[Site/Physician Letterhead]

[DATE]

Health Plan Administrator
[HEALTH PLAN NAME]
[ADDRESS / PO BOX]
[CITY], [STATE] [ZIP CODE]

RE: **[PATIENT NAME]**
[INSURANCE IDENTIFICATION NUMBER]

Special Report for Category III CPT Code: 0408T
Description: *Category III Code 0408T Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes*
Reason for use: No permanent CPT code exists to precisely represent the insertion of the Optimizer® Smart system

On behalf of my patient, **[INSERT PATIENT NAME]**, this letter provides clinical information on this patient's condition, and a formal explanation of the for the Optimizer® Smart System to help relieve symptoms of chronic heart failure for medically necessary health care services to be performed. **[INSERT PATIENT NAME]** is a **[INSERT AGE AND GENDER]** who presented to me with **[INSERT DIAGNOSIS HERE]**.

PATIENT'S CLINICAL NEED FOR THE OPTIMIZER® SMART SYSTEM

[Patient Name] is **[age]** years old and has suffered from **[Dyspnea on exertion; shortness of breath; paroxysmal nocturnal dyspnea (PND); orthopnea; fatigue; cachexia;] for [duration of current symptoms]**. In addition, on physical examination and despite optimal medical therapy (OMT), my patient has demonstrated **[edema; elevated jugular vein pulse (JVP); 3rd heart sound; plural effusion; basilar crackels; and achieves ≤ 300 meters distance during the 6-minute walk test suggestive of significant mortality risk]. He/she has a past medical history of [MI; CABG; PCI]. Lastly, my patient has been hospitalized [insert number] times for heart failure in the past 12 months.**

[Patient Name] has a confirmed LVEF of **[25-45%]**. Currently, **[he/she]** is not responding to medication management and has exhausted or failed conservative and standard of care treatment. **[He/she] is not a suitable candidate for Cardiac Resynchronization Therapy (CRT) because: [insert physician's free text here].** My patient's symptoms impact functional capacity as defined by the NYHA Heart Failure Classification as:
Level I – No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)
Level II – Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpation, dyspnea (shortness of breath)
Level III – Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity cause fatigue, palpitation, or dyspnea.
Level IV – Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

In discussion with my patient, we have decided to opt for the Optimizer® Smart Implantable Pulse Generator (IPG) to address this condition.

DESCRIPTION OF THE PROCEDURE

The Optimizer® Smart System treats a life-threatening disease, (chronic, moderate-to-severe heart failure), and addresses an unmet medical need in patients who fail to get adequate benefits from standard treatments and are not suited for treatment with other FDA approved heart failure devices such as CRT.
The insertion procedure is similar to that of an ICD, and is described here:

The patient is taken to the catheterization lab and positioned on the table. Using the modified Seldinger (or other) technique, a guidewire is placed into the subclavian vein and an introducer sheath is placed over a guidewire. (Alternatively, the cephalic vein is exposed and accessed for introduction of the guidewire and catheter). This sequence is repeated as two ventricular leads are individually threaded through the respective introducer sheath and positioned and anchored to the right ventricular septum (high to mid) under fluoroscopic guidance. Utilizing a similar technique as utilized for the ventricular leads, the right atrial lead is then placed and anchored into the right atrium. The implanted leads are then tested utilizing an external lead system analyzer.

A subcutaneous pocket is fashioned with use of a scalpel and other acceptable methodology, such as blunt dissection and electrocautery. The leads are connected to the pulse generator and the generator is placed in the pocket. If the patient has a concomitant cardiac rhythm device, a crosstalk test between the two devices is performed. ***CCM***® is then turned off, the generator pocket is closed with sutures and the patient is taken to the recovery area. ***CCM***® can then be reactivated in the recovery area at the physician's discretion. As well, the femoral (arterial) sheath will be removed once the bleeding times have returned to normal.

The Optimizer® Smart System was approved on March 21, 2019 under the FDA Breakthrough Technology device designation program. It is a unique implantable medical device that delivers Cardiac Contractility Modulation therapy. The Optimizer® Smart System is similar in its mode of insertion to an Implantable Cardioverter Defibrillator (ICD), but does not affect the heart rate or rhythm.

Device Description: The Optimizer® Smart Implantable Pulse Generator (IPG) Technology

CCM® Therapy
The Optimizer® Smart IPG continuously monitors cardiac electrical activity and synchronizes delivery of ***CCM***® signals to intrinsic cardiac activity sensed by pacemaker leads placed in the right atrium and in the right ventricular septum. The IPG incorporates sense amplifiers to detect cardiac activation from intracardiac electrograms (IEGMs) sensed by each of the leads and processes this information using the IPG's control algorithm to time ***CCM***® therapy to take place only during the ventricular absolute refractory period. ***CCM***® therapy is delivered each day for five hours during separate one-hour increments. Additionally, ***CCM***® signal delivery is inhibited if noise is detected on any of the sensing channels, when the atrial rate exceeds a pre-programmed limit, during an atrial or ventricular arrhythmia, and when a Premature Ventricular Contraction (PVC) is present.

The Optimizer® Smart system was the first breakthrough device to go before the Circulatory System Devices Panel of the FDA's Medical Devices Advisory Committee on Dec. 4, 2018, receiving a 12-0 vote on the benefit-to-risk ratio of the device. Impulse Dynamics received FDA approval for the Optimizer® Smart system on March 21, 2019. The FDA's announcement regarding approval and approval letter is enclosed.

Indications for Use - Optimizer® Smart is indicated to improve 6-minute hall walk distance, quality of life and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for CRT, and have an LVEF ranging from 25% to 45%.

Cardiac contractility modulation as delivered by Optimizer® Smart is an established device that is of benefit to patients with symptomatic heart failure on OMT and with normal or mildly prolonged QRS duration, thus providing support for the large complement of heart failure patients who do not have an indication for CRT.

VALUATION & CROSSWALK CODE

"Crosswalk" Code for Valuation: [INSERT "CROSSWALK" CPT CODE]

The implant procedure for the Optimizer® System is appropriately billed using CPT code 0408T (*Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes*).

As this is a Category III CPT code, no Relative Value Units (RVUs) have been assigned to this procedure. However, based on my clinical experience, I believe the time and intensity to complete the implant procedure for the Optimizer® System compares to **[INSERT PROCEDURE CPT CODE and CPT DESCRIPTION OF AN EXISTING PROCEDURE THAT MOST CLOSELY APPROXIMATES THE OPTIMIZER® PROCEDURE – EXAMPLES MAY INCLUDE CPT 33249 or 33270 or OTHERS]**. As we charge **[$XXX.XX]** for the **[SIMILAR IMPLANT PROCEDURE]**, I will be submitting a charge of **[$XXX.XX]** for the Optimizer® Smart system, which covers the time and medical expertise necessary to perform this procedure.

I have attached the FDA approval letter for the Optimizer® Smart system. In addition, I have enclosed a copy of the recently published IDE clinical trial that demonstrates the effectiveness of the Optimizer® Smart system in trial patients that were very similar to **[INSERT PATIENT NAME's]** condition.

Documentation: Attached are clinical notes detailing the procedure to be performed on **[DATE]** on **[PATIENT NAME].**

Should you have further questions or concerns, please do not hesitate to call me at **[INSERT PHYSICIAN TELEPHONE NUMBER]**. Thank you for your immediate attention and anticipated pre-authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

[Attach clinical notes, FDA approval letter, evidence summary]

[i] Abraham et al, A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation. JACC Heart Fail.2018;6:874–883. doi: 10.1016/j.jchf.2018.04.01