C8923	2D TTE 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	\$715.18	5573	Level 3 Imaging with Contrast
C8924	2D TTE 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	\$368.12	5572	Level 2 Imaging with Contrast
C8925	2D 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	\$715.18	5573	Level 3 Imaging with Contrast
C8926	TEE with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	\$715.18	5573	Level 3 Imaging with Contrast
C8927	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	\$715.18	5573	Level 3 Imaging with Contrast
C8928	TTE 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	\$715.18	5573	Level 3 Imaging with Contrast
C8929	TTE 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	\$715.18	5573	Level 3 Imaging with Contrast
C8930	TTE 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	\$715.18	5573	Level 3 Imaging with Contrast
Contrast Agents				
Q9950* - Lumason	Injection sulfur hexafluoride lipid microspheres (\$101.75 per 5 mil vial)	\$-	N/A	Packaged
Q9956 - Optison	Injection, octafluoropropane microspheres, per ml	\$-	N/A	Packaged
Q9957 - Definity	Injection, perflutren lipid microspheres, per ml	\$-	N/A	Packaged

* Temporary pass-through payment, bill in addition to APC for contrast procedure

Source: <https://www.cms.gov/license/ama?file=/files/zip/addendum-b-january-2021.zip#Regulations-and-Notices/Items/CMDLPage=1&DLSort=10&DLSort=2&DLSortDir=descending>

Ordering

Typically handled by Pharmacy, but labs may order directly thru manufacturer

National Drug Codes (NDCs):

Optison	10 Digit NCDs
5 vial pack	0407 – 2707 – 03
18 vial pack	0407 – 2707 – 18

Definity	10 Digit NCDs
4 vial pack	11994 – 011 – 04
16 vial pack	11994 – 011 – 16

Lumason	10 Digit NCDs
5 kits per box	0270 – 7099 – 07
20 vial pack	0270 – 7099 – 16



NDCs are unique 10-digit codes, composed of three segments, used to identify drugs. The first segment identifies the labeler (manufacturer), the second segment identifies the product, and the third identifies the packaging

Teamwork

Team effort – Sonographers, Nurses, and Physicians working together to better patient care/outcomes, workflow efficiencies, and the highest quality, diagnostic images



"Quality is not an act, it is a habit" - Aristotle

Resources

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Keywords: Echocardiography, Contrast, Guidelines, Imaging

Expert Consensus Statement from the American Society of Echocardiography on Hypersensitivity Reactions to Ultrasound Enhancing Agents in Patients with Allergy to Polyethylene Glycol (Peg)

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From the ¹Wright Cardiovascular Institute and the ²Division of Immunology and Allergy, Oregon Health & Science University, Portland, OR; ³Sore-Lake's Mid-America Heart Institute, Kansas City, MO; ⁴Maritime Heart Center, Dalhousie University, Halifax, Nova Scotia, Canada; ⁵Division of Cardiovascular Medicine, University of Nebraska Medical Center, Omaha, NE; ⁶Department of Pharmacy Practice, Oregon State University, Corvallis, OR; and ⁷Medical Heart and Lung Institute, Imperial College, London, UK


ContrastZone

- Consensus Statement on UEA
- The Basics
- Guideline Documents
- Recommended Laboratory Practices
- WEBINAR SERIES - Basics of Bubbles
- Videos and Webinars
- Posters and DVDs
- Coding for Contrast
- Helpful Information from Industry
- Frequently Asked Questions
- Educator Summit 2020: Contrast and Competency

ContrastZone

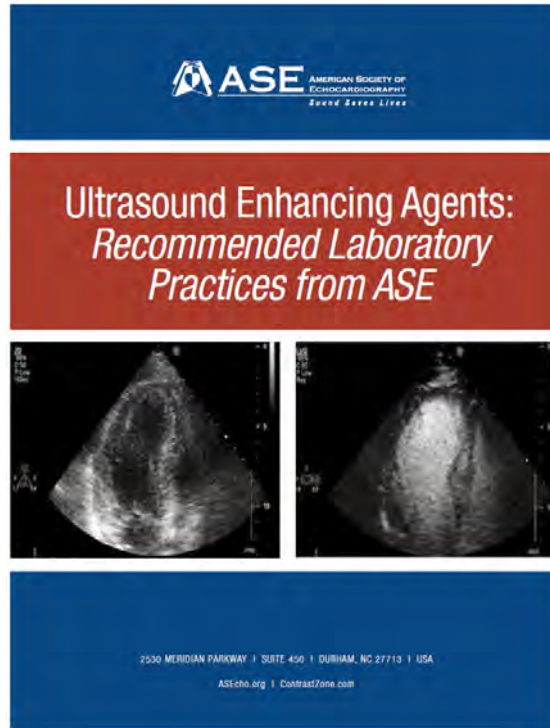
ASE Consensus Statement on Hypersensitivity Reactions to Ultrasound Enhancing Agents

In an effort to help improve quality and encourage the appropriate use of ultrasound contrast, ASE established the ContrastZone website to provide the cardiovascular ultrasound community with a central place on the web to find both basic and advanced information about Ultrasound Enhancing Agents (UEA), also known as ultrasound contrast. This site includes links to recent ASE guidelines and standards, how-to videos, reimbursement information, and success stories from busy labs on how to incorporate UEA into everyday practice to improve overall quality. Explore the menu to learn more!



	Pre High MI Flash	Immediate Post Flash	1 Second Post Flash	2 Seconds Post Flash	4 Seconds Post Flash
Rest					
Stress					

An example of a stress-induced perfusion defect in the left anterior descending coronary artery (LAD) territory (arrows). Note that end-systolic replenishment within the LAD territory in the apical four-chamber window is normal under resting conditions but delayed in the LAD territory (arrows) during dobutamine stress imaging. Figure 13 from "Clinical Applications of Ultrasonic Enhancing Agents in Echocardiography: 2018 American Society of Echocardiography Guidelines Update". JASE, March 2018



Ultrasound Enhancing Agents: Recommended Laboratory Practices from ASE

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- UEA Guidelines and Standards
- Recommended Practices
- Consensus Statement on PEG
- ContrastZone website

