

Implantable Cardiac Defibrillator (ICD) and BiV-ICD Worksheet

Last Name: _____ First Name: _____ D.O.B: _____

Date of Procedure: _____ Implanting Physician: _____

Diagnosis: _____

Complete the following sections to determine if medical necessity criteria meet National Coverage Determination (NCD) requirements.

1. Irreversible brain damage from pre-existing cerebral disease
 No - go to question 2 Yes - STOP patient DOES NOT meet Medicare NCD

Indications for implanting cardiac defibrillators for life-threatening tachyarrhythmias:

2. Documented episode of cardiac arrest due to Ventricular Fibrillation (VF) not due to a transient or reversible cause (myocardial infarction with documented cardiac enzyme release within 48 hours of the event, QT prolongation secondary to electrolyte imbalance or drug use, severe CAD with an ejection fraction over 50% that is amendable to revascularization, or if the event occurred as result of a respiratory arrest).

No - go to question 3 Yes - STOP patient meets Medicare NCD Criterion #B.1

3. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by EPS, not associated with an acute MI and not due to a transient or reversible cause .

If induced, Date of EP Study required: _____

No - go to question 4 Yes - STOP patient meets Medicare NCD Criterion #B.2

4. Patient has **any** of the following contraindications:

- Unable to give informed consent
- Acute MI within the past 40 calendar days (Typical rise and gradual fall of troponins or more rapid rise and fall [CK-MB] of biochemical markers of myocardial necrosis, with at least one of the following: ischemic symptoms, development of pathologic Q waves on ECG, ECG changes indicative of ischemia or coronary artery intervention, e.g., angioplasty)
- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm
- Had a CABG or PTCA within the past 90 calendar days
- Clinical symptoms or finding that would make them a candidate for coronary revascularization
- Any disease other than cardiac, associated with the likelihood of survival less than 1 year.

No - go to question 5 Yes - STOP patient does not meet Medicare NCD

5. Documented familial or inherited conditions with a high risk of life threatening VT,

Long QT syndrome Hypertropic cardiomyopathy Other _____

No - go to question 6 Yes - STOP patient meets Medicare NCD Criterion #B.3

6. Coronary artery disease (CAD) with documented prior MI > 40 days, LVEF ≤ 35%, and inducible, sustained VT or VF at EP study. Date of MI _____ Date of EP Study _____

Date EF Obtained _____ EF% _____ Obtained By: Cath ECHO MUGA

No - go to question 7 Yes - STOP patient meets Medicare NCD Criterion #B.4

7. Documented prior MI > 40 days prior and LVEF ≤ 30% , NYHA Class I-III

Date of MI _____ Date EF Obtained _____ EF% _____

NYHA Class I Class II Class III

No - go to question 8 Yes - STOP patient meets Medicare NCD Criterion #B.5

8. Ischemic Dilated Cardiomyopathy (ICDM), documented prior MI, NYHA II/III heart failure and LVEF ≤ 35%

Date of MI _____ NYHA Class II Class III

Date EF Obtained _____ EF% _____ Obtained By: Cath ECHO MUGA

No - go to question 9 Yes - STOP patient meets Medicare NCD Criterion #B.6



Implantable Cardiac Defibrillator (ICD) and BIV-ICD Worksheet

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Flint, Michigan

9. Non-ischemic dilated cardiomyopathy >270 calendar days, NYHA Class II or III heart failure, and LVEF ≤35%. NYHA []
Class II [] Class III
Date EF Obtained _____ EF% _____
By: [] Cath [] ECHO [] MUGA []
[] No - go to question 10 [] Yes - STOP patient meets Medicare NCD Criterion #B.7

10. Criteria for implanting Bi-V - Meets cardiac resynchronization therapy (CRT) criteria, with NYHA Class IV, CRT Criteria:
[] Meets at least one criterion above (2, 3, 5, 6, 7, 8 or 9) and
[] Meets established reasonable and medically necessary criteria for CRT-D/Bi-V device:
[] Diagnosis
[] Measured EF _____
[] LV function _____
[] QRS width _____
[] Patient symptoms _____
[] No - go to question 11 [] Yes - STOP patient meets Medicare NCD Criterion #B.8

11. Non-ischemic dilated cardiomyopathy > 90 calendar days, NYHA Class II or III, and LVEF ≤ 35%
NYHA [] Class II [] Class III
[] No - go to question 12 [] Yes - STOP patient meets Medicare NCD Criterion #B.9

Replacements and Upgrades

12. Replacement of Existing ICD
[] No - go to question 13 [] Yes - Indicate Reason for both Replacement and Initial Implant
[] Malfunction [] Recall [] Battery depletion [] Device end-of-life [] Infection
[] Upgrade - if Bi-V complete section 10
Reason for initial implant: [] VT [] VF [] Cardiac arrest [] Cardiomyopathy [] Other: _____

Clinical Trials

13. Meets Category B investigational device exemption (IDE) or CMS Clinical Trial Policy WITH written protocol on file, IRB approval, approval by 2 or more qualified individuals who are not part of the research team and certification that investigators are not disqualified.
Yes - STOP patient meets Medicare NCD Criterion #C
TRIAL NAME: _____

Other Criteria (Medicare patients require authorization before submitting claim; Other payers may accept additional indications)

14. [] NYHA Class I ischemic or Class II ischemic/non-ischemic, stable on optimal pharmacologic therapy for heart failure, with LVEF <30%, and left bundle branch block with QRS >130ms (MADIT - II)
15. [] NYHA Class III/IV heart failure, patient remains symptomatic despite recommended optimal medical therapy, with LVEF <35% and QRS >120ms (COMPANION Criteria)
16. [] Other conditions: _____

Physician Signature: _____ Date: _____
Hospital/Boarding Review Performed by: _____ Date: _____