

Cohere Medicare Advantage Policy Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

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 - Myocardial Perfusion Imaging Single

Photon Emission Computed Tomography (MPI-SPECT)

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

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Medical Necessity Criteria

Service: Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Benefit Category

Diagnostics tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service. 124-27,30-35

Related CMS Documents

Please refer to <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage. 124-27,30-35

- National Coverage Determination (NCD). Single Photon Emission
 Computed Tomography (SPECT) (220.12)
- <u>Local Coverage Determination (LCD). Cardiology Non-emergent</u>
 Outpatient Stress Testing (L35083)
- Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing (A56423)
- Local Coverage Determination (LCD). Cardiology Non-emergent Outpatient Stress Testing (L38396)
- <u>Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing</u> (A56952)
- Local Coverage Determination (LCD). Cardiac Radionuclide Imaging (L33457)
- Billing and Coding: Cardiac Radionuclide Imaging (A56476)
- <u>Local Coverage Determination (LCD). Cardiovascular Nuclear Medicine</u> (L33560)
- Billing and Coding: Cardiovascular Nuclear Medicine (A56743)
- Local Coverage Determination (LCD). Cardiovascular Nuclear Medicine (L33960)
- Billing and Coding: Cardiovascular Nuclear Medicine (A56494)

Recommended Clinical Approach

Myocardial perfusion imaging - single photon emission computed tomography (MPI-SPECT) is typically appropriate for patients with chest pain (or an ischemic equivalent) and an intermediate (16 to 50%) or high (greater than 50%) pretest probability (PTP) of obstructive (greater than or equal to 50% stenosis) coronary artery disease (CAD). (See the Pre-Test Probability of CAD published by the CAD Consortium). An exercise stress test is appropriate if the patient can exercise to a satisfactory workload. If the patient cannot exercise or has echocardiographic (ECG) abnormalities that interfere with the ECG interpretation during exercise, a pharmacologic MPI-SPECT or cost-effective alternatives such as stress echocardiography or coronary computed tomographic angiography (CCTA) should be considered. Limitations of MPI-SPECT include cost and radiation. Interpretation of MPI-SPECT can be affected by attenuation artifacts related to soft tissue overlying the heart or extracardiac radioisotope (e.g., liver or gastrointestinal uptake adjacent to the heart).²⁻³ In patients with known CAD, guideline-directed medical therapy (GDMT) for angina includes beta blockers, calcium channel blockers, long-acting nitrates, and ranolazine.¹³

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 Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT). 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:

- <u>Inherent risk of procedure:</u> There are inherent risks of imaging, including cumulative radiation exposure, and contrast extravasation into surrounding tissues.⁴⁻⁷
- Potential danger to pregnancy: MPI-SPECT 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.⁴ Fetal risk

- includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁴
- Enhanced Increased healthcare costs and complications from the inappropriate use of emergency services and additional interventions.⁵

The clinical benefits of using these criteria include:

- <u>Diagnostic accuracy:</u> Vasodilator stress perfusion cardiac magnetic resonance (CMR), as performed with gadobutrol 0.1 mmol/kg body weight, is superior for the diagnosis and exclusion of coronary artery disease (CAD) versus gated SPECT. Positron emission tomography (PET) MPI is more effective than MPI-SPECT in predicting major adverse cardiovascular events (MACEs) in patients following kidney transplant. SPECT, however, appears to be superior to stress echocardiography (ECHO) in the diagnosis of isolated circumflex stenosis, as well as for the correct identification of multivessel CAD.⁶⁻⁷
- <u>Screening at-risk patients for CVD:</u> While the accuracy of MPI-SPECT is not high for the diagnosis of CAD, it is recommended to screen patients at-risk.⁸
- Utilization of MPI-SPECT decreases the utilization of coronary angiography and revascularization.
- Assessment of infection-associated cardiac complications: Individuals with a history of COVID-19 have been shown to be more prone to having MPIs that demonstrate abnormalities, such as ischemia. 10
- Enhanced overall patient satisfaction and healthcare experience.

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 and ensure 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

- → Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT) is considered appropriate if ANY of the following is TRUE^{II-12,16,36}:
 - ◆ Patient with new, recurrent, or worsening cardiac or anginal equivalent symptoms and **ANY** of the following:
 - Physical inability to reach maximum exercise workload; OR
 - Uninterpretable ECG with ANY of the following:
 - o Complete Left Bundle Branch Block (LBBB); OR
 - Ventricular paced rhythm; OR
 - Pre-excitation pattern (e.g., Wolff-Parkinson-White);
 OR
 - o Greater than 1 mm ST segment depression; OR
 - Left ventricular hypertrophy (LVH) with repolarization abnormalities; OR
 - Patient on digoxin therapy; OR
 - History of CAD based on prior anatomic evaluation of the coronary arteries or a history of coronary artery bypass graft surgery (CABG)/percutaneous coronary intervention (PCI); OR
 - Syncope (abrupt, transient, complete loss of consciousness) with an intermediate (ASCVD risk 7.5% to 20%) or high CHD risk (greater than 20%) (ATP III risk criteria), or an intermediate or high CAD risk (greater than or equal to 16%) on the Pre-test probability of CAD (CAD consortium) AND cardiac etiology is suspected based on initial evaluation, including history, physical examination, or ECG¹; OR
 - Known or suspected ventricular arrhythmia [frequent PVCs (greater than 30 PVCs per hour), non-sustained ventricular tachycardia, sustained ventricular tachycardia, ventricular fibrillation]; OR
 - Prior normal or submaximal exercise stress test with suspicion of a false negative result; OR

- Prior equivocal or borderline testing where ischemia remains a concern; OR
- Taking beta blocker, calcium channel blocker, and/or antiarrhythmic medication and documentation supports that adequate workload may not be attainable to enable fully diagnostic exercise study; OR
- History of false positive exercise stress test (e.g., one that is abnormal, but the abnormality does not appear to be due to macrovascular CAD); OR
- Evaluation of chest pain syndrome in patients with ANY of the following:
 - Intermediate to high pre-test probability for CAD based on the <u>Pre-test probability of CAD (CAD</u> <u>consortium)</u> calculator; **OR**
 - o Prior revascularization; OR
 - Elevated cardiac troponins, Non-ST segment elevation MI [NSTEMI]; OR
- Patients with hypertrophic cardiomyopathy (HCM); OR
- ◆ New-onset atrial fibrillation with no prior cardiac evaluation; **OR**
- Patients with established CAD who experienced an acute coronary syndrome (ACS) event (STEMI, NSTEMI, unstable angina) within the past 90 days provided that they did not undergo coronary angiography at the time of the acute event and are currently clinically stable and able to exercise; OR
- Disease condition(s) associated with CAD (e.g., atherosclerotic abdominal aortic aneurysm, peripheral vascular disease, carotid artery disease, chronic renal failure) and ALL of the following:
 - No stress imaging evaluation performed within the preceding 2 years; OR
- Patients without cardiac symptoms and ANY of the following:
 - Elevated cardiac troponin; OR
 - Underwent a PCI (with stent) procedure more than 2 years prior with no evaluation for CAD in the past 2 years; OR
 - Underwent a CABG more than 5 years prior with no evaluation for CAD in the past 2 years; OR
- New, recurrent, or worsening left ventricular dysfunction/congestive heart failure; OR

- ◆ Preoperative testing before intermediate or high-risk surgery^{(Table 1),14,29} and ANY of the following:
 - Planned solid organ transplant (renal, pancreas, combined renal pancreas, liver, lung, or intestinal); OR
 - No known or suspected heart disease^{A,29} and ALL of the following:
 - No recent (3-8 months) testing; AND
 - New or worsening possible cardiac symptoms; AND
 - Functional status less than 4 METS and ANY of the following:
 - ◆ High risk vascular surgery^(Table 1) or high risk nonvascular surgery^(Table 1); OR
 - ◆ Intermediate risk vascular surgery^(Table 1); **OR**
 - ◆ Intermediate risk nonvascular surgery^(Table 1) with at least an intermediate(16% or greater) pre-test probability of obstructive CAD by the CAD Consortium Calculator; OR
 - Known or suspected heart disease^{B,29} and ANY of the following:
 - No recent (3-8 months)stress testing and ANY of the following:
 - High risk vascular surgery^(Table 1) or high risk nonvascular surgery^(Table 1); OR
 - Intermediate risk vascular surgery and ANY of the following:
 - Greater than 4 metabolic equivalents of tasks (METS) and ALL of the following:
 - Without new or worsening possible cardiac symptoms; AND
 - Revised Cardiac Risk Index of 3 or greater (intermediate or high risk);
 OR
 - Less than 4 METS with or without new or worsening possible cardiac symptoms;
 OR
 - Greater than 4 METS with new or worsening possible cardiac symptoms;
 OR

- Intermediate nonvascular surgery^(Table 1) and ANY of the following:
 - Less than 4 METS with or without possible cardiac symptoms; OR
 - Greater than 4 METS with new or worsening possible cardiac symptoms;
 OR
- Low-risk vascular or nonvascular surgery^(Table 1)
 planned and ANY of the following:
 - New or worsening possible cardiovascular symptoms; OR
 - <u>Revised Cardiac Risk Index</u> of 3 or greater (intermediate or high risk); **OR**
- Prior cardiac stress testing within 3 to 8 months and ANY of the following:
 - High-risk vascular surgery^(Table 1) with risk factors that the physician feels warrant repeat testing; OR
 - New findings on transthoracic echocardiography (TTE) such as new wall motion abnormalities, new significant valvular disease, or significant drop in ejection fraction; OR
 - New or worsening possible cardiovascular symptoms;
 OR
- ◆ Coronary calcium Agatston score greater than 400; **OR**
- Planned solid-organ transplant when no cardiac evaluation has been performed within the past year; OR
- Evaluation for transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) after organ transplantation;
 OR
- ◆ Coronary stenosis, as documented by **ANY** of the following:
 - Coronary angiography with stenosis greater than 50%; OR
 - CCTA with stenosis greater than 40%; OR
- 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.

ANo Known or Suspected Heart Disease by History, Exam, or Electrocardiogram (ECG)²⁹: Heart disease is not suspected based on history of no prior cardiac event, lack of cardiac risk factors, or prior cardiac testing indicating no ischemic heart disease, VHD, or HF. Exam does not suggest underlying heart disease by lack of murmurs, other than functional, and no signs of cardiac decompensation (i.e., rales, edema not explained by other causes, or S3 gallop). ECG does not show prior myocardial infarction, left ventricular hypertrophy, LBBB, or atrial fibrillation. B-type natriuretic peptide (BNP) or proBNP, if measured, is normal.

Electrocardiogram²⁹: PCI, CABG, prior infarct, cardiac risk factors (HTN, HLD, DM, tobacco use, FHx premature CAD), disease conditions associated with atherosclerosis (PAD, carotid disease, abdominal aneurysm, stroke due to atherosclerosis), prior cardiac testing showing CAD, heart failure, moderate or severe valvular disease, rales, old infarct on EKG, LVH with repolarization changes, LBBB or atrial fibrillation. There may be prior evidence of biomarker elevation (troponin, proBNP) in the absence of other explanatory findings. B-type natriuretic peptide (BNP) or proBNP, if measured, is more than 3x the upper limit of normal.

	Surgical Risk Level		
Specialty	Low	Intermediate	High
Vascular	1. Carotid stenting (monitored anesthesia care) 2. Renal artery stenosis angioplasty or stent 3. Vein stripping	 Infra-inguinal peripheral angioplasty/stent Carotid stenting (carotid approach, general anesthesia) Open carotid endarterectomy Above or below knee amputation 	 Abdominal aortic aneurysm repair Aorto-femoral bypass graft Thoracic aortic aneurysm repair Infra-inguinal open peripheral revascularization
General	Laparoscopic appendectomy Hemorrhoidectomy	Open appendectomy Ostomy procedures Inguinal/umbilical hernia repair Laparoscopic lysis of adhesions/obstructi on Laparoscopic cholecystectomy Laparoscopic colon resection, segmental, for tumor	 Laparoscopic bariatric surgery Open cholecystectomy Hepatic radiofrequency ablation tumor ablation Splenectomy Open colonic segmental resection tumor Laparoscopic colonic abdominal perineal resection Open lysis of adhesions/bowel obstruction Esophageal Heller myotomy Nissen fundoplication Cancer resection (gastric pull-through) Open bariatric surgery Pancreatic/Whipple resection (tumor/ulcer) Hepatic segmental resection Colonic open abdominal perineal resection
Endocrine	Thyroidectomy Parathyroidectomy	1. Adrenalectomy	-

		2. Pheochromocytoma resection	
Ortho.	 Shoulder arthroscopy Knee arthroscopy Ankle arthroscopy Closed joint reduction 	Shoulder arthroplasty Hip fracture pinning	1. Hip/ankle/knee arthroplasty
Thoracic	-	Pleural procedures (decortication, pleurodesis) VATS lung biopsy VATS wedge/lobe resection Thymectomy	 Open wedge/lobe resection Tracheal surgery Lung reduction Pneumonectomy
Neuro- functional	Deep brain stimulator placement Seizure mapping procedures	-	-
Neuro- intracranial	-	 Hydrocephalus shunt/repair Subdural drainage Transsphenoidal resection 	 Intracranial tumor resection Open intracranial aneurysm resection Acoustic neuroma/cranial nerve tumor resection
Neuro/ Ortho. Spine	-	1. Laminectomy	Spinal fusion Extreme lateral interbody fusion procedures (abdominal)
Genito- urinary	 Transurethral prostate resection Transurethral bladder tumor resection Ureteral stents Nephrostomy Extracorporeal shock wave lithotripsy 	1. Bladder repair	Radical retropubic prostatectomy Nephrectomy Cystectomy
Gyn.	1. Vaginal hysterectomy	Total abdominal hysterectomy	-

	2. Diagnostic gynecologic procedures (laparoscopy)	2. Bilateral salpingo-oophorect omy	
Breast	Diagnostic breast surgery (lumpectomy, node dissection) Simple mastectomy	Complex breast surgery	_
Plastic Surgery	Hand Cosmetic procedures	Reconstructive flaps Post-bariatric repair abdominoplasty	_
Ear, Nose, Throat	Diagnostic laryngoscopy Diagnostic esophagoscopy	Nasal septal procedures Functional endoscopic sinus surgery	Head/neck cancer dissection (with/without laryngectomy)
Oral & Maxillofaci al Surgery	1. Jaw reduction	Temporomandibular procedures/osteoto my	-
Podiatry	Arthroplasty Toe amputation Bunion procedure	-	-
Eye	Cataract repair Retinal surgery Eye muscle surgery		
Organ Transplant	_	-	 Renal Transplant Pancreas Transplant Kidney-Pancreas Combined Transplant Liver Lung Intestinal

Non-Indications

- - Routine screening in asymptomatic patients with ANY of the following, unless under specific conditions as outlined above:
 - Diabetes mellitus; OR
 - Preoperative evaluation for low-risk nonvascular surgery;
 OR
 - Routine screening of patients beyond the first cardiac stress test in the absence of a documented change in condition (i.e. new symptoms or progression of existing symptoms); OR
 - ALL of the following:
 - Low pretest probability (PTP) of CAD; AND
 - Interpretable ECG; AND
 - Ability to exercise; OR
 - ◆ **ANY** of the following:
 - Recent (2-4 days) acute myocardial infarction (MI); OR
 - High-risk unstable angina; OR
 - Uncontrolled arrhythmia causing symptoms or hemodynamic compromise; OR
 - Critical aortic stenosis; OR
 - Decompensated or uncontrolled congestive heart failure;
 OR
 - Systolic blood pressure (BP) at rest greater than 200 mmHG or diastolic BP at rest greater than 110 mmHg; OR
 - Acute pulmonary embolus or pulmonary infarction; OR
 - Acute myocarditis or pericarditis; OR
 - Acute aortic dissection.

<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. 18-19

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.¹⁸⁻¹⁹

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. 18-19

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.¹⁸⁻¹⁹

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

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	
78451	Single-photon emission computed tomography (SPECT) myocardial perfusion imaging study with stress	
78452	Multiple single-photon emission computed tomograph (SPECT) myocardial perfusion imaging studies with stress	
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)	
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection	

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Definitions

Symptomatic/Ischemic Equivalent: Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are any constellation of clinical findings the physician believes is consistent with CAD manifestations. Examples of such findings include but are not limited to, pain, pressure, tightness, or discomfort in the chest, shoulders, arms, neck, back, upper abdomen, or jaw, new ECG abnormalities, or other symptoms/findings suggestive of CAD. Clinical presentations in the absence of chest pain (e.g., dyspnea with exertion, fatigue, or reduced/worsening effort tolerance) consistent with CAD may also be considered an ischemic equivalent.²⁰

Pretest Probability (of Obstructive CAD): Pretest probability of CAD is the likelihood that the patient has obstructive CAD, calculated before the test result is known. These guidelines reference the 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of chronic coronary syndromes model to calculate the pretest probability based on age, sex, and type of chest pain. 12,15,21-23,25-27 Additional information such as a coronary artery calcium (CAC) score or risk factors for CAD (such as diabetes mellitus, smoking, family history of premature CAD [first degree relative: male less than 55 years old or female less than 65 years old, hypertension, or dyslipidemia) can be used to improve the identification of obstructive CAD. (Use the CAD Consortium Calculator).

Medical Evidence

Huck et al. (2024) conducted a retrospective study to evaluate patients post-kidney transplant due to the risk of major adverse cardiovascular events (MACEs). The population is also at higher risk of developing cardiovascular disease. Single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and pretransplant positron emission tomography (PET) were utilized in the study of 393 patients. Results were taken from a follow-up period of 5.9 years. Overall PET MPI was more effective than SPECT-MPI to predict MACEs in patients post-kidney transplant. Future research should include the effectiveness of normal PET vs SPECT when evaluating low-risk patients.²

Kelderman et al. (2022) performed a systematic review on using MPI SPECT to diagnose cardiovascular disease in patients assessed for kidney transplantation. Thirteen studies that focused on MPI-SPECT were identified and included in the meta-analysis of 1245 MPI SPECT scans. The pooled sensitivity was 0.66 (95% CI 0.53 to 0.77), pooled specificity was 0.75 (95% CI 0.63 to 0.84) and the area under the curve (AUC) was 0.76. The authors note that while the accuracy is not high with MPI-SPECT for the diagnosis of CAD, it is recommended to screen patients at-risk.⁸

Patel et al. (2019) conducted a single-center randomized control trial (RCT) to determine the clinical efficacy of pharmacological MPI-SPECT and PET MPI in patients with coronary artery disease (CAD) and ischemia. A total of 322 symptomatic patients were included. The following pharmacologic agents were given to patients: aspirin therapy (88.8%), beta-blockers (76.7%), and statin therapy (77.3%). Seven patients (2.2%) had a diagnostic failure at 60 days; however, no major differences in diagnostic failure rates were observed overall. Decreased utilization of coronary angiography or revascularization was noted. (ClinicalTrials.gov Identifier NCT00976053).

A number of recent articles provided recommendations for several common clinical scenarios. Gulati et al. (2021)¹² provided insights into the evaluation and diagnosis of chest pain, Winchester et al. (2023)¹¹ provided appropriate use criteria (AUC) for the detection and risk assessment of chronic coronary

disease, and Doherty et al. (2024)²⁹ updated a previous AUC document for the cardiovascular evaluation for nonemergency, noncardiac surgery, focusing more on ischemic heart disease, valvular heart disease, and heart failure (rather than cardiovascular disease in general) and their relation to the risks associated with various types of surgery (solid organ transplant, vascular, non-vascular).

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024			
Review History			
Version 1.1	03/18/2025	 Updated policy per CMS revisions for 2/6/25 Updated Effective date Updated Links and Bookmarks 	
Version 1.2	04/21/2025	 Updated policy per CMS revisions for 3/20/25 Updated Effective date Updated Links and Bookmarks/References 	