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**INLAND EMPIRE HEALTH PLAN**

## **IEHP UM Subcommittee Approved Authorization Guidelines**

### ***Attain Performa(TM) Quadripolar Lead Study***

#### **Policy:**

Based on a review of the literature and on guidelines for Experimental/Investigational Studies, IEHP adopts coverage for “Medtronic Attain Performa Quadripolar Leads (Model 4298, 4398, and 4598)”; in conjunction with the implantation of a Medtronic (CRT-D) Cardiac Resynchronization Defibrillator system. Requests must meet the required 1) eligibility, 2) inclusion criteria, and 3) exclusion criteria of the study as outlined by the “**Attain Performa(TM) Quadripolar Lead Study Requirements**” below. Payment for a Category B IDE device or an IRB approved device (provided to a nonhospital patient) and the related services may not exceed what the level of coverage (i.e. Medicare and /or Medi-Cal) would have paid for a comparable approved device and related services.

Attain Performa(TM) Quadripolar Lead Study Requirements:

#### **I. Eligibility:**

- a. Ages eligible for study: 18 Years and older
- b. Genders eligible for study: Both
- c. Accepts healthy volunteers: No

#### **II. Criteria:**

Inclusion Criteria:

- a. Patient is indicated for implant of a CRT-D device and left-heart lead per local indications (In US only this is based on Class I and II indications for CRT-D implant per HRS/ACC/AHA guidelines)
- b. Patient (or legally authorized representative) has signed and dated the study-specific Consent Form
- c. Patient is expected to remain available for follow-up visits
- d. Patient understands the study and agrees to comply with study protocol

#### **III. Exclusion Criteria:**

- a. Patient has a previous LV lead implanted or previous implant attempt within 30 days of enrollment or has ongoing AEs from a previous unsuccessful implant attempt
- b. Patient has contraindications for standard transvenous cardiac pacing (e.g., mechanical right heart valve)

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*A Public Entity*

## **IEHP UM Subcommittee Approved Authorization Guidelines**

Attain Performa(TM) Quadripolar Lead Study

Page 2 of 5

- c. Patient has had a heart transplant (Note: Patients waiting for heart transplants are allowed in the study)
- d. Patient is contraindicated for < 1 mg dexamethasone acetate
- e. Patient is currently enrolled or planning to participate in a potentially confounding drug or device study during the course of this study. (Note: Co-enrollment in concurrent studies may be allowed provided that documented pre-approval is obtained from Medtronic's study manager)
- f. Patient has a life expectancy less than 180 days
- g. Patient with exclusion criteria required by local law (e.g. age, pregnancy, breast feeding, etc.)
- h. In US, women of childbearing potential must have a negative pregnancy test 7 days prior to implant to be included
- i. Patient is unable to tolerate an urgent thoracotomy

## **Medicare Benefit Policy Manual, Chapter 14 - Medical Devices:**

### **A. Section 10 - Coverage of Medical Devices:**

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
- I. For dates of service on or after November 1, 1995, Medicare may cover certain FDA-approved and Institutional Review Board (IRB) approved investigational devices and services incident to, provided the investigational device meets the following conditions:
    1. Appears on the listing of devices eligible for coverage/payment on CMS' master file of IDE devices;
    2. Is reasonable and necessary for the individual patient;
    3. The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file; and,
    4. There is no national coverage policy that would otherwise prohibit Medicare coverage.
  - II. Devices that may be covered under Medicare include the following categories:
    - Devices approved by the FDA through the Pre-Market Approval (PMA) process;
    - Devices cleared by the FDA through the 510(k) process;
    - FDA-approved IDE Category B devices; and
    - Hospital Institutional Review Board (IRB) approved IDE devices

**B. Section 20 - FDA Approval Investigational Device Exemptions (IDEs):**

The FDA assigns a special identifier number that corresponds to each device granted an investigational device exemption (IDE). Under the Food, Drug, and Cosmetic Act, devices are categorized into three classes. Class I devices are the least regulated. These are devices that the FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations. Class II devices are those which, in addition to general controls, require special controls such as performance standards or post-market surveillance, to assure safety and effectiveness. Class III devices are those which cannot be classified into class I or class II because insufficient information exists to determine that either special or general controls, would provide reasonable assurance of safety and effectiveness. Class III devices require pre-market approval.

For purposes of assisting CMS in determining Medicare coverage, the FDA will place all approved IDEs in one of two categories.

- **20.1 - Category A**

**Experimental** - Innovative devices believed to be in class III for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective).

- **20.2 - Category B**

Nonexperimental and/or investigational devices believed to be in classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

**C. Section 30 - Coverage of FDA-Approved IDEs:**

The CMS does not cover Category A devices under Medicare because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

The CMS may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

**D. Section 70 - Payment for IDE Category B Devices states:**

Payment for a Category B IDE device or an IRB approved device (provided to a nonhospital patient) and the related services may not exceed what Medicare would have paid for a comparable approved device and related services.

**IEHP UM Subcommittee Approved Authorization Guidelines**

Attain Performa(TM) Quadripolar Lead Study

Page 4 of 5

**Background:**

**U.S. National Institutes of Health (2013):**

The purpose of the study is to evaluate the safety and efficacy of the Medtronic Attain Performa Quadripolar Leads (Model 4298, 4398, and 4598) during and post the implant procedure. This study will also assess the interactions of the Attain Performa leads with the entire Medtronic CRT-D system. Please refer to this study by its ClinicalTrials.gov identifier: NCT01751022

**ClinicalTrials.gov - <http://clinicaltrials.gov/show/NCT01751022>**

**Attain Performa(TM) Quadripolar Lead Study (See Attachment A)**

**ClinicalTrials.gov Identifier:** NCT01751022

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<b>Revised:</b>

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**IEHP UM Subcommittee Approved Authorization Guidelines**

Attain Performa(TM) Quadripolar Lead Study

Page 5 of 5

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**Disclaimer**

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