Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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

1. Technology Name: *Rapid ASPECTS*

2. Manufacturer Name: *iSchemaView, Inc. (In the process of a change in name to RapidAI)*

3. Trade Brand of Technology: *RapidAI*

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*

Brief Description of Service, Device or Drug:

Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using computed tomography (CT) image data. The Software automatically registers images and segments and analyzes ASPECTS Regions of Interest (ROIs). Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT Score.

Rapid ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known Middle Cerebral Artery (MCA) or Internal Carotid Artery (ICA) occlusion, for evaluation of extent of disease. Extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score.

This device provides information that may be useful in the characterization of early ischemic brain tissue injury during image interpretation (within 6 hours). Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring.

Rapid ASPECTS is not intended for primary interpretation of CT images, it is used to assist physician evaluation. Rapid ASPECTS has been validated in patients with known MCA or ICA occlusion prior to ASPECT scoring.

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

1. Technology Name:

   Pharyngeal Electrical Stimulation

2. Manufacturer Name:

   Phagenesis Ltd.

3. Trade Brand of Technology:

   Phagenyx® 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:

   Phagenyx is a neurostimulation device to treat neurogenic dysphagia (swallowing disorder)

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

1. Technology Name:

The technology name is satralizumab-mwge injection, for subcutaneous use.

2. Manufacturer Name:

The manufacturer name is Genentech, Inc.

3. Trade Brand of Technology:

The trade name of the product is ENSPRYNG™ (satralizumab-mwge) injection, for subcutaneous use.

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

No, the technology is not a device and has not received Breakthrough Device designation.

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 is not a product that has been designed by the FDA as a QIDP or LPAD.

5. Brief Description of Service, Device or Drug:

ENSPRYNG is an interleukin-6 (IL-6) receptor antagonist that received US Food and Drug Administration (FDA) approval on August 14, 2020, for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 antibody (AQP4-IgG) positive. ENSPRYNG is the first subcutaneous, the first self-administered, and the third of only three FDA-approved drugs available for the treatment of this severe chronic autoimmune disease of the central nervous system.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: **Idecabtagene vicleucel**

2. Manufacturer Name: **Celgene Corporation, now a wholly owned subsidiary of Bristol Myers Squibb (BMS)**

3. Trade Brand of Technology: **The trade/brand name for idecabtagene vicleucel will not be finalized until the product receives FDA approval.**

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **Idecabtagene vicleucel 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. **Idecabtagene viclecuel is not a QIDP or LPAD.**

5. Brief Description of Service, Device or Drug:

   Idecabtagene viclecuel is an investigational, B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell immunotherapy that is anticipated to be indicated for the treatment of adult patients with relapsed or refractory (RR) multiple myeloma (MM) (RRMM) who have received at least three prior therapies including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 antibody (e.g., triple-class-exposed). The idecabtagene vicleucel CAR is comprised of a murine extracellular single chain variable fragment (scFv)-BCMA targeting domain, a CD8 alpha (α) hinge and transmembrane domain, a CD3-zeta (ζ) T-cell activation domain, and a 4-1BB (CD137) costimulatory domain. This structure is unique to idecabtagene vicleucel; no other CAR T-cell therapy is comprised of the combination of these targeting, hinge and transmembrane, activation, and costimulatory domains. A single dose of idecabtagene vicleucel contains a cell suspension of 150 to 540 x 10^6 CAR+ T-cells with a target dose of 450 × 10^6 CAR+ viable T-cells.

   Idecabtagene viclecuel is unique from existing treatments for RRMM because there are currently no FDA-approved CAR T-cell therapies indicated for the treatment of MM. The CAR T-cell therapies that are currently approved by the FDA are approved for the treatment of various types of non-Hodgkin's lymphoma (NHL), which is a different disease than MM. Idecabtagene vicleucel is unique from the CAR T-cell therapies used for the treatment of NHL because it contains a BCMA recognition domain to target myeloma cells. Conversely, the CAR T-cell therapies available today use a CD19 recognition domain to target NHL cancer cells. In summary, there are no CAR T-cell therapies approved for the treatment of RRMM, and there are no approved CAR T-cell therapies that include a BCMA targeting domain.

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Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: **Lisocabtagene maraleucel**

2. Manufacturer Name: **Juno Therapeutics, Inc., a Bristol Myers Squibb Company**

3. Trade Brand of Technology: **The trade/brand name for lisocabtagene maraleucel will not be finalized until the product receives FDA approval.**

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

   Lisocabtagene maraleucel 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.

   Lisocabtagene maraleucel is not a QIDP or LPAD.

5. Brief Description of Service, Device or Drug:

   Lisocabtagene maraleucel is an investigational, CD-19 directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy comprised of individually formulated CD8 and CD4 CAR T-cells that is anticipated to be indicated for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade-B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. Lisocabtagene maraleucel is genetically engineered to have a CAR on the cell surface that directs the immune cell to mount an immune response and destroy the cancerous tumor cells.

   Lisocabtagene maraleucel is unique from existing CAR T-cell products because it is comprised of two individually formulated cryopreserved patient-specific helper (CD4) and killer (CD8) CAR T-cells in suspensions that are thawed and infused separately in a defined composition. A single dose of lisocabtagene maraleucel contains 50 to 110 × 106 CAR-positive viable T-cells, consisting of 1:1 CAR-positive viable T-cells of the CD8 and CD4 components, with each component supplied separately in one or more single-dose vials. This process results in a precise number of CAR T-cells administered by infusion to each lisocabtagene maraleucel patient.

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

1. Technology Name: baricitinib

2. Manufacturer Name: Eli Lilly

3. Trade Brand of Technology: baricitinib (marketed under Olumiant® brand name upon FDA approval)

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

   No, baricitinib is a drug and therefore has not received Breakthrough Device designation.

   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.

   Baricitinib has not received a Qualified Infectious Disease Product designation nor Limited Population Pathway for Antibacterial and Antifungal Drugs designation.

4. Brief Description of Service, Device or Drug:

   Baricitinib is currently under investigation as a treatment for “coronavirus disease 2019” (COVID-19) for hospitalized patients. Some cytokines associated with cytokine storm (e.g., IL-6, IL-2, IL-10), known to be upregulated in COVID-19 infection, signal via the JAK/STAT pathway. These kinases have been implicated in SaRS-CoV-2 endocytosis and viral propagation; they may reduce host cell infectivity by SaRS-CoV-2.

   Olumiant® (baricitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis, who have had inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: EXALT™ Model D Single-Use Duodenoscope

2. Manufacturer Name: Boston Scientific Corporation

3. Trade Brand of Technology: EXALT™ Model D Single-Use Duodenoscope

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:

   EXALT™ Model D Single-Use Duodenoscope is the first FDA cleared single-use, flexible duodenoscope used to facilitate access to the pancreaticobiliary system during endoscopic retrograde cholangiopancreatography (ERCP) procedures. EXALT™ Model D Single-Use Duodenoscope is intended to eliminate the risk of patient-to-patient transmission of infection related to reprocessing of reusable duodenoscopes. ERCP procedures are performed to examine the bile and pancreatic ducts. EXALT Model D enables passage and manipulation of accessory devices into the pancreaticobiliary system for diagnostic and/or therapeutic purposes. Most commonly the scope is used to facilitate therapeutic maneuvers such as removal of gallstones from the bile ducts, dilation of strictures in the bile or pancreatic ducts, or to relieve an obstruction by inserting a plastic or metal stent.

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

1. Technology Name:
   Cefiderocol

2. Manufacturer Name:
   Shionogi & Co., Ltd

3. Trade Brand of Technology:
   FETROJA®

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.
   Yes, QIDP was granted in 2015 for several indications including HABP/VABP.

5. Brief Description of Service, Device or Drug:
   FETROJA® (cefiderocol) is an injectable siderophore cephalosporin discovered and developed by Shionogi & Co., Ltd., Japan with antibacterial/ bactericidal activity against Gram-negative aerobic bacteria by binding to penicillin-binding proteins and inhibiting bacterial cell wall synthesis. FETROJA® is unique in that, in addition to the typical entry via porin channels, the siderophore part of the molecule enable it to be actively transported across the outer cell membrane of bacteria into the periplasmic space using the bacterial siderophore iron uptake mechanism. Cefiderocol's structure also confers enhanced stability to β- lactamases, and has activity limited to GN aerobic bacteria only.

   FETROJA is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex, *Escherichia coli*, *Enterobacter cloacae* complex, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens.* This was approved in September 2020.

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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:

   Not 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 Manna-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.

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 is in the process of completing a rolling submission to FDA of the Biologics License Application (BLA) for narsoplimab in the treatment of HSCT-TMA, also known as transplant-associated thrombotic microangiopathy (TA-TMA).

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: **OXEI (Oxygen Saturation Endoscopic Imaging)**

2. Manufacturer Name: **FUJIFILM Corporation**

3. Trade Brand of Technology: **FUJIFILM EP-7000X System**

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **Yes. The device received Breakthrough Device designation from the FDA on September 17, 2020.**

   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 device is not a QIDP or LAPD.**

5. Brief Description of Service, Device or Drug:

   The EP-7000X System is an endoscopic video imaging system used for endoscopic observation, diagnosis, treatment and image recording in minimally invasive surgeries in abdominal, gynecologic, and thoracic areas. The EP-7000X System allows for the visualization of hemoglobin oxygen saturation (StO_2) levels of blood in superficial tissue under a 2D endoscopic image, which helps physicians identify tissue which is not appropriately oxygenated and thus potentially ischemic.

   The EP-7000X System is comprised of the following principal components: (1) Processor VP-7000; (2) Light Source BL-7000X; (3) Image Processing Unit EX-0; and (4) Video Laparoscope EL-R740M. Per the Breakthrough Device designation letter from the FDA, each component has a separate proposed indication. A summary of the proposed indications is as follows:

   - **Processor VP-7000: The VP-7000 unit is intended to process electronic signals transmitted from a video endoscope.**
   - **Light Source BL-7000X: The BL-7000X Light Source is intended to provide illumination to an endoscope.**
   - **Image Processing Unit EX-0: The Image Processing Unit EX-0 is intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of an endoscopic observation image area in patients at risk for ischemic states.**
   - **Video Laparoscope EL-R740M: The Video Laparoscope EL-R740M is intended to be used with a video processor, light source, monitor, hand instruments, electrosurgical unit and other ancillary equipment for minimally invasive observation, diagnosis and treatment in abdominal, gynecologic and thoracic areas.**

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

1. Technology Name:

   CERAMENT® G

2. Manufacturer Name:

   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

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 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:

- 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.

- Secondary mode of action: is to prevent colonization of gentamicin-sensitive microorganisms in order to protect bone healing.

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

1. Technology Name:

   aprevo™ Intervertebral Body Fusion Device

2. Manufacturer Name:

   Carlsmed, Inc.

3. Trade Brand of Technology:

   aprevo™ Intervertebral Body Fusion 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 *aprevo* Intervertebral Body Fusion Devices are designed to stabilize the lumbar spinal column and facilitate fusion. The devices are personalized to incorporate patient-specific features to allow the surgeon to tailor the deformity correction to the individual needs of the patient. These features include height, width, depth, front-to-back angulations, side-to-side angulations, and an anatomical interface to fit against the anatomy of the patient's vertebral endplates more precisely. The individualized surgical correction plan and device configurations are developed using patient CT scans to create 3D virtual models of the deformity and surgical correction plan. The *aprevo* devices are additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and have a cavity intended for the packing of bone graft.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: Persona® IQ

2. Manufacturer Name: Zimmer Biomet and Canary Medical

3. Trade Brand of Technology: Persona® Personalized Knee System (Zimmer Biomet); Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System (Canary Medical)

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

   Yes, the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System received Breakthrough Device designation from the FDA in October 2019.

   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:

   Persona IQ combines the Persona® Personalized Knee System and the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP). Persona IQ is the first to world intelligent implant that enables easy access to objective data and delivers clinical insights for total knee arthroplasty patients.

   The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System is a tibial extension implant containing electronics and software coupled with a base station and cloud analytics platform to process and visualize the resultant data for patients and their health care professional (HCP). The HCP user of the system includes the surgeon, a physician assistant, a nurse, or other medically trained staff under the supervision of a doctor. Using internal motion sensors (3-D accelerometers and 3-D gyroscopes), the CTE collects kinematic data pertaining to a patient's gait and activity level following total knee arthroplasty (TKA). The kinematic data produced by the CTE implant is intended as an adjunct to the TKA post-procedure standard of care, as directed by the physician. It is designed for use and

assembled with the Zimmer Biomet Persona Personalized Knee System (K113369) tibial baseplate. In addition to its data collection capabilities, the CTE implant provides additional stability to the complete knee prosthesis in the same manner as a traditional tibial extension.

The CTE with CHIRP System is designed to provide granular assessment of patient TKA functionality passively through remote collection of their kinematic data with high levels of compliance during the acute 90-day episode of care and continuously for up to 20 years. The kinematic data generated from the CTE implant will afford the doctor and the patient the opportunity to monitor their TKA's function, potentially improving the delivery and quality of healthcare for the patient.

The CTE with CHIRP System uses two different base station configurations. The Operating Room (OR) Base Station system is used only during the surgical implantation to wake up the CTE from its manufactured state, to insure it is operating to specification, to record TKA serial number information, and to set the time zero starting point for data collection. The Home Base Station System is intended for use in the patient's home environment and is used to query the CTE while the patient is asleep to upload data daily for up to 20 years to the Canary Cloud where it is processed by the system's Canary Medical Gait Parameter (CMGP) software into clinically relevant metrics.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: INDIGO Aspiration System with Lightning Aspiration Tubing

2. Manufacturer Name: Penumbra, Inc.

3. Trade Brand of Technology: INDIGO Aspiration System with Lightning Aspiration Tubing

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 INDIGO Aspiration system with Lightning Aspiration tubing is an intelligent mechanical thrombectomy aspiration system powered by the Penumbra Engine which utilizes a unique mechanism of action that enables and optimizes thrombus removal procedures by differentiating between thrombus and blood.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: **Amivantamab**
2. Manufacturer Name: **Janssen Biotech, Inc.**
3. Trade Brand of Technology: **Amivantamab 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)?

   Amivantamab 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.

   Amivantamab 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:

   Amivantamab is a bispecific monoclonal antibody that is able to inhibit the epidermal growth factor receptor (EGFR) and c-MET tyrosine kinase signaling pathways known to be involved in the pathogenesis of non-small cell lung cancer (NSCLC).

   In March 2020, amivantamab received breakthrough therapy designation from the FDA for the treatment of patients with metastatic NSCLC due to exon 20 ins mutations whose disease has progressed on or after platinum-based chemotherapy. Currently, no therapy is FDA-approved for this patient population and the most commonly used therapies are associated with limited efficacy.

Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: **Ciltacabtagene autoleucel**

2. Manufacturer Name: **Janssen Biotech, Inc.**

3. Trade Brand of Technology: **Ciltacabtagene autoleucel 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)?

   Ciltacabtagene autoleucel 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.

   Ciltacabtagene autoleucel 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:

   Ciltacabtagene autoleucel 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. Ciltacabtagene autoleucel is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

   Ciltacabtagene autoleucel'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 ciltacabtagene autleucel in previously treated patients with relapsed and refractory MM.

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: Single-use duodenoscope
2. Manufacturer Name: Ambu, Inc.
3. Trade Brand of Technology: aScope™ Duodeno
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 aScope Duodeno is a disposable endoscope for use in the upper gastrointestinal tract. The endoscope is packaged sterile and is single-use. The device is used for endoscopy and endoscopic surgery within the duodenum, also known as endoscopic retrograde cholangiopancreatography (ERCP).

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Baltimore, Maryland 21244-1850

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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: Device for percutaneous creation of an arteriovenous fistula using thermal resistance energy

2. Manufacturer Name: Avenu Medical, Inc.

3. Trade Brand of Technology: Ellipsys® Vascular Access System

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 Ellipsys® Vascular Access System is a device that enables percutaneous creation of an arteriovenous fistula (AVF), which is used to access the bloodstream for hemodialysis. A physician (surgeon, interventional nephrologist, or interventional radiologist) inserts a crossing needle through the proximal radial artery and pierces an adjacent vein in the forearm, then uses a specialized catheter to bring the artery and vein together and “welds” the two vessels together with thermal resistance energy, creating an anastomosis.

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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:** Oversleeve based, High Intensity Intra-procedural cleansing colonoscopy device

2. **Manufacturer Name:** Motus GI

3. **Trade Brand of Technology:** Pure Vu System

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 Pure-Vu System is designed to connect to currently marketed colonoscopes to avoid aborted and delayed colonoscopies due to poor visualization of the colon mucosa by providing high intensity intra-procedural cleansing of the colon during a colonoscopy. The Pure-Vu System is comprised of a Workstation (WS) that controls the function of the system and a disposable Oversleeve that is mounted on a colonoscope and inserted into the patient.

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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: Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 Coronary IVL Catheter

2. Manufacturer Name: Shockwave Medical, Inc

3. Trade Brand of Technology: Shockwave C^2 Intravascular Lithotripsy 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 IVL Catheter is a proprietary lithotripsy device delivered through the coronary arterial system of the heart to the site of an otherwise difficult to treat calcified stenosis, including calcified stenosis that are anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion. Energizing the lithotripsy device will generate intermittent sound waves within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a coronary artery stenosis using low balloon pressure.

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Baltimore, Maryland 21244-1850

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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: The Neovasc Reducer™ System
2. Manufacturer Name: Neovasc Inc.
3. Trade Brand of Technology: Neovasc Reducer™
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes. The Reducer System was granted Breakthrough Device designation by the FDA in October 2018.

   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 Neovasc Reducer System is implanted percutaneously via the right or left jugular vein into the coronary sinus (CS). The Reducer is a stainless-steel mesh device designed to create a focal narrowing in the lumen of the CS to generate a pressure gradient across it.

   The Reducer System comprises of the Reducer device pre-mounted on a customized hourglass shaped balloon catheter. When inflated, the expanded balloon gives the metal mesh its final hourglass configuration.

   The Reducer creates a permanent and controlled narrowing of the coronary sinus to improve perfusion to ischemic myocardium and lead to relief of angina symptoms in patients with refractory angina.

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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:

   Trilaciclib

2. Manufacturer Name:

   G1 Therapeutics, Inc.

3. Trade Brand of Technology:

   The trade/brand name of trilaciclib will not be finalized until the product receives 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, trilaciclib 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, trilaciclib is not a QIDP or a LPAD.

5. Brief Description of Service, Device or Drug:

   Trilaciclib is a first-in-class myelopreservation therapy that has the potential to mitigate chemotherapy induced myelosuppression (CIM).

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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Centers for Medicare & Medicaid Services
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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: Harmony™ Transcatheter Pulmonary Valve System

2. Manufacturer Name: Medtronic

3. Trade Brand of Technology: Harmony™ Transcatheter Pulmonary Valve System

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

   Yes, Harmony™ Transcatheter Pulmonary Valve System has received 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.

   Not applicable

5. Brief Description of Service, Device or Drug:

   The Harmony™ transcatheter pulmonary valve (TPV) is a bioprosthetic heart valve developed from porcine (pig's) pericardial tissue mounted on self-expanding nitinol struts sewn to a polyester fabric. The Harmony™ TPV is implanted in the patient's heart between the right ventricle and the bifurcation of the pulmonary arteries to treat patients with congenital heart disease who are indicated for pulmonary valve replacement.

Centers for Medicare & Medicaid Services
Center for Medicare Management
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Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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1. Technology Name: Veklury (remdesivir)

2. Manufacturer Name: Gilead Sciences, Inc.

3. Trade Brand of Technology: Veklury®

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

   No, Veklury is a drug and therefore does not qualify for Breakthrough Device designation.

   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, Veklury has not been designated by the FDA as a QIDP or LPAD.

5. Brief Description of Service, Device or Drug:

   Veklury is an investigational nucleotide analog with broad-spectrum antiviral properties, demonstrating activity countering viral pathogens such as MERS, SARS, and SARS-CoV-2, the virus responsible for COVID-19.

   The FDA has recently authorized the emergency use of Gilead's Veklury to treat hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19. Gilead submitted a new drug application (NDA) on August 7, 2020 for Veklury for treatment of COVID-19 and has received Fast Track designation and Priority Review.

   Veklury has been tested in randomized, double blind, placebo controlled clinical trial for its efficacy in treating COVID-19 with a primary outcome of reduced time to recovery including in severe and critical disease. Veklury shortened the time to recovery for patients with COVID-19 by a median of 5 days compared to placebo.

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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

1. Technology Name: ISC-REST (Ischemia Care Respiratory and Stroke Test)

2. Manufacturer Name: Ischemia Care, LLC

3. Trade Brand of Technology: Not applicable.

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 ISC-REST combines (i) a blood test for cause of stroke (ISCDx), (ii) plus a respiratory panel that includes COVID screening, (iii) plus a COVID antibody test. The primary purpose of ISC-REST is to stratify ischemic stroke patients by cause, including COVID status, to simplify care pathways to prevent a secondary stroke which is often more severe, costly, and debilitating. ISC-REST targets strokes of “unknown cause” that are diagnosed as “cryptogenic”, that represent up to 40% of all ischemic strokes. When cause of stroke is identified, secondary prevention protocols maybe adopted to prevent recurrent stroke.

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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: **Steripath® Micro™ Blood Collection System**

2. Manufacturer Name: **Magnolia Medical Technologies, Inc.**

3. Trade Brand of Technology: **Steripath® Micro™ Blood Collection System**

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 Steripath® Micro™ Blood Collection System is a proprietary and patent-protected Initial Specimen Diversion Device® (ISDD®) for blood culture collection and contamination prevention. Steripath Micro ISDD is a class II medical device that received 510(k) clearance from the FDA on October 8, 2020. The Steripath ISDD product portfolio, including the Steripath Micro ISDD, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination[1].**

   The motivation to design and develop the Steripath Micro ISDD was inspired by the fact that a meaningful percent of patients who present symptomatic for sepsis are compromised, hypotensive (low blood pressure) and hypovolemic (low blood volume), have difficult intravenous access (DIVA) or are small in stature with lower blood volume. There are no other clinically proven FDA 510(k)-cleared technology solutions indicated to reduce blood culture contamination for these patient populations. The Steripath Micro, which employs clinically proven ISDD technology, is the first FDA 510(k)-cleared device indicated to reduce blood culture contamination[1], designed specifically to address the unmet need of these patient populations.

   Steripath Micro is a single-use disposable device used for blood culture collection by nurses, phlebotomists and technicians in emergency departments and inpatient units in acute care hospitals to reduce blood culture contamination and false positive diagnostic test results for sepsis. Specifically, the Steripath Micro platform architecture uses syringe-driven (or blood culture bottle-driven) negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood. The initial specimen is the portion known to most likely contain contaminants. Once diversion is complete the user simply presses a button to isolate the

diverted blood and automatically a second independent blood flow pathway opens to collect the blood specimen into the syringe (or blood culture bottle) for culture.

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[1] The Steripath® Micro Blood Collection System is a system to draw blood for in vitro diagnostic testing.

The Steripath® Micro Blood Collection System is indicated for use as a blood collection system that diverts and sequesters the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion.

Additionally, components of the system may be used for infusion following sample collection after disconnection of the Initial Specimen Diversion Device® (ISDD®).

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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: **Pathogen reduced cryoprecipitated fibrinogen complex (PRCFC)**

2. Manufacturer Name: **Cerus Corporation**

3. Trade Brand of Technology: **The name of this technology is pending FDA review.**

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **Yes, PRCFC has been awarded Breakthrough Device designation from the Food and Drug Administration (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. **No, PRCFC is not a QIDP.**

5. Brief Description of Service, Device or Drug:

   PRCFC is a treatment for fibrinogen deficiency-related bleeding, including massive hemorrhage. PRCFC replaces the fibrinogen that these patients have lost due to excessive bleeding. After thawing, PRCFC has a five-day shelf life at room temperature and therefore is immediately available as a ready-to-transfuse fibrinogen source, thereby providing a significant benefit for patients with massive hemorrhage in a real time-critical fashion that is not achievable with existing fibrinogen replacement today.

Centers for Medicare & Medicaid Services
Center for Medicare Management
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Baltimore, Maryland 21244-1850

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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:

   RECELL® Autologous Cell Harvesting Device

2. Manufacturer Name:

   Avita Medical

3. Trade Brand of Technology:

   RECELL

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

   Yes, the RECELL Autologous Cell Harvesting Device has received 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.

   No.

5. Brief Description of Service, Device or Drug:

   The RECELL System is used to process and apply an autologous skin cell suspension for the treatment of acute thermal burn wounds. The autograft procedure utilizing the RECELL system involves harvesting a small graft from the patient's healthy skin and placing it into the RECELL System for immediate processing into an autologous skin cell suspension that is then applied to the surgically prepared burn wound.

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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: 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

   Lifileucel will be approved under the Biologics License Application (BLA) regulatory pathway

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 as 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 BRAF inhibitor with MEK inhibitor. Upon FDA approval, lifileucel will be the first and only cell 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 and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the infusion of lifileucel, the TIL migrate back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens.

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

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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Centers for Medicare & Medicaid Services
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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: Molnupiravir

   Manufacturer Name: Merck & Co., Inc

2. Trade Brand of Technology: As of the submission of this application, the trade/brand name has not yet been determined.

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

   Not applicable; molnupiravir 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, molnupiravir has not been designated by the FDA as a QIDP. Molnupiravir is not approved by FDA for any use at this time, and Merck is not seeking approval under FDA's LPAD pathway.

4. Brief Description of Service, Device or Drug:

   Molnupiravir is being developed for the treatment of patients with COVID-19. Molnupiravir is the 5´-isobutyrate prodrug of the broadly active, direct-acting antiviral ribonucleoside analog N-hydroxycytidine (NHC).

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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1. **Technology Name**: Caption Guidance

2. **Manufacturer Name**: Caption Health, Inc.

3. **Trade Brand of Technology**: Caption Guidance

4. **A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?** Yes, FDA granted breakthrough device designation in 2018.

   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)? No

5. **Brief Description of Service, Device or Drug**: Caption Guidance is an FDA-cleared AI-guided medical imaging acquisition system intended to assist medical professionals in the acquisition of cardiac ultrasound images.

   The system is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients, specifically in the acquisition of the following standard views:
   - Parasternal Long-Axis (PLAX),
   - Parasternal Short-Axis at the Aortic Valve (PSAX-AV),
   - Parasternal Short-Axis at the Mitral Valve (PSAX-MV),
   - Parasternal Short-Axis at the Papillary Muscle (PSAX-PM),
   - Apical 4-Chamber (AP4),
   - Apical 5-Chamber (AP5),
   - Apical 2-Chamber (AP2),
   - Apical 3-Chamber (AP3),
   - Subcostal 4-Chamber (SubC4), and
   - Subcostal Inferior Vena Cava (SC-IVC).

Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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

1. Technology Name: brexucabtagene autoleucel

2. Manufacturer Name: Kite Pharma Inc., a Gilead Company

3. Trade Brand of Technology: TECARTUS®

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: TECARTUS is a CD19-directed, genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory (r/r) mantle cell lymphoma. TECARTUS was approved by the United States Federal Food & Drug Administration (FDA) on July 24, 2020 under the FDA's Accelerated Approval Program. Accelerated approval was based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Earlier, TECARTUS was granted Breakthrough Therapy Designation by the FDA for the treatment of r/r MCL.

   TECARTUS is a single infusion product consisting of autologous T cells that have been engineered ex vivo to express an anti-CD19 chimeric antigen receptor (CAR) that targets CD19 on the cell surface of normal and malignant B cells. The anti-CD19 CAR T-cell products used in TECARTUS are manufactured from the patient's own T cells, which are obtained via leukapheresis. TECARTUS is a distinct cellular product and has a unique manufacturing process customized for B-cell malignancies with a high circulating tumor cell burden and designed to minimize the CD19-expressing tumor cells in the final product. The T cells from the harvested leukocytes from the leukapheresis product are enriched by positive selection, activated by culturing with anti-CD3 and anti-CD28 antibodies, and then transduced with a retroviral vector containing an anti-CD19 CAR gene. These engineered T cells are then propagated in culture to generate a sufficient number of cells to achieve a therapeutic effect upon infusion back into the patient.

   TECARTUS is the first and only CAR T-cell immunotherapy indicated for treatment of r/r MCL.

Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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

1. Technology Name: lurbinectedin

2. Manufacturer Name: Jazz Pharmaceuticals, Inc.

3. Trade Brand of Technology: ZEPZELCA™

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

- Brief Description of Service, Device or Drug:

  ZEPZELCA is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. The New Drug Application (NDA) for ZEPZELCA was approved by the FDA on June 15, 2020, under the FDA's Accelerated Approval Program with Priority Review and in advance of the FDA's previously announced Prescription Drug User Fee Act (PDUFA) target action date of August 16 2020. Earlier, ZEPZELCA was granted Orphan Drug Designation.

  ZEPZELCA is a novel synthetic antineoplastic compound with a unique mode of action and chemical structure. It is a synthetic marine-derived agent. The ZEPZELCA mechanism of action is based on the inhibition of transcription-dependent replication stress and genome instability of tumor cells. ZEPZELCA impacts the tumor microenvironment through multiple interactions by altering the survival of tumor-associated macrophages and the production and function of key oncogenic inflammatory and growth factors, as shown in preclinical data. Additionally, ZEPZELCA has been shown to induce immunogenic cell death.

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:

   RECARBRIO (imipenem, cilastatin, and relebactam) for injection for intravenous use.

2. Manufacturer Name:

   Merck & Co.

3. Trade Brand of Technology:

   RECARBRIO

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

   No, RECARBRIO has not received a Breakthrough Device designation as it 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.

   Yes, RECARBRIO has been designated by the FDA as QIDP for all of its indications.

5. Brief Description of Service, Device or Drug:

   RECARBRIO is a fixed-dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel β-lactamase inhibitor (BLI). RECARBRIO is indicated in patients 18 years of age and older for the treatment of the following infections caused by susceptible gram-negative bacteria:

   Hospital-Acquired Bacterial Pneumonia (HABP) and Ventilator-Associated Bacterial Pneumonia (VABP)

   RECARBRIO is indicated for the treatment of patients 18 years of age and older with HABP and VABP, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus*

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influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, and *Serratia marcescens.*

Complicated Urinary Tract Infections (cUTI), including Pyelonephritis

RECARBRIO is indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa.*

Approval of this indication is based on limited clinical safety and efficacy data for RECARBRIO.

Complicated Intra-abdominal Infections (cIAI)

RECARBRIO is indicated in patients 18 years of age and older who have limited or no alternative treatment options for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible gram-negative microorganisms: *Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis,* and *Pseudomonas aeruginosa.*

Approval of this indication is based on limited clinical safety and efficacy data for RECARBRIO.

RECARBRIO was approved for NTAP for FY 2021 for the treatment of the following infections caused by susceptible gram-negative bacteria: (a) complicated urinary tract infections (cUTI), including pyelonephritis (b) complicated intra-abdominal infections (cIAI).

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1. **Technology Name:**

The technology name is StrataGraft® skin tissue for topical application.

2. **Manufacturer Name:**

The manufacturer is Stratatech Corporation, a Mallinckrodt company.

3. **Trade Brand of Technology:**

Subject to final Food and Drug Administration (FDA) approval, the trade name for the product is StrataGraft® skin tissue for topical application.

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

StrataGraft skin tissue is not a medical device and has not received 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.

StrataGraft skin tissue has not been designated by the FDA as a QIDP or LPAD.

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

StrataGraft skin tissue is an investigational biological drug for which Mallinckrodt Pharmaceuticals intends to seek FDA approval for the proposed indication of treatment of adult patients with severe thermal burns that contain intact dermal elements, and for which surgical intervention is clinically indicated. FDA approval is anticipated by February 2, 2021.

StrataGraft skin tissue is a viable, bioengineered, regenerative skin construct that provides durable wound closure, epidermal barrier function, and regenerative healing in adults with severe thermal burns that contain intact dermal elements while reducing or eliminating the need for harvest of donor site tissue. The active cellular components of StrataGraft skin tissue are the viable and metabolically active allogeneic human NIKS® keratinocytes and normal human dermal fibroblasts.

Centers for Medicare & Medicaid Services
Center for Medicare Management
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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:**

The technology name is TERLIVAZ® (terlipressin) injection, for intravenous use.

2. **Manufacturer Name:**

The manufacturer is Mallinckrodt Pharmaceuticals.

3. **Trade Brand of Technology:**

Subject to final Food and Drug Administration (FDA) approval, the trade name for the product is TERLIVAZ® (terlipressin) injection, for intravenous use.

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

TERLIVAZ is not a medical device and has not received 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.

TERLIVAZ has not been designated by the FDA as a QIDP or LPAD.

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

Terlipressin, a synthetic, systemic vasoconstrictor with selective activity at vasopressin-1 receptors, is a pro-drug for the endogenous/natural porcine hormone lysine-vasopressin.

Terlipressin is an investigational drug for which Mallinckrodt Pharmaceuticals is seeking FDA approval for the proposed indication of treatment of patients with hepatorenal syndrome type 1 (HRS-1). FDA approval is anticipated by June 30, 2021.

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7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

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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.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: Briefcase for PE

2. Manufacturer Name: Aidoc, Inc.

3. Trade Brand of Technology: Aidoc Briefcase for PE

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 Briefcase for PE is an FDA cleared solution providing an AI-based triage and notification of suspected Pulmonary Embolism cases enabling shorter time to notification. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings in contrast enhanced chest CT examinations (including dedicated CTPAs). Presenting the radiologist with notification facilitates earlier triage by prompting the user to assess the relevant original images in the PACS. Thus, the suspect case receives attention earlier than would have been the case in the standard of care practice alone.

   The software system is based on an algorithm programmed component and is comprised of a standard off-the-shelf operating system, the Microsoft Windows server 2012 64bit, and additional applications, which include PostgreSQL, DICOM module and the BriefCase Image Processing Application. The device consists of the following three modules: (1) Aidoc Hospital Server (AHS); (2) Aidoc Cloud Server (ACS); and (3) Aidoc Worklist Application that is installed on the radiologist' desktop and provides the user interface in which notifications from the BriefCase software are received.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Technology Name: SDH

2. Manufacturer Name: Viz.ai, Inc.

3. Trade Brand of Technology: Viz SDH

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: Viz SDH is a radiological computer-assisted triage and notification software system intended for use by hospital networks and trained clinicians that analyzes non-contrast computed tomography (CT) images of the head acquired in the acute setting, sends notifications to a neurosurgical specialist(s) that a suspected subdural hematoma (SDH) has been identified, and recommends review of those images. The analysis runs in parallel to the hospital's usual standard of care and CT image analysis workflow.

   SDH is a single software system comprised of three components:

   - An algorithm that uses artificial intelligence and deep learning to automatically identify suspected SDHs on CT imaging and alerts on-call neurosurgical physicians within minutes.
   - A secure, HIPAA-compliant text messaging and calling platform that allows clinical teams to coordinate patient care and treatment decisions; and
   - A mobile image viewer that enables the viewing of Digital Imaging and Communications in Medicine (DICOM) images on a mobile device.

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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CENTERS FOR MEDICARE & MEDICAID SERVICES

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1. Technology Name: **fosfomycin for injection**

2. Manufacturer Name: **Nabriva Therapeutics US, Inc.**

3. Trade Brand of Technology: **CONTEPO™**

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.

   Yes. The FDA has designated CONTEPOP™ as a Qualified Infectious Disease Product.

5. Brief Description of Service, Device or Drug:

   CONTEPO™ (fosfomycin for injection), has been developed for treatment of complicated urinary tract infections (cUTI). Given its microbiologic and clinical profile, it is expected that CONTEPO will play an important role in the treatment of hospitalized patients with a serious infection suspected or confirmed to be caused by drug resistant bacteria. Use of CONTEPO for initial appropriate therapy will obviate the need to use carbapenems to treat infections suspected or confirmed to be caused by ESBL and pathogens. This carbapenem sparing-effect should help reduce the rate of carbapenem resistance in the United States. CONTEPO provides a much needed alternative to available therapies for patients who have no other antibiotic option

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1. Technology Name: NexoBrid® (concentrate of proteolytic enzyme enriched in Bromelain) Powder and Gel for Gel

2. Manufacturer Name: Vericel

3. Trade Brand of Technology: NexoBrid®

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

   No, NexoBrid® is a biologic and therefore has not received a Breakthrough Device designation.

   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, NexoBrid® has not been designated by the FDA as QIDP or LPAD.

5. Brief Description of Service, Device or Drug:

   NexoBrid® is a non-surgical, biologic option for removal of nonviable burn tissue, or eschar, in adult patients with deep partial-thickness and/or full-thickness thermal burns.

   The active ingredient of NexoBrid is a mixture of a concentrate of proteolytic enzymes enriched in bromelain. The mechanism of action of NexoBrid is mediated by the proteolytic activity of its enzymes and is associated with selective debridement of eschar and denatured collagen while sparing healthy tissue.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

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1. Technology Name:

   VGS Venous External Support (VEST) Device

2. Manufacturer Name:

   Vascular Graft Solutions

3. Trade Brand of Technology:

   VGS VEST

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?
   No, but an application for Breakthrough Device Designation (BDD) is pending with the FDA. We will update CMS on the status of the BDD application when FDA's decision is received.

   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 VGS Venous External Support (VEST) device is an external mechanical support for autologous saphenous vein grafts that are created during Coronary Artery Bypass Surgery (CABG). Comprised of a braid of cobalt chromium wires, the VEST device is a permanent implant placed outside the vein graft by a cardiac surgeon during the CABG procedure to support the saphenous vein graft. The VEST is deployed over the entire length of the vein graft before the anastomoses are completed and remains in place once both the proximal and distal anastomoses have been completed without any additional fixation.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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1. Technology Name: STROKE NCCT

2. Manufacturer Name: Viz.ai, Inc.

3. Trade Brand of Technology: Viz STROKE NCCT

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: Viz STROKE NCCT is designed to analyze non-contrast computed tomography (NCCT) images of the head for findings suggestive of stroke, aggregating the information and classifying the scan as low, medium or high suspicion that the patient is suffering a stroke. The device combines image findings into a single classification to facilitate the effective triage and diagnosis of patients by a specialist. Upon detecting high suspicion of stroke, the product generates a notification to the neurovascular specialist. Notification of the specialist of findings occurs in parallel to the standard of care image interpretation.

   Viz STROKE NCCT is a software system comprised of three components:

   - An algorithm that uses artificial intelligence and deep learning to automatically identify suspected LVOs on NCCT imaging and alerts on-call stroke physicians within minutes;
   - A secure, HIPAA-compliant text messaging and calling platform that allows clinical teams to coordinate patient care and treatment decisions; and
   - A mobile image viewer that enables the viewing of Digital Imaging and Communications in Medicine (DICOM) images on a mobile device.