

# MedStar Health, Inc.

## POLICY AND PROCEDURE MANUAL

Policy Number: PA.100.MH  
Last Review Date: 05/19/2016  
Effective Date: 07/01/2016

### PA.100.MH – Cardiac Defibrillator

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers Subcutaneous Implantable Cardiac Defibrillators (S-ICDs) medically necessary for the following indications:

The member will meet all of the following criteria for S-ICD placement (1-4):

1. Candidate for ICD implantation based on ACC/AHA/HRS and CMS indications
2. No indication of cardiac rhythms requiring pacing
3. Passed the S-ICD Electrogram (EGM) screening
4. Any of the following conditions putting the member at high risk for complications from endovascular ICD implantation:
  - a. Prior device infection
  - b. Active systemic infection (bacteremia, sepsis, open ulcers, etc.) or prior systemic infection related to and necessitating implantable device removal
  - c. Vascular occlusion
  - d. Member on dialysis
  - e. Hypercoagulable state
  - f. Member < 50 years old with the expected longevity of ICD placement over 10 years duration

Note: The S-ICD system must have FDA approval and be used only for FDA approved indications.

#### Background

Sudden cardiac death can be defined as a death due to cardiac causes within one hour of the onset of symptoms. Ventricular fibrillation (VF) or ventricular tachycardia (VT) are the leading causes for sudden cardiac death. The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias, VF and VT. The device consists of a pulse generator and electrodes for sensing and defibrillating.

According to the FDA, the S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, continual (incessant) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing. The S-ICD monitors cardiac rhythms and delivers defibrillation

## PA.100.MH – Cardiac Defibrillator

Policy Number: PA.100.MH

Last Review Date: 05/19/2016

Effective Date: 07/01/2016

when ventricular tachyarrhythmias are detected. After delivery of a shock, the S-ICD provides post-shock bradycardia pacing therapy when needed.

### Code:

33270: Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluations, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed

### References

1. Aziz S, Leon AR, El-Chami MF. The subcutaneous defibrillator: a review of the literature. J Am Coll Cardiol. 2014 Apr 22;63(15):1473-1479. doi: 10.1016/j.jacc.2014.01.018. Epub 2014 Feb 12. <http://www.sciencedirect.com/science/article/pii/S0735109714003295>
2. Brady, GH, Smith, WM, Hood, MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med. 2010 July; 363(1); 36-44. <http://www.nejm.org/doi/full/10.1056/NEJMoa0909545#t=article>
3. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD). NCD No. 20.4 – Implantable Automatic Defibrillators. Effective Date: 01/27/2005. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=3&bc=AgAAgAAAAAAAAA%3d%3d&>
4. Centers for Medicare and Medicaid Services (CMS). Medicare Claims Processing Manual: Chapter 32- Billing Requirements for Special Services. Revised: 11/06/2014. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>
5. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network (MLN) Matters, MM#3604. Transmittal CR#R497CP. Billing for Implantable Automatic Defibrillators for Beneficiaries in a Medicare Advantage (MA) Plan and Use of the QR Modifier to Identify Patient Registry Participation. Updated: 2/16/2013. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm3604.pdf>
6. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network (MLN) Matters, MM#4237. Transmittal CR#R819CP. Modifications to QR Modifier Edit for Automatic Implantable Cardiac Defibrillator (ICD Services). Updated: 10/26/2012. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm4273.pdf>
7. Hayes Technology Brief. S-ICD (Subcutaneous Implantable Cardioverter Defibrillator; Boston Scientific Corp) for Prevention of Sudden Cardiac Death. Annual Review October 19, 2015.

## PA.100.MH – Cardiac Defibrillator

Policy Number: PA.100.MH

Last Review Date: 05/19/2016

Effective Date: 07/01/2016

8. Lambiase PD, Barr C, Theuns DA, et al. EFFORTLESS Investigators. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. *Eur Heart J*. 2014 Jul 1;35(25):1657-1665. doi: 10.1093/eurheartj/ehu112. Epub 2014 Mar 26. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4076663/>
9. Jarman, JWE and Todd, DM. United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: important lessons to learn. *Europace*. 2013 February; 15(8): 1158-1165. <http://europace.oxfordjournals.org/content/15/8/1158.long>
10. National Institute for Health and Clinical Excellence (NICE), Interventional Procedure Guidance (IPG). Insertion of a subcutaneous implantable cardioverter defibrillator for prevention of sudden cardiac death, IPG454, Published: April 2013. <https://www.nice.org.uk/guidance/IPG454>
11. Olde Nordkamp, LRA, Warnaaars, JLF, Kooiman, KM, et al. Which patients are not suitable for a subcutaneous ICD: incidence and predictors of failed QRS-T-wave morphology screening. *J Cardiovasc Electrophysiol*. 2014 May; 25(5): 494-499. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12343/abstract;jsessionid=3EA0D7F890673C9C9457859D1361A89B.f01t04>
12. Russo, AM, Stainback, RF, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use of Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy. *J Am Coll Cardiol*. 2013 March; 61(12): 1320-1364. <http://content.onlinejacc.org/article.aspx?articleid=1659563>
13. Sanghera R, Sanders R, Husby M, et al. Development of the subcutaneous implantable cardioverter-defibrillator for reducing sudden cardiac death. *Ann N Y Acad Sci*. 2014 Oct 10. doi: 10.1111/nyas.12550. [Epub ahead of print]. <http://onlinelibrary.wiley.com/doi/10.1111/nyas.12550/abstract;jsessionid=BC530604D8954324101996C9208BEF0C.f04t04>
14. U.S. Food and Drug Administration (FDA). Subcutaneous Implantable Defibrillator (S-ICD) System - P110042. (PMA Applicant: Cameron Health, Inc.) Approval Date: Sept, 28. 2012. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm326541.htm>
15. Weiss, R, Knight, BP, Gold, MR, et al. Safety and efficacy of a totally subcutaneous implantable cardioverter defibrillator. *Circulation*. 2013 August; 128: 944-953. <http://circ.ahajournals.org/content/128/9/944.long>

### Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of

## **PA.100.MH – Cardiac Defibrillator**

Policy Number: PA.100.MH  
Last Review Date: 05/19/2016  
Effective Date: 07/01/2016

medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.