



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 12/10/15
LAST REVIEW DATE: 09/18/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

HEART TRANSPLANT

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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HEART TRANSPLANT (cont.)

Description:

Heart transplant is a surgical procedure in which a heart from a cadaveric donor is placed in the body of a recipient.

Potential contraindications subject to the judgment of the transplant center:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy
- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance (PVR) greater than 5 Woods units, or trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg despite treatment (may be candidates for combined heart-lung transplantation)
- Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation (may be a candidate for combined heart-lung transplantation)

Definitions:

Adult: 18 years of age and older

Child: Younger than 18 years of age



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HEART TRANSPLANT (cont.)

Criteria:

Heart transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

Pretransplantation Evaluation:

The psychosocial criteria listed below must only be met prior to the actual transplant procedure.

- Psychosocial screening for an individual that does not have fulminant cardiac failure¹ with documentation of **ALL** of the following:
 1. Drug/alcohol screening with documentation of **ONE** of the following:
 - No drug/alcohol abuse by history
 - Drug and alcohol free for a period greater than or equal to 6 months
 2. Behavioral health disorder screening with documentation of **ONE** of the following:
 - No behavioral health disorder by history
 - Behavioral health disorder by history with documentation of **BOTH** of the following:
 - No severe psychosis/personality disorder
 - Mood/anxiety disorder excluded/treated
 3. Individual understands surgical risk and post procedure compliance and follow-up
 4. Adequate social/family support

HEART TRANSPLANT (cont.)

Criteria: (cont.)

Adult End-Stage Heart Failure:

- Human heart transplant is considered **medically necessary** for selected adult individuals with documentation that pretransplantation evaluation criteria above are met and documentation of **ANY** of the following:
 1. Documentation of **ANY** of the following accepted indications for transplantation:
 - Hemodynamic compromise due to heart failure demonstrated by **ANY** of the following:
 - a. Maximal VO₂ (oxygen consumption) <10 mL/kg/min with achievement of anaerobic metabolism
 - b. Refractory cardiogenic shock
 - c. Documented dependence on intravenous inotropic support to maintain adequate organ perfusion
 - Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty
 - Recurrent symptomatic ventricular arrhythmias refractory to ALL accepted therapeutic modalities
 2. Documentation of **ANY** of the following probable indications for transplantation:
 - Maximal VO₂ <14 mL/kg/min and major limitation of the patient's activities
 - Recurrent unstable ischemia not amenable to bypass surgery or angioplasty
 - Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretics drugs, and salt restriction.
- Inadequate indications for transplantation unless other factors as listed above are present include:
 1. Ejection fraction <20%
 2. History of functional class III or IV symptoms of heart failure
 3. Previous ventricular arrhythmias
 4. Maximal VO₂ >15 mL/kg/min
- Heart retransplantation after a failed primary heart transplant is considered **medically necessary** for individuals who meet above criteria for heart transplantation.

HEART TRANSPLANT (cont.)

Criteria: (cont.)

Pediatric End-Stage Heart Failure:

- Human heart transplant is considered **medically necessary** for selected pediatric individuals with documentation that pretransplantation evaluation criteria above are met and documentation of **ANY** of the following:
 1. Heart failure with persistent symptoms at rest requiring at least **ONE** of the following:
 - Continuous infusion of intravenous inotropic agents
 - Mechanical ventilator support
 - Mechanical circulatory support
 2. Pediatric heart disease with symptoms of heart failure and **ANY** of the following:
 - Severe limitation of exercise and activity (if measurable, such individuals would have a peak maximum oxygen consumption <50% predicted for age and sex);
 - Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease;
 - Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator;
 - Restrictive cardiomyopathy with reactive pulmonary hypertension;
 - Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotropic heart transplantation in the future
 - Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle
 - Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.
- Heart retransplantation after a failed primary heart transplant is considered **medically necessary** for individuals who meet above criteria for heart transplantation.
- Heart transplantation for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
- ¹ Individuals with fulminant cardiac failure do not need to meet psychosocial screening criteria.



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Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 7.03.09 BCBS Association Medical Policy Reference Manual. Heart Transplant. Re-issue date 08/09/2018, issue date 07/31/1996.
2. InterQual ® Care Planning Procedures Adult. Transplantation, Cardiac.



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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'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' 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 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.

