



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: [Hemolung Respiratory Assist System \(Hemolung RAS\)](#)
2. Manufacturer Name: [ALung Technologies, Inc.](#)
3. Trade Brand of Technology: [Hemolung Respiratory Assist System \(Hemolung RAS\)](#)
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? [Yes](#)

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. [No](#)
5. Brief Description of Service, Device or Drug:

[The Hemolung RAS provides low-flow, veno-venous extracorporeal carbon dioxide removal \(ECCO2R\) using a single, 15.5 French dual lumen catheter inserted percutaneously in the femoral or jugular vein. Low-flow ECCO2R with the Hemolung RAS provides partial ventilatory lung support independent of the lungs as an alternative or supplement to invasive mechanical ventilation. The Hemolung RAS removes up to 50% of basal metabolic CO2 production at circuit blood flows of 350-550 mL/min. See Figure 1. The Hemolung RAS is a fully integrated system designed to minimize the complication risks and operational complexity associated with extracorporeal gas exchange therapy.](#)

[The Hemolung RAS removes CO2 directly from the blood resulting in rapid reduction in arterial CO2 \(PaCO2\) and concomitant increase in arterial pH \(ie correcting hypercapnia and hypercapnic acidosis\). This physiologic response mitigates the harmful clinical sequelae from hypercapnic acidosis and facilitates de-escalation of high pressure and high volume ventilatory support or prevent intubation, both of which are known predictors for improved clinical outcomes.](#)

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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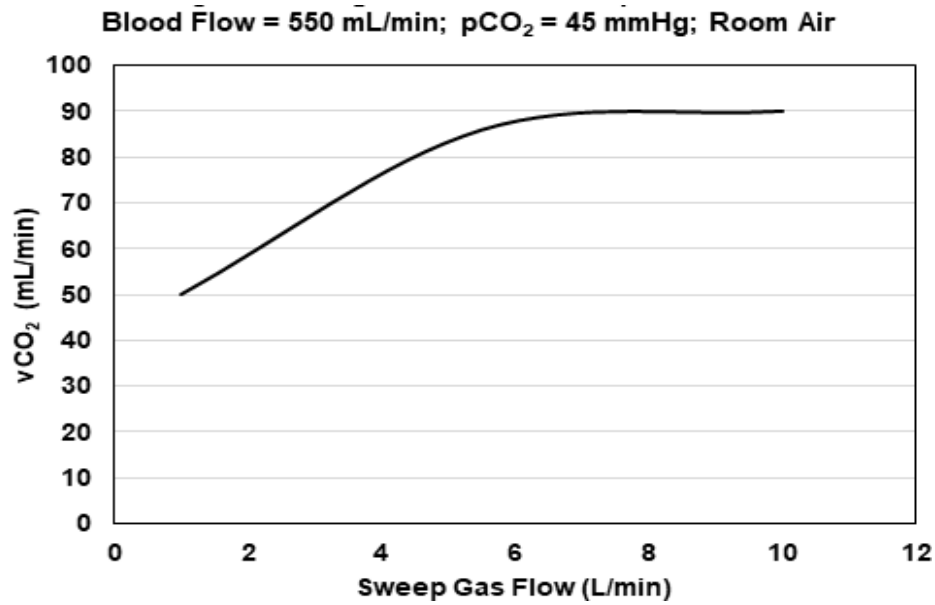


Figure 1: In-Vitro Hemolung CO₂ Removal Performance versus sweep gas flow at set blood flow and PCO₂

The Hemolung RAS is not intended to provide therapeutic levels of oxygenation. During Hemolung therapy, blood passing through the circuit is oxygenated; however, at low extracorporeal blood flows, the limited oxygen carrying capacity of blood precludes meaningful oxygenation of mixed venous blood.

Extracorporeal therapy with the Hemolung requires continuous systemic anticoagulation with unfractionated heparin or a standard of care alternative to prevent clotting of blood in the circuit.

The Hemolung RAS is for use in hospital critical care units by advanced health care providers including physicians, registered nurses, perfusionists, and respiratory therapists.

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1. Technology Name:

Phagenyx® System.

2. Manufacturer Name:

Phagenesis Ltd.

3. Trade Brand of Technology:

Phagenyx® System (EPSB3 Base Station and PNX-1000 catheter).

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Yes. Breakthrough Device designation was initially granted on December 4th 2019 and then granted again on January 29th 2021 with a revised indication for use.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No.

5. Brief Description of Service, Device or Drug:

The Phagenyx® System is designed to treat neurogenic dysphagia. Neurogenic dysphagia is dysphagia arising from the disruption of any of the neurological systems or processes involved in the execution of a coordinated safe swallow. Neurogenic dysphagia is commonly seen after stroke, traumatic brain injury or prolonged mechanical ventilation.

Phagenyx® uses electrical pulses to stimulate sensory nerves in the oropharynx. Once excited, these nerves send signals to the motor cortex in the brain, increasing cortical activity, promoting neuroplasticity and restoring swallowing control through functional cortical reorganization.

The Phagenyx® system is comprised of two parts, a sterile single patient use Catheter (PNX-1000) and a Base Station (EPSB3). The Catheter is a two-part fine bore flexible tube that is

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introduced nasally and extends down as far as the patients' stomach. It incorporates two bipolar ring electrodes on its outer surface to deliver the electrical pulses. The Base Station is a touch screen computer that optimizes and delivers the electrical pulses to the electrodes. Patient treatments require 10 minutes of stimulation per day with a 3 or 6 day course of treatment.

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1. Technology Name: [ClotTriever® Thrombectomy System](#)
2. Manufacturer Name: [Inari Medical, Inc.](#)
3. Trade Brand of Technology: [ClotTriever® Thrombectomy System](#)
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?
[An application for Breakthrough Device Designation \(BDD\) is pending with the FDA](#)

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.
5. Brief Description of Service, Device or Drug:
[The ClotTriever Thrombectomy System is indicated for the removal of soft thrombi and emboli from the peripheral vasculature as well as treatment of deep vein thrombosis \(DVT\). Post-thrombotic syndrome \(PTS\) is a known complication of DVT, and an indicator of advanced venous disease. PTS can be diagnosed using multiple clinical and diagnostic modalities. There is significant focus on prevention of PTS after initial deep vein thrombosis \(DVT\) occurrence due to its significant impact to quality of life. Current treatments focus on symptom relief and include compression therapy, medical management through anticoagulation drugs, surgery and endovascular interventions. The ClotTriever Thrombectomy System is an endovascular intervention seeking a specific indication for the treatment and prevention of PTS.](#)

For the complete application requirements, please see the instructions at
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1. Technology Name: Detour System
2. Manufacturer Name: Endologix, Inc.
3. Trade Brand of Technology: Stent Graft System
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.
5. Brief Description of Service, Device or Drug: The DETOUR™ System (previously referred to as the PQ Bypass System) is an approach to fully percutaneous femoral-popliteal bypass. Under fluoroscopic guidance a proprietary TORUS stent graft System is deployed from the popliteal artery into the femoral vein, and from the femoral vein into the superficial femoral artery (SFA) in a continuous, overlapping fashion through two independent anastomoses. The intended result is a large lumen, endograft bypass that delivers unobstructed, pulsatile flow from the SFA ostium to the popliteal artery.

For the complete application requirements, please see the instructions at
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1. **Technology Name:**
Aidoc for PE Care Coordination
2. **Manufacturer Name:**
Aidoc Medical Ltd.
3. **Trade Brand of Technology:**
ABriefor PE Care Coordination
4. **A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?**
No.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.
No.
5. **Brief Description of Service, Device or Drug:**
Aidoc for PE Care Coordination is a solution providing triage, prioritization and automated measurements for use on CTPA images. The device is intended to assist the broader PE care team (physicians, radiologists, cardiologists and relevant medical professionals) by flagging and communicating suspected positive findings along with providing automatic measurements to assist with patient risk stratification. The PE care team (physicians, radiologists, cardiologists, and relevant medical professionals) is presented with alerts that are sent to both mobile smartphone and workstation devices.

For the complete application requirements, please see the instructions at
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1. Technology Name: **Ciltacabtagene autoleucel (referred to herein as cilta-cel)**
2. Manufacturer Name: **Janssen Biotech, Inc. of Johnson & Johnson Health Care Systems Inc.**
3. Trade Brand of Technology: **Cilta-cel does not yet have a brand name.**
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Cilta-cel is a drug and is not a device eligible for a Breakthrough Device designation from the FDA.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

Cilta-cel is not an antibiotic and thus is not qualified to be designated a QIDP by the FDA.

5. Brief Description of Service, Device or Drug:

Cilta-cel is an autologous chimeric-antigen receptor T cell (CAR-T) therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. Cilta-cel is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

Cilta-cel's CAR-T technology consists of harvesting the patient's own T cells, programming them to express a chimeric antigen receptor that identifies BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells and reinfusing these modified cells back into the patient where they hunt down and eliminate myeloma tumor cells.

The Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for cilta-cel in previously treated patients with relapsed and refractory multiple myeloma.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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1. Technology Name: **Darzalex Faspro®** (daratumumab and hyaluronidase-fihj) injection, for subcutaneous use
2. Manufacturer Name: **Janssen Biotech, Inc. of Johnson and Johnson Healthcare Systems Inc.**
3. Trade Brand of Technology: **Darzalex Faspro®**
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Darzalex Faspro® is a drug and is not a device eligible for a Breakthrough Device designation from the FDA.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

Darzalex Faspro is not an antibiotic and thus is not qualified to be designated a QIDP by the FDA.

5. Brief Description of Service, Device or Drug:

Darzalex Faspro® is a subcutaneous formulation of daratumumab, a CD38-directed cytolytic antibody, indicated for the treatment of systemic light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients. Darzalex Faspro® is the first and only FDA-approved treatment for patients with AL amyloidosis. Darzalex Faspro® is also approved for multiple indications for treatment of patients with multiple myeloma (MM), from newly diagnosed (NDMM) to relapsed/refractory MM (RRMM).

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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1. Technology Name: **teclistamab**
2. Manufacturer Name: **Janssen Pharmaceutical Companies of Johnson and Johnson Healthcare Systems Inc.**
3. Trade Brand of Technology: **Teclistamab does not yet have a brand name.**
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Teclistamab is a drug and is not a device eligible for a Breakthrough Device designation from the FDA.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

Teclistamab is not an antibiotic and thus is not qualified to be designated a QIDP by the FDA.

5. Brief Description of Service, Device or Drug:

Teclistamab is the first treatment of its kind for multiple myeloma. Teclistamab is a full-sized bispecific antibody with two distinct binding regions: one that binds CD3 on T cells and another that binds BCMA on myeloma cells. This dual binding brings T cells into proximity with target myeloma cells and triggers T cell activation, leading to a cascade of 'effector' events whereby T cells are induced to produce chemicals that then destroy the myeloma cells. These events include release of cytotoxic granules like perforin and granzyme which poke holes in the target cells, triggering cell death. T cell activation also leads to production of cytokines, chemical signals that activate other T cells to create a microenvironment that leads to further immune activation, augmenting the anti-tumor response.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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1. Technology Name: **Spesolimab**
2. Manufacturer Name: **Boehringer Ingelheim Pharmaceuticals, Inc.**
3. Trade Brand of Technology:
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **No, Spesolimab is not a breakthrough device.**

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. **Spesolimab is neither a QIDP nor a LPAD.**
5. Brief Description of Service, Device or Drug: **Spesolimab is a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36R signaling. Binding of spesolimab to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL36 α , β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. IL-36R signaling is differentiated from TNF- α , integrin and IL-23 inhibitory pathways by directly and simultaneously blocking both inflammatory and pro-fibrotic pathways. Genetic human studies have established a strong link between IL36R signaling and skin inflammation.**

Spesolimab is currently under investigation for the treatment of flares in adult patients with generalized pustular psoriasis (GPP).

For the complete application requirements, please see the instructions at
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1. Technology Name:

FlowSense™

2. Manufacturer Name:

Rhaeos, Inc.

3. Trade Brand of Technology:

FlowSense™

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No

5. Brief Description of Service, Device or Drug:

The technology is a single-use, non-invasive and wireless sensor that detects and analyzes flow of cerebrospinal fluid (CSF) in implanted CSF shunts. The device transmits information wirelessly with a tablet application where the flow measurement results are displayed.

The thermal flow sensor is used by clinicians including neurosurgeons and emergency room physicians on hydrocephalus patients to determine shunt functionality before shunt revision surgery or after surgery to confirm flow in a newly placed shunt. The clinician places FlowSense on the skin overlying the shunt tubing (on or near the clavicle) and analyzes the results displayed on the tablet application to determine if the CSF shunt is functioning and whether any intervention is needed.

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1. Technology Name: XENOVIEW (hyperpolarized 129 Xenon (129 Xe) gas for inhalation,
2. Manufacturer Name: Manufacturer is Polarean, Inc.
3. Trade Brand of Technology: XENOVIEW™ Hyperpolarized 129 Xenon (129 Xe) gas for inhalation
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? No

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug:

XENOVIEW is drug/device combination drug used in conjunction with chest magnetic resonance imaging (MRI). Polarean's Xenon Hyperpolarizer System produces hyperpolarized 129 Xenon (HP 129 Xe) to enable functional lung imaging using MRI. The initial drug material, XENOVIEW gas blend, is derived from a non-radioactive isotope of xenon (Xe). XENOVIEW, using the Polarean Hyperpolarizer system, consists of 89% Helium 10% Nitrogen and 1% Xe (v/v) gas blend provided in a size 302 aluminum gas cylinder. The 1% xenon in the gas blend is enriched for 129Xe (i.e. >80% purity of Xe 129 isotope). This new chemical entity, Xe is a monoatomic, inert, stable, noble gas. It is naturally abundant in air at a level of 0.087 parts per million (ppm). Atmospheric Xe is composed of 9 non-radioactive isotopes, which 129 Xenon represents 26.40%. Mechanistically, hyperpolarized 129Xe is not metabolized to achieve its primary purpose. After imaging, the hyperpolarized 129Xe is exhaled from the body during normal respiration. The safety profile of XENOVIEW for MRI lung diagnostics is superior to alternative lung imaging options. It does not use any ionizing radiation allowing safe images of ventilated air spaces ventilation defect volume well suited for longitudinal therapeutic evaluation.

. The gas blend cylinder is connected to the Xenon Hyperpolarizer, which produces HP 129Xe at the hospital where it will be administered to a patient. The method of production is based on an optical excitation process and involves no chemical reactions.

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Hyperpolarization of the ^{129}Xe allows for detection of the patient inhaled HP ^{129}Xe gas by MRI, producing highly-detailed, 3-dimensional (3-D) MRI images enabling physicians to clearly, accurately, and quantitatively, visualize the spatial distribution of the patient's regional pulmonary function and lung ventilation. Studies have verified the pulmonary function and ventilation with patient clinical signs and symptoms as well as to CT lung images. XENOVUE offers excellent visualization of MRI images without nephrotoxicity as in the case of CT images (which visualize structure as opposed to function) using contrast agents in addition to imparting ionizing radiation to the patient.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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1. Technology Name:

Proposed Brand Name: DefenCath (To be submitted for approval by FDA)

2. Manufacturer Name:

CorMedix Inc.

3. Trade Brand of Technology:

Generic: Solution of Taurolidine (13.5 mg/mL) and Heparin (1000 USP Units/mL)

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **N/A – not a device**

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

YES - DefenCath received QIDP designation by FDA in 2015 and is requesting approval of the New Drug Application under LPAD

5. Brief Description of Service, Device or Drug:

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. Taurolidine, the antimicrobial compound in Defencath™, is a derivative of the amino acid taurine, with *in vitro* studies indicating broad antimicrobial activity against gram-positive and gram-negative bacteria, including antibiotic resistant strains, as well as mycobacteria and clinically relevant fungi. In the United States, DefenCath™ was designated by FDA as a Qualified Infectious Disease Product (QIDP) in 2015 and has been granted FDA Fast Track status. CorMedix has completed a Phase 3 clinical trial, known as LOCK-IT-100,

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which demonstrated a highly significant and clinically relevant 71% decrease in catheter-related bloodstream infection (CRBSI) in patients receiving hemodialysis for the treatment of kidney failure when compared with heparin alone, which is the current standard of care for a catheter lock solution.

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1. Technology Name: **maribavir**
2. Manufacturer Name: **Takeda Pharmaceuticals U.S.A., Inc.**
3. Trade Brand of Technology: **To be provided at time of FDA approval**
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **No**
B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. **No**
5. Brief Description of Service, Device or Drug:

Maribavir, an orally bioavailable anti-cytomegalovirus (CMV) compound, is the only antiviral agent presently in Phase 3 development for the treatment of post-transplant patients with CMV in solid organ transplant (SOT) or hematopoietic cell transplant (HCT). Maribavir is an investigational treatment that has not been approved for use by the FDA. If approved, maribavir will be the first therapy in a new class of drugs known as benzimidazole ribosides.

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1. Technology Name:

The product, which is currently referred to as RBX2660, is a broad consortium microbiota-based live biotherapeutic suspension. A brand name and generic name will be available upon approval by the US Food & Drug Administration (FDA).

2. Manufacturer Name: **The applicant is Ferring Pharmaceuticals Inc., an affiliate of the manufacturer, Rebiotix, Inc.**

3. Trade Brand of Technology: **Live biotherapeutic product.**

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **No.**

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. **No.**

5. Brief Description of Service, Device or Drug:

RBX2660 is being investigated to reduce recurrence of *Clostridioides difficile* infection (CDI) in adults following antibiotic treatment for recurrent CDI (rCDI) inclusive of the first recurrence. The product comes in a pre-packaged, single-dose 150 mL microbiota suspension for rectal administration. It contains diverse spore-forming and non-spore-forming bacteria, including *Bacteroides*, which are biologically sourced, health screened, and pathogen tested to ensure patient safety.

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1. Technology Name: Shockwave intravascular Lithotripsy (IVL) System with the Shockwave S⁴, Shockwave M⁵, and Shockwave M⁵⁺ for patients on dialysis
2. Manufacturer Name: Shockwave Medical, Inc
3. Trade Brand of Technology: Shockwave S⁴, Shockwave M⁵, and Shockwave M⁵⁺ Peripheral IVL Catheters
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Application is pending

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug:

The Shockwave S⁴, Shockwave M⁵, and Shockwave M⁵⁺ Peripheral IVL Catheters are proprietary lithotripsy devices delivered through the peripheral arterial system of the lower extremities to the site of an otherwise difficult to treat calcified stenosis. The IVL Catheter is comprised of an integrated balloon with an array of integrated lithotripsy emitters for the localized delivery of pulsatile mechanical energy.

The Shockwave S⁴, Shockwave M⁵, and Shockwave M⁵⁺ Peripheral IVL Catheter, in conjunction with the IVL Generator and Connector Cable are used to deliver localized, lithotripsy-enhanced, balloon dilatation of calcified, stenotic arteries. The lithotripsy “breaks up” the calcified lesions, allowing for balloon dilatation to provide access for the primary procedure being performed. The Shockwave S⁴, Shockwave M⁵, and Shockwave M⁵⁺ Peripheral IVL Catheters are utilized in modifying intimal and medial calcium for patients on renal dialysis.

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1. Technology Name: Shockwave L⁶ Peripheral IVL Catheter
2. Manufacturer Name: Shockwave Medical, Inc
3. Trade Brand of Technology: Shockwave L⁶ Peripheral IVL Catheter
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Application is expected to be filed and is pending

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug:

The Shockwave L⁶ Peripheral IVL Catheter is a proprietary lithotripsy device delivered through the peripheral arterial system of the lower extremities to the site of an otherwise difficult to treat calcified stenosis. The IVL Catheter is comprised of an integrated balloon with an array of integrated lithotripsy emitters for the localized delivery of pulsatile mechanical energy.

The Shockwave L⁶ Peripheral IVL Catheter, in conjunction with the IVL Generator and Connector Cable, are used to deliver localized, lithotripsy-enhanced, balloon dilatation of calcified, stenotic arteries. The lithotripsy “breaks up” the calcified lesions, allowing for balloon dilatation to provide access for the primary procedure being performed. The Shockwave L⁶ Peripheral IVL Catheter can assist in modifying intimal and medial calcium in the common femoral or iliac vessels that then enable a transfemoral procedure to be performed.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: **Proprietary name: UPLIZNA® (inebilizumab-cdon)**
2. Manufacturer Name: **The BLA holder and manufacturer is HTI-DAC. Horizon Therapeutics USA, Inc. is the distributor and/or labeler. "Horizon" is used throughout the NTAP application.**
3. Trade Brand of Technology: **UPLIZNA**
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?
No, it has not.
B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.
No, it has not.

5. Brief Description of Service, Device or Drug:

UPLIZNA (inebilizumab-cdon) is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) for adult patients who are anti-aquaporin-4 (AQP4) antibody positive. UPLIZNA is proven to reduce the risk of relapses (also referred to as attacks) that may lead to permanent disability in NMOSD patients. UPLIZNA may be used in the context of hospitalizations due to NMOSD relapses.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: Magnus Neuromodulation System (MNS) with SAINT technology
2. Manufacturer Name: Magnus Medical, Inc.
3. Trade Brand of Technology: Magnus Neuromodulation System (MNS) with SAINT technology
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. Not Applicable

5. Brief Description of Service, Device or Drug:

The Magnus Neuromodulation System (MNS) with SAINT technology is a novel, personalized form of non-invasive neuromodulation intended for treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Specifically, the system consists of a target identification software suite, which analyzes functional and structural MRI images to generate a personalized target for treatment of MDD in any given patient; a neurostimulation platform, which delivers magnetic pulses to the brain using an electromagnetic coil; and a neuronavigation platform, which allows the coil to be placed over an intended region of the brain with millimeter-level precision. Stimulation is delivered to the personalized target according to an accelerated, rapid treatment schedule of 10 sessions per day over 5 days.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

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1. Technology Name: Nelli® Seizure Monitoring System
2. Manufacturer Name: Neuro Event Labs, Inc.
3. Trade Brand of Technology: Nelli® Seizure Monitoring System
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug:

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 seizure events with a positive motor component. The software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate) to enable the detection and classification of epileptic events using pre-trained artificial intelligence (AI). Nelli records, processes, and provides physicians secure access to raw audiovisual recordings of patients to assist with the characterization of seizures and peri-ictal events.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

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1. Technology Name: **Mosunetuzumab is the international non-proprietary name**
2. Manufacturer Name: **Genentech, Inc.**
3. Trade Brand of Technology: Subject to Food and Drug Administration (FDA) approval, the trade name for the product mosunetuzumab will be finalized.
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **No. The product is not a device.**

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. **No. The technology has not been designated as a QIDP.**
5. Brief Description of Service, Device or Drug: **Mosunetuzumab is a bispecific, humanized monoclonal antibody BTCT4465A, with an antigen-recognition site for the T-cell surface antigen CD3, and the other for the B-cell tumor-associated antigen (TAA). It binds to and cross-links T cells to tumor cells, resulting in a cytotoxic T-lymphocyte (CTL) response against CD20-expressing tumor B cells.**

Mosunetuzumab is an investigational drug for which Genentech, Inc. intends to seek FDA approval for the proposed indication of treatment of adults with relapsed or refractory follicular lymphoma and who have received at least 2 prior systemic therapies.

Upon FDA approval, mosunetuzumab is anticipated to be a novel first-in-class therapy for the treatment of any non-Hodgkin lymphoma (NHL).

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name:

ISS500

2. Manufacturer Name:

BrainsGate Ltd.

3. Trade Brand of Technology:

ISS500

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

No.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No.

5. Brief Description of Service, Device or Drug:

The ISS500 is a medical device intended to treat acute ischemic stroke patients in a 24-hour window from stroke onset. The ISS500 utilizes a miniature implant to stimulate the SPG to increase cerebral collateral blood flow in the affected hemisphere and reduce disability of the patient.

The miniature implant is injected through the Greater Palatine Canal in the hard palate of the mouth, under the guidance of a navigation system. Treatment is delivered 4 hours a day for 5 days, after which the implant is removed from the patient.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

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1. Technology Name:

Corvia Atrial Shunt (InterAtrial Shunt Device: IASD® System II)

2. Manufacturer Name:

Corvia Medical, Inc.

3. Trade Brand of Technology:

Corvia Atrial Shunt (InterAtrial Shunt Device: IASD® System II)

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No

5. Brief Description of Service, Device or Drug:

The Corvia Atrial Shunt creates a controlled interatrial shunt between the left and right atrium to mitigate increases in left atrial pressure in patients with heart failure with preserved ejection fraction (HFpEF) and mid-range ejection fraction (HFmrEF) with elevated left atrial pressures, who remain symptomatic despite standard guideline directed medical therapy

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

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1. Technology Name: **REGEN-COV™ (casirivimab and imdevimab)**
2. Manufacturer Name: **Regeneron**
3. Trade Brand of Technology: **REGEN-COV™**
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **No, it has not.**

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. **No, it has not.**
5. Brief Description of Service, Device or Drug: **Casirivimab and imdevimab (REGEN-COV, formerly known as REGN-COV2 or REGEN-COV2) is a combination of two monoclonal antibodies (also known as REGN10933 and REGN10987, respectively) and was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19. The two potent, virus-neutralizing antibodies that form the combination bind non-competitively to the critical receptor binding domain of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment and protects against spike variants that have arisen in the human population. The anti-SARS-CoV-2 spike protein neutralizing mAbs have demonstrated in vivo efficacy in both therapeutic and prophylactic settings in mouse and non-human primate models, with decreases in viral load and lung pathology. REGN-COV's development and manufacturing has been funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.**

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

Note: The information provided on this tracking form will be made publicly available.



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: *Endovascular Repair of the Thoracic Aortic Arch and Descending Thoracic Aorta with Preservation of the Left Subclavian Artery Flow*
2. Manufacturer Name: *W. L. Gore & Associates, Inc.*
3. Trade Brand of Technology: *GORE® TAG® Thoracic Branch Endoprosthesis*
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **Yes**

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. **No**

5. Brief Description of Service, Device or Drug:

Once approved, the GORE® TAG® Thoracic Branch Endoprosthesis (TBE device) will be the first FDA-approved, endovascular device that can repair a variety of pathologies to the descending thoracic aorta that involve Zone 2 of the aortic arch by means of an entirely endovascular procedure. The GORE® TAG® Thoracic Branch Endoprosthesis is a modular device consisting of an Aortic Component, a Side Branch (SB) Component, and an optional Aortic Extender (AE) Component. Each component is pre-mounted on a catheter delivery system for delivery from a distal access site over an aortic or branch artery guidewire. Together, these three components comprise the GORE® TAG® Thoracic Branch Endoprosthesis being proposed for New Technology status.

The TBE device can be used as a stand-alone device or in conjunction with the commercially-available Conformable GORE® TAG® Thoracic Endoprosthesis to accommodate the intended treatment site. The TBE device enables a fully endovascular treatment for certain pathologies, which include but are not limited to thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2022

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1. Technology Name:

iFuse Bedrock Granite Implant System

2. Manufacturer Name:

SI-BONE, Inc.

3. Trade Brand of Technology:

iFuse Bedrock Granite Implant System

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

A request with the FDA for Breakthrough Device designation is pending

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No

5. Brief Description of Service, Device or Drug:

The iFuse Bedrock Granite implant is a sterile, single-use permanent implant that combines features of a porous fusion device and the threaded length and posterior rod connection features of a typical pedicle fixation screw. The iFuse Bedrock Granite Implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacroala-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name:

LigaPASS 2.0 PJK Prevention System

2. Manufacturer Name:

Medtronic

3. Trade Brand of Technology:

LigaPASS 2.0 PJK Prevention System

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Yes.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No.

5. Brief Description of Service, Device or Drug:

The LigaPASS 2.0 PJK Prevention is intended for use when ligament augmentation is considered appropriate to mitigate the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJF).

The LigaPASS 2.0 PJK Prevention System consists of a polyester (PET) band and titanium alloy medial open connector with 2 set screws. The LigaPASS 2.0 PJK Prevention System provides surgeons the ability to mimic anatomical muscle and ligament functionality and stabilization between vertebrae adjacent to fused levels in a spine surgery. The LigaPASS 2.0 PJK Prevention System is designed to restore balance and stability as a complement to a posterior thoracolumbar

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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fixation system. Ergonomic instrumentation provides smooth assembly with selfstabilizing tensioners and torque-limiting locking tools.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. **Technology Name:** Treosulfan injection, for intravenous use.
2. **Manufacturer Name:** Medexus Pharma, Inc.
3. **Trade Brand of Technology:** At the time of this submission, the trade brand name of Treosulfan has not yet been confirmed.
4. **A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?** No.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No.

5. Brief Description of Service, Device or Drug:

Treosulfan is a new chemical entity currently under FDA review through a New Drug Application with a proposed indication for use as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients older than one year with acute myeloid leukemia (AML) or with myelodysplastic syndrome (MDS). Both AML and MDS are malignant cancers associated with high relapse rates and low original survival (OS) rates. At the time of this submission, Treosulfan has not yet received FDA approval. FDA approval is anticipated by June 30, 2022.

alloHSCT is currently the most effective therapy for patients with high-risk malignant or certain non-malignant disorders, as it can reduce the risk of relapse or progression and ultimately increase survival in these patient populations. The goal of alloHSCT is to cure patients of their disease by replacing their hematopoietic stem cells (i.e. bone marrow stem cells) with stem cells from a healthy related or unrelated donor. Conditioning/preparative treatments, such as the Treosulfan-based regimen, are critical to the success of alloHSCT.

Conditioning/preparative treatments prior to alloHSCT have traditionally included Myeloablative Conditioning (MAC), which includes high-dose total body irradiation (TBI) and high-dose chemotherapy-based regimens; and Reduced Intensity Conditioning (RIC), in which cytotoxic components of the regimen are reduced or replaced with less toxic but immunosuppressive agents. However, MAC regimens are associated high treatment-related toxicity and transplantation-related mortality (TRM), while RIC regimens usually pose a higher risk of relapse. Treosulfan is designed to address this tension between relapse rates and high treatment-related toxicity and TRM and was developed in an effort to address the significant unmet medical need for improved alloHSCT conditioning regimens that can reduce treatment-related toxicity and the risk of TRM without increasing the incidence of relapse.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name:

CERAMENT® G

2. Manufacturer Name:

Bonesupport AB (Initial importer BONESUPPORT Inc.)

3. Trade Brand of Technology:

CERAMENT® G

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

Yes.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No. N/A.

5. Brief Description of Service, Device or Drug:

CERAMENT® G is an injectable combination device/drug bone void filler, consisting of calcium sulfate, hydroxyapatite ("HA") and gentamicin sulfate. CERAMENT® G delivers 17.5 mg gentamicin/ mL paste.

CERAMENT® G is indicated for use as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) where there is a need for supplemental bone void filler material.

By combining calcium sulfate and hydroxyapatite, an optimal balance is achieved between implant resorption rate and bone remodeling rate. Calcium sulfate acts as a resorbable carrier for

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hydroxyapatite. Hydroxyapatite has a slow resorption rate and high osteoconductivity promoting bone remodeling and gives long-term structural support to the newly formed bone.

By eluting gentamicin, CERAMENT® G can inhibit the colonization of the bone void filler by gentamicin sensitive microorganisms in order to protect bone healing.

The use of CERAMENT® G eliminates the need to harvest autologous bone, thereby avoiding donor site morbidity (e.g., pain, infection, etc.) in patients with a diagnosed infection.

CERAMENT® G is used as part of the surgical procedure for the management of osteomyelitis and has two modes of action:

1. Primary mode of action: serves as a resorbable ceramic bone void filler intended to fill gaps and voids in the skeleton system created when infected bone is debrided.
2. Secondary mode of action: is to prevent colonization of the bone void filler by gentamicin-sensitive microorganisms in order to protect bone healing.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: Lifileucel
2. Manufacturer Name: Iovance Biotherapeutics
3. Trade Brand of Technology: Brand name not yet determined and will be confirmed upon US Food and Drug Administration (FDA) approval
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? No

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug: Lifileucel is under investigation as a one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for the proposed indication in the treatment of patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD-1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or a BRAF inhibitor with a MEK inhibitor. Upon FDA approval, lifileucel will be the first and only therapy indicated for this patient population.

TIL therapy with lifileucel involves the adoptive cell transfer of autologous T-cells directly isolated from the tumor tissue and expanded *ex vivo* without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state, low numbers, and a hostile microenvironment prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them *ex vivo* in the presence of growth factors, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the one-time infusion of the personalized lifileucel TIL cell therapy, the TIL migrate back into primary and metastatic tumors, where they amplify and rejuvenate the patient's own immune system triggering specific tumor cell killing upon recognition of tumor antigens.

Lifileucel has been granted Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug and Fast Track designations in metastatic melanoma.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: Omidubicel
2. Manufacturer Name: Gamida Cell Inc.
3. Trade Brand of Technology: not yet determined
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? No

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug: Omidubicel is a patient-specific advanced cellular therapy under development as a donor source for potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant (HSCT) for the treatment of patients with hematologic malignancies.

Gamida Cell has pioneered a new approach with its proprietary nicotinamide-based (NAM) technology that preserves the multipotency of progenitor cells for long-term repopulation, while increasing cell quantity for transplantation. Omidubicel consists of CD34+ *ex vivo* manipulated progenitor cells and is comprised of 2 cell fractions, a Cultured Fraction (CF) and a Non-cultured Fraction (NF) derived from the same cord blood unit.

- The CF is composed of allogeneic, *ex vivo* manipulated hematopoietic CD34+ progenitor cells using umbilical cord blood cells as starting material. The cells are manipulated in the presence of a propriety NAM technology used to inhibit differentiation (of the hematopoietic progenitor cells CD34+) and to increase the migration, bone marrow homing and engraftment efficiency of the hematopoietic progenitor cells.
- The NF is composed of allogeneic, non-manipulated, hematopoietic mature myeloid and lymphoid cells from cord blood.

The US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for development of omidubicel for improvement of neutrophil engraftment in patients receiving umbilical cord blood transplantation for hematological malignancies. Orphan Drug Designation was granted for this novel HSCT donor source for the enhancement of cell engraftment and immune reconstitution in patients receiving a hematopoietic stem cell transplant.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: TERLIVAZ® (terlipressin) for injection
2. Manufacturer Name: Mallinckrodt Hospital Products Inc.
3. Trade Brand of Technology: TERLIVAZ® (terlipressin) for injection
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

No.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No.

5. Brief Description of Service, Device or Drug:

Terlipressin is a potent, synthetic vasopressin analogue with 6-fold greater selectivity for the vasopressin receptors (V1) vs. vasopressin receptors (V2). Terlipressin is a synthetic vasopressin analogue that acts as a V1 receptor mediated vasoconstrictor, particularly in the splanchnic area, and is classified under the pharmacotherapeutic group posterior pituitary lobe hormone (vasopressin and analogues). Terlipressin is a sterile, preservative-free, lyophilized powder for intravenous administration.

Terlipressin is an investigational drug for which Mallinckrodt is seeking FDA approval for the proposed indication of treatment of adults with hepatorenal syndrome type 1 (HRS-1).

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name:

Narsoplimab

2. Manufacturer Name:

Omeros Corporation

3. Trade Brand of Technology:

No yet identified.

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

No.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

No.

5. Brief Description of Service, Device or Drug:

Narsoplimab is a fully human monoclonal antibody with a unique mechanism of action targeting mannan-binding lectin serine protease 2 (MASP-2), the effector enzyme of the lectin pathway of the complement system. Narsoplimab inhibits MASP-2 and activation of the lectin pathway. Narsoplimab prevents complement-mediated inflammation and exhibits anticoagulant effects, while leaving intact the respective functions of the classical and alternative pathways of innate immunity.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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The U.S. Food and Drug Administration (FDA) has granted breakthrough therapy designation to narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). At the time of this application, Omeros has submitted the Biologics License Application (BLA) for narsoplimab in the treatment of HSCT-TMA, also known as transplant-associated thrombotic microangiopathy (TA-TMA).

The Prescription Drug User Fee Act (PDUFA) date is October 17, 2021. As of October 1, 2021, FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. FDA stated that the notification does not reflect a final decision on the information under review. FDA did not provide specific details of the deficiencies in its notification; however, in a meeting held on September 30, 2021, FDA expressed its intention to work with Omeros to resolve any issues as expeditiously as possible. We currently do not expect any such resolution to occur by the October 17, 2021 PDUFA date.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name:

Precision TAVI™ Coronary Obstruction Module

2. Manufacturer Name:

DASISimulations

3. Trade Brand of Technology:

Precision TAVI™ Coronary Obstruction Module

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

A Breakthrough Device Designation request is pending with the FDA

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. *Not applicable*

5. Brief Description of Service, Device or Drug:

The Precision TAVI Coronary Obstruction Module provides intelligent decision support powered by artificial intelligence (AI) and machine learning to help physicians accurately predict potential coronary obstructions in transcatheter aortic valve replacement (TAVR) procedures. The Precision TAVI Coronary Obstruction Module may assist physicians in the evaluation of patients with severe aortic stenosis as part of consideration for surgical replacement vs trans-catheter replacement and further considering the need for coronary protection measures or other interventional measures.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2022

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name:

Thoraflex™ Hybrid Device

2. Manufacturer Name:

Terumo Aortic

3. Trade Brand of Technology:

Thoraflex™ Hybrid Device

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No

5. Brief Description of Service, Device or Drug:

The Thoraflex™ Hybrid Device is intended for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm and/or dissection by open surgical repair. It is comprised of a proximal crimped polyester surgical graft, central polyester collar and distal nitinol ring stents supported by thin-wall polyester fabric. The three sections are pre-joined in the middle forming a single integrated device. During surgery the Thoraflex™ Hybrid Delivery System is introduced through the opened aortic arch into the descending thoracic aorta. When the correct orientation and position has been achieved, the delivery system is unsheathed allowing the distal stent to be deployed within the diseased distal aorta. The delivery system and associated components are then removed leaving the completely deployed device in situ. Once the delivery system has been removed, the collar is sutured to the native aortic vessel providing fixation and stability to the device. The remaining surgical graft anastomoses are then performed.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: TOPS™ System
2. Manufacturer Name: Premia Spine, Inc
3. Trade Brand of Technology: TOPS™ System
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD. No
5. Brief Description of Service, Device or Drug:
The TOPS System is a motion preserving device comprised of a titanium construct with an interlocking polycarbonate urethane (PcU) articulating core. After posterior decompression, it is inserted and affixed using pedicle screws preserving normal spinal motion and providing stabilization of the lumbar intervertebral segment. The TOPS System replaces anatomical structures, such as the lamina and the facet joints, that are removed during spinal decompression treatment to alleviate pain. The internal stoppers replace the natural bony elements that served as stoppers during axial rotation. The boot and internal components take the place of the supraspinous ligament, interspinous ligament, and ligamentum flavum in their ability to help control flexion and lateral bending.

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: VITARIA® System
2. Manufacturer Name: LivaNova plc
3. Trade Brand of Technology: Neurostimulator
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.
5. Brief Description of Service, Device or Drug: The VITARIA® System is a vagal nerve stimulation system is an active implantable neuromodulation system comprised of a pulse generator, lead and programming computer system that delivers autonomic regulation therapy (ART) using vagus nerve stimulation for patients living with heart failure and reduced ejection fraction (HFrEF).

For the complete application requirements, please see the instructions at
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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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) 2023

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: *Paired Vagus Nerve Stimulation Therapy*
2. Manufacturer Name: *MicroTransponder, Inc.*
3. Trade Brand of Technology: *ViviStim® Paired VNS System*
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? *Yes*

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD? *No*

Brief Description of Service, Device or Drug:

The ViviStim® Paired VNS System is intended to be used to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

The Vivistim® Paired VNS System is comprised of an Implantable Pulse Generator (IPG), an implantable Stimulation Lead and an external paired stimulation controller which is composed of the external Wireless Transmitter (WT) and the external Stroke Application & Programming Software (SAPS). The external paired stimulation controller (SAPS and WT) enables the implanted components (the IPG and Lead) to stimulate the vagus nerve during rehabilitation.

For the complete application requirements, please see the instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

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