

**Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2014**

1. Technology Name: **Four-Factor Prothrombin Complex Concentrate (Human)(4F-PCC)**
2. Manufacturer Name: **CSL Behring**
3. Trade Brand of Technology: **The FDA has not yet approved a brand name for the product.**
4. Brief Description of Service, Device or Drug:

**4F-PCC is a replacement therapy for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. 4F-PCC contains the vitamin K-dependent coagulation factors II, VII, IX and X, together known as the prothrombin complex, and antithrombotic proteins C and S.**

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1. Technology Name: **Zilver® PTX® Drug Eluting Peripheral Stent**
2. Manufacturer Name: **Cook Medical**
3. Trade Brand of Technology: **Zilver® PTX® Drug Eluting Peripheral Stent**
4. Brief Description of Service, Device or Drug:

**The Zilver® PTX® Drug Eluting Peripheral Stent is a self-expanding vascular stent made of nitinol and coated with the drug paclitaxel. The stent is a flexible, slotted tube that is preloaded in a 6.0 or 7.0 French delivery catheter. The Zilver® PTX® stent is designed to provide support while maintaining flexibility in the vessel upon deployment. Post-deployment, the stent is designed to impart an outward radial force upon the inner lumen of the vessel, establishing patency in the stented region. The Zilver® PTX® Drug Eluting Peripheral Stent is intended for use in the treatment of symptomatic vascular disease of the above-the-knee femoropopliteal arteries (superficial femoral arteries).**

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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 system to treat partial onset seizures. Responsive electrical stimulation is delivered directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain activity through one or two electrode-containing leads that are placed at 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. Stimulation is delivered only when abnormal**

**electrocorticographic activity is detected. The typical patient is treated with a total of 5 minutes of stimulation a day.**

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1. Technology Name: **Transcatheter mitral valve repair system**
2. Manufacturer Name: **Abbott Vascular**
3. Trade Brand of Technology: **MitraClip<sup>®</sup> System**
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 procedure was designed to provide an option for treatment of patients with significant mitral regurgitation (MR). The MitraClip System includes a MitraClip device implant, a Steerable Guide Catheter and a Clip Delivery System.**

**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.**

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1. Technology Name: **Argus<sup>®</sup> II Retinal Prosthesis System**
2. Manufacturer Name: **Second Sight Medical Products Inc.**
3. Trade Brand of Technology: **Argus II System**
4. Brief Description of Service, Device or Drug:

**The Argus II System is an active implantable medical device that partially restores vision for patients that are profoundly blind due to retinitis pigmentosa. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera.**