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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) 2025

Number of Requests: 39

Technology Name

Generic Name: odronextamab

Applicant Name: Regeneron Pharmaceuticals, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Odronextamab is the first and only novel, fully human CD20xCD3 bispecific antibody with an IgG4-based structure in B-cell non-Hodgkin lymphoma (B-NHL) created using Regeneron's proprietary Veloci-Bi® technology for the treatment of adults with relapsed or refractory follicular lymphoma, pending Food and Drug Administration approval.

Note: The information on this tracking form was provided by the applicant at the time of application submission.

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Technology Name

Generic Name: Annalise Enterprise CTB Triage - OH

Trade Name: Annalise Enterprise CTB Triage - OH

Applicant Name: Annalise-Ai Pty 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:

This device is an FDA-cleared device used to aid in triage and prioritization of studies with features suggestive of obstructive hydrocephalus (OH). The device analyzes studies using an AI algorithm to identify findings and make study-level output available to an order and imaging management system for worklist prioritization or triage.

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Technology Name

Generic Name: Quicktome Neurological Visualization and Planning Tool

Trade Name: Quicktome Software Suite

Applicant Name: Omniscient Neurotechnology

Application Pathway: Traditional

Brief Description of the Technology:

The Quicktome Software Suite provides AI-enabled visualization and analysis of the human connectome and brain networks, leveraging diffusion-weighted MRI and/or resting-state fMRI scans.

Technology Name

Generic Name: Pulsed Field Ablation (PFA) Loop Catheter

Trade Name: PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter

Applicant Name: Medtronic, 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 PulseSelect™ catheter is used to treat atrial fibrillation by pulmonary vein isolation by pulsed field ablation (PFA). PFA uses non-thermal electrical impulses to destroy selected cardiac tissue by irreversibly increasing the permeability of the cell membranes, inducing cell death.

Technology Name

Generic Name: Paradise Ultrasound Renal Denervation System

Trade Name: Paradise™ Ultrasound Renal Denervation System

Applicant Name: ReCor 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 system uses a minimally invasive procedure to lower blood pressure by treating overactive renal nerves with ultrasound energy. The system is indicated to reduce blood pressure in adult (≥22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications.

Technology Name

Trade Name: Symplicity Spyral(TM) Multi-Electrode Renal Denervation Catheter

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:

The Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter, when used with Symplicity G3™ Generator, supplies targeted radiofrequency (RF) energy to the renal nerves, safely disrupting overactive sympathetic signaling between the kidneys and brain, delivering clinically significant, safe, and sustained blood pressure reductions.

Technology Name

Generic Name: Thoracoabdominal branch endoprosthesis device

Trade Name: GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)

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:

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) is used for endovascular repair in patients with Type IV thoracoabdominal aortic aneurysms (TAAA) and high-surgical risk patients with pararenal abdominal aortic aneurysms (PAAA) who have appropriate anatomy. The TAMBE Device is comprised of multiple required components.

Technology Name

Generic Name: lovotibeglogene autotemcel (lovo-cel)

Applicant Name: bluebird bio, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Lovo-cel is an investigational, one-time autologous gene therapy for treatment of patients 12-years old or older with sickle cell disease and a history of vaso-occlusive events. Lovo-cel adds functional copies of a modified form of the β-globin gene to durably produce anti-sickling adult hemoglobin and fundamentally impact SCD at the genetic level.

Technology Name

Generic Name: Transcatheter Tricuspid Valve Replacement System

Trade Name: Edwards EVOQUE Tricuspid 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 Edwards EVOQUE tricuspid valve replacement system ("EVOQUE system") is designed to replace the native tricuspid valve utilizing a bioprosthetic valve that is inserted using a catheter-based technology.

Technology Name

Generic Name: Drug-eluting percutaneous transluminal coronary angioplasty catheter

Trade Name: AGENT™ Paclitaxel-Coated Balloon Catheter, henceforth referred to as AGENT, AGENT Drug-Coated Balloon (DCB), or the AGENT device

Applicant Name: Boston Scientific 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 AGENT Paclitaxel-Coated Balloon Catheter is a semi-compliant percutaneous coronary intervention (PCI) catheter; the balloon portion of the device is coated with a TransPax coating. The AGENT Drug Coated Balloon is designed to inhibit restenosis by delivering the drug, paclitaxel, to the diseased coronary arterial tissue.

Technology Name

Generic Name: aztreonam-avibactam

Trade Name: TBD

Applicant Name: Manufacturer

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:

Aztreonam-avibactam (ATM-AVI) is an investigational treatment for infections caused by Gram-negative bacteria with limited treatment options. It combines aztreonam, a monobactam β-lactam, with avibactam, a recent broad-spectrum β-lactamase inhibitor.

Technology Name

Generic Name: Transdermal GFR Measurement System utilizing Relmapirazin

Trade Name: Transdermal GFR Measurement System utilizing Lumitrace (Needs FDA confirmation)

Applicant Name: MediBeacon, 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 Transdermal Glomerular Filtration Rate (TGFR) Measurement System is a three-component system: (1) an optical skin sensor, (2) a monitor and (3) Lumitrace (relmapirazin), a proprietary fluorescent tracer agent removed from the blood exclusively by the GFR mechanism of the kidney.

Technology Name

Generic Name: lifileucel

Applicant Name: Iovance Biotherapeutics, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Lifileucel is an investigational one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy with the proposed indication for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

Technology Name

Generic Name: Vascular Conduit Solution

Trade Name: DuraGraft

Applicant Name: Marizyme, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

DuraGraft is a first-in-class product used during coronary artery bypass grafting surgery (CABG) to protect the vascular endothelium of harvested vascular grafts during the ischemic graft storage interval.

Technology Name

Generic Name: LimFlow System

Trade Name: LimFlow System

Applicant Name: LimFlow Inc. (Manufacturer)

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 LimFlow System is a single-use, medical device system designed to treat patients who have chronic limb-threatening ischemia (CLTI) with no suitable endovascular or surgical revascularization options and are at risk of major amputation The LimFlow System received Breakthrough Device Designation from the FDA on October 3, 2017.

Technology Name

Generic Name: Tricuspid Transcatheter Edge-to-Edge Repair

Trade Name: TriClip ™ G4

Applicant Name: Abbott

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 TriClip System is intended for reconstruction of the insufficient tricuspid valve through tissue approximation via a transcatheter approach. The TriClip Implant is a percutaneously delivered mechanical implant that helps close the tricuspid valve leaflets resulting in fixed tricuspid leaflets approximation throughout the cardiac cycle.

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Technology Name

Generic Name: Ankle fusion cage

Trade Name: restor3d TIDAL Fusion Cage

Applicant Name: restor3d

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 restor3d TIDAL Fusion Cage can be used to aid in healing for fractures, bone voids, absent bone or surgical resections in conjunction with an intramedullary nail for TTC fusion. The restor3d TIDAL Fusion cages also serve to support and contain bone graft materials which aid in arthrodesis.

Technology Name

Generic Name: Taurolidine/Heparin Taurolidine (13.5 mg mL) and Heparin (1000 USP U mL)

Trade Name: DefenCath

Applicant Name: CorMedix (manufacturer)

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:

DefenCath™ is a proprietary formulation of taurolidine and heparin that is under development for use as a catheter lock solution, with the aim of reducing the risk of bloodstream infections from in-dwelling catheters in patients undergoing hemodialysis.

Technology Name

Generic Name: Venous External Support

Trade Name: VEST

Applicant Name: Vascular Graft Solutions (VGS)

Application Pathway: Traditional

Brief Description of the Technology:

An external support device fitted over the saphenous vein graft bypass conduit in CABG surgery. It prevents common vein graft failures as a result of graft kinking and intimal hyperplasia, which improves outcomes of CABG by reducing clinical events such as coronary re-intervention (PCI or re-do CABG), and MACCE, including MI, angina, and death.

Technology Name

Generic Name: Marnetegragene autotemcel

Trade Name: TBD - the new technology is referenced as RP-L201 for purposes of this application

Applicant Name: Rocket Pharmaceuticals, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

RP-L201 will be the first autologous hematopoietic stem cell (HSC)-based gene therapy for the treatment of severe Leukocyte Adhesion Deficiency-Type I (severe LAD-I) – a rare, hereditary, immunodeficiency disorder.

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Technology Name

Generic Name: Iloprost injection

Trade Name: AURLUMYN

Applicant Name: Eicos Sciences

Application Pathway: Traditional

Brief Description of the Technology:

AURLUMYN is a sterile solution of iloprost formulated for intravenous administration for the treatment of severe frostbite to reduce the risk of digit amputation.

Note: The information on this tracking form was provided by the applicant at the time of application submission.

Technology Name

Generic Name: VITEK REVEAL AST System

Trade Name: VITEK® REVEAL™ AST System

Applicant Name: bioMerieux

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 system is an in vitro diagnostic automated system for the quantitative antimicrobial susceptibility testing of organisms from positive blood culture. Test results from the system are intended to be used in conjunction with Gram stain, organism identification and other clinical laboratory findings to inform antibiotic therapy treatment decisions

Technology Name

Generic Name: Donislecel-jujn (Allogeneic Pancreatic Islet Cellular Suspension for hepatic portal vein infusion)

Trade Name: Lantidra

Applicant Name: CellTrans Inc.

Application Pathway: Traditional

Brief Description of the Technology:

LANTIDRA is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Lantidra is used in conjunction with concomitant immunosuppression.

Technology Name

Generic Name: ASTar System

Trade Name: ASTar System

Applicant Name: Q-linea

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 ASTar® System is a new, fully automated system for rapid antimicrobial susceptibility testing (AST). The proprietary AST technology is based on broth microdilution (BMD), optimized for high sensitivity and short time-to-result, delivering phenotypic AST with true minimum inhibitory concentration (MIC) results in approximately six hours.

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Technology Name

Generic Name: Pedicle Screw System

Trade Name: VADER® Pedicle System

Applicant Name: Icotec 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 VADER Pedicle System is a pedicle screw system, made from high strength carbon fiber reinforced polyether ether ketone which provides low artifact imaging (in MRI, CT, etc.). The device is approved for stabilizing the thoracic and/or lumbar spinal column in tumor patients and is seeking an expanded indication for use in spinal infections.

Technology Name

Generic Name: ceftobiprole medocaril

Trade Name: ZEVTERA

Applicant Name: Basilea Pharmaceutica International Ltd, Allschwil

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:

ZEVTERA (ceftobiprole medocaril) is an advanced generation intravenous bactericidal cephalosporin antibiotic for challenging infections that are caused by Gram positive bacteria such as Staphylococcus aureus, including MRSA, Streptococcus pneumoniae, including PNSP and Enterococcus faecalis, as well as non-ESBL producing Enterobacterales

Technology Name

Generic Name: cefepime-taniborbactam, for infusion, intravenous use

Applicant Name: Venatorx Pharmaceuticals, 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:

Cefepime-taniborbactam is an investigational β-lactam antibiotic/β-lactamase inhibitor combination under development for the treatment of complicated urinary tract infections, including pyelonephritis, melioidosis, and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia, pending Food and Drug Administration approval.

Technology Name

Generic Name: talquetamab-tgvs

Trade Name: TALVEY

Applicant Name: Johnson & Johnson Health Care Systems, INC

Application Pathway: Traditional

Brief Description of the Technology:

TALVEY is the first and only approved medicine targeting GPRC5D. TALVEY is a bispecific T-cell engaging antibody binding to CD3 expressed on the surface of T-cells and GPRC5D expressed on the surface of multiple myeloma cells. While all approved bispecific antibodies and CAR-T therapies in RRMM target BCMA, TALVEY targets the novel antigen GPRC5D.

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 a hospital inpatient or home setting for adults and children 6 years of age and older. Nelli's software is designed to automate the analysis of audio and video data to identify seizureevents with a positive motor component.

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Technology Name

Trade Name: FFX® System

Applicant Name: SC MEDICA

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:

FFX® Implants are titanium devices which are implanted between the two facets to be stabilized. They are intended to be used with bone graft and facet screws to achieve lumbar fusion through immobilization of the lumbar facet joints.

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Technology Name

Generic Name: lisocabtagene maraleucel

Trade Name: BREYANZI

Applicant Name: Bristol Myers Squibb (BMS)

Application Pathway: Traditional

Brief Description of the Technology:

BREYANZI® (lisocabtagenbe maraleucel) is a CD19-directed, autologous CAR T-cell immunotherapy comprised of individually formulated CD8 and CD4 CAR T-cells. It is anticipated to be indicated for the treatment of adult patients with R/R CLL/SLL who received a prior BTKi and BCL2i.

Technology Name

Generic Name: elranatamab-bcmm

Trade Name: ELREXFIO™

Applicant Name: Pfizer, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

ELREXFIO is a BCMA-directed CD3 T-cell engager indicated for the treatment of adult patients with RRMM who have received at least four prior lines of therapy including a PI, an IMiD, and an anti-CD38 mAb. It is a bispecific, humanized IgG2Δa kappa antibody derived from two mAbs. It is a fixed-dose, subcutaneous treatment.

Technology Name

Generic Name: HEPZATO KIT (melphalan for injection/Hepatic Delivery System)

Trade Name: HEPZATO KIT (melphalan for injection/Hepatic Delivery System)

Applicant Name: Delcath Systems

Application Pathway: Traditional

Brief Description of the Technology:

The HEPZATO™ KIT (melphalan for injection/Hepatic Delivery System) is a drug/device combination product consisting of melphalan and the Hepatic Delivery System (HDS). It is indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases.

Technology Name

Generic Name: FloPatch FP120

Trade Name: FloPatch FP120

Applicant Name: Flosonics Medical (R.A. 1929803 Ontario Corp.)

Application Pathway: Traditional

Brief Description of the Technology:

FloPatch FP120 is the world's first wireless, wearable Doppler ultrasound system designed to enable rapid, repeatable, and trusted dynamic assessments of blood flow. The small, lightweight medical device adheres to a patient's neck and wirelessly transmits blood flow data to a secure iOS mobile application for instant quantification.

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Technology Name

Generic Name: Drug Eluting Resorbable Scaffold System

Trade Name: Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

Applicant Name: Abbott

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 Esprit BTK Everolimus Eluting Resorbable Scaffold is a temporary scaffold that will resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb threatening ischemia (CLTI).

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Technology Name

Generic Name: exagamglogene autotemcel (exa-cel)

Trade Name: Not Yet Established

Applicant Name: Vertex Pharmaceuticals Incorporated

Application Pathway: Traditional

Brief Description of the Technology:

Exa-ceI is a one-time, CRISPR/CAS9 modified autologous CD34+ hematopoietic stem & progenitor cell (HSPC) cellular therapy administered via stem cell transplant. Exa-cel is intended to treat the underlying cause of sickle cell disease with recurrent vaso-occlusive crises (severe SCD) and transfusion dependent beta-thalassemia (TDT).

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Technology Name

Generic Name: Selux DPBC and AST System (AST Gen 1.5)

Trade Name: Selux Next-Generation Phenotyping System

Applicant Name: Selux Diagnostics, 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 Selux Direct from Positive Blood Culture (DPBC) Rapid AST Platform is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents.

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Technology Name

Generic Name: pulsed field ablation catheter system

Trade Name: FARAPULSE™ Pulsed Field Ablation (PFA) System

Applicant Name: Boston Scientific

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 FARAPULSE™ Pulsed Field Ablation (PFA) system is used to conduct cardiac ablations, in order to treat Atrial Fibrillation (AF). An AF ablation conducted with a PFA catheter causes irreversible electroporation, resulting in cellular death in cardiac cells and electrically isolating the pulmonary veins in the heart.

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Technology Name

Generic Name: odronextamab

Applicant Name: Regeneron Pharmaceuticals, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Odronextamab is the first and only novel, fully human CD20xCD3 bispecific antibody with an IgG4-based structure in B-cell non-Hodgkin lymphoma (B-NHL) created using Regeneron's proprietary Veloci-Bi® technology, pending Food and Drug Administration approval.

Note: The information on this tracking form was provided by the applicant at the time of application submission.