Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2015

1. Technology Name:

REASANZ™ (serelaxin) Injection 1 mg/mL Solution for I.V. Infusion

2. Manufacturer Name:

Novartis Pharmaceuticals Corporation

3. Trade Brand of Technology:

The brand name of the new technology is REASANZ™

4. Brief Description of Service, Device or Drug:

Serelaxin is a recombinant form of the naturally occurring human relaxin-2 peptide hormone, for treatment of acute heart failure (AHF). The drug is infused over a 48-hour period in an inpatient hospital setting.

Serelaxin represents a new pharmacologic approach to the treatment of AHF. In summary, findings from the RELAX-AHF clinical trial demonstrate that serelaxin provides improved initial clinical status (e.g., dyspnea); reduced rate of subsequent worsening of clinical status (e.g. in-hospital worsening heart failure, worsening renal function and other end-organ damage); reduced length of hospital stay; and reduced risk of cardiovascular and all-cause mortality, in combination with a favorable safety profile (see additional clinical trial data and information provided in the full application). As a result, serelaxin represents a significant advance in therapy in an area of medical need.

Serelaxin is under FDA review and has a projected action date in Q2 2014. The proposed indication is as follows: *REASANZ™ (serelaxin) is indicated to improve the signs and symptoms of acute heart failure and to reduce the rate of worsening of heart failure.*

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1. Technology Name: WATCHMAN® Left Atrial Appendage Closure Technology

2. Manufacturer Name: Boston Scientific Corporation

3. Trade Brand of Technology: WATCHMAN® Left Atrial Appendage Closure Technology

4. Brief Description of Service, Device or Drug:

The WATCHMAN Left Atrial Appendage Closure Technology is intended to prevent thromboembolism from the left atrial appendage, thereby reducing the risk of systemic emboli and stroke in high-risk patients with non-valvular atrial fibrillation (AF) who are eligible for warfarin therapy but for whom the risks of long term oral anticoagulation outweigh the benefits.

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1. Technology Name: CardioMEMS Heart Failure Monitoring System

2. Manufacturer Name: CardioMEMS, Inc.

3. Trade Brand of Technology: CardioMEMS™ HF System

4. Brief Description of Service, Device or Drug: The CardioMEMS HF System provides pulmonary artery (PA) pressure data using a wireless sensor. Pulmonary artery pressure monitoring is used in the management of heart failure. Changes in PA pressure can be used along with signs and symptoms of heart failure to adjust medications. The System utilizes radiofrequency energy to power the sensor and to measure PA pressure. The system consists of three components: (1) Implantable Sensor with Delivery Catheter; (2) Patient Electronics Unit; and (3) Pulmonary Artery Pressure Database

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1. Technology Name:

Transcatheter mitral valve repair (TMVR)

2. Manufacturer Name:

Abbott Vascular

3. Trade Brand of Technology:

MitraClip®

4. Brief Description of Service, Device or Drug:

The MitraClip System is a first-of-a-kind transcatheter mitral valve repair system designed to perform reconstruction of the insufficient mitral valve while the heart is beating as an alternative to the conventional surgical approach. The MitraClip System includes the Steerable Guide Catheter and the MitraClip Clip Delivery System which includes the MitraClip device implant. The MitraClip procedure is a transcatheter intervention based on the double-orifice surgical repair technique where access to the left atrium from the femoral vein is achieved using transseptal techniques and devices. Fluoroscopic and echocardiographic guidance is used throughout the procedure to visualize the devices and the vasculature and cardiac anatomy. The MitraClip System enables placement of the device implant on the mitral valve leaflets resulting in permanent leaflet approximation and a double mitral valve orifice. If placement of one MitraClip implant does not result in an acceptable reduction in MR, a second MitraClip implant may be placed to further reduce MR.

The FDA labeled indication is as follows:

"The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation."

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1. Technology Name: Responsive Neurostimulation

2. Manufacturer Name: NeuroPace, Inc.

3. Trade Brand of Technology: RNS® System

4. Brief Description of Service, Device or Drug:

The RNS System is an implantable medical device developed by NeuroPace for treating persons with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The RNS System is the first closed loop, responsive brain stimulation system. The device delivers responsive neurostimulation directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain electrical activity through one or two leads containing electrodes that are placed near the patient's seizure focus/foci. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical stimulation through the leads to interrupt those patterns before an individual experiences seizures. Stimulation is delivered only when abnormal electrical activity is detected. The typical patient is treated with a total of about five minutes of stimulation a day.

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1. Technology Name: **Endovascular suturing system.**

2. Manufacturer Name: **Aptus Endosystems, Inc., Sunnyvale, CA.**

3. Trade Brand of Technology: **Heli-FX™ EndoAnchor System**

4. Brief Description of Service, Device or Drug:

The Heli-FX EndoAnchor System is a mechanical fastening device that is designed to enhance the long-term durability and reduce the risk of repeat interventions in endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR). By deploying small helical screws (EndoAnchors™) to connect the graft to the aorta, the Heli-FX system seeks to provide a permanent seal and fixation, similar to the stability achieved with an open surgical anastomosis.

The Heli-FX EndoAnchor System can be used during primary EVAR and TEVAR procedures to enhance an endograft's inherent fixation and sealing mechanisms. It can also be used to repair endovascular grafts that have developed endoleaks, migrated away from the implant site, or are at risk of developing these complications, which are often seen after EVAR and TEVAR.

The Heli-FX System may be used in conjunction with the endovascular grafts from various manufacturers to provide fixation and sealing between the grafts and the native artery.

The Heli-FX EndoAnchor procedure has its own distinct beginning, middle and end from that of the endovascular graft procedure. The Heli-FX system requires the use of components that are separate and distinct from the components used to implant endovascular grafts.

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Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2015

1. Technology Name: **Dalbavancin, an intravenous (IV) antibiotic.**

2. Manufacturer Name: **Durata Therapeutics, Inc.**

3. Trade Brand of Technology: **The proposed trade/brand name of the new technology is: Dalvance.**

4. Brief Description of Service, Device or Drug:

Dalbavancin is a new intravenous (IV) lipoglycopeptide antibiotic administered as a once-weekly 30 minute infusion via a peripheral line for the treatment of patients with acute bacterial skin and skin structure infections, or ABSSSI. Dalbavancin's unique pharmacokinetic profile demonstrates rapid bactericidal activity that is potent and sustained against serious Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA). Dalbavancin's once-weekly dosing, a simpler regimen than the current standard of care of daily or multiple-times daily intravenous dosing, allows for the discontinuation of IV access with its attendant risks of line-related thrombosis and infection.

Dalbavancin's mechanism of action involves the interruption of cell wall synthesis resulting in bacterial cell death. In vitro and in vivo nonclinical microbiology and pharmacology data provide evidence for the potential therapeutic usefulness of dalbavancin in the treatment of clinical infections caused by gram-positive bacteria, including MRSA. The feature that differentiates dalbavancin from existing antibacterial agents active against MRSA is its long half-life, which allows use of a once-weekly treatment regimen; a complete course of therapy consists of single doses of dalbavancin administered on Day 1 and Day 8.