Ambulatory Event Monitors

There is a wide variety of devices available for outpatient cardiac rhythm monitoring. The primary purpose of these devices is the evaluation of suspected arrhythmias that have not been detected by office or hospital-based 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 delivery of the information from patient to clinician.

A brief description of the major categories of devices is given below. There has been a trend in recent years toward using novel technology to increase the efficiency, comfort and convenience of these devices. These technologic advances include the development of devices that are smaller and more convenient to use, as well as novel ways to rapidly transmit information such as by use of mobile devices. These advances in technology may present challenges in categorizing new devices.

Some of the newer devices are described below for informational purposes in assigning them to the most relevant category. However, since there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review.

Continuous monitoring devices (Holter monitors and similar devices)

Ambulatory Holter electrocardiography (EKG) is a widely used noninvasive test in which EKG is continuously recorded over an extended period of time, typically 24 to 48 hours, to evaluate symptoms suggestive of cardiac arrhythmias, i.e., palpitations, dizziness, or syncope. However, Holter monitoring will be ineffective in detecting arrhythmias if a patient experiences infrequent symptoms. Therefore, the sensitivity of Holter monitoring is low for detection of arrhythmias that are intermittent.

Continuous monitoring devices with longer recording periods

Some newer devices are continuous monitors that are similar to traditional Holter monitoring in concept, but offer other advantages such as the ability to monitor for longer periods of time.

- The Zio® Patch system (iRhythm Technologies, Inc., San Francisco, CA) is a long-term continuous monitoring system that is most analogous to a Holter monitor that records and stores information for longer time periods. It is primarily used for asymptomatic monitoring. This system consists of a patch worn over the left pectoral region of the body that records continuously for up to 14-days, and the patient keeps a symptom log. At the end of the recording period, the patient mails back the recorder in a pre-paid envelope to a central station and a full report is provided to the physician within a few days.

- The BodyGuardian Remote Monitoring System™ (Preventice®, Inc., Minneapolis, MN) continuously detects and records a variety of physiologic data including ECG tracing, respiratory rate, and activity level for up to 30 days. The data can be transmitted to the physician’s office via
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a cellular telephone, and information can be viewed by the patient and physician through the internet.

Non-continuous monitoring devices (ambulatory event monitors and similar devices)

Ambulatory event monitors (AEMs) were developed to provide longer periods of monitoring by using noncontinuous monitoring. In this technique, the recording device is either worn continuously and activated only when the patient experiences symptoms or is carried by the patient and applied and activated when symptoms are present. The recorded EKGs are then stored for future analysis or transmitted by telephone to a receiving station, (e.g., a doctor's office; hospital; or cardiac-monitoring service), where the EKGs can then be analyzed. AEMs can be used for extended periods of time, typically up to 1 month or until the patient experiences symptoms. Since the EKGs are recorded only during symptoms, there is good correlation with any underlying arrhythmia. Conversely, if no EKG abnormality is noted, a noncardiac etiology of the patient's symptoms can be sought. Several different types of AEMs are available:

Noncontinuous devices with memory: These devices are carried by the patient and applied to the precordial area via nongel electrodes when the symptoms are occurring or, alternatively, a recording device may be worn on the wrist and then activated when symptoms are present. The limitation of these devices is that an arrhythmia of very short duration would be difficult to record. In addition, noncontinuous devices require reasonable dexterity on the part of the patient to apply the device correctly during a symptomatic period. This is a particular limitation if the patient is incapacitated during symptomatic periods.

- The Zio® Event Card (iRhythm Technologies, Inc., San Francisco, CA) is a noncontinuous realtime recording device that can be worn up to 30 days. This device can be worn comfortably under clothing (including during sleep), as it weighs less than 2 ounces and is similar in size to a standard credit card. Upon activation by the patient, the card is able to record the previous 45 seconds of electrocardiography (ECG) activity into memory plus the first 15 seconds after the button is pushed. This is made possible because this device continuously scans for ECG activity but only records upon symptom activation. After the device is activated, the patient is responsible for calling the iRhythm National Clinical Center (NCCC) who then instructs the patient on sending the event over the phone line.

- The REKA E100™ system is a noncontinuous single-lead cardiac event monitor. This device is the size of a hockey puck and weighs no more than a few ounces. There are 2 options depending on the patient’s circulation: 1) a zero-lead device that is separate from the body and may be carried in a purse or coat pocket; or if a patient’s circulation is determined to be inadequate, 2) a single electrode lead that the patient connects to the device at the time of an event. The zero-lead device records an event by patient activation and can record and store up to 2,000 readings. The patient has the option of sending stored event information to the physician across a free-of-charge phone app or the Internet in their computer. Internet transmission requires one of the following systems: Android, Blackberry, iPhone 3, 3S, 4, and 4S, iPad, iPod Touch®, Microsoft, or Windows.

Continuous "memory loop" devices: These devices are able to continuously store a single channel of EKG data in a refreshed memory. If the patient activates the device, the EKG is then recorded from the memory loop for the preceding 30 to 90 seconds and for the next minute or so. Therefore, these types of devices permit recording of the onset of arrhythmias and/or transient or incapacitating events. They obviously must be worn continuously.

Implantable continuous "memory loop" devices: An implantable loop recorder device is inserted just under the patient’s skin in the chest area during an outpatient surgical procedure. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for more than one year.
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**Auto-triggered devices:** All of the previously described devices require activation by the patient. More recently, auto-triggering technology has become available, which can be adapted to memory loop devices. For example, event monitors can be programmed to detect heart rates greater than 165 beats per minute, less than 40 beats per minute, or an asystole of greater than 3 seconds.

**Implantable continuous “memory loop” devices with autotrigger:** These devices combine the long-term monitoring available with implantable devices with the autotriggers seen on newer event monitors. These devices contain algorithms that are programmed to detect heart rates exceeding an upper or lower limit and asystole of greater than 3 seconds. They typically contain other autotriggers, such as a variable RR interval seen with atrial fibrillation. For example, the Reveal® XT ICM (Medtronic, Inc., Minneapolis, MN) is an implantable memory loop device cleared for marketing by the U.S. Food and Drug Administration (FDA) in 2008 that allows patient-activated rhythm recording, rhythm recording at prespecified time intervals, or auto-triggered rhythm recording. Sizes of implantable devices are decreasing: in February 2014, the FDA cleared for marketing the Reveal LINQ™, a miniaturized implantable memory loop device that is approximately 1 mL that includes auto-triggered or patient activated rhythm recording.

**Mobile Cardiac Outpatient Telemetry (MCOT):**

Ambulatory event monitors store the recorded data, which are ultimately transmitted either to a physician’s office or to a central recording station. In contrast, outpatient cardiac telemetry provides real-time monitoring and analysis. For example, CardioNet® now owned by BioTelemetry, Inc. (Malvern, PA), (Conshohocken, PA) offers mobile cardiac outpatient telemetry. In this system, the patient wears a 3-lead sensor, which constantly communicates with the CardioNet monitor, a lightweight unit that can be carried in a pocket or purse. When an arrhythmia is detected according to preset parameters, the EKG is automatically transmitted to a central CardioNet service center, where the EKG is immediately interpreted, with results sent to the referring physician. The referring physician can request the level and timing of response, ranging from daily reports to stat results. Other systems for outpatient cardiac telemetry include the HEARTLink II™ system (Cardiac Telecom Corp.), the VST™ (Vital Signs Transmitter, Biowatch Medical), the Lifestar™ ambulatory cardiac telemetry (ACT) system (Card Guard Scientific Survival, Israel), and the SEEQ™ Mobile Cardiac Telemetry System (Medtronic, Minneapolis, MN). The eCardio Verité™ system (eCardio, Houston, TX) is a multifunctional model that can be changed between a patient-activated event monitor and a continuous telemetry monitor.

The VectraplexECG™ System is a real-time continuous Mobile Cardiac Outpatient Telemetry device to measure ischemic ECG changes that can be indicative of a myocardial infarction (MI). This device utilizes the Internet to communicate real-time ECG changes to the physician. The patient is hooked up to a mini-tablet by either 5 electrodes, which communicate 15-lead ECG data, or 10 electrodes that communicate 12-lead ECG data. While this system is primarily intended to monitor for ischemia, the continuous ECG monitoring would presumably detect rhythm disturbances, as well as ischemic changes.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

**Policy**

BCBSNC will provide coverage for Ambulatory Event Monitors when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Outpatient Cardiac Telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered investigational. BCBSNC does not cover services that are considered investigational.

**Benefits Application**

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be
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reviewed before applying the terms of the policy.

When Ambulatory Event Monitors are covered

The use of patient-activated or auto-activated external ambulatory event monitors and long-term
ambulatory monitoring may be considered medically necessary as a diagnostic alternative to Holter
monitoring in:

- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of
cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope)
- Patients with atrial fibrillation who have been treated with catheter ablation, and in whom
discontinuation of systemic anticoagulation is being considered
- Patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate
treatment response
- Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation
including a 24-hour Holter monitor.

The use of implantable ambulatory event monitors, either patient-activated or auto-activated, may be
considered medically necessary only in the small subset of patients who experience recurrent symptoms
so infrequently that a prior trial of other external ambulatory event monitors has been unsuccessful.

The use of continuous ambulatory monitors that record and store information for periods longer
than 48 hours may be considered medically necessary as a diagnostic alternative to Holter
monitoring or patient-activated or auto-activated external ambulatory event monitors in the
following situations:

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

When Ambulatory Event Monitors are not covered

Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered
investigational as a diagnostic alternative in patients who experience infrequent symptoms (less frequently
than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or
syncope).

Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investiga-
tional, including but not limited to monitoring effectiveness of antiarrhythmic therapy and detection of
myocardial ischemia by detecting ST segment changes.

Policy Guidelines

For the use of auto-activated event monitors for arrhythmia detection in patients with suspected
arrhythmias, a number of studies have indicated that auto-trigger event monitors detect additional
episodes of arrhythmias compared to Holter monitoring or patient-triggered devices. This evidence has led
to the acceptance of auto-trigger event monitors as the gold standard for detecting arrhythmias that occur
infrequently.

For the use of autoactivated event monitors for detection of atrial fibrillation (AF) in patients who have
been treated with catheter ablation, there is evidence that auto-trigger devices can pick up asymptomatic
episodes of atrial fibrillation in treated patients and that identifying asymptomatic episodes may lead to
modifications in treatment.
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For the use of auto activated event monitors for the detection of AF in patients with cryptogenic stroke, the most direct evidence consists of one well-designed and well-controlled RCT which demonstrated improved AF detection rates for patients managed with 30 days of auto triggered event monitoring compared with those managed with 24-hour Holter monitoring. Observational studies support this finding. There are recognized management changes which lead to improved outcomes for patients with stroke and AF (i.e., initiation of oral anticoagulation). Therefore, the published evidence is sufficient to determine that auto trigger event monitors improve the net health outcome for patients with suspected arrhythmia, for patients who have undergone catheter ablation for AF and in whom discontinuation of systemic anticoagulation is being considered, and for patients with cryptogenic stroke.

Similarly, for the use of implantable event monitors for the detection of AF in patients with cryptogenic stroke, the most direct evidence consists of an RCT comparing the use of an auto triggered implantable monitor with routine care in patients with cryptogenic stroke. This study demonstrated improvements in AF detection rate with event monitoring compared with routine care. The published evidence is sufficient to determine that implantable event monitors for AF detection improve the net health outcome for patients with cryptogenic stroke.

For the evaluation of patients with infrequent symptoms who have not had arrhythmias detected with standard Holter monitoring or external event monitors, there is little direct evidence regarding outcomes associated with implantable loop recorders. Implantable loop recording devices likely have greater sensitivity in detecting arrhythmias in patients presenting with symptoms suggestive of arrhythmia. The available evidence does not clearly define the indications for an implantable loop recorder; however, given the small but higher risk associated with an implantable device, for patients presenting with signs or symptoms suggestive of an arrhythmia, it would be reasonable to consider the use of an implantable loop recorder after a trial of an external loop recorder does not yield a definitive diagnosis.

Newer continuous monitoring devices are available that use novel technology and record information for longer periods than a Holter monitor, e.g., up to 2 weeks. The available evidence for these devices consists of cross-sectional studies that show that they typically detect greater numbers of arrhythmias during extended follow up than 24- or 48-hour Holter monitoring. However, the appropriate comparison group would be patient- or auto triggered event monitors, and no studies were identified that compared longer recording devices with patient- or auto triggered event monitors. Direct evidence for improved outcomes with the use of these types of monitors is lacking. The evidence for a significant incremental improvement in outcomes when continuous monitoring devices are used is lacking. Therefore, the available published evidence is considered insufficient to determine that continuous monitoring devices with longer recording periods improve the net health outcome for patients with suspected arrhythmias.

Mobile Cardiac Outpatient Telemetry (MCOT) is another option for long-term cardiac monitoring. For the use of MCOT for the evaluation of patients with suspected arrhythmias, evidence from one RCT and uncontrolled case series, along with clinical input, suggests that MCOT is likely to be as effective at detecting arrhythmias as auto triggered event monitors. Although MCOT has the theoretical advantage of allowing a rapid response to a potentially emergent arrhythmia, none of the available studies have clearly shown an improvement in clinical utility as a result of using MCOT. Further studies are needed to compare MCOT with the auto trigger loop recorder in order to determine whether the faster response possible with real-time monitoring leads to improved outcomes. Direct evidence for improved health outcomes with the use of MCOT for the evaluation of suspected arrhythmias is lacking and evidence for a significant incremental improvement in outcomes with MCOT, compared with standard management, is lacking. Therefore, the available published evidence is considered insufficient to determine that MCOT improves the net outcome for patients with suspected arrhythmias.

Similarly, for the use of MCOT for the detection of AF either in patients following catheter ablation of AF or following cryptogenic stroke, there is no direct evidence comparing MCOT with other detection methods. Single-arm studies report relatively high rates of AF detection with MCOT in patients with cryptogenic stroke. Direct evidence for improved health outcomes with the use of MCOT for the evaluation of AF and evidence for a significant incremental improvement in outcomes with MCOT, compared with standard management is lacking. Therefore, the available published evidence is considered insufficient to determine that MCOT improves the net health outcome for patients with cryptogenic stroke.
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insufficient to determine that MCOT improves the net health outcome for patients who require evaluation for AF.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 93224, 93225, 93226, 93227, 93228, 93229, 93268, 93270, 93271, 93272, 33282, 33284, E0616, 0295T, 0296T, 0297T, 0298T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Specialty Matched Consultant Advisory Panel, 9/00
Medical Policy Advisory Group - 10/00
BCBSA Medical Policy Reference Manual, 2.02.08, 7/12/02
Hanke T, Charitos EI, Stierle U et al. Twenty-four-hour holter monitor follow-up does not provide accurate heart rhythm status after surgical atrial fibrillation ablation therapy: up to 12 months experience with a novel permanently implantable heart rhythm monitor device. Circulation 2009; 120:S177-S184.
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Medical Director review 12/2011

Specialty Matched Consultant Advisory Panel review 4/2012

Medical Director review 8/2012


Medical Director review 12/2012

Specialty Matched Consultant Advisory Panel review 4/2013

Medical Director review 4/2013


Medical Director review 11/2013


Medical Director review 8/2014


Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015
## Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>9/00</td>
<td>Specialty Matched Consultant Advisory Panel. Revised section, &quot;When Ambulatory Event Monitors are not covered&quot; to include routine monitoring for effectiveness of antiarrhythmic therapy and when used for asymptomatic patients.</td>
</tr>
<tr>
<td>12/03</td>
<td>Benefits Application and Billing/Coding sections updated for consistency.</td>
</tr>
<tr>
<td>3/30/06</td>
<td>Specialty Matched Consultant Advisory Panel review 2/27/06 with no changes made to coverage criteria. Added information regarding &quot;Outpatient Cardiac Telemetry&quot; to Description, Policy and Policy Guidelines sections to indicate that this technology is considered investigational. Added policy number to Key Words section. HCPCS codes effective 4/1/06 added to policy.</td>
</tr>
<tr>
<td>4/21/08</td>
<td>Description section extensively revised for clarity. Outpatient cardiac telemetry is considered investigational. Deleted statement from Policy Guidelines section regarding Telemedicine billed under the evaluation and management codes. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn)</td>
</tr>
<tr>
<td>01/05/09</td>
<td>Added new CPT codes 93228 and 93229 to Billing/Coding section. (adn)</td>
</tr>
<tr>
<td>7/20/09</td>
<td>Description section revised. Policy statement changed to read, &quot;Outpatient Cardiac Telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered not medically necessary.&quot; Criteria in the When AEM is Covered section deleted and replaced with the following statements: The use of patient-activated or auto-activated external ambulatory event monitors may be considered medically necessary as a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope). The use of implantable ambulatory event monitors, either patient activated or auto-activated, may be considered medically necessary only in the small subset of patients who experience recurrent symptoms so infrequently that a prior trial of Holter monitor and other external ambulatory even monitors has been unsuccessful. Information in the When AEM is Not Covered section deleted and replaced with the following statements: Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered not medically necessary as a diagnostic alternative in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope). Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic therapy and detection of myocardial ischemia by detecting ST segment changes. Rationale in the Policy Guidelines section revised. References updated. (adn)</td>
</tr>
<tr>
<td>1/5/10</td>
<td>HCPCS Codes S0345, S0346, S0347 deleted.</td>
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number. No changes to policy (mco)

1/4/11  CPT codes 93230, 93231, 93233, 93235, 93236 and 93237 deleted from Billing/Coding section. (mco)


12/30/11  New product information added to “Description” section. New codes effective 1/1/2012: 0295T, 0296T, 0297T, 0298T added to “Billing/Coding” section. “When Covered” section revised to include the following statement: “The use of auto-activated external ambulatory event monitors may be considered medically necessary in patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate treatment response.” “When not Covered” section revised to include the following statement: “The use of long-term ambulatory monitoring, i.e., Zio™ Patch, Zio™ Event Card and the Zeus ECG Utilization Service, is considered not medically necessary because the clinical (health) outcomes and cost effectiveness of extended monitoring have not been shown to be superior to other available approaches.” Policy Guidelines updated. References updated. Medical Director review 12/2011. (mco)

5/15/12  Specialty Matched Consultant Advisory Panel review 4/2012. No changes to policy statements. (mco)

10/01/12  Revised the following statement in the “When Covered” section: “The use of patient-activated or auto-activated external ambulatory event monitors and long-term ambulatory monitoring may be considered medically necessary as a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).” Deleted the following statement from the “When not Covered” section: “The use of long-term ambulatory monitoring, i.e., Zio™ Patch, Zio™ Event Card and the Zeus ECG Utilization Service, is considered not medically necessary because the clinical (health) outcomes and cost effectiveness of extended monitoring have not been shown to be superior to other available approaches.” Removed 0296T, 0297T and 0298T from the Billing/Coding section. Medical Director review 8/2012. (mco)

1/15/13  Description section extensively revised. “When Covered” revised to state: “The use of patient-activated or auto-activated external ambulatory event monitors and long-term ambulatory monitoring may be considered medically necessary as a diagnostic alternative to Holter monitoring in: Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope), Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered; Patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate treatment response.” “When not Covered” section revised to state: “Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic therapy, for patients with cryptogenic stroke, and detection of myocardial ischemia by detecting ST segment changes.” References updated. Medical Director review 12/2012. (mco)


12/10/13  Description section updated. References updated. Policy Guidelines updated. Medical Director review 11/2013. (mco)


8/26/14  Description section updated. Added following coverage criterion to “When Covered” section:
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“Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor.” Policy Guidelines updated. References updated. Medical Director review 8/2014. (mco)

12/30/14 References updated. Billing/Coding section updated to include codes: 0296T, 0297T, 0298T Policy Guidelines section updated. When Covered section updated to indicate that continuous monitors with longer recording periods may be considered medically necessary with criteria. Policy statement unchanged. (td)


9/1/15 Description section updated. Policy Statement and When Covered section updated to reflect change in MCOT coverage statement from not medically necessary to investigational. Policy Guidelines section updated. References updated. (td)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.