



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 01/31/17
LAST REVIEW DATE: 01/22/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

PERCUTANEOUS TRANSCATHETER CLOSURE OF PARAVALVULAR LEAK

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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PERCUTANEOUS TRANSCATHETER CLOSURE OF PARAVALVULAR LEAK (cont.)

Description:

Paravalvular leak (PVL) is a complication of aortic and mitral valve replacement. When a new valve is implanted, the surgeon stitches the valve into place. The stitches can become loose due to wear and tear or they may pull through and blood can leak through the gaps. Traditionally, open-heart surgery is required to repair the leak. Paravalvular closure is a minimally invasive technique that has been investigated to repair paravalvular leaks. Devices used in percutaneous closure include Amplatzer Vascular Plugs and Occlutech Paravalvular Leak Device. These devices are not FDA approved for percutaneous closure.

Criteria:

For closure devices for atrial and ventricular septal defects and patent foramen ovale, see BCBSAZ Medical Coverage Guideline #O831, *“Closure Devices for Atrial and Ventricular Septal Defects and Patent Foramen Ovale”*.

For transcatheter mitral valve repair, see BCBSAZ Medical Coverage Guideline #O918, *“Transcatheter Mitral Valve Repair”*.

- Percutaneous transcatheter closure for the treatment of paravalvular leaks is considered **experimental or investigational** based upon:
1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

PERCUTANEOUS TRANSCATHETER CLOSURE OF PARAVALVULAR LEAKS (cont.)

Resources:

Literature reviewed 01/30/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. Alkhoul M, Rihal CS, Zack CJ, et al. Transcatheter and Surgical Management of Mitral Paravalvular Leak: Long-Term Outcomes. *JACC Cardiovasc Interv.* Oct 9 2017;10(19):1946-1956.
2. Azevedo AI, Braga P, Rodrigues A, et al. Percutaneous closure of periprosthetic paravalvular leaks: A viable alternative to surgery? *Rev Port Cardiol.* Jul - Aug 2017;36(7-8):489-494.
3. Goktekin O, Vatankulu MA, Ozhan H, et al. Early experience of percutaneous paravalvular leak closure using a novel Occlutech occluder. *EuroIntervention : journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology.* Feb 2016;11(10):1195-1200.
4. Murakami T, Suehiro Y, Nishimura S, et al. Transcatheter closure through transapical access for mitral paravalvular leak after previous trans-septal mitral operation. *General thoracic and cardiovascular surgery.* Mar 31 2016.
5. Nietlispach F, Maisano F, Sorajja P, Leon MB, Rihal C, Feldman T. Percutaneous paravalvular leak closure: chasing the chameleon. *European heart journal.* Dec 14 2016;37(47):3495-3502.
6. Smolka G, Pysz P, Kozlowski M, et al. Transcatheter closure of paravalvular leaks using a paravalvular leak device - a prospective Polish registry. *Postepy w kardiologii interwencyjnej = Advances in interventional cardiology.* 2016;12(2):128-134.
7. UpToDate.com. Complications of prosthetic heart valves. 11/16/2016.
8. UpToDate.com. Management and prognosis of surgical aortic and mitral prosthetic valve regurgitation. 06/21/2017.
9. Wells JAt, Condado JF, Kamioka N, et al. Outcomes After Paravalvular Leak Closure: Transcatheter Versus Surgical Approaches. *JACC Cardiovasc Interv.* Mar 13 2017;10(5):500-507.



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Resources: (cont.)

10. Yildirim A, Goktekin O, Gorgulu S, et al. A New Specific Device in Transcatheter Prosthetic Paravalvular Leak Closure: A Prospective Two-Center Trial. *Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions*. Oct 2016;88(4):618-624.
11. Zhang Y, Pan X, Qu X, et al. Comparison of transcatheter and surgical treatment of paravalvular leak: Results from a 5-year follow-up study. *Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions*. Oct 25 2017.



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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 nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodilnih 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 تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

