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CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2017

1. Technology Name: Titan Spine Endoskeleton® nanoLOCK™ Interbody Device

2. Manufacturer Name: Titan Spine

3. Trade Brand of Technology: Titan Spine Endoskeleton® nanoLOCK™

4. Brief Description of Service, Device or Drug:

   The nanoLOCK™ is a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system to treat patients with degenerative disc disease. One of the key distinguishing features is the surface manufacturing technique and materials which produce macro, micro, and nano surface textures. The unique combination of surface topographies enable initial implant fixation, mimic an osteoclastic pit for bone growth, and especially produce the nano-scale features that interface with the integrins on the outside of the cellular membrane. These generate better osteogenic and angiogenic responses that enhance bone growth, fusion and stability. nanoLOCK™'s clinical features also reduce pain, improve recovery time, lower rates of device complications such as debris and inflammation.

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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) 2017

1. Technology Name: defibrotide

2. Manufacturer Name: Jazz Pharmaceuticals, Inc.

3. Trade Brand of Technology: Defitelio®. The trade brand name of Defitelio for defibrotide has been conditionally approved by the United States (US) Food and Drug Administration (FDA) and is subject to FDA confirmation in connection with approval of the New Drug Application (NDA).

4. Brief Description of Service, Device or Drug: If approved by the FDA, Defitelio will be the first and only approved treatment for patients in the US with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with evidence of multi-organ dysfunction following hematopoietic stem-cell transplantation (HSCT). Defibrotide has been granted Orphan Drug Designation for the treatment of VOD (2003) and for prevention of VOD (2007).

   Defibrotide is the sodium salt of a highly complex, polydisperse mixture of predominantly single-stranded polydeoxyribonucleotides, having a mean weighted molecular weight of 13-20 kDa. Defibrotide is prepared by controlled depolymerization of DNA isolated from swine intestinal mucosa using a particular combination of physico-chemical conditions. Critical factors in the pathophysiology of VOD include endothelial cell damage, which is triggered by cytotoxic chemotherapy regimens, and results in a prothrombotic-hypofibrinolytic state. While the mechanism of action has not been fully elucidated, preclinical data suggest that defibrotide stabilizes endothelial cells by reducing endothelial cell activation and by protecting endothelial cells from further damage, resulting in the restoration of thrombo-fibrinolytic balance. *In vitro*, defibrotide has been shown to increase tissue plasminogen activator (t-PA) and thrombomodulin expression, and to decrease *von Willebrand factor* (vWF) and *plasminogen activator inhibitor-1 (*PAI-1) expression, thereby reducing endothelial cell activation and increasing endothelial cell-mediated fibrinolysis. Defibrotide has also been shown to bind to the plasma membrane of endothelial cells, protecting them from damage caused by chemotherapy, tumor necrosis factor-α (TNF-α), serum starvation, and perfusion. *In vitro*, defibrotide has a direct effect in enhancing the enzymatic activity of plasmin, hydrolyzing fibrin clots to soluble fibrin degradation products.

   The NDA for Defitelio is under Priority Review by the FDA. Based on the timelines established by the PDUFA (Prescription Drug User Fee Act), the User Fee goal date is March 31, 2016. An ICD-10-PCS application has been submitted requesting a unique code to identify Defitelio as a new technology for NTAP purposes.

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:

Non-invasive, adjustable remote controlled implants for use in spinal and orthopedic applications

2. Manufacturer Name:

Ellipse Technologies, Inc.

3. Trade Brand of Technology:

MAGEC® Spinal Bracing and Distraction System

4. Brief Description of Service, Device or Drug:

Ellipse has developed the MAGEC® (MAGnetic Expansion Control) System for use in children with severe spinal deformities. The MAGEC® System is composed of an implantable rod, the External Remote Controller (ERC) and accessories. The implanted MAGEC® spinal rod is used to brace the spine during growth to minimize the progression of scoliosis. It is secured using standard commercially available fixation components, such as laminar hooks and/or pedicle screws. The MAGEC® rods are available in 4.5 mm and 5.5 mm diameters.

After the MAGEC® rod has been implanted, the ERC is placed externally over the patient's spine at the location of the magnet in the MAGEC® rod. Periodic, non-invasive distraction of the rod is performed to lengthen the spine and to provide adequate bracing during growth. Routine X-ray or ultrasound is used to confirm the position and amount of distraction. The frequency of distraction sessions is customized to the needs of the patient by the treating surgeon.

For the complete application requirements, please see the instructions at
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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) 2017

1. Technology Name:

   XVIVO Perfusion System (XPS™)

2. Manufacturer Name:

   XVIVO Perfusion AB (Sweden)
   XVIVO, Perfusion, Inc. (US Distributor, Englewood, CO)

3. Trade Brand of Technology:

   XPS™ with STEEN Solution™

4. Brief Description of Service, Device or Drug:

   The XVIVO Perfusion System transforms marginal donor lungs (those unsuitable for transplant) into viable transplantable organs through a warming and perfusion technique thereby increasing the number of lungs available for transplant, and improving the early and late outcome after transplantation.

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) 2017

1. **Technology Name:**

   Andexanet Alfa

2. **Manufacturer Name:**

   Portola Pharmaceuticals Inc.

3. **Trade Brand of Technology:**

   The international non-proprietary name of the new technology is Andexanet Alfa

4. **Brief Description of Service, Device or Drug:**

   Andexanet Alfa is a recombinant, modified, and truncated human Factor Xa protein. It is being developed as a direct antidote for both Factor Xa inhibitors (e.g., rivaroxaban, apixaban, and edoxaban) and indirect Factor Xa inhibitors (e.g., enoxaparin and fondaparinux). Andexanet Alfa is expected to be the first and only antidote available to treat patients receiving an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation.

   A Biologics License Application for Andexanet Alfa will be submitted for review by the U.S. Food and Drug Administration (FDA) in November 2015. Andexanet Alfa has been granted Orphan Drug Designation, Breakthrough Therapy Designation, and will undergo Priority Review by the FDA.

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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) 2017

1. Technology Name: **Endovascular Repair of Common Iliac Artery Aneurysm with Preservation of Internal and External Iliac Artery Flow**

2. Manufacturer Name: **W.L. Gore and Associates, Inc.**

3. Trade Brand of Technology: **GORE® EXCLUDER® Iliac Branch Endoprosthesis**

4. Brief Description of Service, Device or Drug: **The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is a modular two component endoprosthesis implant system (stent-graft). Each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. The IBE Device is designed to be used in conjunction with the current GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE Device excludes the common iliac aneurysm from systemic blood flow while preserving blood flow in the external iliac (perfusing the lower limb) and internal iliac arteries (perfusing pelvic organs, musculature and nerves).**

   This will be the first approved, purpose-built endovascular device for patients whose conditions (common iliac or aortoiliac aneurysm) put them at risk for negative clinical outcomes due to limitations of current treatment methods which may not preserve internal iliac artery perfusion. Current repair options for these patients include intentional occlusion and coverage of the internal iliac artery, undergoing a more extensive surgical operation to place a bypass graft, or the use of combinations of devices in a non-indicated, variable, and inconsistent manner.

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) 2017

1. Technology Name: **EDWARDS INTUITY Elite™ Valve System**
2. Manufacturer Name: **Edwards Lifesciences**
3. Trade Brand of Technology: **EDWARDS INTUITY Elite™ Valve System**
4. Brief Description of Service, Device or Drug: **Bovine Aortic Pericardial Bio-Prosthetic Heart Valve (Rapid Deployment Valve System)**

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) 2017

1. Technology Name:

   Idarucizumab

2. Manufacturer Name:

   Boehringer Ingelheim

3. Trade Brand of Technology:

   Praxbind®

4. Brief Description of Service, Device or Drug:

   Praxbind® (Idarucizumab) is a humanized monoclonal antibody fragment (Fab) molecule which binds directly to and reverses the anticoagulant effect of PRADAXA® (dabigatran etexilate mesylate). PRADAXA® is an oral direct thrombin inhibitor indicated: (1) to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation; (2) for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5-10 days; and (3) to reduce the risk of recurrence of DVT and PE in patients who have been previously treated. Idarucizumab is the only FDA approved therapy indicated in patients treated with PRADAXA® when reversal of the anticoagulant effects of dabigatran is needed: (1) for emergency surgery/urgent procedures; (2) in life-threatening or uncontrolled bleeding. Each Praxbind® dose is 5 grams given as two 2.5 gram bolus intravenous injections or consecutive infusions.

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) 2017

1. Technology Name: MIRODERM Biologic Wound Matrix

2. Manufacturer Name: Miromatrix Medical, Inc.

3. Trade Brand of Technology: MIRODERM – a bioengineered skin substitute

4. Brief Description of Service, Device or Drug:

   MIRODERM Biologic Wound Matrix is a new non-crosslinked acellular wound matrix that is derived from the porcine liver and is processed and stored in a phosphate buffered aqueous solution. MIRODERM is the result of a patented Perfusion Decellularization process that rapidly removes cellular material while maintaining the native architecture, vasculature and tissue structure. Following decellularization, MIRODERM is isolated from partial thickness liver sections following slight compression of the liver. This allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The partial thickness allows for one surface of MIRODERM to retain the native liver capsule (an epithelial basement membrane) and the other opposite surface to be comprised of open liver matrix.

   MIRODERM is the only acellular skin substitute product that is derived from liver, keeping intact the high vascular density of the native liver. Other acellular biologic wound substitute products are derived from dermis, urinary bladder, or small intestine submucosa, all of which are thin, dense and relatively avascular tissue compared to the open and highly vascularized substrate present in the liver.

   Miromatrix' perfusion decellularization technology has enabled the decellularization of whole organs previously unobtainable by immersion decellularization, where tissues are immersed in a decellularization solution which is diffusion based thus limiting the ability to fully decellularize thick, complex tissues such as the liver. Miromatrix' perfusion decellularization overcomes these hurdles by facilitating rapid access to the whole organ through the native vasculature by cannulating the vasculature and perfusing (running) a mild detergent solution through the native blood vessels, as opposed to immersing a tissue. Because organs are dense with vascular capillaries, most cells are located in close proximity to a capillary, resulting in an exponential increase in the effective surface area of the detergent and decreased time to dissolve the cellular material as it is expelled through the venous system (as opposed to through the organ wall or capsule).

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: uridine triacetate

2. Manufacturer Name: BTG International Inc. will market and sell Vistogard®™ in the United States (US). Wellstat Therapeutics Corporation is the developer and manufacturer.

3. Trade Brand of Technology: VISTOGARD. The trade brand name of VISTOGARD for uridine triacetate has been conditionally approved by the US Food and Drug Administration (FDA) and is subject to final FDA confirmation at time of approval of the VISTOGARD new drug application (NDA).

4. Brief Description of Service, Device or Drug: If approved by the FDA, VISTOGARD will be the first and only approved antidote indicated to treat patients at risk of serious toxicity following an overdose of 5-fluorouracil (5-FU) and patients exhibiting symptoms of serious toxicity within 96 hours of 5-FU administration. Uridine triacetate has been granted orphan drug designation from the FDA as an antidote in the treatment of 5-FU poisoning and from the European Medicines Agency (EMA) as a treatment for 5-FU overdose.

   VISTOGARD (uridine triacetate) oral granules is an antidote to 5-FU toxicity containing uridine triacetate. Uridine triacetate is an acetylated pro-drug of uridine. VISTOGARD provides bioavailable uridine, a direct biochemical antagonist of 5-FU toxicity. In normal cells, VISTOGARD stops the process of cell damage and cell death caused by 5-FU, and counteracts 5-FU toxicity. VISTOGARD protects normal cells and allows recovery from damage caused by 5-FU, without interfering with the primary antitumor mechanism of 5-FU. Uridine derived from VISTOGARD is converted into uridine triphosphate (UTP), which competes with FUTP for incorporation into RNA, preventing further cell death and dose-limiting toxicities. VISTOGARD delivers 4- to 7-fold more uridine into the systemic circulation compared to equimolar doses of uridine itself. Maximum concentrations of uridine in plasma following oral VISTOGARD are generally achieved within 2 to 3 hours, and the half-life ranges from approximately 2 to 2.5 hours.

   The NDA for VISTOGARD is under Priority Review by the FDA. Based on the timelines established by the PDUFA (Prescription Drug User Fee Act), the User Fee goal date is March 10, 2016. An ICD-10-PCS application has been submitted requesting a unique code to identify VISTOGARD as a new technology for NTAP purposes.

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