BlueCross BlueShield Arizona

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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
SECTION: SURGERY	**LAST REVIEW DATE: 09/17/24**
	CURRENT EFFECTIVE DATE: 09/17/24
	LAST CRITERIA REVISION DATE: 09/17/24
NEXT ANNUAL REVIEW DATE: 3RD QTR 2025	**ARCHIVE DATE:**

TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

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.

Mitral valve-in-valve replacement is a minimally invasive procedure designed to treat individuals with failing surgical bioprosthetic mitral valves who are at high risk for complications with repeat open-heart surgery. The Edwards SAPIEN 3 Transcatheter Heart Valve received FDA approval in June 2017 for individuals with a failing surgical bioprosthetic mitral valve who are at high or prohibitive risk for repeat surgery. The procedure involves deploying the replacement valve within the failing bioprosthetic valve using a catheter-based transapical or transseptal approach. Once in position, the replacement valve is expanded, pushing the leaflets of the failing bioprosthetic valve aside and taking over the valve function.

Two devices, MitraClip™ and PASCAL™, have 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. MitraClip is also approved for individuals with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy. The Edwards SAPIEN 3 transcatheter heart valve has been approved by the U.S. Food and Drug Administration for transcatheter mitral valve-in-valve replacement (TMViVR) in individuals with a failing surgical bioprosthetic mitral valve who are at high or greater risk for repeat surgery.

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 individuals who have been determined to be at prohibitive risk for mitral valve surgery by a heart team.

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TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

Criteria:

- Transcatheter mitral valve repair (TMVR) for individuals with symptomatic, primary mitral regurgitation (MR) who are considered at prohibitive risk for open surgery is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Device is FDA-approved for use in mitral valve repair

  2. **ONE** of the following:

     - Presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater and/or
     - Presence of a logistic EuroSCORE of 20% or greater.

- TMVR for individuals with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Device is FDA-approved for use in mitral valve repair

  2. **ONE** of the following:

     - Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography
     - New York Heart Association (NYHA) functional class II, III, IVa (ambulatory) and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies

- TMVR for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

- Transcatheter mitral valve-in-valve replacement (TMViVR) is considered ***medically necessary*** with documentation of **ALL** of the following:
  1. Device is FDA-approved for use in mitral valve-in-valve repair
  2. Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve
  3. New York Heart Association heart failure class II, III, or IV symptoms
  4. **ONE** of the following:
     - Individual is not an operable candidate for open surgery as documented by at least 2 cardiovascular specialists (including a cardiac surgeon)
     - Individual is an operable candidate but is considered at increased surgical risk for open surgery, as documented by at least 2 cardiac specialists (including a cardiac surgeon)
     - Individual is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon)

- TMViVR for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 09/17/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 09/17/24 may be requested from the BCBSAZ Medical Policy and Technology Research

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Coding:

CPT: 0345T, 0483T, 0484T, 0544T, 33418, 33419

History:

	Date:	Activity:
Medical Policy Panel	09/17/24	Review with revisions
Medical Directors (Dr. Raja, Dr. Sutanto)	09/05/24	Review with revisions
Medical Policy Panel	07/16/24	Review with no revisions
Medical Policy Panel	07/05/23	Review with revisions
Medical Policy Panel	08/16/22	Approved guideline (Effective 09/19/22)

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
SECTION: SURGERY	**LAST REVIEW DATE: 09/17/24**
	CURRENT EFFECTIVE DATE: 09/17/24
	LAST CRITERIA REVISION DATE: 09/17/24
NEXT ANNUAL REVIEW DATE: 3RD QTR 2025	**ARCHIVE DATE:**

TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

Policy Revisions:

09/17/24:	Added:	"Transcatheter mitral valve-in-valve replacement (TMViVR) is considered ***medically necessary*** with documentation of **ALL** of the following: 1. Device is FDA-approved for use in mitral valve-in-valve repair; 2. Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve; 3. New York Heart Association heart failure class II, III, or IV symptoms; 4. **ONE** of the following: Individual is not an operable candidate for open surgery as documented by at least 2 cardiovascular specialists (including a cardiac surgeon), Individual is an operable candidate but is considered at increased surgical risk for open surgery, as documented by at least 2 cardiac specialists (including a cardiac surgeon), Individual is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon)" to Criteria section; "TMViVR for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met: 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or 3. Insufficient evidence to support improvement of the net health outcome; or 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or 5. Insufficient evidence to support improvement outside the investigational setting." to Criteria section.
09/17/24	Updated:	Description section; Resources section
07/05/23	Added:	"Insufficient evidence to support improvement of the net health outcome; or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to experimental or investigational criteria bullets
07/05/23	Revised:	"Insufficient evidence to support improvement outside the investigational setting" from #3 to #5 in experimental or investigational criteria bullets
07/05/23	Updated:	Description section; Resource section

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
SECTION: SURGERY	**LAST REVIEW DATE: 09/17/24**
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TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

TRANSCATHETER MITRAL VALVE REPAIR OR REPLACEMENT

<u>Multi-Language Interpreter Services</u>:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 تماس حاصل نمایید.

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799