



## CLINICAL POLICY

### Billing for Replacement / Recalled Implantable Cardiac Devices

**A. EFFECTIVE DATE :**

April 7, 2021

**B. PURPOSE :**

This policy will outline process to assure compliance with the Centers for Medicare and Medicaid Services Provider Reimbursement Manual to pursue free or reduced cost replacement medical devices that are subject to manufacturer recall or failure under warranty.

**C. POLICY :**

The proper procedure (below) will be followed to prevent or reduce cost to the patient for replacing a recalled implanted cardiac device.

**D. SCOPE :**

JDH Cardiology Clinics

**E. DEFINITIONS :**

None

**F. MATERIAL(S) NEEDED :**

None

**G. PROCEDURE :**

1. Upon notification of recall by either FDA alerts or vendor and/or manufacturer warranty notification, the physician (electrophysiologist and/or interventional cardiologist) will make the clinical decision if explanation is appropriate. Documentation will be made in permanent medical record.
2. If the explanted device is subject to a recall or warranty credit, the Lead Technologist in the Interventional Laboratory will notify the Material Management Supply Coordinator, providing patient name, product description and serial number(s).
3. The Director of Patient Financial Services will be notified and will enter a modifier notifying the payer that a recall/warranty credit may be due for the explanted device.
4. Material Management Supply Coordinator will send the explanted device description to vendor representative to determine if a credit is due.
5. Upon receipt and determination, this response will be forwarded to the Director of Patient Financial Services and the Interventional Laboratory for documentation in the Cardiology data management system and medical record.

**H. ATTACHMENTS :**

None

**I. REFERENCES :**

None

**J. SEARCH WORDS :**

Recalled, devices, replacement, billing

**K. ENFORCEMENT:**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**L. STAKEHOLDER APPROVALS :**

On File

**M. COMMITTEE APPROVALS :**

None.

**N. FINAL APPROVAL :**

- |   |                           |
|---|---------------------------|
| 1. <u>Andrew Agwunobi (Signed)</u><br>Andrew Agwunobi, MD, MBA<br><b>UConn Health Chief Executive Officer</b>                 | <u>04/16/2021</u><br>Date |
| 2. <u>Anne Horbatuck (Signed)</u><br>Anne D. Horbatuck, RN, BSN, MBA<br><b>Clinical Policy Committee Co-Chair</b>             | <u>04/16/2021</u><br>Date |
| 3. <u>Scott Allen (Signed)</u><br>Scott Allen, MD<br><b>Clinical Policy Committee Co-Chair</b>                                | <u>04/15/2021</u><br>Date |
| 4. <u>Caryl Ryan (Signed)</u><br>Caryl Ryan, MS, BSN, RN<br><b>VP Quality and Patient Service &amp; Chief Nursing Officer</b> | <u>04/13/2021</u><br>Date |

**O. REVISION HISTORY :**

Date Issued: 10/2/2014

Date Revised: 4/2021

Date Reviewed: 2/6/2015, 11/30/2017