



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 05/06/15
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE: 06/19/18
ARCHIVE DATE:

BIVENTRICULAR PACEMAKER (CARDIAC RESYNCHRONIZATION THERAPY) FOR THE TREATMENT OF HEART FAILURE

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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BIVENTRICULAR PACEMAKER (CARDIAC RESYNCHRONIZATION THERAPY) FOR THE TREATMENT OF HEART FAILURE (cont.)

Description:

Biventricular pacing, also known as cardiac resynchronization (CRT), can improve hemodynamic status in individuals with chronic heart failure (CHF). It is a dual chamber pacemaker that provides specially timed electrical impulses to simultaneously stimulate the heart's right and left ventricles to contract. The system consists of a pulse generator that is implanted in the chest and connected to 3 leads that deliver the electrical impulses. One lead is placed in the right atrium and the other two in the right and left ventricles.

Several types of CRT devices are available including, *but not limited to*:

1. Stand-alone biventricular pacemaker (e.g., InSync® Biventricular Pacing System)
2. Biventricular pacemaker combined with an automatic implantable cardiac defibrillator (ICD) (e.g., COGNIS®, CONTAK CD® CRT-D System, CONTAK RENEWAL, InSync® ICD Model 7272, LIVIAN®, Ilesto and Iforia series and Tupos LV/ATx CRT-D/Kronos LV-T CRT-D Systems)
3. Biventricular pacemaker combined with an automatic ICD that incorporates fluid monitoring via bioimpedance. This device differs from the others in that it has a component that can monitor for CHF. This component is an automatic intrathoracic fluid status monitor called OptiVol™ Fluid Status Monitoring. OptiVol monitors the amount of fluid in the chest by measuring changes in bioimpedance (electrical resistance of tissue to flow of current). Measurements are performed many times per day.

Devices and implantation techniques have been investigated to allow for multisite pacing through the use of multiple leads within the coronary sinus or through the use of multipolar left ventricular pacing leads which can deliver pacing stimuli at multiple sites. Triventricular pacing, or triple-site CRT, is a variation of conventional CRT that uses a third pacing lead. Several CRT devices incorporate a 4th lead, providing quadripolar pacing. These devices include the Viva™ Quad XT, Viva Quad S, Attain Performa®, Dynagen™ X4 and Inogen™ X4.



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BIVENTRICULAR PACEMAKER (CARDIAC RESYNCHRONIZATION THERAPY) FOR THE TREATMENT OF HEART FAILURE (cont.)

Criteria:

For automatic external or wearable cardioverter defibrillator, see BCBSAZ Medical Coverage Guideline #O347, “Automatic External Defibrillator and Wearable Cardioverter Defibrillator”.

For automatic or subcutaneous implantable cardioverter defibrillator, see BCBSAZ Medical Coverage Guideline #O655, “Automatic Implantable and Subcutaneous Implantable Cardioverter Defibrillators”.

- Biventricular pacemaker with or without an accompanying implantable cardiac defibrillator is considered **medically necessary** as a treatment for heart failure with documentation of **ALL** of the following:
 1. **ONE** of the following:
 - New York Heart Association (NYHA) Class III or IV and left ventricular ejection fraction of 35% or less, or
 - NYHA Class II and left ventricular ejection fraction of 30% or less
 2. Left bundle branch block (LBBB) or QRS duration of greater than or equal to 150 msec
 3. Sinus rhythm
 4. Treatment with a guideline-directed medical therapy (GDMT). GDMT may include, *but not limited to*, **ANY** of the following medications, either individually or in combination, unless contraindicated:
 - Angiotensin-converting enzyme (ACE) inhibitor
 - Aldosterone receptor antagonist
 - Angiotensin receptor blocker (ARB)
 - Beta-blocker
 - Digoxin
 - Diuretics



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Criteria: (cont.)

- Biventricular pacemaker with or without an accompanying implantable cardiac defibrillator for individual who does not meet above criteria but who has an indication for a ventricular pacemaker is considered **medically necessary** as an alternative to a right ventricular pacemaker with documentation of **ALL** of the following:
1. NYHA class I, II, III or IV heart failure
 2. Left ventricular ejection fraction of 50% or less
 3. The presence of atrioventricular (AV) block with requirement for a high percentage of ventricular pacing as documented by **ONE** of the following:
 - 3rd degree AV block
 - 2nd degree AV block or a PR interval of 300 msec or greater when paced at 100 beats per minute
 4. Treatment with a guideline-directed medical therapy (GDMT). GDMT may include, *but not limited to*, **ANY** of the following medications, either individually or in combination, unless contraindicated:
 - Angiotensin-converting enzyme (ACE) inhibitor
 - Aldosterone receptor antagonist
 - Angiotensin receptor blocker (ARB)
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Criteria: (cont.)

- Biventricular pacemaker with or without an accompanying implantable cardiac defibrillator 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.

These indications include, *but are not limited to*:

- Heart failure with atrial fibrillation
- NYHA class I heart failure

- Intrathoracic fluid monitoring sensor (i.e., OptiVol) as a component of a biventricular pacemaker 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, and
4. Insufficient evidence to support improvement outside the investigational setting.

- Triventricular (triple-site) cardiac resynchronization therapy (CRT) using an additional pacing lead 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, and
4. Insufficient evidence to support improvement outside the investigational setting.



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BIVENTRICULAR PACEMAKER (CARDIAC RESYNCHRONIZATION THERAPY) FOR THE TREATMENT OF HEART FAILURE (cont.)

Criteria: (cont.)

- Cardiac resynchronization therapy with wireless left ventricular endocardial pacing 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, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 06/19/18. 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.

Resources prior to 06/21/16 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.02.10 BCBS Association Medical Policy Reference Manual. Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure. Re-issue date 05/04/2018, issue date 07/16/1999.
2. American College of Cardiology Foundation/American Heart Association Task Force. 2013 ACCF/AHA guideline for the management of heart failure. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013.



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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'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo 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.

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Multi-Language Interpreter Services: (cont.)

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:

Blue Cross Blue Shield of Arizona ، داتته باتشيد حق اين را داريد كه كمك و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 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: หากคน หรือคนทอดกลางช่วยเหลื่อมคาถามเกยวกับ Blue Cross Blue Shield of Arizona คนสมททททจะไดรบความช่วยเหลอมและขอมลในภาษา ของคนใดโดยไมมคาไจจาย พตคยภมลาม โทร 877-475-4799