

# Prior Authorization Form

NOTE: Refer to the Provider Manual for additional services requiring **Prior Authorization**

Fax Form To: 616 942-0024

## Implantable Cardioverter Defibrillators (ICD) & Biventricular Pacemakers

### Member

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_

ID #: \_\_\_\_\_ DOB: \_\_\_\_\_

Primary Care Physician: \_\_\_\_\_ PCP Phone: \_\_\_\_\_ PCP Fax: \_\_\_\_\_

Has PCP been notified of request?  Yes  No Is this authorization related to:  Work Injury  Motor Vehicle Accident

### Requested By:

Provider Name: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Address: \_\_\_\_\_ Contact Name: \_\_\_\_\_ Date of Request: \_\_\_\_\_

### Directed To:

Provider Name: \_\_\_\_\_ Facility: \_\_\_\_\_

Address: \_\_\_\_\_ Address: \_\_\_\_\_

Provider Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Facility Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Contact Name: \_\_\_\_\_ Contact Name: \_\_\_\_\_ Date of Service: \_\_\_\_\_

### Clinical Information:

ICD check the condition(s) that apply:  Initial Placement  Replacement - Date of Original Placement: \_\_\_\_\_

If replacement, reason for replacement: \_\_\_\_\_

Manufacturer Name: \_\_\_\_\_ Model #: \_\_\_\_\_

**Implantable Cardioverter Defibrillators (ICDs)** are covered consistent with the recommendations for Class I and Class IIa indications found in the ACC/AHA/HRS Guidelines for Device-Based Therapy, June 2008. Guidelines are available @ <http://content.onlinejacc.org/cgi/content/full/j.jacc.2008.02.032>

### ADULT CRITERIA

Patients must be on optimal medical therapy, have a reasonable expectation of survival with good functional status for more than 1 year, **and** meet **one** of the following criteria.

#### Please check the indication that applies to this request for prior authorization:

- Survivor of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT) after evaluation to define the cause of the event and to exclude any completely reversible causes. (Class I)  
**Date of event:** \_\_\_\_\_
- \*Left ventricular dysfunction with prior MI (Ischemic Cardiomyopathy) and one of the following:
- LVEF less than 35% due to prior MI who are at least 40 days post-myocardial infarction and who are in NYHA functional Class II or III. (Class I)
  - LVEF less than 30%, at least 40 days post-myocardial infarction, and are in NYHA functional Class I. (Class I)
  - nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study. (Class I)
- EF** \_\_\_\_\_ **Date of MI** \_\_\_\_\_
- \*Nonischemic dilated cardiomyopathy with an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. (Class I) **EF** \_\_\_\_\_

#### \*Indications must also meet the following criteria:

- Patients must be able to give informed consent; Priority Health's Decision Support Tool is required.
  - Ejection fractions must be measured by angiography, radionuclide scanning, echocardiography, or MRI.
  - MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology committee for the Redefinition of Myocardial Infarction<sup>1</sup> (**Please see Medical Policy #91410 Cardioverter Defibrillators for additional criteria**)
- Syncope of undetermined origin and one of the following:
- clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study. (Class I)
  - significant LV dysfunction, and nonischemic dilated cardiomyopathy. (Class IIa)

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## Implantable Cardioverter Defibrillators (ICD) & Biventricular Pacemakers-Cont'd

- Ventricular Tachycardia and one of the following:
  - a. structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. (Class I)
  - b. sustained VT and normal or near normal ventricular function. (Class IIa)
- Familial or inherited conditions (**Please refer to Medical Policy #91410 Cardioverter Defibrillators for specific criteria**)
- Non hospitalized patients awaiting heart transplantation (Class IIa)
- Cardiac sarcoidosis (Class IIa)
- Giant cell myocarditis (Class IIa)
- Chagas disease (Class IIa)
- Biventricular Pacemakers Biventricular Pacemakers (Cardiac Resynchronization Therapy)/Combination Resynchronization-Defibrillation Devices for Congestive Heart Failure, alone or in combination with an AICD(CRT/AICD). May be covered when **all** of the following are met:
  - 1. Device is FDA approved
  - 2. Patient has NYHA Class III or IV
  - 3. LVEF  $\leq$  .35
  - 4. QRS duration  $\geq$ 120 msec
  - 5. Patient is on appropriate pharmacological regimen prior to implant, unless contraindicated

### PEDIATRIC PATIENTS AND PATIENTS WITH CONGENITAL HEART DISEASE CRITERIA

Please check the indication that applies to this request for prior authorization:

- Patient is a survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes. (Class I)
- Patient has symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients. (Class I)
- Patient has congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study. (Class IIa)

**Microvolt T-Wave Alternans (MTWA) testing is a covered benefit.**

NOTE: ICDs are considered experimental and **not a covered benefit** for any indication other than Class I and IIa indications listed above. ICDs are also **not covered** if any of the following is present:

1. Irreversible brain damage, disease or dysfunction that precludes the ability to give informed consent.
2. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure, advanced cerebrovascular disease), associated with a likelihood of survival less than 1 year.
3. Member has asymptomatic VT or symptomatic VT/VF that is
  - a. associated with acute myocardial infarction within 2 days,
  - b. due to a remediable cause,
  - c. controlled by appropriate drug therapy, and
  - d. amenable to definitive therapy (e.g., ablative procedures, surgery);
4. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm.
5. Had a CABG or PTCA within the past 3 months.
6. Had an acute MI within the past 40 days.
7. Clinical symptoms or findings that would make them a candidate for coronary revascularization.
8. For primary prevention of SCD in members with NYHA Class IV drug-refractory congestive heart failure.
9. The planned ICD has not received full market approval from the FDA.

**\*\*\*ALL FIELDS MUST BE COMPLETE AND LEGIBLE FOR PRIOR AUTHORIZATION REVIEW\*\*\***



## **Provider Information Sheet**

### **Patient Decision Support Tools for Implantable Cardiodefibrillators (ICD) for patients with non-ischemic (NIDCM) and ischemic dilated cardiomyopathies (IDCM)**

#### **Intended use**

This decision support tool is intended to be use by cardiologists counseling patients on the risk and benefits of implantable cardioverter defibrillators. At a minimum, this decision support tool would be used by the physician implanting the device.

#### **Patient target audience**

This tool is written for patients with ischemic and non-ischemic dilated cardiomyopathies who are considering use of an ICD for primary prevention of sudden cardiac death. It is not intended for patients who have a history of ventricular arrhythmia, sudden cardiac death, or other indications for an ICD.

#### **Which patients should use this form?**

Although providers can use this form for any payor, Priority Health requires that its members receiving an ICD for NIDCM and IDCM indications sign this form to indicate that they have reviewed the risks and benefits.

#### **Who should receive a copy of this form once it's completed?**

- Patient
- Patient chart
- Priority Health

#### **How will Priority Health use the information in this form?**

The Priority Health Medical Management Department will use this information as part of the prior authorization process. It should be submitted along with the prior authorization request; failure to do so will result in a coverage denial.

#### **How often will the information content on this tool be updated?**

The tool will expire one year from the last update. The tool will be updated with any new data from randomized clinical trials or from meta-analyses. Any participating physician or facility can request an update to the information. Comments on changes and updates will be solicited from network providers.

#### **Where will updated forms be available?**

Forms will be accessible via *priorityhealth.com* in the provider section under provider tools

## PATIENT INFORMATION: IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS (ICD)

**Use of this guide.** This guide is intended to provide you with information about a procedure and to help you ask questions of your doctor. Please review and sign once you have discussed the information with your physician.

**What is an ICD? An implantable cardioverter-defibrillator** or ICD is a small, minicassette-sized device implanted in the chest to continuously monitor your heart rhythm and deliver precise, calibrated electrical shocks when needed. This controls abnormal, rapid heartbeats. The electrical shock delivered by the ICD can prevent sudden death from many dangerous heart rhythm disturbances. The ICD may also end other types of irregular heart rhythms.

### **What is ischemic dilated cardiomyopathy (IDCM) and non-ischemic dilated cardiomyopathy (NIDCM)?**

*Cardiomyopathy* is a disease of the heart muscle. Known causes of cardiomyopathy include coronary artery disease and valvular heart disease.

*Dilated cardiomyopathy* results when one or more of the heart chambers become enlarged (dilated) and their pumping ability becomes less forceful. The effectiveness of that pumping ability is called the ejection fraction. Although it can affect people of all ages, dilated cardiomyopathy occurs most often in those who are middle-age. It is more common among men than women.

*Ischemic dilated cardiomyopathy (IDCM)* is the result of poor blood supply (ischemia) and injury to the heart muscle. This can occur due to coronary artery disease or a heart attack.

*Non-ischemic dilated cardiomyopathy (NIDCM)* can result from heart damage that is not the result of poor blood supply. Some causes of NIDCM are long-term high blood pressure, diseases of the heart valves or a virus.

### **Which patients with IDCM and NIDCM are likely to benefit from ICD placement?**

Patients most likely to benefit are those who have an enlarged heart with poor muscle squeeze. This is especially true for patients with an ejection fraction of <35%.

### **Which patients are not likely to benefit?**

#### **Patients who:**

- Have had a heart attack or procedures such as a stent, CABG, bypass, or angioplasty in the last 40 days.
- Have severe heart failure (class IV), which is heart disease resulting in an inability to take part in physical activity without discomfort. Symptoms may be present even at rest, with increased discomfort during physical activity.
- Are candidates for a heart procedure, including those listed above.
- Have a non-heart related illnesses that is likely to result in death within one year.

### **What are the benefits of an implanted cardio defibrillator (ICD)?**

**Life-expectancy.** Physicians cannot predict who will or will not benefit from the device. Not everyone will benefit. The chance of benefiting depends on why the ICD is implanted.

Clinical studies performed at university medical centers have shown that for patients who have ischemic dilated cardiomyopathy, 18 patients need to be treated for 2 years to provide one person an additional year of life. For patients who have non-ischemic dilated cardiomyopathy, 25 patients need to be treated for 2 years to provide one person an additional year of life.

**Quality-of-life.** ICD implantation is intended solely as prevention against the possibility of sudden cardiac death. It is not designed to improve the function of the heart muscle. Therefore, patients who have an ICD do not usually have improvement of symptoms such as shortness of breath or fatigue.

The device is also not designed to prevent all disturbances of heart rhythm (arrhythmia). Patients with an ICD may experience, or continue to experience brief losses of consciousness (palpitations or syncope). If these symptoms occur they are not necessarily related to the ICD, but rather to the heart disease itself.

Some patients who receive ICD shocks may experience increased anxiety and distress. Appropriate shocks can be expected in one out of ten patients approximately one year after implantation. Arrhythmia causing multiple ICD shocks may require therapy with antiarrhythmic drugs. An ICD will not decrease the need for other heart medications or regular doctor visits.

**Medication use.** Most candidates for an ICD are already taking multiple medications. After receiving an ICD, 50 percent of patients with ICDs can discontinue using rhythm-controlling medications. Most can also reduce the number and/or dosage of their medications. You will likely need to continue taking heart medications such as ACE inhibitors. Always consult your physician before changing any medication.

### **What are the risks of an implanted cardioverter-defibrillator (ICD)?**

Please discuss the risks of an ICD with your physician. Your physician's experience may be different.

- About 1 in a 1000 patients will have a serious event such as death, heart attack or stroke during or immediately after placement of the device.
- About 1 in 20 patients will have a less serious complication such as collapsed lung, blood around the ICD, infection, fluid build-up around the heart, broken ICD wires or other malfunction.
- Less than 1 in 20 patients will require re-operation within one year of device placement.
- Most ICD-related complications are not life-threatening and can be managed either medically or surgically. Additional stay in the hospital may be required.

### **What can I expect when living with an ICD?**

Over the course of five years, 18-30 percent of patients will experience appropriate shocking by the ICD. A slightly higher percentage of patients will receive a shock for non-life-threatening reasons.<sup>1</sup> In general, for single shocks patients should contact their physicians. For multiple shocks, patients should proceed to the nearest emergency department. Each patient should discuss with their physician what to do when the ICD delivers one or more shocks

Patients with an ICD need to avoid metal detectors (e.g. airports or courthouses), MRIs, cellular phones within six inches of the chest area and strong electrical or magnetic fields (e.g. slot machines, amusement park rides, working on a car engine with the motor running.)

### **What if the ICD needs to be replaced?**

ICDs may need to be replaced due to malfunction, or advisories and recalls by the manufacturer. In a Canadian study of patients undergoing ICD replacement the following risks were identified:

- About 6 in 100 patients had a serious complication such as infection or bleeding requiring reoperation.
- About 2 in 100 patients had a less serious complication such as infected incision
- 2 deaths occurred in the study of 533 patients having replacement of the ICD

Your physician's complication rates may be different than the results of this study. Please discuss the risks of replacement with your physician.

I have read and discussed with my physician the risks and benefits associated with an ICD.

\_\_\_\_\_  
Patient name

\_\_\_\_\_  
Physician name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

\_\_\_\_\_