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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) 2027

Number of Requests: 36

Technology Name

Generic Name: tabelecleucel (tab-cel)

Applicant Name: Pierre Fabre Pharmaceuticals, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Tab-cel is an allogeneic Epstein-Barr virus (EBV)-specific T-cell immunotherapy under investigation as monotherapy for treatment of adult and pediatric patients 2 years of age and older with EBV positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy including an anti-CD20 containing regimen.

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Technology Name

Trade Name: GORE® VIABAHN® Venous Stent

Applicant Name: W.L. Gore & Associates, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The GORE® VIABAHN® Venous Stent is an open-structure polymer lattice device providing intraluminal support in the Inferior Vena Cava (IVC) and, if clinically warranted, the Common Iliac Veins, at the iliocaval confluence in patients with symptomatic vessel obstruction.

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Technology Name

Generic Name: Eminent Spine 3D Pedicle System

Trade Name: Eminent Spine 3D Titanium Pedicle Screw System

Applicant Name: Dagen Hybner

Application Pathway: Traditional

Brief Description of the Technology:

The Eminent Spine 3D Titanium Pedicle consists of a fully threaded, 3D printed porous pedicle screw assembly along with instruments used to place the implant under traditional guidance or navigation support. The implant has design features for stabilization of the lumbar, thoracic, and sacral spine segments.

Technology Name

Generic Name: Peripheral Stent

Trade Name: Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System

Applicant Name: Micro Medical Solutions

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The MicroStent Peripheral Stent System is intended to improve luminal diameter in the treatment of ischemia in the lower leg.

Technology Name

Generic Name: Command Center Electronic Glycemic Management System eGMS

Trade Name: Command Center

Applicant Name: Glytec, LLC

Application Pathway: Traditional

Brief Description of the Technology:

The technology is indicated for use in adult/pediatric patients as a glycemic management tool intended to evaluate current and cumulative blood glucose values and coupled with multiple various inputs, to recommend a dosage of insulin. It is an EMR-integrated cloud based software device" that affects care delivery, and medication management.

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Technology Name

Generic Name: Etuvetidigene autotemcel

Trade Name: Waskyra

Applicant Name: Fondazione Telethon

Application Pathway: Traditional

Brief Description of the Technology:

Etuvetidigene autotemcel is a gene therapy drug product consisting of a drug substance of an autologous cluster of differentiation (CD)34+ cell-enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human Wiskott-Aldrich syndrome (WAS) gene, for the treatment of WAS.

Technology Name

Generic Name: interatrial shunt

Trade Name: Ventura lnteratrial Shunt System

Applicant Name: JNJ Medtech V-Wave, Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Ventura lnteratrial Shunt System includes the lnteratrial Shunt and delivery system. It is indicated for NYHA Class III HF patients who remain symptomatic on guideline-directed medical therapy, have a LVEF of ≤40%, and are judged by a Heart Team to be appropriate for Shunt therapy, to reduce the risk of hospitalization for heart failure.

Technology Name

Generic Name: posterior cervico-thoracic system

Trade Name: CMORE® CT System

Applicant Name: icotec ag, Industriestrasse 12, 9450 Altstaetten, Switzerland

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The CMORE® CT System will be used to stabilize the posterior cervical (C1 - C7) and upper thoracic spine (T1 - T3). CMORE® implants are manufactured from high strength carbon fiber reinforced polyether-ether-ketone (branded as BlackArmor®). The system features a variety of screw sizes and types, as well as rod shapes to accommodate patient anatomy.

Technology Name

Trade Name: Trilogy Transcatheter Aortic Valve Regurgitation System

Applicant Name: JenaValve

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The JenaValve Trilogy Heart Valve System for transcatheter aortic valve implantation differs from other available systems in that it is deployed so that the THV expands radially at the native annulus and clips onto the native aortic leaflets to anchor the THV. The THV is uniquely designed to anchor in the diseased regurgitant aortic valve.

Technology Name

Generic Name: Transcatheter mitral valve replacement

Trade Name: SAPIEN M3 Transcatheter Mitral Valve Replacement System

Applicant Name: Edwards LifeSciences LLC

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The SAPIEN M3 Transcatheter Mitral Valve Replacement System is a transcatheter mitral valve replacement (TMVR) system which is designed to allow for replacement of the native mitral valve in patients with symptomatic mitral valve regurgitation or symptomatic mitral stenosis.

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Technology Name

Generic Name: Landiolol

Trade Name: RAPIBLYK

Applicant Name: AOP Health US LLC

Application Pathway: Traditional

Brief Description of the Technology:

RAPIBLYK (landiolol) is an intravenous beta-adrenergic blocker for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter. Its uniquely rapid action and high selectivity for β1 cardio-receptors lowers heart rate with reduced side effects in critically ill patients.

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Technology Name

Generic Name: InVision Precision Cardiac Amyloid

Trade Name: InVision Precision Cardiac Amyloid

Applicant Name: Invision Medical Technology

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The InVision Precision Cardiac Amyloid (InVision PCA) is a Software as a Medical Device (SaMD) machine-learning disease detection algorithm to identify high suspicion of cardiac amyloidosis from routinely obtained echocardiogram videos. The device assists clinicians in the diagnosis of cardiac amyloidosis.

Technology Name

Generic Name: Branched Aortic Arch Stent Graft

Trade Name: NEXUS® Aortic Arch Stent Graft System

Applicant Name: ENDOSPAN

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The NEXUS Aortic Arch Stent Graft System is a branched endovascular stent graft system designed specifically for repair of aortic arch pathologies (aneurysms, chronic dissections, penetrating ulcers, intramural hematoma) involving Zone 0 (ascending aorta) and the arch.

Technology Name

Trade Name: PrismaLung

Applicant Name: Vantive Health, LLC

Application Pathway: Traditional

Brief Description of the Technology:

PrismaLung+ (PL+) is a single-use, extracorporeal carbon dioxide removal ($ECCO_2R$) medical device. It is designed to partially remove carbon dioxide (CO_2) from a patient's blood in a circuit outside the body.

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Technology Name

Generic Name: Prademagene zamikeracel

Trade Name: ZEVASKYN™

Applicant Name: Abeona Therapeutics, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

ZEVASKYN™ is an autologous cell sheet-based gene therapy for adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The full-length COL7A1 gene is transduced ex vivo into keratinocytes from patient biopsies, expanded into collagen VII–producing sheets to correct the underlying defect.

Technology Name

Generic Name: VUNO Med-DeepCARS

Trade Name: VUNO Med-DeepCARS®

Applicant Name: VUNO Med Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

DeepCARS® is an artificial intelligence (AI) based technology that monitors and assesses the risk of impending cardiac arrest within a 24-hour period among inpatients in general hospital wards.

Technology Name

Generic Name: Neuroimmune Modulation Therapy

Trade Name: SetPoint System

Applicant Name: SetPoint Medical Corporation

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The SetPoint System is a fully integrated, rechargeable, implantable vagus nerve stimulation system used to treat individuals with moderate to severe rheumatoid arthritis who have experienced a loss of efficacy, inadequate response or intolerance to one or more biologic or targeted synthetic disease modifying antirheumatic drugs (DMARDs).

Technology Name

Generic Name: Transdermal test for Assessment of Glomerular Filtration Rate (GFR)

Trade Name: MediBeacon® Transdermal GFR Measurement System (TGFR)

Applicant Name: MediBeacon

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The MediBeacon® Transdermal GFR System (TGFR) provides an assessment of GFR at the point of care and employs an intravenously administered fluorescent tracer agent which has been engineered to be excreted exclusively by the kidneys. Noninvasive transdermal fluorescence detection of the excretion rate of the agent is converted into a GFR reading

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Technology Name

Generic Name: Epicardial access system

Trade Name: ViaOne Epicardial Access System

Applicant Name: CardioVia Ltd

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The ViaOne Epicardial Access System (ViaOne) is a sterile, single use device, designed to allow safe pericardial access utilizing a proprietary mechanism of entry into the pericardial sac with a blunt tip and a concealed needle.

Technology Name

Generic Name: Peptide Enhanced Bone Void Filler

Trade Name: PearlMatrix™ P-15 Peptide Enhanced Bone Graft

Applicant Name: Cerapedics Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

PearlMatrix™ P-15 Peptide Enhanced Bone Graft is a composite bone graft material consisting of a synthetic peptide, found naturally occurring in human Type I collagen (P-15), adsorbed onto calcium phosphate particles, which are incorporated into a fibrous collagen matrix putty as an inert carrier.

Technology Name

Generic Name: N/A

Trade Name: CARA System

Applicant Name: Cara Medical

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The CARA System software simulates the path of the conduction system using anatomical landmarks identifiable on CTA imaging to enable Conduction Guided Intervention (CGI). CARA augmented fluoroscopy can be used to help the operator visualize, during the procedure, the proximity of his tools and device to the patient's conduction system.

Technology Name

Generic Name: PMcardio

Trade Name: PMcardio® STEMI AI ECG Model

Applicant Name: Powerful Medical Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The STEMI AI ECG Model is a stand-alone software device intended to analyze resting 12-lead ECGs of patients presenting with symptoms suspicious for acute coronary syndromes in the hospital setting. The technology identifies ECG patterns of STEMI/STEMI-equivalents as an adjunctive decision support tool used by healthcare professionals.

Technology Name

Generic Name: Bayesian Health Sepsis Flagging Device

Trade Name: Bayesian Health Sepsis Flagging Device

Applicant Name: Bayesian Health

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Bayesian Health Sepsis Flagging Device (previously named the Targeted Real-time Early Warning System (TREWS)) is artificial intelligence and machine learning-based SaMD intended for use in conjunction with clinical assessments and other laboratory findings to aid the early detection and/or risk prediction of sepsis within the next 4 days.

Technology Name

Generic Name: Lumenless Catheter-Delivered Integrated Bipolar Small-Diameter Defibrillation Lead

Trade Name: OmniaSecure™ MRI SureScan™ Lead Model 3930M

Applicant Name: Medtronic

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Medtronic's OmniaSecure™ defibrillation lead is an implantable defibrillation lead designed to deliver pacing, sensing, cardioversion, and defibrillation therapy for patients at risk of life-threatening ventricular arrhythmias. It differs from other defibrillation leads via its small diameter and high projected reliability.

Technology Name

Generic Name: clemidsogene lanparvovec-sngl

Trade Name: NAVSUNLI

Applicant Name: NS Pharma

Application Pathway: Traditional

Brief Description of the Technology:

NAVSUNLI (clemidsogene lanparvovec-sngl) is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of patients with mucopolysaccharidosis type II (MPS II; Hunter syndrome).

Technology Name

Generic Name: Filler, recombinant human bone morphogenetic protein, collagen scaffold, Osteoinduction

Trade Name: Infuse(TM) Bone Graft

Applicant Name: Medtronic Sofamor Danek USA, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Infuse™ Bone Graft is a bone graft material designed to promote bone formation at the site of implantation. It consists of two primary components, Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) and an Absorbable Collagen Sponge which serves as a delivery matrix and scaffold for bone growth.

Technology Name

Generic Name: Orca-T (generic name not yet established)

Applicant Name: Orca Bio

Application Pathway: Traditional

Brief Description of the Technology:

Orca-T is an allogeneic stem cell and T-cell immunotherapy under evaluation for the curative treatment of multiple hematologic malignancies. A single dose is composed of cellular infusions of highly purified regulatory T-cells, hematopoetic stem cells and conventional T-cells sourced from the peripheral blood of an 8/8 HLA-matched donor.

Technology Name

Generic Name: Xanomeline and Trospium Chloride

Trade Name: COBENFY

Applicant Name: Bristol Myers Squibb

Application Pathway: Traditional

Brief Description of the Technology:

COBENFY is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. It was approved under a New Drug Application.

Technology Name

Generic Name: Peripheral Temporary and Retrievable Stent System

Trade Name: Spur Peripheral Retrievable Stent System

Applicant Name: Reflow Medical, Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Spur® Peripheral Retrievable Stent System is intended as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm.

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Technology Name

Generic Name: N/A

Trade Name: BriefCase-Triage CARE Multi-triage CT Body

Applicant Name: Aidoc Medical Ltd., Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

BriefCase-Triage: CARE Multi-Triage CT Body is a single-model, 11-clinical indication radiological triage device. Its purpose is to flag and communicate suspected positive findings for a wide range of clinically actionable, time-sensitive conditions in the abdominopelvic region.

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Technology Name

Trade Name: XT3 System

Applicant Name: Biodynamik, Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Biodynamik XT3 System is an automated osteodistraction system for performing transverse bone distraction procedure to trigger angiogenesis and improve perfusion for healing and limb salvage of ischemic chronic wounds.

Technology Name

Generic Name: Not applicable

Trade Name: Nelli Seizure Monitoring System

Applicant Name: Neuro Event Labs

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Nelli is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component.

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Technology Name

Generic Name: emapalumab-lzsg

Trade Name: GAMIFANT

Applicant Name: Sobi, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

GAMIFANT® (emapalumab-lzsg) is now approved for the treatment of adult and pediatric patients with hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS

Technology Name

Generic Name: Ceribell Delirium Monitor System

Trade Name: Ceribell Delirium Monitor System

Applicant Name: Ceribell, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Ceribell Delirium Monitor System is a medical device system comprised of proprietary software, signal acquisition headbands and a recorder. The software utilizes a machine learning model to analyze EEG signals to detect features indicative of delirium in order to provide more effective diagnosis of delirium.

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Technology Name

Generic Name: narsoplimab-wuug

Trade Name: none

Applicant Name: Omeros Corporation

Application Pathway: Traditional

Brief Description of the Technology:

Narsoplimab is a fully human monoclonal antibody targeting MASP-2, the effector enzyme of the lectin pathway of complement. By inhibiting MASP-2, narsoplimab blocks lectin pathway activation, preventing inflammation and providing anticoagulant effects, while preserving the functions of the complement system's classical and alternative pathways.

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Technology Name

Trade Name: CERAMENT® V

Applicant Name: BONESUPPORT Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

CERAMENT V is a resorbable, vancomycin-eluting ceramic bone graft substitute intended for use as a bone void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis. CERAMENT V is indicated for use on vancomycin-sensitive microorganisms.

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