Tracking Form for Blinatumomab for New Technology Add-On Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2016

1. Technology Name:
   Blinatumomab

2. Manufacturer Name:
   Amgen Inc.

3. Trade Brand of Technology:
   The brand name of the new technology is yet to be determined. Once the brand name is determined, we will notify CMS.

4. Brief Description of Service, Device or Drug:
   Blinatumomab is in a new class of molecular constructs called bi-specific T-cell engagers (BiTE®). This BiTE® antibody represents an innovative immunotherapy approach for fighting cancer by helping the body's immune system to detect and target cancer cells. BiTE® constructs are designed to selectively attach to a molecule on the tumor cell surface and to a molecule on the surface of normal T-cells. By attaching to both the tumor and the T-cell and bringing the two into close proximity, the T-cells are able to fight the tumor cell.

   Blinatumomab, which is the first and most advanced BiTE®, targets cells expressing CD19, a protein which is present on B-cell derived leukemias and lymphomas. Blinatumomab helps T-cells target CD19 bearing tumor cells, with the intent of allowing T-cells to kill the cancer cell. Blinatumomab is an investigational anti-cancer immunotherapy that has shown efficacy in patients with Philadelphia-negative (Ph-) relapsed/refractory (R/R) B-precursor acute lymphoblastic leukemia (ALL) who have failed chemotherapy.

   A Biologics License Application for blinatumomab is under review by the U.S. Food and Drug Administration (FDA) for the treatment of adults with Ph- R/R B-precursor ALL, a rare aggressive cancer of the blood and bone marrow. Blinatumomab has been granted Orphan Drug Designation, Breakthrough Therapy Designation, and Priority Review by the FDA.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage--.

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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) 2016

1. Technology Name: AngelMed Guardian

2. Manufacturer Name: Angel Medical Systems, Inc

3. Trade Brand of Technology: Angel Medical Guardian ischemic monitoring device

4. Brief Description of Service, Device or Drug: The AngelMed Guardian® implantable ischemia detection system (Angel Medical Systems, Shrewsbury, NJ) is designed to provide early detection and patient alerting for ischemic and other cardiac events in ambulatory patients. An implantable device monitors the intracardiac electrogram (ICEG) signal, from the tip of a steroid-eluting pacemaker-lead placed at the right ventricle apex. The implantable device monitors the ST-segment of the sensed ICEG to detect and alert patients to excessive ST-segment shift events. The algorithm computes the ST-segment shift of each beat compared to average baseline ST-segment levels sampled across the prior 24 hours and normalizes this as a percent of the baseline average R-wave height to derive a measure of ST-Shift%. Both positive and negative ischemia detection thresholds are defined for ST-Shift%. Low, high, and irregular heart rates are also detected by the Guardian.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.--.

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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) 2016

1. Technology Name: isavuconazole
2. Manufacturer Name: Astellas Pharma
3. Trade Brand of Technology: CRESEMBIA
4. Brief Description of Service, Device or Drug:

CRESEMBIA® (isavuconazole) is an intravenous and oral broad-spectrum antifungal for the treatment of severe invasive and life-threatening fungal infections, including invasive aspergillosis and mucormycosis (zygomycosis).

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage—.

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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) 2016

1. Technology Name:
   Drug Coated Balloon for Peripheral Angioplasty

2. Manufacturer Name:
   Medtronic, Inc.
   710 Medtronic Parkway
   Minneapolis, MN 55432
   USA

3. Trade Brand of Technology:
   The IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

4. Brief Description of Service, Device or Drug:

   The IN.PACT Admiral Drug Coated Balloon is a device-drug combination product comprised of a device component (an over-the-wire balloon catheter) and a drug component (a paclitaxel-urea coating on the balloon), intended for the treatment of peripheral arterial disease, specifically, superficial femoral and popliteal artery disease. The device is engineered for two modes of action: the primary mode of action is attributable to the balloon’s mechanical dilatation of de novo or non-stented restenotic lesions in the vessel while the secondary mode of action consists of drug delivery and application of paclitaxel (the product’s Active Pharmaceutical Ingredient (API)) to the vessel wall to inhibit the restenosis normally associated with the proliferative response to the PTA procedure. The mechanical balloon dilatation restores patency of the lumen and triggers the delivery of the drug component from the balloon’s surface to augment the effectiveness of the mechanical dilatation by preventing restenosis of the vessel.

   The IN.PACT Admiral DCB is used for treatment of peripheral arterial occlusive disease, to dilate vessels that have been narrowed due to atherosclerotic disease and deliver paclitaxel medication to inhibit restenotic response. DCB are a potentially ideal treatment option combining acute restoration of vessel patency by balloon dilatation with long term maintenance of such patency through the antiproliferative drug delivered without leaving metallic implants behind and preserving anatomical sites for future treatment options including surgical bypass.

   For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.

   Note: The information provided on this tracking form will be made publicly available.
1. Technology Name: CEFTAZIDIME AVIBACTAM

2. Manufacturer Name: Actavis, Inc.

3. Trade Brand of Technology: Brand name to be announced upon approval

4. Brief Description of Service, Device or Drug:

   CEFTAZIDIME AVIBACTAM is an intravenous beta-lactam-beta-lactamase inhibitor combination antibacterial drug consisting of an anti-pseudomonal cephalosporin (ceftazidime) and a novel beta-lactamase inhibitor (avibactam). Ceftazidime is a currently-available extended spectrum cephalosporin with diminishing activity due to increasing levels of antibiotic resistance. Avibactam is a non-beta-lactam beta-lactamase inhibitor that restores and enhances the activity of ceftazidime against clinically important Class A, Class C, and some Class D beta-lactamase enzymes.

For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

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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) 2016

1. Technology Name:
   Drug-Coated Balloon PTA Catheter

2. Manufacturer Name:
   CR Bard, Inc

3. Trade Brand of Technology:
   LUTONIX® Drug-Coated Balloon PTA Catheter

4. Brief Description of Service, Device or Drug:
   The LUTONIX® DCB is a guidewire-compatible, over the wire (OTW) catheter with a paclitaxel antiproliferative coating on the balloon surface available in several working lengths. It is intended to dilate stenotic or obstructive lesions in the femoropopliteal artery to improve limb perfusion and decrease the incidence of restenosis.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage--.

Note: The information provided on this tracking form will be made publicly available.
1. Technology Name: idarucizumab

2. Manufacturer Name:
   Boehringer Ingelheim Pharmaceuticals, Inc.

3. Trade Brand of Technology:
   A trade name for idarucizumab has not yet been finalized.

4. Brief Description of Service, Device or Drug:
   Idarucizumab is a fully humanized fragment antigen binding (Fab) molecule directed specifically against dabigatran. Each idarucizumab dose is 5 grams, administered intravenously as two 2.5 gram injections within a period of 15 minutes.

   Idarucizumab is being developed as a specific antidote to dabigatran, an anticoagulant which works by directly inhibiting thrombin, thereby blocking the final step of the coagulation cascade. Adverse effects of anticoagulant therapy may include bleeding, which in some cases can be life-threatening or fatal. Furthermore, some emergent medical and surgical procedures require rapid reversal of anticoagulants to safely perform the procedure in a timely manner. Idarucizumab specifically binds to dabigatran, thereby inactivating it, and allowing thrombin to act in blood clot formation.

   Idarucizumab represents a new pharmacologic approach to neutralizing the anticoagulant effect of dabigatran. Idarucizumab has been studied in animal models as well as healthy human volunteers, during which idarucizumab infusion led to immediate, complete, and sustained reversal of dabigatran anticoagulant activity.

   Boehringer Ingelheim plans to submit a new drug application (NDA) for idarucizumab to the FDA in 2015. If approved, it is expected to be the only FDA approved therapy to neutralize the anticoagulant effect of dabigatran.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.--.

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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) 2016

1. **Technology Name:**
   Orbital atherectomy

2. **Manufacturer Name:**
   Cardiovascular Systems, Inc.

3. **Trade Brand of Technology:**
   DIAMONDBACK 360® Coronary Orbital Atherectomy System (OAS)

4. **Brief Description of Service, Device or Drug:**
   The Cardiovascular Systems, Inc. (CSI) DIAMONDBACK 360® Coronary Orbital Atherectomy System (OAS) is a catheter-based system designed for facilitating stent delivery in patients with coronary artery disease who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to de novo, severely calcified coronary artery lesions. The OAS consists of the hand-held CSI DIAMONDBACK 360® Coronary Orbital Atherectomy Device (OAD), the CSI Saline Infusion Pump (OAS pump), the CSI VIPERWIRE Advance Coronary Guide Wire (VIPERWIRE guide wire), and the CSI VIPERSLIDE Lubricant. All of the components are required in order to use the OAS. The OAS reduces occlusive material (i.e., coronary plaque) and restores luminal patency to facilitate stent delivery.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage--.

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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) 2016

1. Technology Name: VERASENSE™ Knee Balancer System

2. Manufacturer Name:

   OrthoSensor, Inc.
   1855 Griffin Road  Suite A-310
   Dania Beach, FL 33323

3. Trade Brand of Technology: VERASENSE™ Knee Balancer System

4. Brief Description of Service, Device or Drug:

The VERASENSE™ Knee Balancer System is a sterile, single patient use device for intraoperatively providing a means to dynamically balance the knee during total knee arthroplasty (TKA). Quantitative metrics, through real time wireless information viewed on a monitor, are used to provide improved soft tissue stability during TKA. The VERASENSE™ device includes an intelligent tibial trial insert composed of an array of responsive sensors delivering quantified kinetic balance data to the surgeon. The quantitative data enables evidence based decisions regarding tissue dissection during TKA resulting in a more stable outcome.

The VERASENSE™ device combines dual sensor elements, coupled with micro-processing technology, to accurately depict intra-articular kinetics and contact point location within the knee. The intelligent tibial trial insert is carefully placed by the surgeon in the knee capsule. Proper placement does not require any force or infiltration of the bony or soft tissue of the knee. The VERASENSE™ device uses robust wireless communication protocols that overcome line-of-sight or other interference issues, therefore it does not require line of sight or direct antenna based tracking during the TKA.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

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1. Technology Name: WATCHMAN® Left Atrial Appendage (LAA) Closure Technology

2. Manufacturer Name: by Boston Scientific Corporation

3. Trade Brand of Technology: WATCHMAN®

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.

For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage--.

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