MEDICAL POLICY

SUBJECT: CONTRAST AGENTS FOR ECHO-CARDIOGRAPHY (OPTISON™, DEFINITY®)

POLICY NUMBER: 11.01.05
CATEGORY: Technology Assessment

EFFECTIVE DATE: 10/18/01
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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
I. Based upon our criteria and assessment of the peer-reviewed literature, Optison™ and Definity® contrast agents have been medically proven to be effective and therefore, medically appropriate when used with echocardiography in patients with suboptimal routine echocardiograms. Clinical indications include, but are not limited to:
   A. enhancement of endocardial border definition to improve assessment of regional and global left ventricular function;
   B. myocardial perfusion imaging by intravenous contrast echocardiography;
   C. augmentation of spectral and color flow Doppler image.

POLICY GUIDELINES:
I. Contraindications for Optison™ and Definity® include:
   A. pregnancy or lactation;
   B. recent cerebrovascular event or transient ischemic attack within the previous 6 months;
   C. confinement to an intensive care unit or on a mechanical ventilator;
   D. New York Heart Association class IV congestive heart failure;
   E. left ventricular ejection fraction less than 20%; or
   F. severe liver disease.

II. Contraindications for Optison also include known or suspected hypersensitivity to blood, blood products or albumin.

DESCRIPTION:
Optison™ (octafluoropropane), perflutren protein-type A microspheres is a second-generation ultrasound contrast agent, which is a suspension of albumin microspheres containing the gas perfluoropropane. This echocardiography contrast agent is a blood-borne substance consisting of microscopic gas-filled bubbles that pass freely through the venous and arterial vasculature. They exist only in the intravascular space and are non-toxic. Ultrasound contrast agents can increase the diagnostic power of echocardiography by improving the visualization of the primary pumping chamber, and may better distinguish between normal and abnormal heart structure and motion – two critical indicators of cardiac health.

Definity® (perflutren lipid microsphere), is a non-blood based ultrasound contrast agent which is comprised of lipid-coated microspheres filled with octafluoropropane gas that are small enough to pass through the pulmonary capillaries. It can be given by IV bolus injection or continuous IV infusion.

RATIONALE:
Definity® (Perflutren Lipid Microsphere Injectable Suspension) received FDA approval in 2001. In April 2008 the FDA issued a warning regarding Definity® noting that serious cardiopulmonary reactions, including fatalities, have occurred during or following perflutren-containing microsphere administration. Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension) received FDA approval in 1997. In June 2008 the FDA issued a warning regarding Optison™ noting that serious cardiopulmonary reactions, including fatalities, have occurred during or following perflutren-containing microsphere administration.
Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than protocol updates.

CPT: No codes

HCPCS:
- A9700 Supply of injectable contrast material for use in echocardiography, per study
- Q9955 Injection, perflexane lipid microspheres, per ml
- Q9956 Injection, octafluoropropane microspheres, per ml
- Q9957 Injection, perflutren lipid microsphere, per ml

ICD9:
- 426 Conduction disorders

ICD10:
- I44.0-I44.7 Atrioventricular and left bundle-branch block (code range)
- I45.0-I45.9 Other conduction disorders (code range)

REFERENCES:

KEY WORDS:
- Contrast agent, Definity, Optison, Perflutren.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a Local Coverage Determination (LCD) for Transthoracic Echocardiography. Please refer to the following LCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/led-details.aspx?LCDId=27381&ContrId=181&ver=53&ContrVer=1&CntrctrSelected=181*1&Cntrctr=181&name=National+Government+Services%2eInc.+%(1302%2eMAC%5B+Part+B%5D&s=41&DocType=All&be=AggAAAIAAAAAAAA%3d%3d&