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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Cardiovascular

Appropriate Use Criteria: Transcatheter Ablation for Management of Atrial Fibrillation

Proprietary

Table of Contents

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 ongoing 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.

Transcatheter Ablation for Management of Atrial Fibrillation

General Information

Guideline Scope

This guideline addresses the use transcatheter ablation procedures for management of atrial fibrillation (AF). Pulmonary vein isolation (PVI), ablation of other areas of atrial tissue (performed at the same sitting as PVI), and atrioventricular (AV) node ablation are included. In addition, accessory pathway ablation for management of pre-excited AF is addressed. Ablation for treatment of other supraventricular and ventricular arrhythmias is beyond the scope of this document (*see the Carelon Clinical Appropriateness Guidelines for Transcatheter Ablation of Supraventricular and Ventricular Arrhythmias*).

Description

Pulmonary Vein Isolation

When a decision is made to pursue a rhythm control (as distinct from a rate control) strategy in the management of atrial fibrillation, the options include pharmacologic rhythm control or ablation. Most ablation procedures for AF are performed using a transcatheter approach wherein the left atrial tissue surrounding pulmonary venous ostia is treated with either radiofrequency current, cryothermal ablation, or electroporation. Electroporation is also known as pulsed field ablation (PFA). The goal of PVI is to electrically isolate the pulmonary veins, often the site of origin of the arrhythmia, from the left atrial tissue. Ablation of other sites within the atrium is sometimes performed in conjunction with PVI with a goal of lowering recurrence of atrial fibrillation, although evidence of improved outcomes with this approach is lacking.

As with any procedure, justification of PVI must be based on the expectation that the benefit of the procedure exceeds the risk. This risk/benefit balance assumes that rhythm control is more beneficial than rate control and that ablation is more beneficial than pharmacological rhythm management. Decisions to perform PVI must also be informed by the known procedural failure rates, the need for repeat procedures, the reality that some ablated patients will also need medications to maintain sinus rhythm, and the evidence that procedural volume of the operator is a determinant of both procedural success and complication rate. Decisions regarding anticoagulation should be based on the risk of an embolic event versus the risk of bleeding (using contemporary risk evaluation tools). PVI success of failure should not alter decision making with regard to anticoagulation.

PVI is an invasive procedure, and it is not without potential complications. As with any invasive cardiac procedure, vascular access complications are not uncommon. Major complications are fortunately less common but may include cardiac perforation with pericardial tamponade, pulmonary vein stenosis, atrial esophageal fistula, embolic events, and even death. PVI is usually performed with fluoroscopic guidance which exposes the patient to ionizing radiation. Use of electroanatomical mapping systems, when available, can reduce such exposure.

Transcatheter ablation of AV node for management of AF

In the management of AF, when a decision is made to pursue a rate control (as distinct from a rhythm control) strategy, pharmacologic agents that slow AV conduction are the first approach. Some patients on maximally tolerated doses of these medications continue to have unacceptably high ventricular response rates. Provided that rhythm control cannot be offered, these patients benefit from AV node ablation. Most patients will require lifelong permanent pacing following AV node ablation and for this reason, ablation is performed more frequently in older patients and/or those who already have a device capable of ventricular pacing.

Transcatheter accessory pathway ablation for pre-excited AF

Pre-excited AF occurs when a patient with an accessory pathway(s) with short refractory period conducts (or has the potential to conduct) atrial impulses to the ventricle resulting in higher ventricular response rates than those seen in AF with conduction via the AV node. Ablation of the accessory pathway(s) prevents this potentially fatal arrhythmia. Patients with asymptomatic pre-excitation also carry some risk and may benefit from ablation.

Definitions

Paroxysmal AF – Two or more episodes of AF spontaneously terminating within 7 days

Persistent AF – AF that persists for more than 7 days or requires cardioversion (electrical or pharmacological) for termination. When persistent AF lasts for more than one year, it is considered longstanding persistent.

Permanent AF – When a decision has been made not to pursue rhythm control strategies, the patient is said to have permanent AF

Class I antiarrhythmic agents – quinidine, procainamide, disopyramide, mexiletine, flecanide, propafenone

Class III antiarrhythmic agents – amiodarone, dronedarone, dofetilide, ibutilide, sotalol, vernakalant

Clinical Indications

PVI for management of atrial fibrillation

Initial and one repeat* PVI is considered medically necessary in the following scenarios:

Paroxysmal AF – **ANY** of the following:

- Persistent symptoms despite treatment with least one Class I or Class III antiarrhythmic medication
- Symptomatic, and all class I and Class III antiarrhythmic medications are contraindicated
- As an initial therapy in patients with recurrent paroxysmal atrial fibrillation

Persistent AF of less than 12 months duration – **EITHER** of the following:

- Persistent symptoms despite treatment with least one Class I or Class III antiarrhythmic medication
- Symptomatic and all class I and Class III antiarrhythmic medications are contraindicated

Persistent or paroxysmal AF – **ANY** of the following:

- Symptoms related to AF in patients who have heart failure
- Symptomatic AF in patients with hypertrophic cardiomyopathy when pharmacologic rhythm control fails, is contraindicated, or not desired
- To avoid pacemaker implantation in patients with AF-related bradycardia or symptomatic post-conversion pause

*After PVI has been attempted twice, requests for additional PVI procedures will be subject to a higher level of review and will be considered on a case-by-case basis.

Additional linear or focal intracardiac catheter ablation for management of AF

Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation, performed at the time of PVI (CPT code 93657), has not been shown to improve patient outcomes and is therefore considered to be **not medically necessary**.

Transcatheter ablation of AV node for management of AF

Transcatheter ablation of AV node is considered medically necessary for management of atrial fibrillation when **ALL** of the following apply:

- Ventricular response rate is unacceptably high despite maximum tolerated doses of rate control medications, or individual has tachycardia-mediated cardiomyopathy
- Individual is not a candidate for (or has failed) pharmacological rhythm control
- Individual is not a candidate for (or has failed) PVI

Transcatheter ablation of accessory pathway for management of pre-excited AF

Transcatheter ablation of accessory pathway is considered medically necessary for management of pre-excited atrial fibrillation for **EITHER** of the following:

- Symptomatic pre-excited AF
- Asymptomatic preexcitation in an individual with a high-risk EP study who either has a high-risk occupation or participates in competitive athletics

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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

93650	Intracardiac catheter ablation of **atrioventricular node** function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of **supraventricular** tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by **pulmonary vein isolation**, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)

History

Status	Review Date	Effective Date	Action
Reaffirmed	01/30/2025	Unchanged	Independent Multispecialty Physician Panel (IMPP) review. Criteria reaffirmed. The addition of “with a goal of lowering recurrence of atrial fibrillation” is to differentiate from ablative procedures performed at the same sitting as PVI to treat other arrhythmias (EG atrial flutter treated with CTI ablation) that are identified.
Created	09/07/2023, 07/18/2023	07/01/2024	IMPP review. Removed coverage for ablation of areas beyond the pulmonary veins in patients undergoing PVI. Added references. Original effective date.