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MEDICAL POLICY – 2.02.30

Transcatheter Mitral Valve Repair

BCBSA Ref. Policy:	2.02.30
Effective Date:	Aug. 1, 2023
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Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.131 Transcatheter Pulmonary Valve Implantation

7.01.132 Transcatheter Aortic-Valve Implantation for Aortic Stenosis

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Introduction

The heart has four chambers, two upper and two lower. The mitral valve is between the upper and lower left chambers. After blood has been pumped from the upper left chamber to the lower left chamber, the mitral valve closes. The mitral valve is made up of small pieces of tissue called leaflets. If the leaflets don't close properly when the left lower chamber pumps blood out to the body some of the blood can leak back into the upper left chamber. This is known as mitral valve regurgitation. Medication can be used to help manage the symptoms of mitral valve regurgitation. Open heart surgery is a treatment option. If a person is too sick for surgery, a nonsurgical procedure may be used to place a clip to close the leaky mitral valve. In this procedure, a long, hollow tube (a catheter) is threaded through a specific vein into the heart. The catheter then becomes the pathway for getting the clip to the mitral valve. Imaging is used to make sure the device is correctly placed. This policy describes when transcatheter mitral valve repair is considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Transcatheter mitral valve repair (i.e., MitraClip Clip Delivery System)	**Transcatheter mitral valve repair (TMVR) using a device approved by the U.S. Food and Drug Administration for use in mitral valve repair may be considered medically necessary for individuals with symptomatic, primary mitral regurgitation who are considered at prohibitive risk for open surgery.** **Prohibitive risk for open mitral valve repair surgery may be determined based on:** • The documented presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater **AND/OR** • The documented presence of a logistic EuroSCORE of 20% or greater **Transcatheter mitral valve repair with a device approved by the U.S. Food and Drug Administration may be considered medically necessary for individuals with heart failure and moderate-to-severe or severe* symptomatic secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy**.** **Note:** * Moderate to severe or severe MR may be determined by: • Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography • New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies. **Note:** ** Optimal guideline directed medical therapy (see **Appendix**) **Transcatheter mitral valve repair is considered investigational in all other situations.**

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Name of the Food and Drug Administration (FDA) approved device to be used
- Documentation that individual has symptomatic primary mitral regurgitation

AND

- Individual is at greater risk for open mitral valve repair surgery based on:
  - The documented presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater

  AND/OR
  - The documented presence of a logistic EuroSCORE of 20% or greater

Coding

Code	Description
CPT	
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture (e.g. Edwards Cardioband Mitral Valve Reconstruction System or Carillon Mitral Contour System)
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis (e.g. MitraClip Delivery System or PASCAL Precision Transcatheter Valve Repair System)
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure) (e.g. MitraClip Delivery System or PASCAL Precision Transcatheter Valve Repair System).

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Evidence Review

Description

Transcatheter mitral valve repair (TMVR) is an alternative to surgical therapy for mitral regurgitation (MR). MR is a common valvular heart disease that can result from a primary structural abnormality of the mitral valve (MV) complex or a secondary dilatation of an anatomically normal MV due to a dilated left ventricle caused by ischemic or dilated cardiomyopathy. Surgical therapy may be underutilized, particularly in individuals with multiple comorbidities, suggesting that there is an unmet need for less invasive procedures for MV repair. One device, MitraClip, has approval from the U.S. Food and Drug Administration for the treatment of severe symptomatic MR due to a primary abnormality of the MV (primary MR) in individuals considered at prohibitive risk for surgery and for individuals with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy.

Background

Mitral Regurgitation

Epidemiology and Classification

Mitral regurgitation (MR) is the second most common valvular heart disease, occurring in 7% of people older than age 75 years and accounting for 24% of all individuals with valvular heart disease.[1-2] MR with accompanying valvular incompetence leads to left ventricular (LV) volume overload with secondary ventricular remodeling, myocardial dysfunction, and left heart failure. Clinical signs and symptoms of dyspnea and orthopnea may also be present in individuals with valvular dysfunction.[3] MR severity is classified as mild, moderate, or severe disease on the basis of echocardiographic and/or angiographic findings (1+, 2+, and 3-4+ angiographic grade, respectively).

Individuals with MR generally fall into two categories — primary (also called degenerative) and secondary (also called functional) MR. Primary MR results from a primary structural abnormality in the valve, which causes it to leak. This leak may result from a floppy leaflet (called prolapse) or a ruptured cord that caused the leaflet to detach partially (called flail).[4] Because the primary cause is a structural abnormality, most cases of primary MR are surgically corrected. Secondary MR results from left ventricular (LV) dilatation due to ischemic or dilated cardiomyopathy. This causes the mitral valve (MV) leaflets not to coapt or meet in the center.[3] Because the valves are structurally normal in secondary MR, correcting the dilated LV using medical therapy is the primary treatment strategy used in the US.

Standard Management

Surgical Management

In symptomatic individuals with primary MR, surgery is the main therapy. In most cases, MV repair is preferred over replacement, as long as the valve is suitable for repair and personnel with appropriate surgical expertise are available. The American College of Cardiology and the American Heart Association have issued joint guidelines for the surgical management of MV, which are outlined in **Table 2**.[5]

The use of standard open MV repair is limited by the requirement for thoracotomy and cardiopulmonary bypass, which may not be tolerated by elderly or debilitated individuals due to their underlying cardiac disease or other conditions. In a single-center evaluation of 5737

individuals with severe MR in the United States, Goel et al (2014) found that 53% of individuals did not have MV surgery performed, suggesting an unmet need for such individuals.[6]

Isolated MV surgery (repair or replacement) for severe chronic secondary MR is not generally recommended because there is no proven mortality reduction and an uncertain durable effect on symptoms. Recommendations from major societies[7,8] regarding MV surgery in conjunction with coronary artery bypass graft surgery or surgical aortic valve replacement are weak because the current evidence is inconsistent on whether MV surgery produces a clinical benefit.[9,10,11,12]

Transcatheter Mitral Valve Repair

Transcatheter approaches have been investigated to address the unmet need for less invasive MV repair, particularly among inoperable individuals who face prohibitively high surgical risks due to age or comorbidities. MV repair devices under development address various components of the MV complex and generally are performed on the beating heart without the need for cardiopulmonary bypass.[1,13] Approaches to MV repair include direct leaflet repair[14], repair of the mitral annulus via direct annuloplasty, or indirect repair based on the annulus' proximity to the coronary sinus. There are also devices in development to counteract ventricular remodeling and systems designed for complete MV replacement via catheter.

Direct Leaflet Approximation

Devices currently approved by the FDA for transcatheter mitral valve repair (TMVR) undergo direct mitral leaflet repair (also referred to as transcatheter edge-to-edge repair). Of the TMVR devices under investigation, the MitraClip, has the largest body of evidence evaluating its use; it has been in use in Europe since 2008.[14] The MitraClip system is deployed percutaneously and approximates the open Alfieri edge-to-edge repair approach to treating MR. The delivery system consists of a catheter, a steerable sleeve, and the MitraClip device, which is a 4-mm wide clip fabricated from a cobalt-chromium alloy and polypropylene fabric. MitraClip is deployed via a transfemoral approach, with trans-septal puncture used to access the left side of the heart and the MV. Placement of the MitraClip leads to coapting of the mitral leaflets, thus creating a double-orifice valve.

The PASCAL (PAddles Spacer Clasps ALfieri) Mitral Repair System (Edwards Lifesciences) is also a direct coaptation device and works in a similar manner to the MitraClip system.[15] PASCAL has been in clinical use since 2016 and was approved for use in Europe in 2019.[16] The delivery

system consists of a 10-mm central spacer that attaches to the MV leaflets by 2 paddles and clasps.

Other Mitral Valve Repair Devices

Devices for TMVR that use various approaches are in development. Techniques to repair the mitral annulus include those that target the annulus itself (direct annuloplasty) and those that tighten the mitral annulus via manipulation of the adjacent coronary sinus (indirect annuloplasty). Indirect annuloplasty devices include the Carillon Mitral Contour System (Cardiac Dimension) and the Monarc device (Edwards Lifesciences). The CE-marked Carillon Mitral Contour System is comprised of self-expanding proximal and distal anchors connected with a nitinol bridge, with the proximal end coronary sinus ostium and the distal anchor in the great cardiac vein. The size of the connection is controlled by manual pullback on the catheter. The Carillon system was evaluated in the Carillon Mitral Annuloplasty Device European Union Study (AMADEUS) and the follow-up Tighten the Annulus Now study, with further studies planned.[17] The Monarc system also involves two self-expanding stents connected by a nitinol bridge, with one end implanted in the coronary sinus via internal jugular vein and the other in the great cardiac vein. Several weeks after implantation, the biologically degradable coating over the nitinol bridge degrades, allowing the bridge to shrink and the system to shorten. It has been evaluated in the Clinical Evaluation of the Edwards Lifesciences Percutaneous Mitral Annuloplasty System for the Treatment of Mitral Regurgitation (EVOLUTION I) trial.[18]

Direct annuloplasty devices include the Mitralign Percutaneous Annuloplasty System (Mitralign) and the AccuCinch System (Guided Delivery Systems), both of which involve transcatheter placement of anchors in the MV; they are cinched or connected to narrow the mitral annulus. Other transcutaneous direct annuloplasty devices under investigation include the enCorTC device (Micardia), which involves a percutaneously insertable annuloplasty ring that is adjustable using radiofrequency energy, a variation on its CE-marked $enCor_{SQ}$ Mitral Valve Repair System, and the Cardioband Annuloplasty System (Valtech Cardio), an implantable annuloplasty band with a transfemoral venous delivery system.

Transcatheter Mitral Valve Replacement

Permavalve (MicroInterventional Devices), under investigation in the United States, is a transcatheter MV replacement device that is delivered via the transapical approach. On June 5, 2017, the SAPIEN 3 Transcatheter Heart Valve (Edwards Lifesciences) was approved by FDA as MV replacement device. These replacement valves are outside the scope of this policy.

Medical Management

The standard treatment for individuals with chronic secondary MR is medical management. Individuals with chronic secondary MR should receive standard therapy for heart failure with reduced ejection fraction; standard management includes angiotensin converting enzyme inhibitor (or angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor), β-blocker and mineralocorticoid receptor antagonist, and diuretic therapy as needed to treat volume overload.[3,4] Resynchronization therapy may provide symptomatic relief, improve LV function, and in some individuals, lessen the severity of MR.

Summary of Evidence

For individuals who have symptomatic primary mitral regurgitation (MR) and are at prohibitive risk for open surgery who receive transcatheter mitral valve repair (TMVR) using MitraClip or PASCAL, the evidence includes a noninferiority randomized controlled trial (RCT) and single-arm prospective cohort with historical cohort and registry studies. The relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The primary evidence includes the pivotal EVEREST II HRR and EVEREST II REALISM studies, the Transcatheter Valve Therapy Registry study, and the CLASP IID/IIF study. Studies evaluating MitraClip have demonstrated that MitraClip implantation is feasible with a procedural success rate greater than 90%, 30-day mortality ranging from 2.3% to 6.4% (less than predicted Society of Thoracic Surgeons (STS) mortality risk score for MR repair or replacement; range, 9.5%-13.2%), postimplantation MR severity grade of 2+ or less in 82% to 93% of individuals, and a clinically meaningful gain in quality of life (5-point to 6-point gains in ySF-36 scores). At one year, freedom from death and MR more than 2+ was achieved in 61% of individuals but the one-year mortality or heart failure hospitalization rates remain considerably high (38%). Conclusions related to the treatment effect on mortality based on historical controls cannot be made because the control groups did not provide unbiased or precise estimates of the natural history of individuals eligible to receive MitraClip. Given that primary MR is a mechanical problem and there is no effective medical therapy, an RCT comparing TMVR with medical management is not feasible or ethical. The postmarketing data from the U.S. is supportive that MitraClip surgery is being performed with short-term effectiveness and safety in select patient population. The CLASP IID/IIF randomized cohort demonstrated that PASCAL is noninferior to MitraClip in safety and effectiveness for individuals with primary MR at prohibitive surgical risk, and the single-arm registry cohort demonstrated that PASCAL is safe and effective in individuals with complex

mitral valve (MV) anatomy precluding the use of MitraClip. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure and symptomatic secondary mitral regurgitation (SMR) despite the use of maximally tolerated guideline-directed medical therapy who receive TMVR using MitraClip, the evidence includes a systematic review, two RCTS, and multiple observational studies. The relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The trials had discrepant results potentially related to differences in primary outcomes. The larger trial, with individuals selected for nonresponse to maximally tolerated therapy, found a significant benefit for MitraClip up to 5 years compared to medical therapy alone, including benefits in overall survival and hospitalization for heart failure. Improvements in MR severity, quality of life measures, and functional capacity persisted to 36 months in individuals who received TMVR. The systematic review confirmed the benefit of MitraClip found in the larger RCT but had important methodological limitations. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic primary or secondary MR and are surgical candidates who receive TMVR using MitraClip, the evidence includes a systematic review, one RCT and a retrospective comparative observational study in individuals aged ≥75 years. The relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that MitraClip did not reduce MR as often or as completely as the surgical control, although it could be safely implanted and was associated with fewer adverse events at one year. Long-term follow-up from the RCT showed that significantly more MitraClip individuals required surgery for MV dysfunction than conventional surgery patients. For these reasons, this single trial is not definitive in demonstrating improved clinical outcomes with MitraClip compared with surgery. Additional RCTs are needed to corroborate these results. The observational study in individuals aged ≥75 years found that although MitraClip was associated with improved one-year survival and a lower rate of all acute complications compared with surgical repair, it had lower five-year survival and greater MR recurrence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic primary or secondary MR who receive TMVR using devices other than MitraClip or PASCAL, the evidence includes a randomized study, nonrandomized prospective studies, and noncomparative feasibility studies. The relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The randomized, sham-controlled trial for the indirect annuloplasty device Carillon offers promising safety data, however further studies are needed to determine efficacy and

long-term outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02444338	A RandomizEd Study of tHe MitrACliP DEvice in Heart Failure Patients With Clinically Significant Functional Mitral Regurgitation (RESHAPE-HF)	650	June 2024
NCT04009434	Treatment of Concomitant Mitral Regurgitation by Mitral Valve Clipping in Patients With Successful Transcatheter Aortic Valve Implantation	1162	Aug 2023
NCT01626079[a]	Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (The COAPT Trial) and COAPT CAS (COAPT)	614 in COAPT and 162 in COAPT CAS	July 2024 (5-year follow-up per protocol)[b]
NCT04198870[a]	Percutaneous MitraClip Device or Surgical Mitral Valve REpair in PAtients With PrImaRy MItral Regurgitation Who Are Candidates for Surgery (REPAIR MR)	500	Feb 2032
NCT05090540	Transcatheter Edge to Edge Mitral Valve Repair Versus Standard Surgical Mitral Valve Operation for Secondary Mitral Regurgitation	600	Dec 2023
NCT05051033	Percutaneous or Surgical Repair In Mitral Prolapse And Regurgitation for >65 Year-Olds (PRIMARY)	450	Jan 2032
NCT05021614[a]	Evaluation of the Efficacy and Safety of the Transcatheter Mitral Valve Repair System in Patients With Moderate and Above Degenerative Mitral Regurgitation at High Surgical Risk	150	Sep 2027
NCT04734756[a]	A Prospective, Multicenter, Objective Performance Criteria Study to Evaluate the Safety and Effectiveness of Dragonfly Transcatheter Mitral Valve Repair System for the	120	May 2027

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Treatment of Degenerative Mitral Regurgitation (DMR) Subjects		
NCT04733404[a]	A Prospective, Multicenter, Objective Performance Criteria Study to Evaluate the Safety and Effectiveness of Dragonfly Transcatheter Mitral Valve Repair System for the Treatment of Functional Mitral Regurgitation (FMR) Subjects	120	Sep 2027
NCT04430075[a]	Transcatheter Repair of Mitral Regurgitation With Edwards PASCAL Transcatheter Valve Repair System: A European Prospective, Multicenter Post Market Clinical Follow-Up (PMFC)	500	Jun 2028
NCT03706833[a]	Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP IID/IIF): A Prospective, Multicenter, Randomized, Controlled Pivotal Trial to Evaluate the Safety and Effectiveness of Transcatheter Mitral Valve Repair With the Edwards PASCAL Transcatheter Valve Repair System Compared to Abbott MitraClip in Patients With Mitral Regurgitation	1275	Jan 2028
NCT05332782	Outcomes of Patients tReated with Mitral Transcatheter Edge-to-edge Repair for Primary Mitral Regurgitation Registry (PRIME-MR)	2000	Jan 2026
NCT05496998[a]	Transcatheter Mitral Valve Replacement With the Medtronic IntrepidTM TMVR Transfemoral System in Patients With Severe Symptomatic Mitral Regurgitation - APOLLO-EU Trial	360	Nov 2026
NCT05417945[a]	A Prospective, Multicenter Study to Evaluate the JensClip Transcatheter Valve Repair System	124	Dec 2024
NCT05455489	GISE Registry of Transcatheter Treatment of Mitral Valve Regurgitation With the MitraClip G4	264	Aug 2029

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial. [b] Primary results have been published, long-term follow-up ongoing.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate

reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from four academic medical centers, one of which provided four responses, for a total of seven responses, while this policy was under review in 2015. Input supported the use of TMVR in individuals with primary (degenerative) MR at prohibitive risk of open surgery. The greatest consensus for selection criteria to determine "prohibitive risk" was for the use of the Society of Thoracic Surgeons predictive operative risk of 12% or higher, or a logistic EuroSCORE of 20% or higher.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology and American Heart Association

In 2020, the American College of Cardiology and American Heart Association presented updated expert consensus on the management of mitral regurgitation (MR).[70] The recommendations are as follows: "At present, transcatheter mitral repair using an edge-to-edge clip device can be considered for the treatment of patients with primary MR and severe symptoms who are felt to be poor surgical candidates. Surgical or transcatheter treatment for secondary MR is undertaken only after appropriate medical and device therapies have been instituted and optimized, as judged by the multidisciplinary team with input from a cardiologist with experience managing heart failure and MR."

Also in 2020, the American College of Cardiology and American Heart Association released updated guidelines on the management of valvular heart disease.[5] The guidelines state that

TMVR is of benefit to individuals with severely symptomatic primary MR who are at high or prohibitive risk for surgery, and to a subset of individuals with secondary MR who remain severely symptomatic despite guideline-directed management and therapy for heart failure. Relevant recommendations on interventions for primary and secondary MR are shown in **Table 2**.

Table 2. Recommendations on Interventions for Primary and Secondary MR

Recommendation	COR	LOE
Primary MR		
In symptomatic patients with severe primary MR (Stage D), mitral valve intervention is recommended irrespective of LV systolic function	1 (Strong)	B-NR[1]
In asymptomatic patients with severe primary MR and LV systolic dysfunction (LVEF <60%, LVESD >40 mm) (Stage C2), mitral valve surgery is recommended	1 (Strong)	B-NR[1]
In patients with severe primary MR for whom surgery is indicated, mitral valve repair is recommended in preference to mitral valve replacement when the anatomic cause of MR is a degenerative disease, if a successful and durable repair is possible	1 (Strong)	B-NR[1]
In asymptomatic patients with severe primary MR and normal LV systolic function (LVEF >60% and LVESD >40 mm) (Stage C1), mitral valve repair is reasonable when the likelihood of a successful and durable repair without residual MR is >95% with an expected mortality rate of <1% when it can be performed at a Primary or Comprehensive Valve Center	2a (Moderate)	B-NR[1]
In asymptomatic patients with severe primary MR and normal LV systolic function (LVEF >60% and LVESD <40 mm) (Stage C1) but with a progressive increase in LV size or decrease in EF on ≥3 serial imaging studies, mitral valve surgery may be considered irrespective of the probability of a successful and durable repair	2b (Weak)	C-LD[2]
In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, TEER is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year	2a (Moderate)	B-NR[1]
In symptomatic patients with severe primary MR attributable to rheumatic valve disease, mitral valve repair may be considered at a Comprehensive Valve Center by an experienced team when surgical treatment is indicated, if a durable and successful repair is likely	2b (Weak)	B-NR[1]
In patients with severe primary MR where leaflet pathology is limited to less than one half the posterior leaflet, mitral valve replacement should not be performed unless mitral valve repair has been attempted at a Primary or Comprehensive Valve Center and was unsuccessful	3: Harm (Strong)	B-NR[1]
Secondary MR		

Recommendation	COR	LOE
In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD <70 mm, and pulmonary artery systolic pressure <70 mmHg	2a (Moderate)	B-R[3]
In patients with severe secondary MR (Stages C and D), mitral valve surgery is reasonable when CABG is undertaken for the treatment of myocardial ischemia	2a (Moderate)	B-NR[1]
In patients with chronic severe secondary MR from atrial annular dilation with preserved LV systolic function (LVEF >50%) who have severe persistent symptoms (NYHA class III or IV) despite therapy for HF and therapy for associated AF or other comorbidities (Stage D), mitral valve surgery may be considered	2b (Weak)	B-NR[1]
In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent severe symptoms (NYHA class III or IV) while on optimal GDMT for HF (Stage D), mitral valve surgery may be considered	2b (Weak)	B-NR[1]
In patients with CAD and chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) (Stage D) who are undergoing mitral valve surgery because of severe symptoms (NYHA class III or IV) that persist despite GDMT for HF, chordal-sparing mitral valve replacement may be reasonable to choose over downsized annuloplasty repair	2b (Weak)	B-R[3]

Source: Adapted from Otto et al (2020)[5]

[1]Moderate, nonrandomized; [2]Limited data; [3]Moderate, randomized.

AF: atrial fibrillation; CABG: coronary artery bypass graft; CAD: coronary artery disease; COR: class of recommendation; EF: ejection fraction; GDMT: guideline-directed medical therapy; HF: heart failure; LOE: level of evidence; LV: left ventricular; LVEF: left ventricular ejection fraction; LVESD: left ventricular end-systolic diameters; MR: mitral regurgitation; MV: mitral valve; NYHA: New York Heart Association; TEE: transesophageal echocardiogram; TEER: transcatheter edge-to-edge repair

American College of Cardiology, American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

The American College of Cardiology, American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons (2014) issued a position statement on transcatheter therapies for mitral regurgitation (MR).[71] This statement outlined critical components for successful transcatheter MR therapies and recommended ongoing research and inclusion of all individuals treated with transcatheter MR therapies in a disease registry.

National Institute for Health and Care Excellence

The NICE guideline on heart valve disease management (2021) makes the following recommendations related to TMVR:[72]

- "1.5.10 - Consider transcatheter edge-to-edge repair, if suitable, for adults with severe primary mitral regurgitation and symptoms, if surgery is unsuitable.
- 1.5.14 - Consider transcatheter mitral edge-to-edge repair for adults with heart failure and severe secondary mitral regurgitation, if surgery is unsuitable and they remain symptomatic on medical management."

Medicare National Coverage

The Centers for Medicare & Medicaid Services issued a national coverage decision for the use of TMVR in 2015, which was updated in 2021.[73]

The Centers for Medicare & Medicaid Services determined that it would cover TMVR under Coverage with Evidence Development for the treatment of symptomatic moderate-to-severe or severe functional (secondary) MR or significant symptomatic degenerative (primary) MR when all of the following conditions are met:

1. "The procedure is furnished with a [TMVR] system that has received FDA [Food and Drug Administration] premarket approval (PMDA).
2. The patient (preoperatively and postoperatively) is under the care of a heart team...
3. Each patient's suitability for surgical mitral valve repair, [TMVR], or palliative therapy must be evaluated, documented…
4. An interventional cardiologist or cardiac surgeon from the heart team must perform the mitral valve [TMVR]...
5. Mitral valve [TMVR] must be furnished in a hospital with appropriate infrastructure and experience...
6. The heart team and hospital are participating in a prospective, national, audited registry...
7. The registry shall collect all data necessary and have a written executable analysis plan..."

Regulatory Status

In October 2013, the MitraClip Clip Delivery System (Abbott Vascular) was approved by the FDA through the premarket approval process for treatment of "significant symptomatic mitral regurgitation (MR ≥3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at a prohibitive risk for mitral valve surgery by a heart team."[19]

In March 2019, the FDA approved a new indication for MitraClip for "treatment of patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy. Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators."

In September 2022, the FDA approved the PASCAL Precision Transcatheter Valve Repair System through the premarket approval process for treatment of "significant, symptomatic mitral regurgitation (MR ≥3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team."[20]

FDA product code for MitraClip and PASCAL: NKM.

References

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Appendix

Figure 1

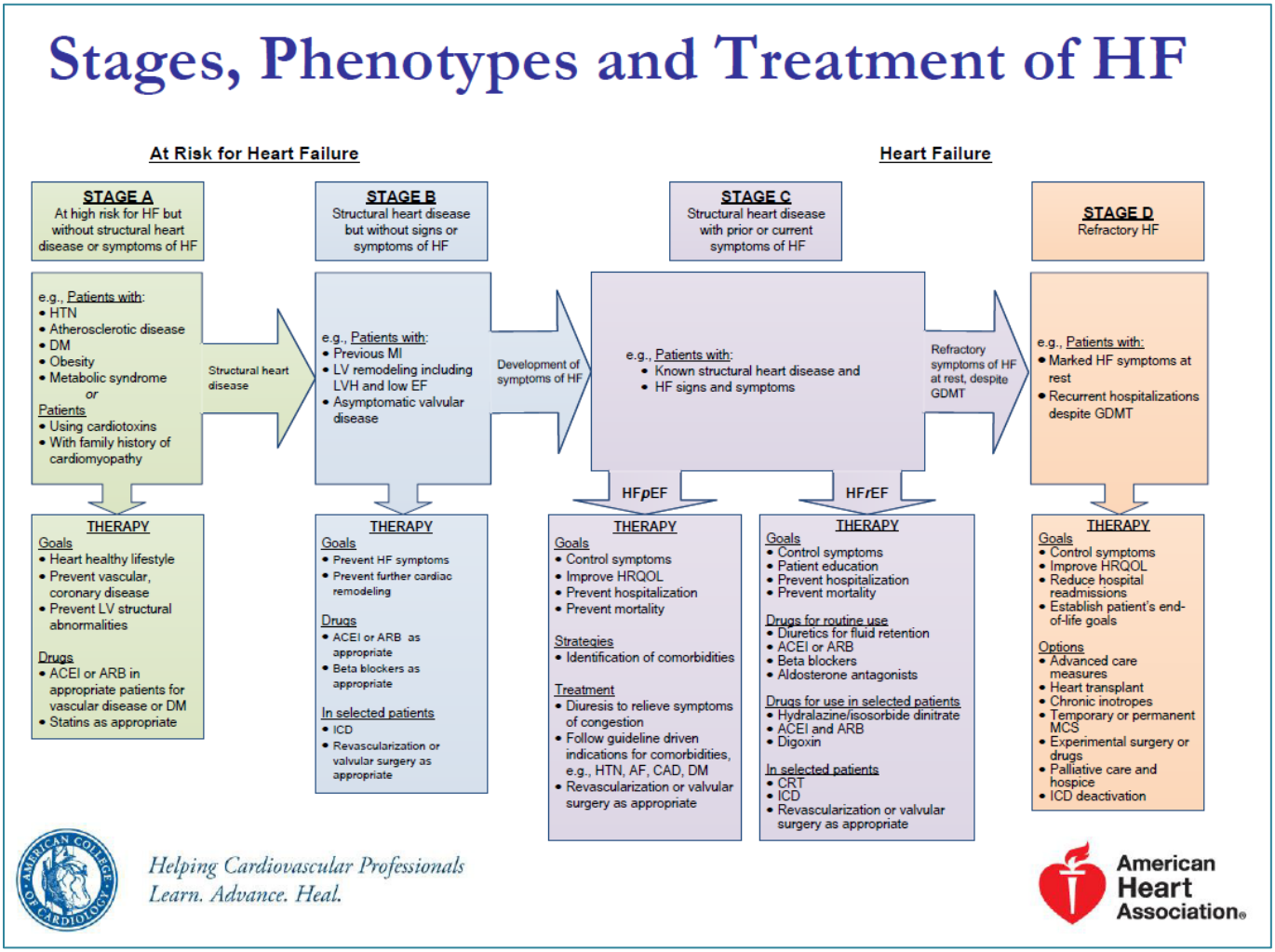
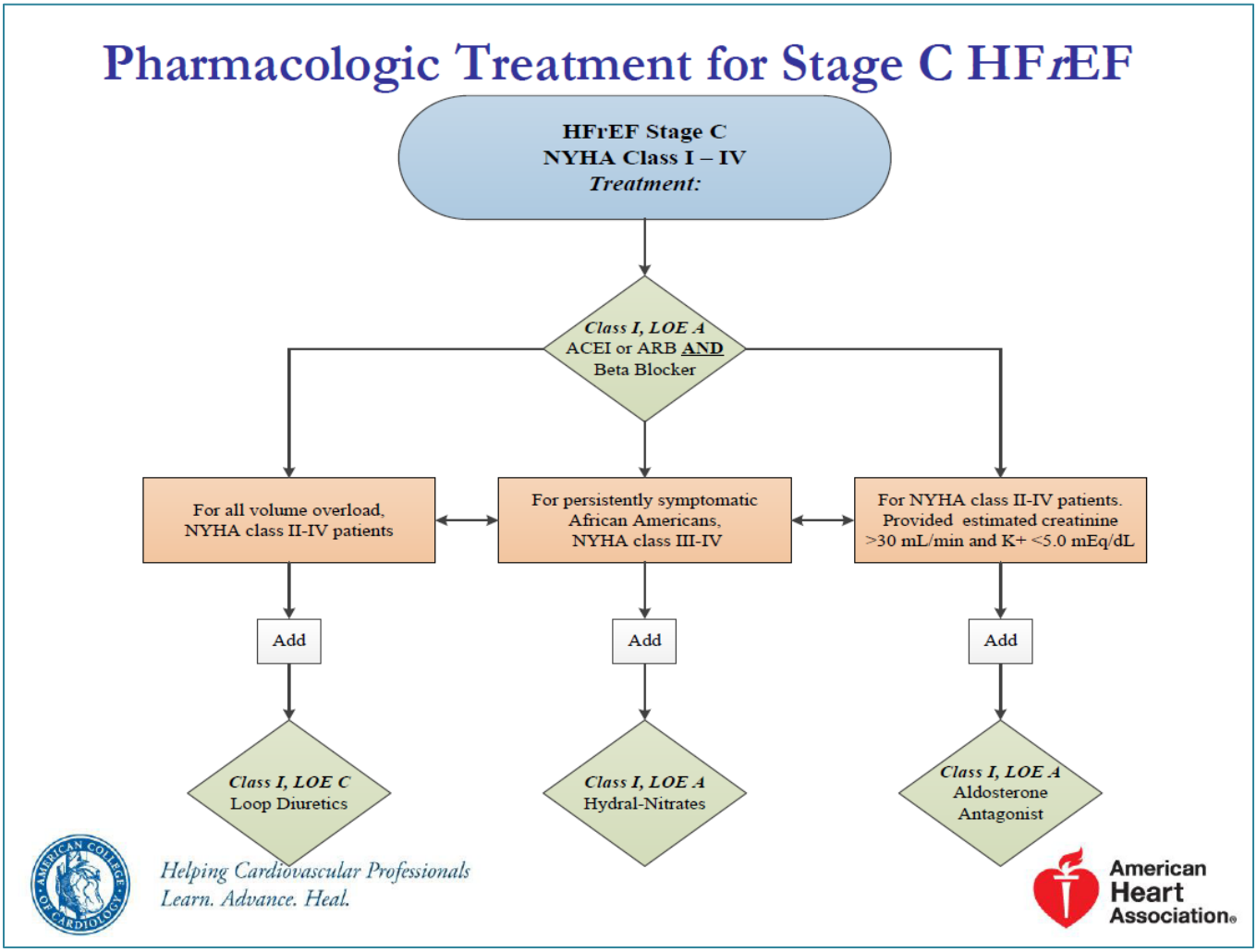

Stages, Phenotypes and Treatment of HF
At Risk for Heart Failure
Heart Failure
STAGE A
At high risk for HF but without structural heart disease or symptoms of HF
STAGE B
Structural heart disease but without signs or symptoms of HF
STAGE C
Structural heart disease with prior or current symptoms of HF
STAGE D
Refractory HF
e.g., Patients with:
• HTN
• Atherosclerotic disease
• DM
• Obesity
• Metabolic syndrome
or
Patients
• Using cardiotoxins
• With family history of cardiomyopathy
Structural heart disease
e.g., Patients with:
• Previous MI
• LV remodeling including LVH and low EF
• Asymptomatic valvular disease
Development of symptoms of HF
e.g., Patients with:
• Known structural heart disease and
• HF signs and symptoms
Refractory symptoms of HF at rest, despite GDMT
e.g., Patients with:
• Marked HF symptoms at rest
• Recurrent hospitalizations despite GDMT
HFpEF
HFrEF
THERAPY
Goals
• Heart healthy lifestyle
• Prevent vascular, coronary disease
• Prevent LV structural abnormalities
Drugs
• ACEI or ARB in appropriate patients for vascular disease or DM
• Statins as appropriate
THERAPY
Goals
• Prevent HF symptoms
• Prevent further cardiac remodeling
Drugs
• ACEI or ARB as appropriate
• Beta blockers as appropriate
In selected patients
• ICD
• Revascularization or valvular surgery as appropriate
THERAPY
Goals
• Control symptoms
• Improve HRQOL
• Prevent hospitalization
• Prevent mortality
Strategies
• Identification of comorbidities
Treatment
• Diuresis to relieve symptoms of congestion
• Follow guideline driven indications for comorbidities, e.g., HTN, AF, CAD, DM
• Revascularization or valvular surgery as appropriate
THERAPY
Goals
• Control symptoms
• Patient education
• Prevent hospitalization
• Prevent mortality
Drugs for routine use
• Diuretics for fluid retention
• ACEI or ARB
• Beta blockers
• Aldosterone antagonists
Drugs for use in selected patients
• Hydralazine/isosorbide dinitrate
• ACEI and ARB
• Digoxin
In selected patients
• CRT
• ICD
• Revascularization or valvular surgery as appropriate
THERAPY
Goals
• Control symptoms
• Improve HRQOL
• Reduce hospital readmissions
• Establish patient's end-of-life goals
Options
• Advanced care measures
• Heart transplant
• Chronic inotropes
• Temporary or permanent MCS
• Experimental surgery or drugs
• Palliative care and hospice
• ICD deactivation
Helping Cardiovascular Professionals
Learn. Advance. Heal.
American Heart Association

Figure 2



Source: https://www.heart.org/idc/groups/heart-public/@wcm/@mwa/documents/downloadable/ucm_489089.pdf Now archived.

History

Date	Comments
09/08/14	New Policy. Policy created with literature review through June 4, 2014. Transcatheter mitral valve repair considered investigational for all indications.
01/12/15	Coding update. New CPT codes 33418-33419, effective 1/1/15, added to policy; codes 0343T and 0344T deleted 12/31/14 noted on policy.

Date	Comments
12/08/15	Annual Review. Added policy statement that Transcatheter mitral valve repair with the MitraClip is now medically necessary to treat degenerative mitral regurgitation when criteria are met. (Previously considered Investigational). Updated Policy Guidelines, with clarification about documented presence of risk score from one of the stated tools in the prohibitive risk definition. Added FDA indications for use. Policy updated with literature review through June 1, 2015; references added. Policy statement changed as noted. Codes 0343T and 0344T removed as deleted from codebook effective 12/31/14.
02/01/16	Coding update. Added 93799.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through March 30, 2016; references 25, 29, 31, 37, and 41 added. Policy statements unchanged.
10/21/16	Minor formatting edit. Restored reference hyperlinks.
08/01/17	Annual Review, approved July 11, 2017. Policy moved into new format. Policy updated with literature review through March 23, 2017; references 27-28 and 36 added. "Cleared" changed to "approved" in the medically necessary policy statement.
01/23/18	Coding update, added CPT codes 0483T and 0484T (new codes effective 1/1/18).
08/01/18	Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 29, 34-35, and 53 added. In the policy degenerative mitral regurgitation was replaced with primary mitral regurgitation and functional mitral regurgitation was replaced with secondary mitral regurgitation including the policy statement to be in consistent with language used in the guidelines. Data from FDA documents were added. Removed CPT code 93799.
07/01/19	Coding update, added CPT code 0544T (new code effective 7/1/19).
08/01/19	Annual Review, approved July 11, 2019. Policy updated with literature review through March 2019, references 50-51 added. Regulatory Status section updated with new indication. Policy statement added; transcatheter mitral valve repair with an FDA-approved device considered medically necessary for patients with heart failure and secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy. Information regarding optimal medical therapy added. Removed CPT 0483T and 0484T.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/26/20	Policy will remain active and will no longer be deleted effective July 2, 2020.
07/02/20	Minor update. Related policy 7.01.132 removed; this policy is deleted and replaced with InterQual criteria.
01/01/21	Annual Review, approved December 1, 2020. Policy updated with literature review through March 23, 2020; references added. Policy statements unchanged.

Date	Comments
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through March 30, 2021; references added; guidelines section updated. Policy statements unchanged.
08/01/22	Annual Review, approved July 11, 2022. Policy updated with literature review through March 16, 2022; references added to review of evidence for 'Other Transcatheter Mitral Valve Repair Devices'; guidelines section updated. Minor editorial refinements to policy statements; intent unchanged.
08/01/23	Annual Review, approved July 10, 2023. Policy updated with literature review through March 13, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/24	Coding update. Added descriptions in parenthesis for CPT codes 0544T, 33418 and 33419.

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CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-607-0546 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-607-0546 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-607-0546 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-607-0546 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-607-0546 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-607-0546 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-607-0546 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-607-0546 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-607-0546 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-607-0546 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-607-0546 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-607-0546 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-607-0546 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-607-0546 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-607-0546 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-607-0546 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-607-0546 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-607-0546 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-607-0546 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-607-0546 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-607-0546 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-607-0546 (TTY: 711) تماس بگیرید.

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