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

MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 10/31/12
LAST REVIEW DATE: 04/15/14
LAST CRITERIA REVISION DATE: 05/29/14
ARCHIVE DATE:

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, SUBCUTANEOUS

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.

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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

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 implantable cardioverter defibrillator (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.

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, SUBCUTANEOUS (cont.)

Description: (cont.)

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 totally subcutaneous ICD (S-ICD) has been developed. This device 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 subcutaneous ICD device has received FDA approval.

Criteria:

- The use of a subcutaneous ICD for all indications in adult and pediatric individuals 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:

1. 7.01.44 BCBS Association Medical Policy Reference Manual. Implantable Cardioverter Defibrillator (ICD). Re-issue date 03/13/2014, issue date 03/31/1996.