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Clinical Appropriateness Guidelines

Cardiovascular

Appropriate Use Criteria: Ambulatory Cardiac Rhythm Monitoring

Proprietary

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Ambulatory Cardiac Rhythm Monitoring

Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
93228	External 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; review and interpretation with report by a physician or other qualified health care professional
93229	External 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 transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional
C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator and programmer

General Information

Description

Cardiac rhythm abnormalities are common and usually benign. However, some arrhythmias have adverse prognostic implications and require intervention to avert serious consequences. Atrial fibrillation is associated with embolic phenomena, most commonly stroke. Ventricular arrhythmias may cause syncope or sudden cardiac death (SCD). Sustained supraventricular tachyarrhythmias are a cause of cardiomyopathy and heart failure, and bradyarrhythmia may precipitate syncope, near syncope, or rarely SCD.

Although rhythm abnormalities may occur without symptoms, palpitation is the most common symptom of cardiac arrhythmia. Syncope, near syncope, impaired exercise tolerance, dyspnea, and chest pain are also manifestations. Because arrhythmia management and prognosis depend on the specific rhythm disturbance, it is important to have electrocardiographic documentation. Resting EKG may sometimes be diagnostic (atrial fibrillation for example) but when the arrhythmia is intermittent, rhythm monitoring for longer time periods may be warranted. Monitoring device selection is based on several factors, most notably the frequency of the symptoms (if present) and the degree of clinical risk posed by the arrhythmia. Holter monitors are not suitable for evaluation of symptoms occurring less frequently than every 48 hours. Patch-type recorders are useful when longer periods of monitoring are required. Loop recorders facilitate even longer periods of monitoring and are particularly useful when temporal correlation to symptoms is required or when screening for asymptomatic arrhythmia (provided they have auto-triggering capability). In general, cardiac telemetry is reserved for those patients who have non-diagnostic results on ambulatory event monitoring. Implantable recorders have the most restrictive indications (see [below](#)). Patient-triggered recording (on any device with that capability) can only provide useful data when the patient remains coherent enough (during an arrhythmic event) to initiate recording and this may further inform the choice of monitoring equipment. Auto-triggering (recording initiated by rhythm abnormality without patient involvement) is useful in the evaluation of asymptomatic arrhythmia or when the patient is likely to be unable to initiate recording when the arrhythmia occurs (e.g., syncope evaluation).

Guideline Scope

Cardiac rhythm monitoring devices fall broadly into the following categories:

1. **Implantable recording devices** – Devices implanted subcutaneously which continuously record and transmit cardiac electrical activity. This device is also known as implantable loop recorder (ILR).
2. **Mobile cardiac outpatient telemetry** – External ambulatory monitoring devices capable of real-time recording and automatic transmission of cardiac electrical activity. These devices are also known as mobile outpatient cardiac telemetry or real-time remote heart monitors.
3. Ambulatory event monitors – External devices which can record cardiac electrical activity for up to 30 days.
 - Patch-type monitors record data continuously which is stored for later analysis
 - Loop recorders are triggered to record (either by the patient who becomes symptomatic or by the occurrence of an arrhythmia). Transmission over a phone line facilitates reporting while the device is still worn by the patient.
4. Holter monitor – External device that provides continuous recording and storage of cardiac electrical activity for a period of up to 48 hours. Recorded data are interpreted later when the device is removed. It is also known as an ambulatory EKG recording device.

This guideline addresses the appropriate use of **implantable recording devices (1)** and **mobile cardiac outpatient telemetry (2)** when used to monitor cardiac rhythm in the outpatient ambulatory setting.

Definitions

Cryptogenic stroke – Symptomatic cerebral infarction which, despite standard diagnostic evaluation, has no probable cause. Standard diagnostic evaluation in this context includes imaging to exclude large vessel (neck and brain) pathology, brain imaging to exclude small vessel disease, transthoracic and (if negative) transesophageal echocardiography to evaluate for cardiac source of embolism, basic lab work to exclude coagulopathy, and preliminary cardiac rhythm monitoring (usually inpatient telemetry at the time of the stroke or Holter monitoring shortly thereafter).

Symptoms suggestive of arrhythmia – syncope, presyncope, episodic dizziness, or recurrent palpitation

Recurrent syncope – two or more syncopal episodes within the past 5 years

Non-diagnostic – When performed for evaluation of symptoms suggestive of arrhythmia, rhythm monitoring is nondiagnostic when no rhythm disturbance correlating with symptoms is uncovered. This occurs when the patient remains asymptomatic throughout the monitoring period. If the symptoms do occur and are not associated with rhythm abnormality, the symptoms can be assumed not to be related to arrhythmia (and the study is therefore diagnostic). When monitoring is performed to evaluate for asymptomatic arrhythmia (e.g., atrial fibrillation following cryptogenic stroke), a non-diagnostic study is one where the arrhythmia in question did not occur during the monitoring session.

Clinical Indications

Implantable recording device

An implantable recording device is considered medically necessary for detection of atrial fibrillation/flutter following cryptogenic stroke when ALL of the following apply:

- The individual has no prior history of atrial fibrillation/flutter
- Ambulatory monitoring using external equipment has been performed for a period of at least 14 days and is non-diagnostic

- There is no contraindication to anticoagulation
- There is no existing indication for anticoagulation (e.g., prosthetic valve)
- The individual does not have an implanted device (pacemaker, cardiac resynchronization therapy [CRT] device or implantable cardioverter defibrillator [ICD]) capable of monitoring for atrial fibrillation/flutter

An implantable recording device is considered medically necessary for evaluation of recurrent syncope when ALL of the following apply:

- The cause of syncope is not evident despite history, physical examination (including orthostatic blood pressure measurements), electrocardiogram and echocardiogram
- Ambulatory monitoring has been performed for a period of at least 14 successive days and is non-diagnostic
- The syncopal events occur less frequently than every 30 days
- The individual does not have an implanted device (pacemaker, CRT device or ICD) capable of monitoring for arrhythmia

An implantable recording device is considered medically necessary following successful pulmonary vein isolation for atrial fibrillation when BOTH of the following apply:

- The individual had syncope due to post-conversion pause prior to ablation
- The individual does not have a permanent pacemaker

Cardiac telemetry

Mobile cardiac telemetry is considered medically necessary for evaluation of symptoms suggestive of arrhythmia when ALL of the following apply:

- Symptoms occur less frequently than every 48 hours
- Ambulatory event monitoring has been performed for a period of at least 14 days and is non-diagnostic
- The individual does not have an implanted device (pacemaker, CRT device or ICD) capable of monitoring for arrhythmia

Mobile cardiac telemetry is considered medically necessary for detection of atrial fibrillation following cryptogenic stroke when ALL of the following apply:

- The individual has no prior history of atrial fibrillation/flutter
- Ambulatory event monitoring has been performed for a period of at least 14 days and is non-diagnostic
- There is no contraindication to anticoagulation
- There is no existing indication for anticoagulation (e.g., prosthetic valve)
- The individual does not have an implanted device (pacemaker, CRT device or ICD) capable of monitoring for atrial fibrillation/flutter

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History

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