BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 06/20/17**
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AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

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.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Description:

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT) and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. Indications for an ICD implantation can be broadly subdivided into:

1. Secondary prevention, i.e., for use in individuals who have experienced a potentially life-threatening episode of VT (near sudden cardiac death)
2. Primary prevention, i.e., use in individuals who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or VF

The standard ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

A subcutaneous ICD (S-ICD) has been developed that does not employ transvenous leads, and thus avoids the need for venous access and complications associated with venous leads. The S-ICD uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.
The S-ICD device has received FDA approval.

Definitions:

Adult:
Individual 18 years of age or older.

Pediatric:
Individual under 18 years of age.

Familial Assessment:
1st, 2nd, and 3rd degree relatives are blood relatives on the same side of the family (maternal or paternal).

- 1st Degree Relative: Blood-related sibling, parent or child.
- 2nd Degree Relative: Blood-related relative removed by one generation, e.g., grandparent, grandchild, aunt/uncle, niece/nephew or half siblings.
- 3rd Degree Relative: Blood-related relative removed by two generations, e.g., great-grandparent, great-grandchild, great-aunt/uncle, grandniece/nephew or first cousin.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria:

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

For biventricular pacemakers, see BCBSAZ Medical Coverage Guideline #O320, *"Biventricular Pacemaker (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure"*.

Requests for the insertion of an automatic or subcutaneous implantable cardioverter defibrillator will be reviewed by the medical director(s) and/or clinical advisor(s), unless individual has previously been approved by BCBSAZ for a wearable cardioverter defibrillator (WCD).

Automatic Implantable Cardioverter Defibrillator (ICD) for Individuals 18 Years of Age and Older:

Primary Prevention:

- The use of an automatic ICD is considered ***medically necessary*** for primary prevention with documentation of **ANY** of the following:

  1. Ischemic cardiomyopathy with documentation of **ALL** of the following:

     - New York Heart Association (NYHA) functional class I, class II or class III symptoms
     - History of myocardial infarction at least 40 days before ICD treatment
     - Left ventricular ejection fraction of 35% or less
     - Individual has not had a revascularization procedure in the last 90 days (including PTCA or CABG) and is not a candidate for further revascularization procedures

  2. Nonischemic dilated cardiomyopathy with documentation of **ALL** of the following:

     - Left ventricular ejection fraction of 35 % or less
     - Reversible causes of nonischemic dilated cardiomyopathy have been excluded
     - Response to optimal medical therapy has been adequately determined for at least 90 days after treatment on recent echocardiogram or MUGA

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria: (cont.)

Automatic Implantable Cardioverter Defibrillator (ICD) for Individuals 18 Years of Age and Older: (cont.)

Primary Prevention: (cont.)

- The use of an automatic ICD is considered ***medically necessary*** with documentation of **ANY** of the following: (cont.)

  3. Hypertrophic cardiomyopathy (HCM) with documentation of **ALL** of the following:

     - Determined to be at high risk for sudden cardiac death by a cardiologist
     - **ANY** of the following major risk factors for sudden cardiac death:

       a. History of premature HCM-related sudden death in one or more 1st degree relatives less than or equal to 50 years of age
       b. History of unexplained syncope inconsistent with neurocardiogenic origin
       c. Left ventricular hypertrophy greater than 30 mm
       d. One or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria: (cont.)

Automatic Implantable Cardioverter Defibrillator (ICD) for Individuals 18 Years of Age and Older: (cont.)

Primary Prevention: (cont.)

- The use of an automatic ICD is considered ***medically necessary*** with documentation of **ANY** of the following: (cont.)

4. Diagnosis of **ONE** of the following cardiac ion channelopathies:

   - Brugada syndrome with documentation of **ANY** of the following:

     a. A spontaneous diagnostic type 1 ECG who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out)
     b. Develop ventricular fibrillation during programmed electrical stimulation
     c. Documented spontaneous sustained ventricular tachycardia with or without syncope
     d. Survivor of cardiac arrest

   - Catecholaminergic polymorphic ventricular tachycardia with documentation of **ANY** of the following:

     a. Recurrent syncope or polymorphic/bidirectional ventricular tachycardia despite optimal medical management, and/or left cardiac sympathetic denervation
     b. Survivor of cardiac arrest

   - Congenital long QT syndrome with documentation of **ANY** of the following:

     a. Recurrent syncopal events while on beta-blocker therapy
     b. Survivor of cardiac arrest

   - Short QT syndrome with documentation of **ANY** of the following:

     a. Asymptomatic or symptomatic and have a family history of sudden cardiac death
     b. Survivor of cardiac arrest
     c. Symptomatic and have documented spontaneous ventricular tachycardia with or without syncope

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria: (cont.)

Automatic Implantable Cardioverter Defibrillator (ICD) for Individuals 18 Years of Age and Older: (cont.)

Primary Prevention: (cont.)

- The use of an automatic ICD for primary prevention 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

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

  - Acute myocardial infarction less than 40 days before ICD treatment
  - Cardiac revascularization procedure (e.g., coronary artery bypass graft [CABG], percutaneous transluminal coronary angioplasty [PTCA]) in past 3 months or are candidates for a cardiac revascularization procedure
  - Diagnosis of a noncardiac disease that would be associated with life expectancy less than one year
  - NYHA class IV congestive heart failure (unless individual is eligible to receive a combination cardiac resynchronization therapy ICD device)

Secondary Prevention:

- The use of an automatic ICD is considered ***medically necessary*** for secondary prevention in individuals with a history of a life-threatening clinical event associated with ventricular arrhythmic events (e.g., sustained ventricular tachyarrhythmia), after reversible causes (e.g., acute ischemia) have been excluded.

- The use of an automatic ICD for secondary prevention 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria: (cont.)

Automatic Implantable Cardioverter Defibrillator (ICD) for Individuals Under 18 Years of Age:

- The use of an automatic ICD is considered ***medically necessary*** with documentation of **ANY** of the following:

1. Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias
2. Hypertrophic cardiomyopathy (HCM) with documentation of **ALL** of the following:

   - Determined to be at high risk for sudden cardiac death by a cardiologist
   - **ANY** of the following major risk factors for sudden cardiac death:

     a. History of premature HCM-related sudden death in one or more 1st degree relatives less than or equal to 50 years of age
     b. History of unexplained syncope inconsistent with neurocardiogenic origin
     c. Massive left ventricular hypertrophy based on age-specific norms

3. Diagnosis of **ONE** of the following cardiac ion channelopathies:

   - Brugada syndrome with documentation of **ANY** of the following:

     a. A spontaneous diagnostic type 1 ECG who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out)
     b. Develop ventricular fibrillation during programmed electrical stimulation
     c. Documented spontaneous sustained ventricular tachycardia with or without syncope
     d. Survivor of cardiac arrest

   - Catecholaminergic polymorphic ventricular tachycardia with documentation of **ANY** of the following:

     a. Recurrent syncope or polymorphic/bidirectional ventricular tachycardia despite optimal medical management, and/or left cardiac sympathetic denervation
     b. Survivor of cardiac arrest

   - Congenital long QT syndrome with documentation of **ANY** of the following:

     a. Recurrent syncopal events while on beta-blocker therapy
     b. Survivor of cardiac arrest

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria: (cont.)

Automatic Implantable Cardioverter Defibrillator (ICD) for Individuals Under 18 Years of Age: (cont.)

- The use of an automatic ICD is considered ***medically necessary*** with documentation of **ANY** of the following: (cont.)

    3. Diagnosis of **ONE** of the following cardiac ion channelopathies: (cont.)

        - Short QT syndrome with documentation of **ANY** of the following:

            a. Asymptomatic or symptomatic and have a family history of sudden cardiac death
            b. Survivor of cardiac arrest
            c. Symptomatic and have documented spontaneous ventricular tachycardia with or without syncope

    4. Survivor of cardiac arrest, after reversible causes have been excluded
    5. Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in individuals who have undergone an electrophysiologic and hemodynamic evaluation

- The use of an automatic ICD 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, and
    4. Insufficient evidence to support improvement outside the investigational setting.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Criteria: (cont.)

Subcutaneous Implantable Cardioverter Defibrillator (S-ICD):

- The use of a S-ICD is considered ***medically necessary*** in individuals who have an indication for ICD implantation for primary or secondary prevention, who otherwise would have met the above automatic ICD criteria, and with documentation of **ALL** of the following:

  1. Contraindication to an automatic ICD due to **ANY** of the following:

     - History of the need for explantation of an automatic ICD due to a complication, with ongoing need for ICD therapy
     - Lack of adequate vascular access
     - Preservation of existing vascular access (e.g., need for chronic dialysis, younger individual with anticipated long-term need for ICD therapy)
     - High risk for bacteremia, such as individuals on hemodialysis or with chronic indwelling endovascular catheters

  2. No indication for antibradycardia pacing
  3. Absence of ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing

- The use of a S-ICD 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

Resources:

Literature reviewed 06/19/2018. 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. 7.01.44 BCBS Association Medical Policy Reference Manual. Implantable Cardioverter Defibrillator. Re-issue date 05/04/2018, issue date 03/31/1996.

2. Boersma L, Barr C, Knops R, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. *Journal of the American College of Cardiology.* Aug 15 2017;70(7):830-841.

3. Centers for Medicare & Medicaid Services. Medicare National Coverage Analysis (NCA) for Implantable Cardioverter Defibrillators Decision (CAG-00157R4). Accessed 06/02/2018 2018.

4. Friedman DJ, Parzynski CS, Varosy PD, et al. Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. *JAMA cardiology.* Nov 1 2016;1(8):900-911.

5. Gold MR, Aasbo JD, El-Chami MF, et al. Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. *Heart rhythm : the official journal of the Heart Rhythm Society.* Oct 2017;14(10):1456-1463.

6. Kusumoto FM, Bailey KR, Chaouki AS, et al. Systematic Review for the 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Heart rhythm : the official journal of the Heart Rhythm Society.* Nov 3 2017.

7. Priori SG, Blomstrom-Lundqvist C, Mazzanti A, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC)Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). *Eur Heart J.* Aug 29 2015.

8. UpToDate. Subcutaneous implantable cardioverter defibrillators. 11/20/2017.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

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 íłínígóó. 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.

AUTOMATIC IMPLANTABLE AND SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (cont.)

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:
ܐ ܫܟܚ، ܡ ܣ ܩܒܝܠܐ ܕܒܠܘ ܟܪܘܣ ܒܠܘ ܫܝܠܕ ܐܘܦ ܐܘܒ ܣܛܐ ܕ Blue Cross Blue Shield of Arizona، ܫܟܚ، ܫܟܚ ܒܠܘ ܟܪܘܣ ܒܠܘ ܫܝܠܕ ܐܘܦ ܐܘܒ ܣܛܐ ܕ
ܣܝܡܐ ܕܡܡܠܠܐ ܥܡܟ ܣ ܐܝܟ ܕܒܪܝܬ. ܕܡܡܠܠ ܥܡ ܣ ܐܝܟ ܕܒܪܝܬ، ܡܐ ܫܡ، ܟܐ ܐܟܟܫ، ܡܝܢ 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