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.

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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.


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 nilinígíí Blue Cross Blue Shield of Arizona haada yit’éego bina’idilkidgo éí doocdago Háída bíjá aniyleedígíí t’áadoo le’é yina’idilkidgo bee haaz’áanii holqó díí t’áa hazaad’ehjí háká a’doowolgo bee haaz’á díí bágł hálilígíí. Atá halne’iígíí kojí bíchjí’ hóodilíih 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关于插件项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费以您的母语得到帮助和讯息。洽询一位翻译者，请求接电话 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 trong dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تساعدك سؤاله عن خدمات Blue Cross Blue Shield of Arizona الضرورية بلغتك، من دون أي 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 tinutulungan, 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 Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통해시켜 여기에서 877-475-4799로 전화해 주십시오.

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 есть люди, которым 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. Вы можете позвонить 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るため、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: 
آگر شما یا کسی که شما به آن کمک می‌کنید، سوال دارند در مورد اطلاعاتی که در زبان خود را به طور رایگان دریافت نمایید 877-475-4799 لطفاً با ما تماس حاصل نشانید.

Assyrian: 
باز یک چهارم نزدیک جهان، خود را به عنوان Blue Cross Blue Shield of Arizona می‌دانید، سوالات شما را پاسخگویی نمایید. به شما می‌توانم ویژه‌ترین و مطالب غیرقابل اطمینان، 877-475-4799.

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

Thai: หากคุณหรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่มีค่าใช้จ่าย โปรดติดต่อที่ 877-475-4799