MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

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Policy Number: 347

BCBSA Reference Number: 2.02.08 (For Plan internal use only)

Related Policies

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

The use of patient-activated or autoactivated external ambulatory event monitors (AEMs) **OR** continuous ambulatory monitors that record and store information for periods longer than 48 hours may be **MEDICALLY NECESSARY** as a diagnostic alternative to Holter monitoring in the following situations:

- Individuals who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope).
- Individuals with atrial fibrillation (AF) who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered.
- Individuals with cryptogenic stroke who have a negative standard workup for AF including a 24-hour Holter monitor.*

The use of implantable AEMs, either patient-activated or autoactivated, may be considered **MEDICALLY NECESSARY** in the following situations:

- In the small subset of individuals who experience recurrent symptoms so infrequently that a prior trial of other external AEMs has been unsuccessful.
- In individuals who require long-term monitoring for AF or possible AF.*

*The available evidence has suggested that long-term monitoring for atrial fibrillation postablation or after cryptogenic stroke is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not well-defined. Trials demonstrating improved outcomes have used either event monitors or implantable monitors. In addition, there are individual patient considerations that may make 1 type of monitor preferable over another.

Therefore, for the evaluation of individuals with cryptogenic stroke who have had a negative standard workup for atrial fibrillation including 24-hour Holter monitoring, or for the evaluation of atrial fibrillation

after an ablation procedure, the use of long-term monitoring with an external event monitor, OR a continuous ambulatory monitor that records and stores information for periods longer than 48 hours, OR an implantable ambulatory monitor may be considered medically necessary for individuals who meet the criteria outlined above.

The use of outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry as a diagnostic alternative to AEMs in individuals who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, syncope) is considered **MEDICALLY NECESSARY**.[1]

Other uses of AEMs, including outpatient cardiac telemetry and mobile applications, are considered **INVESTIGATIONAL**, including but not limited to monitoring asymptomatic individuals with risk factors for arrhythmia, monitoring the effectiveness of antiarrhythmic medications, and detection of myocardial ischemia by detecting ST- segment changes.

Transtelephonic transmission of post-symptom electrocardiograms and cardiac event monitors **may be MEDICALLY NECESSARY for the following indications, when used to evaluate individuals in remote areas or long distances (such as 100 miles) from physicians capable of interpreting ECG:**[1]

- To detect, characterize, and document symptomatic transient arrhythmias
- To assess anti-arrhythmic drug efficiency, and
- To carry out early post-hospital monitoring of individuals discharged after a myocardial infarction, if 24 hour coverage is provided. Such coverage must be performed by an experienced electrocardiogram technician receiving the calls (tapes and facsimiles do not count). These technicians must have immediate access to a physician, and have been instructed when and how to contact available facilities to assist the patient in case of emergencies.
- This policy statement applies to plain EKGs (ECGs, electrocardiograms) only, transmitted electronically for the purposes of interpretation, and
- Transmitting devices must be capable of transmitting ECG leads I, II, and III, and transmissions must be comparable to readings obtained by conventional ECGs, to permit proper interpretation of abnormal cardiac rhythms.

NOTE: Facsimiles and tapes are not reimbursed.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

Other Information:

- Interpretation of the transmitted telephonic electrocardiogram must be performed by a Blue Cross Blue Shield of Massachusetts contracted Cardiologist when referred for interpretation by a physician.
- Transmission of a telephonic electrocardiogram, when performed by an independent physiological/diagnostic laboratory, must be rendered by a Blue Cross Blue Shield contracted Independent Physiological/Diagnostic Lab.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

CPT Codes

CPT codes:	Code Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
93228	Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; physician review and interpretation with report
93229	Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, physician review and interpretation
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)

93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis
93272	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; physician review and interpretation

Description

Cardiac Arrhythmias

Cardiac monitoring is routinely used in the inpatient setting to detect acute changes in heart rate or rhythm that may need urgent response. For some conditions, a more prolonged period of monitoring in the ambulatory setting is needed to detect heart rate or rhythm abnormalities that may occur infrequently. These cases may include the diagnosis of arrhythmias in patients with signs and symptoms suggestive of arrhythmias as well as the evaluation of paroxysmal atrial fibrillation (AF).

Cardiac arrhythmias may be suspected because of symptoms suggestive of arrhythmias, including palpitations, dizziness, or syncope or presyncope, or because of abnormal heart rate or rhythm noted on exam. A full discussion of the differential diagnosis and evaluation of each of these symptoms is beyond the scope of this review, but some general principles on the use of ambulatory monitoring are discussed.

Arrhythmias are an important potential cause of syncope or near syncope, which in some cases may be described as dizziness. An electrocardiogram (ECG) is generally indicated whenever there is suspicion of a cardiac cause of syncope. Some arrhythmic causes will be apparent on ECG. However, for patients in whom an ECG is not diagnostic, longer monitoring may be indicated. The 2009 joint guidelines from the European Society of Cardiology and 3 other medical specialty societies suggested that, in individuals with clinical or ECG features suggesting an arrhythmic syncope, ECG monitoring is indicated; the guidelines also stated that the "duration (and technology) of monitoring should be selected according to the risk and the predicted recurrence rate of syncope."[1,] Similarly, guidelines from the National Institute for Health and Care Excellence (2023) on the evaluation of transient loss of consciousness, have recommended the use of an ambulatory ECG in individuals with a suspected arrhythmic cause of syncope. The type and duration of monitoring recommended is based on the individual's history, particularly the frequency of transient loss of consciousness.[2,] The Holter monitor is recommended if transient loss of consciousness occurs several times a week. If the frequency of transient loss of consciousness is every 1 to 2 weeks, an external event recorder is recommended; and if the frequency is less than once every 2 weeks, an implantable event recorder is recommended.

Similar to syncope, the evaluation and management of palpitations is patient-specific. In cases where the initial history, examination, and ECG findings are suggestive of an arrhythmia, some form of ambulatory ECG monitoring is indicated. A position paper from the European Heart Rhythm Association (2011) indicated that, for individuals with palpitations of unknown origin who have clinical features suggestive of arrhythmia, referral for specialized evaluation with consideration for ambulatory ECG monitoring is indicated.[3,]

Atrial Fibrillation Detection

AF is the most common arrhythmia in adults. It may be asymptomatic or be associated with a broad range of symptoms, including lightheadedness, palpitations, dyspnea, and a variety of more nonspecific symptoms (eg, fatigue, malaise). It is classified as paroxysmal, persistent, or permanent based on symptom duration. Diagnosed AF may be treated with antiarrhythmic medications with the goal of rate or rhythm control. Other treatments include direct cardioversion, catheter-based radiofrequency- or cryo-energy-based ablation, or 1 of several surgical techniques, depending on the patient's comorbidities and associated symptoms.

Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low flow state increases the risk of thrombosis. The area of the left atrium with the lowest blood flow in AF, and therefore the highest risk of thrombosis, is the left atrial appendage. Multiple clinical trials have demonstrated that anticoagulation reduces the ischemic stroke risk in patients at moderate- or high-risk of thromboembolic events. Oral anticoagulation in patients with AF reduces the risk of subsequent stroke and is recommended by American Heart Association, American College of Cardiology, and Heart Rhythm Society (2014) joint guidelines on patients with a history of stroke or transient ischemic attack.[4,]

Ambulatory ECG monitoring may play a role in several situations in the detection of AF. In patients who have undergone ablative treatment for AF, if ongoing AF can be excluded with reasonable certainty, including paroxysmal AF which may not be apparent on ECG during an office visit, anticoagulation therapy could potentially be stopped. In some cases where identifying paroxysmal AF is associated with potential changes in management, longer term monitoring may be considered. There are well-defined management changes that occur in patients with AF. However, until relatively recently the specific role of long-term (ie, >48 hours) monitoring in AF was not well-described.

Patients with cryptogenic stroke are often monitored for the presence of AF because AF is estimated to be the cause of cryptogenic stroke in more than 10% of patients, and AF increases the risk of stroke.[5,6,] Paroxysmal AF confers an elevated risk of stroke, just as persistent and permanent AF does. In individuals with a high risk of stroke, particularly those with a history of ischemic stroke that is unexplained by other causes, prolonged monitoring to identify paroxysmal AF has been investigated.

Cardiac Rhythm Ambulatory Monitoring Devices

Ambulatory cardiac monitoring with a variety of devices permits the evaluation of cardiac electrical activity over time, in contrast to a static ECG, which only permits the detection of abnormalities in cardiac electrical activity at a single point in time.

A Holter monitor is worn continuously and records cardiac electrical output continuously throughout the recording period. Holter monitors are capable of recording activity for 24 to 72 hours. Traditionally, most Holter monitors have 3 channels based on 3 ECG leads. However, some currently available Holter monitors have up to 12 channels. Holter monitors are an accepted intervention in a variety of settings where a short period (24 to 48 hours) of comprehensive cardiac rhythm assessment is needed (eg, suspected arrhythmias when symptoms [syncope, palpitations] are occurring daily). These devices are not the focus of this review.

Various classes of devices are available for situations where longer monitoring than can be obtained with a traditional Holter monitor is needed. Because there may be many devices within each category, a comprehensive description of each is beyond our scope. Devices vary in how data are transmitted to the location where the ECG output is interpreted. Data may be transmitted via cellular phone or landline, or by direct download from the device after its return to the monitoring center. The device classes are described in Table 1.

Table 1. Ambulatory Cardiac Rhythm Monitoring Devices

Device Class	Description	Device Examples
Noncontinuous devices with memory (event recorder)	Devices not worn continuously but rather activated by patient and applied to skin in the precordial area when symptoms develop	• Zio® Event Card (iRhythm Technologies) • REKA E100™ (REKA Health)
Continuous recording devices	Devices continuously worn and continuously record via ≥1 cardiac	• Zio® XT Patch and ZIO ECG Utilitzation Service (ZEUS) System (iRhythm Technologies)

with longer recording periods	leads and store data longer than traditional Holter (14 d)	
External memory loop devices (patient- or autotriggered)	Devices continuously worn and store a single channel of ECG data in a refreshed memory. When the device is activated, the ECG is then recorded from the memory loop for the *preceding* 30-90 s and for next 60 s or so. Devices may be activated by a patient when symptoms occur (patient-triggered) or by an automated algorithm when changes suggestive of an arrhythmia are detected (autotriggered).	• Patient-triggered: Explorer™ Looping Monitor (LifeWatch Services) • Autotriggered: LifeStar AF Express™ Auto-Detect Looping Monitor (LifeWatch Services) • Autotriggered or patient-triggered: King of Hearts Express® AF (Card Guard Scientific Survival)
Implantable memory loop devices (patient- or autotriggered)	Devices similar in design to external memory loop devices but implanted under the skin in the precordial region	• Autotriggered or patient-triggered: Reveal® XT ICM (Medtronic) and Confirm Rx Insertable™ Cardiac Monitor (Abbott) • Autotriggered: BioMonitor, Biotronik)
Mobile cardiac outpatient telemetry	Continuously recording or auto-triggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis	• CardioNet MCOT (BioTelemetry) • LifeStar Mobile Cardiac Telemetry (LifeWatch Services) • Zio AT (iRhythm)

ECG: electrocardiogram.

There are also devices that combine features of multiple classes. For example, the LifeStar ACT Ex Holter (LifeWatch Services) is a 3-channel Holter monitor, but is converted to a mobile cardiac telemetry system if a diagnosis is inconclusive after 24 to 48 hours of monitoring. The BodyGuardian® Heart Remote Monitoring System (Preventice Services) is an external auto-triggered memory loop device that can be converted to a real-time monitoring system. The eCardio Verité™ system (eCardio) can switch between a patient-activated event monitor and a continuous telemetry monitor. The Spiderflash-T (LivaNova) is an example of an external auto-triggered or patient-triggered loop recorder, but like the Zio Patch, can record 2 channels for 14 to 40 days.

Summary

Various devices are available for outpatient cardiac rhythm monitoring. These devices differ in the types of monitoring leads used, the duration and continuity of monitoring, the ability to detect arrhythmias without patient intervention, and the mechanism of delivering the information from patient to clinician. These devices may be used to evaluate symptoms suggestive of arrhythmias (eg, syncope, palpitations), and may be used to detect atrial fibrillation (AF) in patients who have undergone cardiac ablation of AF or who have a history of cryptogenic stroke.

Ambulatory Event Monitoring

For individuals who have signs and/or symptoms suggestive of arrhythmia(s) who receive patient- or auto-activated external ambulatory event monitoring or continuous ambulatory monitoring storing information for more than 48 hours, the evidence includes prospective and retrospective studies reporting on the diagnostic yield. Relevant outcomes are overall survival (OS) and morbid events. Observational studies have consistently shown that continuous monitoring with longer recording periods detects more arrhythmias than 24- or 48-hour Holter monitoring. Particularly for patients who, without the more

prolonged monitoring, would only undergo shorter term monitoring, the diagnostic yield is likely to identify arrhythmias that may have therapeutic implications. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have AF following ablation who receive long-term ambulatory cardiac monitoring, the evidence includes one randomized controlled trial(RCT) comparing ambulatory event monitoring with standard care and several observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. The RCT evaluating a long-term monitoring strategy after catheter ablation for AF reported significantly higher rates of AF detection. The available evidence has suggested that long-term monitoring for AF postablation is associated with improved outcomes. However, the specific type of monitoring associated with the best outcomes is not established, because different long-term monitoring devices were used across the studies. Trials demonstrating improved outcomes have used event monitors or implantable monitors. In addition, there are individual patient considerations that may make one type of monitor preferable over another. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cryptogenic stroke with a negative standard workup for AF who receive long-term ambulatory cardiac monitoring, the evidence includes systematic reviews of RCTs comparing ambulatory event monitoring with standard care. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. Randomized controlled trials evaluating a long-term AF monitoring strategy post-stroke have reported significantly higher rates of AF detection with longer term ambulatory monitoring. The available evidence has suggested that long-term monitoring for AF after cryptogenic stroke is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not established because different long-term monitoring devices were used across the studies. Trials demonstrating improved outcomes have used event monitors or implantable monitors. In addition, there are individual patient considerations that may make one type of monitor preferable over another. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic with risk factors for AF who receive long-term ambulatory cardiac monitoring, the evidence includes RCTs and observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. Multiple observational studies showed that the use of ambulatory monitors would result in higher AF detection compared with routine care. Randomized controlled trials found higher AF detection and initiation of anticoagulants with monitoring, but no impact on health outcomes. The only RCT (LOOP Trial) with sufficient statistical power and duration to evaluate health outcomes found no difference between monitoring and standard care on the primary endpoint of combined stroke or systemic arterial embolism (HR 0.80; 95% CI 0.61 to 1.05; P =.11) or any secondary endpoints after 6 years of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Implantable Loop Recording

For individuals who have signs and/or symptoms suggestive of arrhythmia with infrequent symptoms who receive patient- or auto-activated implantable ambulatory event monitoring, the evidence includes RCTs comparing implantable loop recordings (ILRs) with shorter term monitoring, usually 24- to 48-hour Holter monitoring, and many observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. Studies assessing prolonged ILRs in patients have reported high rates of arrhythmia detection compared with shorter external event or Holter monitoring. These studies have supported use of a progression in diagnostics from an external event monitor to ILR when longer monitoring is needed. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Outpatient Cardiac Telemetry

For individuals who have signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes an RCT and nonrandomized studies evaluating rates of arrhythmia detection using outpatient cardiac telemetry. Relevant outcomes are OS and morbid events. The

available evidence has suggested that outpatient cardiac telemetry is at least as good at detecting arrhythmias as ambulatory event monitoring. However, studies have not evaluated whether the real-time monitoring feature of outpatient cardiac telemetry leads to reduced cardiac events and mortality. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
7/2024	Annual policy review. References updated. Policy statements unchanged.
7/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2023	Clarified coding information.
7/2022	Annual policy review. Terminology in policy statements revised from "patients" to "individuals"; intent unchanged.
6/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference. Clarified coding information.
7/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2019	Clarified coding information.
10/2018	Annual policy review. Investigational indications revised to describe the use of mobile apps. Effective 10/1/2018.
1/2018	Clarified coding information.
6/2017	Annual policy review. New references added.
7/2016	Annual policy review. Policy statements edited for simplicity to group continuous ambulatory monitors with longer recording periods with external event monitors, and to move language regarding the use of long-term outpatient monitoring for AF to “Policy Guidelines.” 7/1/2016
5/2016	MCOT considered medically necessary. Effective 5/1/2016.
12/2015	Annual policy review. Policy statement related to the use of mobile cardiac outpatient telemetry changed from “not medically necessary” to “investigational.” Effective 12/1/2015.
9/2015	Annual policy review. Policy revised with clarification of policy statements o indicate that the use of EITHER an external long-term monitor OR an implantable monitor (but not both) is medically necessary for the evaluation of cryptogenic stroke. Effective 9/1/2015.
4/2015	Annual policy review. New medically necessary indications described. Effective 4/1/2015.
1/2015	Annual policy review. The phrase “for patients with cryptogenic stroke” removed from the investigational policy statement. Effective 1/1/2015.
12/2014	Annual policy review. New medically necessary indications described. Coding information clarified. Effective 12/1/2014.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
6/2014	Language on MCOT clarified.
4/2014	Annual policy review. Revised to change “loop monitors” to “ambulatory event monitors” and add “The policy statement on outpatient cardiac telemetry was reworded and language was added that the least costly alternative may be considered medically necessary.” Effective 4/1/2014.
3/2014	Annual policy review. Medically necessary criteria for implantable loop monitors revised from “…a prior trial of Holter monitor and other external ambulatory event monitors has

	been unsuccessful" to "…a prior trial of other external ambulatory event monitors has been unsuccessful." Effective 3/1/2014.
1/2014	Annual policy review. New references added.
6/1/2013	Annual policy review. Changes to policy statements.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
10/2010	Annual policy review. Changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
12/31/2009	Annual policy review. Changes to policy statements.
7/2009	Annual policy review. Changes to policy statements.
4/2009	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
3/2009	Annual policy review. No changes to policy statements.
4/2008	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
11/2007	Annual policy review. No changes to policy statements.
6/2007	Annual policy review. No changes to policy statements.
5/2007	Annual policy review. Changes to policy statements.
4/2007	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion.