

Cohere Medicare Advantage Policy -Multiple Gated Acquisition (MUGA) Scan Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Multiple Gated Acquisition (MUGA)

Scan

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Type: $[\underline{X}]$ Adult (18+ yo) | $[\underline{X}]$ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Multiple Gated Acquisition (MUGA) Scan

Benefit Category

Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage. 1-4

- <u>National Coverage Determination (NCD) 220.12. Single Photon Emission</u>
 <u>Computed Tomography (SPECT)</u>
- <u>Local Coverage Determination (LCD) L33457. Cardiac Radionuclide</u>
 Imaging
- <u>Local Coverage Determination (LCD) L33560. Cardiovascular Nuclear</u>
 Medicine
- Local Coverage Determination (LCD) L33960. Cardiovascular Nuclear Medicine
- Billing and Coding: Cardiac Blood Pool Imaging (A54768)
- Billing and Coding: Cardiac Radionuclide Imaging (A56476)
- Billing and Coding: Cardiovascular Nuclear Medicine (A56743)
- Billing and Coding: Cardiovascular Nuclear Medicine (A56494)

Recommended Clinical Approach

A multiple-gated acquisition scan (MUGA scan) is a noninvasive, nuclear medicine test used to evaluate the heart's structural and dynamic properties. Other names include radionuclide angiography (RNA), radionuclide ventriculography (RVG), gated equilibrium radionuclide angiography (ERNA), and blood pool imaging. It uses a radioactive tracer to create a computerized image of the heart as it beats. The primary contemporary use of a MUGA scan is for evaluating the overall ability of the heart to pump blood

by calculating a left and right ventricular ejection fraction and assessing regional wall motion abnormalities. However, there are multiple other possible uses for a MUGA scan, such as the assessment of the orientation of the heart and great vessels in the chest, determination of diastolic dysfunction, evaluation of valve motion, and assessment of intracardiac shunts.^{5,6}

There are a number of protocols that can be utilized. An equilibrium MUGA scan most commonly utilizes technetium-99m (Tc-99m) pertechnetate bound to red blood cells. Accordingly, the technetium remains within the blood pool, and serial imaging studies to assess function can be acquired over several hours. A "first-pass" study radionuclide angiography utilizes rapidly acquired image frames to observe a bolus of technetium-99m or another suitable radionuclide as it moves through the venous system into the right atrium, right ventricle, pulmonary artery, lungs, left atrium, left ventricle and aorta. The procedure can give a separate evaluation of right ventricular function as well as assess for an intracardiac shunt.

Other Cardiac radionuclide imaging includes myocardial infarct avid scintigraphy, which is used in patients in whom it is not possible to make a definitive diagnosis of myocardial infarction by ECG or enzyme testing if the duration from onset of the infarction is greater than 24 hours and less than 7 days. Technetium–99m (stannous) pyrophosphate localizes in recently infarcted myocardium with the most intense visualization, usually 48–72 hours after infarction.

Evaluation of Potential Harms and Clinical Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of a Multiple Gated Acquisition (MUGA) scan. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

• Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, allergic reaction, and contrast extravasation into the surrounding

tissues.^{Z-10}

- Potential danger to pregnancy: MUGA scan imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹¹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.

The clinical benefits of using these criteria include:

- Non-invasive: MUGA scans are less invasive and have lower radiation burdens than procedures like the coronary angiogram (A MUGA scan imparts a relatively low radiation dose (0.3-0.52 rem equivalent in a standard study).⁵ The non-invasive nature of MUGA scans allows for the collection of diagnostic and prognostic information before invasive cardiac evaluations are necessary.⁶
- Cost Effective and Time Efficient: MUGA scans are widely available and inexpensive compared to alternative procedures. Furthermore, a MUGA study may maybe be performed in an hour, taking half the time of a myocardial perfusion study.⁶
- Ease of Administration: MUGA scans have excellent reproducibility in determining left ventricular ejection fraction (LVEF), as the imaging tests produce low rates of intra- and inter-observer variability and operator-dependent variation.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- → MUGA scan is considered appropriate if ANY of the following is TRUE:
 - ◆ A MUGA scan (not first pass) is considered appropriate for evaluation of ventricular size, wall motion, stroke volume, and ejection fraction when this information is medically necessary to direct further evaluation and management for ANY of the following¹⁻⁴:
 - Post-transplant cardiac disease, for **ANY** of the following:
 - Assessment of coronary arteriopathy; OR
 - Evaluation for ventricular dysfunction with post-transplant rejection; OR
 - Assessment of cardiac function for cardiotoxic chemotherapy, as indicated by ANY of the following:
 - Initial baseline study prior to initiation of cardiotoxic chemotherapy (see list below), and ANY of the following:
 - No echocardiogram is planned or performed;
 OR
 - Prior echocardiogram is uninterpretable due to poor visualization window; OR
 - Given the widespread use of echocardiography, serial MUGA imaging should be limited. It can be used for cardiac function monitoring during or at the completion of cardiotoxic chemotherapy, as indicated by ANY of the following^{21,22,23}:
 - Anthracycline drug use [Daunorubicin (Cerubidine), Doxorubicin (Adriamycin),
 Epirubicin (Ellence), Idarubicin (Idamycin),
 Mitoxantrone (Novantrone), Valrubicin (Valstar)] and ANY of the following:

- Every 3 months during therapy; OR
- Six and twelve months post-therapy; OR
- For patients getting very high-dose treatment (e.g., equivalent dose of doxorubicin 250 mg/m² and every additional 50-100 mg/m² during therapy);
 OR
- HER2-targeted therapy [trastuzumab (Herceptin and others), , Pertuzumab (Perjeta), and margetuximab(Margenza)] at ANY of the following intervals:
 - Every 3 months during therapy; OR
 - Every 6 months up to 2 years post therapy; OR
- ◆ Other cardiotoxic treatments including tyrosine kinase inhibitors, proteasome inhibitors, BRAF (v-raf murine sarcoma viral oncogene homolog B1) inhibitors, MEK (mitogen-activated extracellular signal-regulated kinase) inhibitors, immune checkpoint inhibitors, antimetabolites, 5-FU (5 fluorouracil), Bevacizumab (Avastin), Clofarabine (Clolar), Cyclophosphamide (Cytoxan), Imatinib (Gleevec), Ifosfamide (Ifex), Mitomycin (Mutamycin), Sorafenib (Nexavar), Sunitinib (Sutent), Paclitaxel (Taxol), Docetaxel (Taxotere), Capecitabine (Xeloda) periodically (but no more than every 3 months) in high-risk patients, including ANY of the following:
 - High-risk female patient greater than or equal to 50 years old; OR
 - Presence of traditional cardiovascular risk factors (hypertension, smoking, obesity, dyslipidemia, insulin resistance); OR

- Past medical history with ANY of the following:
 - Reduced or low-normal LVEF (50% to 54%) pre-treatment; OR
 - Presence of pre-existing cardiovascular disease (e.g., CAD, PAD, cardiomyopathy, severe valvular heart disease, heart failure, or diabetes); OR
 - Chronic kidney disease stage 2 (eGFR less than 78 ml/min/1.73 m2);
 OR
 - Abnormal Biomarkers including
 ANY of the following:
 - Elevated baseline troponin and/or NT-proBNP; OR
 - Elevated cardiac troponin or NT-proBNP during cancer therapy; OR
- Cardiomyopathy for ANY of the following:
 - Diagnosis of hypertrophic cardiomyopathy and/or myocardial ischemia; OR
 - Differentiation of ischemic from non-ischemic cardiomyopathy; OR
 - In rare cases, MUGA can be used to reassess patients with heart failure reduced ejection fraction if an echocardiogram is technically difficult²⁰; OR
- Evaluation of patient in whom an accurate measure of ejection fraction is needed to make a determination of whether to implant defibrillator or biventricular pacemaker;
 OR
- A first-pass study (for calculation of RV ejection fraction and shunting) is considered appropriate for ANY of the following:^{4,15}

- Need for assessment of RV function or identification of shunt (e.g., suspected congenital abnormality); OR
- Information has not been previously obtained or is likely to be obtained from other planned tests such as echocardiography; OR
- Assessment of right ventricular ejection fraction when transthoracic echocardiography (TTE) or other imaging have proven inadequate; OR
- Infarct avid scintigraphy (typically with tracers such as technetium-99m tetracycline or technetium-99m pyrophosphate) is considered appropriate for ALL of the following: 4,15
 - A clinical scenario where is not possible to make a definitive diagnosis of recent myocardial infarction by ECG or enzyme testing; AND
 - The duration from the onset of the infarction is greater than 24 hours and less than 7 days.
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if ANY of the following is TRUE:
 - New or worsening symptoms, such that repeat imaging would influence treatment; OR
 - One-time clarifying follow-up of a prior indeterminate finding; OR
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- → MUGA scans/cardiac radionuclide imaging are NOT considered appropriate for ANY of the following:
 - Pregnant or lactating patients; OR
 - Known allergy or sensitivity to the radioactive or other materials used during the procedure.

<u>Disclaimer on Radiation Exposure in Pediatric Population</u>

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure. 13,14

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{13,14}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation. 13,14

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{13,14}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing
78473	Cardiac blood pool imaging, gated equilibrium; multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification
78481	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78483	Cardiac blood pool imaging (planar), first pass technique; multiple studies, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78494	Cardiac blood pool imaging, gated equilibrium, spect, at rest, wall motion study plus ejection fraction, with or without quantitative processing
78496	Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (list separately in addition to code for primary procedure)
78466	Myocardial imaging, infarct avid, planar; qualitative or quantitative

78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique
78469	Myocardial imaging, infarct avid, planar; tomographic spect with or without quantification

Medical Evidence

Mitra et al. (2012) describe two important uses of MUGA scans in day-to-day clinical practice: serial assessment of LVEF in patients who are receiving cardiotoxic chemotherapy as well as with intractable heart failure (HF) patients to determine an accurate LVEF. Additionally, in heart failure patients, identifying diastolic dysfunction in HF with preserved LVEF and evaluation of dyssynchrony with MUGA single photon emission tomography prior to cardiac resynchronization therapy.⁵

A 1995 American College of Cardiology guideline from the Committee on Radionuclide Imaging. Gated equilibrium blood pool radionuclide angiography under rest and stress is recommended in chronic ischemic heart disease to determine accurate left and right ventricular ejection fraction values and the ability to assess regional wall motion. Rest and exercise or pharmacological stress may be appropriate.¹⁵

For decades, Multi Gated Acquisition (MUGA) scans were used to detect left ventricular dysfunction. However, due to concerns surrounding serial radiation exposure, echocardiography has largely superseded MUGA scans to become the primary method of medical imaging used to monitor and manage chemotherapy-induced cardiomyopathy. Patients living with breast cancer and patients receiving trastuzumab were found to be particularly vulnerable to radiation exposure and secondary cancer risk associated with repeated MUGA scans. However, the imaging test is still used to monitor left ventricular ejection fraction (LVEF) in clinical settings due to its high reproducibility and ease of administration.

References

- Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 220.12. Single Photon Emission Computed Tomography (SPECT). Published October 1, 2002. Accessed September 17, 2024.
 - https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=271&ncdver=1
- Centers for Medicare & Medicaid Services. Local Coverage
 Determination (LCD) L33457. Cardiac Radionuclide Imaging. Published
 October 1, 2015. Accessed September 17, 2024.
 https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lc
 did=33457&ver=61&stateRegion=all&contractorNumber=all&lcdStatus=
 all&sortBy=title&bc=8
- Centers for Medicare & Medicaid Services. Local Coverage
 Determination (LCD) L33560. Cardiovascular Nuclear Medicine.
 Published October 1, 2015. Accessed September 17, 2024.
 https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33560
- Centers for Medicare & Medicaid Services. Local Coverage
 Determination (LCD) L33960. Cardiovascular Nuclear Medicine.
 Published October 1, 2015. Accessed September 17, 2024.
 https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33960&ver=25&bc=0
- 5. Mitra D, Basu S. Equilibrium radionuclide angiocardiography: Its usefulness in current practice and potential future applications. World J Radiol. 2012 Oct 28;4(10):421-30.
- 6. Odak M & Kayani W. (2023, July 25). MUGA Scan. In StatPearls. StatPearls Publishing. Retrieved November 20, 2023 from https://www.ncbi.nlm.nih.gov/books/NBK564365/.
- 7. The Image Gently Alliance. Procedures cardiac imaging. Updated 2014. Accessed June 26, 2024. https://www.imagegently.org/Procedures/Cardiac-Imaging
- 8. Zhang F, Lu Z, Wang F. Advances in the pathogenesis and prevention of contrast-induced nephropathy. *Life sciences*. 2020 Oct 15;259:118379
- Summers LN, Harry ML, Colling KP. Evaluating our progress with trauma transfer imaging: repeat CT scans, incomplete imaging, and delayed definitive care. *Emergency Radiology*. 2021 Oct;28(5):939-48.
- 10. Nguyen T, Bhosale PR, Cassia L, Surabhi V, Javadi S, Milbourne A, Faria SC. Malignancy in pregnancy: Multimodality imaging and

- treatment. Cancer. 2023 May 15;129(10):1479-91.
- 11. Kjelle E, Brandsæter IØ, Andersen ER, Hofmann BM. Cost of low-value imaging worldwide: a systematic review. *Appl Health Econ Health Policy*. 2024 Mar 1:1-7.
- 12. Walker J., Bhullar N et al. Role of three-dimensional echocardiography in breast cancer: comparison with two-dimensional echocardiography, multiple-gated acquisition scans, and cardiac magnetic resonance imaging. *J Clinical Oncol*. 2010 28(21):3429-3436.
- 13. The Image Gently Alliance. Procedures image gentle and CT scans. Updated 2014. Accessed September 17, 2024. https://www.imagegently.org/Procedures/Computed-Tomography.
- 14. National Cancer Institute. Radiation risks and pediatric computed tomography (CT): A guide for health care. Updated September 4, 2018. Accessed September 17, 2024. https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/pediatric-ct-scans
- 15. Ritchie J, Bateman T et al. Guidelines for Clinical Use of Cardiac Radionuclide Imaging Report of the American College of Cardiology/American 'Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Radionuclide Imaging), Developed in Collaboration With the American Society of Nuclear Cardiology. J Am Coll Cardiol. 1995 Feb, 25 (2) 521–547.
- 16. Huang H, Nijjar PS et al. Accuracy of left ventricular ejection fraction by contemporary multiple gated acquisition scanning in patients with cancer: comparison with cardiovascular magnetic resonance. *J Mag Reson*. 2017;19:1–9.
- 17. Verquer EM. Imaging used to detect and monitor cardiotoxicity from chemotherapy. *Radiol Technol*. 2022;94(1): 51-52.
- 18. Kolla BC, Sunny Roy SS et al. Cardiac imaging methods for chemotherapy-related cardiotoxicity screening and related radiation exposure: Current practice and trends. *Anticancer Res.* 2017; 37(5): 2445-2449.
- 19. Printezi MI, Yousif LI et al. LVEF by multigated acquisition scan compared to other imaging modalities in cardio-oncology: a systematic review. *Curr Heart Fail* Rep..2022;19(3): 136-145.
- 20.Baldassarre LA, Ganatra S, Lopez-Mattei J, Yang EH, Zaha VG, Wong TC, Ayoub C, DeCara JM, Dent S, Deswal A, Ghosh AK. Advances in

- multimodality imaging in cardio-oncology: JACC state-of-the-art review. *J Am Coll Cardiol*. 2022 Oct 18;80(16):1560-78.
- 21. Zheng H, Zhan H. Cardio-oncology guidelines and strength of the evidence. *Cardio Oncol*. 2023 Feb 1;5(1):149-52.
- 22. Stone JR, Kanneganti R, Abbasi M, Akhtari M. Monitoring for chemotherapy-related cardiotoxicity in the form of left ventricular systolic dysfunction: a review of current recommendations. *JCO Oncology Practice*. 2021 May;17(5):228-36.
- 23. Dobson R, Ghosh AK, Ky B, Marwick T, Stout M, Harkness A, Steeds R, Robinson S, Oxborough D, Adlam D, Stanway S. BSE and BCOS guideline for transthoracic echocardiographic assessment of adult cancer patients receiving anthracyclines and/or trastuzumab. *Cardio Oncol.* 2021 Mar 1;3(1):1-6.

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