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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) 2021**

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

1. Technology Name: Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system
2. Manufacturer Name: Accelerate Diagnostics, Inc.
3. Trade Brand of Technology: Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ 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)? No.
5. Brief Description of Service, Device or Drug:

The Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system is the only fast, automated, phenotypic, direct-from-positive blood culture ID/AST technology available. It provides MIC values as well as SIR categorical designations (i.e., susceptible, intermediate, resistant). MIC results are used to not only choose which antimicrobial(s) is/are active for a patient's infection, but also may be used to modify dosing, based on the relative degree of resistance to an antimicrobial the MIC indicates. Both results are significantly faster than other methods (approximately 40 hours faster).



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

1. Technology Name: BAROSTIM NEO® System
2. Manufacturer Name: CVRx, Inc.
3. Trade Brand of Technology: BAROSTIM NEO® System
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Yes, the BAROSTIM NEO® System has received 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)? N/A
5. Brief Description of Service, Device or Drug:

BAROSTIM THERAPY is a neuromodulation therapy that triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. A single 2mm coated electrode with a 7mm silicone backer is sutured to the carotid artery to activate the baroreceptors. It is connected to an implantable pulse generator (IPG) in the chest which provides control of baroreflex activation energy. Parameters are programmed into the IPG using telemetry via a wireless external programming system.

The BAROSTIM NEO System is implanted with a stimulating electrode on the carotid artery and is connected to an implantable pulse generator. Initiation of therapy electrically activates the baroreflex. Parasympathetic activity to the heart and other organs is increased while sympathetic activity to the heart, blood vessels, adrenal glands, kidneys, lungs and other organs is reduced. Through regulation of the sympathetic and parasympathetic activities, blood vessels relax and put less pressure on the heart, allowing it to work more efficiently to relieve congestion and swelling.



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

1. Technology Name: BioFire® FilmArray® Pneumonia Panel
2. Manufacturer Name: BioFire Diagnostics, LLC
3. Trade Brand of Technology: FilmArray
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)? No

5. Brief Description of Service, Device or Drug:

The BioFire Pneumonia Panel is an in-vitro diagnostic device that identifies the major causes of infectious pneumonia by detecting 33 clinically relevant targets, including bacterial and viral targets, from sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples in about an hour. For 15 of the bacteria, the BioFire Pneumonia Panel provides semi-quantitative results, which may help determine whether an organism is a colonizer or a pathogen.

**ATTACHMENT A**

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



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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 Celgene Company (Juno)**
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)?

**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)?

**lisocabtagene maraleucel is not a QIDP.**

5. Brief Description of Service, Device or Drug:

Lisocabtagene maraleucel is an investigational, CD19-directed, chimeric antigen receptor (CAR) T-cell immunotherapy product comprising 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 after at least two prior therapies.

Lisocabtagene maraleucel is manufactured from a patient's own immune cells (T-cells) and 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) CART-cells in suspensions that are thawed and infused separately in a defined composition. Lisocabtagene maraleucel is manufactured and administered at a target dose of CD4 and CD8 CAR T-cells by infusing a calculated volume withdrawn from a vial, resulting in a more precise number of CAR T-cells administered by infusion to each lisocabtagene maraleucel patient compared to other products on the market.



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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:  
The Trade Brand of cefiderocol has not yet been approved by the FDA
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?  
Not Applicable  
  
B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP)?  
Yes
5. Brief Description of Service, Device or Drug:  
Cefiderocol is currently under evaluation by the FDA. Final labeling information is not available at this time, but cefiderocol is expected to be indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible Gram-negative pathogens: *Escherichia coli* (including with concurrent bacteremia), *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Citrobacter freundii*, *Enterobacter cloacae*, *Morganella morganii*, and *Serratia marcescens*. Cefiderocol is administered intravenously, and should be used to treat infections where limited or no alternative treatment options are available and where cefiderocol is likely to be an appropriate treatment option, which may include use in patients with infections caused by documented or highly suspected carbapenem-resistant and/or multidrug-resistant Gram-negative pathogens.



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

1. Technology Name: ContaCT (Radiological Computer-Assisted Triage And Notification Software)
2. Manufacturer Name: Viz.ai, Inc.
3. Trade Brand of Technology: ContaCT
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)? No.
5. Brief Description of Service, Device or Drug: ContaCT is an FDA-authorized radiological computer-assisted triage and notification software system intended for use by hospital networks and trained clinicians that analyzes CT angiogram (CTA) images of the brain acquired in the acute setting, sends notifications to a neurovascular specialist(s) that a suspected large vein occlusion (LVO) has been identified, and recommends review of those images. The ContaCT analysis runs in parallel to the hospital's usual standard of care CTA image analysis workflow.  
  
ContaCT is a single FDA-authorized software system comprised of three components:
  - An algorithm that uses artificial intelligence and deep learning to automatically identify suspected LVOs on CTA 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.



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

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)?

**Yes. The FDA has designated CONTEPO™ as a Qualified Infectious Disease Product (QIDP).**

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

1. Technology Name:

Eluvia™ Drug-Eluting Vascular Stent System (Eluvia)

2. Manufacturer Name:

Boston Scientific Corporation

3. Trade Brand of Technology:

Eluvia™ Drug-Eluting Vascular Stent 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)?

No

5. Brief Description of Service, Device or Drug:

The Eluvia Drug-Eluting Vascular Stent System is a novel implantable stent designed for the treatment of lesions in the femoropopliteal arteries. It is a device/drug combination product composed of an implantable endoprosthesis (stent), a drug coating (a formulation of paclitaxel contained in a polymer matrix) and a stent delivery system. The polymer carries and protects the drug before and during the procedure and ensures that the drug is released into the tissue in a controlled, sustained manner to prevent the re-narrowing of the vessel (restenosis). Eluvia's stent platform is purpose-built to address the mechanical challenges of the SFA with an optimal amount of strength, flexibility and fracture resistance. The Eluvia Stent System is designed to restore blood flow in the peripheral arteries above the knee – specifically the superficial femoral artery and proximal popliteal artery. The stent features a unique drug-polymer combination intended to facilitate sustained release of the drug paclitaxel that can prevent narrowing (restenosis) of the vessel.



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

1. Technology Name:

GammaTile™

2. Manufacturer Name:

GT Medical Technologies, Inc.

3. Trade Brand of Technology:

GammaTile™

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)?

No.

5. Brief Description of Service, Device or Drug:

The GammaTile™ is a customized permanent cesium-131 brain implant with brachytherapy sources in collagen matrix.



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

1. Technology Name: Hemospray® Endoscopic Hemostat
2. Manufacturer Name: Cook Medical
3. Trade Brand of Technology: Hemospray® Endoscopic Hemostat
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)?

No

5. Brief Description of Service, Device or Drug:

Hemospray® is an inert, bentonite powder developed for endoscopic hemostasis. The powder is delivered by use of a carbon dioxide powered delivery system through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleed. Hemospray® is indicated for hemostasis of nonvariceal gastrointestinal bleeding.



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

1. Technology Name: imlifidase
2. Manufacturer Name: Hansa Biopharma AB
3. Trade Brand of Technology: Trade name Idefirix has been conditionally accepted by the FDA
4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? n/a  
  
B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP)? n/a
5. Brief Description of Service, Device or Drug:

Imlifidase intervention allows rapid desensitization and cross-match conversion (clinically significant reduction in donor-specific IgG antibodies) permitting HLA-incompatible transplantation in sensitized kidney transplantation recipients. The IgG concentration in serum from patients treated with imlifidase rapidly, within 1 to 6 hours, decreased to only a small fraction of the pre-implifidase levels.



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

1. Technology Name:

Durvalumab

2. Manufacturer Name:

AstraZeneca PLC

3. Trade Brand of Technology:

IMFINZI™ (durvalumab) 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)?

No, durvalumab 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)?

No, durvalumab has not been designated as a Qualified Infectious Disease Product (QIDP).

5. Brief Description of Service, Device or Drug:

Durvalumab is a selective, high-affinity, human IgG1 monoclonal antibody (mAb) that blocks programmed death-ligand 1 (PD-L1) binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity.

AstraZeneca submitted a supplemental biologics license application for durvalumab in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). If approved, durvalumab will offer a new mechanism of action over the standard of care chemotherapy (etoposide with either cisplatin or carboplatin) for the first-line treatment of ES-SCLC, combining immunotherapy with different platinum-based regimens.



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2021**

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

1. Technology Name: KTE-X19, investigational name
2. Manufacturer Name: Kite Pharma, a Gilead company
3. Trade Brand of Technology: Not yet 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)? No
5. Brief Description of Service, Device or Drug: Kite Pharma is developing KTE-X19 as a novel, investigational, adoptive cellular immunotherapy for the treatment of adult patients with relapsed/refractory mantle cell lymphoma (r/r MCL). When approved by the FDA, KTE-X19 will represent the only FDA-approved CAR T treatment for adult patients with r/r MCL.

KTE-X19 is a single infusion product consisting of autologous T cells that have been engineered ex vivo to express an anti-CD19 CAR that targets CD19 on the cell surface of normal and malignant B cells. The anti-CD19 CAR T-cell products used in KTE-X19 are manufactured from the patient's own T cells, which are obtained via leukapheresis. KTE-X19 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.

KTE-X19 was granted Breakthrough Therapy Designation by the FDA on June 15, 2018 for the treatment of patients with r/r MCL.



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

1. Technology Name: **The NanoKnife System, Irreversible Electroporation (IRE) for the treatment of pancreatic cancer**
2. Manufacturer Name: **AngioDynamics, Inc.**
3. Trade Brand of Technology:

**The NanoKnife System, Irreversible Electroporation (IRE) for the treatment of pancreatic cancer**

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)?

**No**

5. Brief Description of Service, Device or Drug:

**The NanoKnife System is medical device that has been designated a breakthrough device for surgical treatment of patients with unresectable pancreatic cancer. The NanoKnife System consists of a dedicated generator and specialized electrode probes used for inpatient hospital ablation procedures.**

**A NanoKnife IRE procedure is a surgical ablation procedure that delivers a series of high voltage direct current electrical pulses between two or more electrodes placed within a target area of tissue. The electrical pulses produce an electric field which induces electroporation on cells within the target area. Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. After delivering a sufficient number of high voltage pulses, the cells surrounding the electrodes will be irreversibly damaged. This mechanism which causes permanent cell damage is referred to as Irreversible Electroporation (IRE).**

**On March 28, 2019, the FDA approved the investigational device exemption (IDE), including the Category B designation, and on May 3, 2019, CMS approved coverage for the DIRECT Study which is now enrolling patients.**



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

1. Technology Name:

Omadacycline for injection, for intravenous use

2. Manufacturer Name:

Paratek Pharmaceuticals

3. Trade Brand of Technology:

NUZYRA® 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)?

Yes

5. Brief Description of Service, Device or Drug:

NUZYRA for injection is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*.
- Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (methicillin susceptible and resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.



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1. Technology Name:  
The OPTIMIZER Smart System
2. Manufacturer Name:  
Impulse Dynamics
3. Trade Brand of Technology:  
The Optimizer<sup>®</sup> 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)? Not Applicable
5. Brief Description of Service, Device or Drug:  
The Optimizer<sup>®</sup> system is a device-based treatment that provides cardiac contractility modulation therapy for chronic heart failure patients with advanced symptoms that have normal QRS duration and are not indicated for cardiac resynchronization therapy. The Optimizer System consists a rechargeable implantable pulse generator (IPG), a mini-charger utilized by the patient to recharge the IPG and a programmer utilized by qualified health care professionals to program the IPG over a large range of clinical settings.



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1. Technology Name:

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

2. Manufacturer Name:

Merck

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)?

Yes, RECARBRIO received the FDA's QIDP designation.

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  $\beta$ -lactamase inhibitor (BLI). RECARBRIO is indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria:

- Complicated urinary tract infections, including pyelonephritis (cUTI)
- Complicated intra-abdominal infections (cIAI)

Approval of these indications is based on limited clinical safety and efficacy data for RECARBRIO.



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1. Technology Name:

SIVEXTRO (tedizolid phosphate) for injection, for intravenous use; SIVEXTRO (tedizolid phosphate) tablet, for oral use

2. Manufacturer Name:

Merck

3. Trade Brand of Technology:

SIVEXTRO

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

No, SIVEXTRO 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)?

Yes, SIVEXTRO received the FDA's QIDP designation.

5. Brief Description of Service, Device or Drug:

SIVEXTRO is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of SIVEXTRO and other antibacterial drugs, SIVEXTRO should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.



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1. Technology Name:

Soliris® (eculizumab).

2. Manufacturer Name:

Alexion Pharmaceuticals, Inc.

3. Trade Brand of Technology:

Soliris® (eculizumab).

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)? No.

5. Brief Description of Service, Device or Drug:

Soliris, a first-in-class complement inhibitor, is the only FDA approved treatment for adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive. The use of Soliris in adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive is the subject of this application. NMOSD is a rare, severe, autoimmune disease that attacks the central nervous system without warning. These attacks, also referred to as relapses, can cause progressive and irreversible damage to the brain, optic nerve and spinal cord, which may lead to long-term disability. Complement activation due to the anti-AQP4 antibodies is one of the primary underlying causes of the destruction in these patients. In the pivotal trial the time to first relapse was significantly longer in Soliris treated patients compared to patients on placebo with a 94% reduction in risk of relapse for Soliris. Soliris demonstrated statistically significant relapse reduction that was observed for 3+ years:

- At approximately 1 year, 97.9% of patients receiving Soliris were relapse free
- At approximately 3 years, 96.4% of patients receiving Soliris were relapse free



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

1. Technology Name:

SpineJack® Expansion Kit

2. Manufacturer Name:

Stryker, Inc

3. Trade Brand of Technology:

SpineJack® 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)? Not Applicable

5. Brief Description of Service, Device or Drug:

The SpineJack® system is an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity bone cement. The SpineJack® system is designed to be implanted into a collapsed vertebral body via a percutaneous transpedicular approach under fluoroscopic guidance. Once in place, the implants are expanded to mechanically restore vertebral body height and maintain the restoration. The implants remain within the vertebral body and, together with the delivered bone cement, stabilize the restoration, provide pain relief and improve patient mobility. The SpineJack® system further reduces the risk of future adjacent and non-adjacent level fractures.

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



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

1. Technology Name:

The technology name is atezolizumab injection, for intravenous use.

2. Manufacturer Name:

The manufacturer name is Genentech, Inc.

3. Trade Brand of Technology:

The trade name of the product is TECENTRIQ® (atezolizumab) 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)?

No, TECENTRIQ is not a medical 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)?

No, TECENTRIQ has not been designated by the FDA as a QIDP.

5. Brief Description of Service, Device or Drug:

TECENTRIQ is a programmed death-ligand 1 (PD-L1) blocking antibody with four different oncology indications, including one in combination with carboplatin and etoposide, for the first-line treatment of adult patients with Extensive Stage-Small Cell Lung Cancer (ES-SCLC).



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

**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)?**

Terlipressin has not been designated by the FDA as a QIDP.

**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 intends to seek FDA approval for the proposed indication of treatment of patients with hepatorenal syndrome type 1 (HRS-1). FDA approval is anticipated by June 30, 2020.



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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) 2021**

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

1. Technology Name:

Supersaturated Oxygen (SSO<sub>2</sub>) Therapy

2. Manufacturer Name:

TherOx, Inc.

3. Trade Brand of Technology:

DownStream® System

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

No. The FDA Breakthrough Device designation was not available at the time of the TherOx PMA submission.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP)?

No

5. Brief Description of Service, Device or Drug:

SSO<sub>2</sub> Therapy is a targeted one-time 60-min infusion of superoxygenated blood that is administered immediately following PCI in the cardiac catheterization laboratory to treat anterior wall ST-elevation myocardial infarction patients. The timely delivery of SSO<sub>2</sub> Therapy improves microvascular and tissue level flow, reduces infarct size, facilitates recovery of left ventricular function and preserves left ventricular stability, and improves patient outcomes. SSO<sub>2</sub> Therapy is the first and only FDA-approved therapy for the direct treatment of the myocardium once flow has been restored to the heart muscle.



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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) 2021**

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

1. Technology Name: WavelinQ™ EndoAVF System
2. Manufacturer Name: Becton Dickinson & Company ("BD")
3. Trade Brand of Technology: WavelinQ™ (4F) EndoAVF 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)? No
5. Brief Description of Service, Device or Drug:

The WavelinQ™ EndoAVF System is an FDA-cleared technology indicated for the creation of an arteriovenous (AV) fistula in patients who have chronic kidney disease and need hemodialysis. Hemodialysis, a form of treatment for kidney failure patients, is a procedure that removes wastes, salts, and fluid from a patient's blood when the kidneys can no longer perform these functions. To receive dialysis, patients require a vascular access, such as an arteriovenous fistula, to connect to the dialysis machine.

Endovascular AV fistula creation using the magnetic-guided WavelinQ™ EndoAVF System. Endovascular AV fistula creation with the WavelinQ™ EndoAVF System is achieved using flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy and includes vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), venography (to fluoroscopically guide placement and alignment of the venous magnetic RF catheter, ultrasound and final fistulogram to document AV fistula creation.



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2021**

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

1. Technology Name: **lemafulin injection, for intravenous use  
lemafulin tablets, for oral use**
2. Manufacturer Name: **Nabriva Therapeutics US, Inc.**
3. Trade Brand of Technology: **XENLETA™ injection, for intravenous use  
XENLETA™ tablets, for oral use**
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)?

**Yes. The FDA has designated XENLETA™ as a Qualified Infectious Disease Product (QIDP).**

5. Brief Description of Service, Device or Drug:

XENLETA™ (lefamulin) is a pleuromutilin antibacterial agent representing the first intravenous (IV) and oral treatment option from a novel class of antibiotics for community-acquired bacterial pneumonia (CABP). Pleuromutilins inhibit bacterial protein synthesis by binding to the A- and P-sites of the peptidyl transferase center (PTC) in the large ribosomal subunit of the bacterial ribosome. This unique binding site in the highly conserved core of the ribosomal PTC is specific to the pleuromutilins, and it confers a lack of cross-resistance with other classes, as well as a low propensity for developing bacterial resistance.

XENLETA™ is indicated for the treatment of adults with CABP caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydomphila pneumoniae*. XENLETA also has in vitro activity against methicillin resistant *Staphylococcus aureus* as shown in List 2 in the USPI as well as from clinical data from an acute bacterial and skin and skin structure infection phase 2 study comparing 2 different doses of lefamulin to vancomycin.



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2021**

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

1. Technology Name:

ZERBAXA® (ceftolozane and tazobactam) for injection, for intravenous use

2. Manufacturer Name:

Merck

3. Trade Brand of Technology:

ZERBAXA

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

No, ZERBAXA has not received 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)?

Yes, ZERBAXA received QIDP designation for all indications (cUTI, cIAI, HABP, and VABP)

5. Brief Description of Service, Device or Drug:

ZERBAXA (ceftolozane and tazobactam) is a combination of ceftolozane, a cephalosporin antibacterial, and tazobactam, a  $\beta$ -lactamase inhibitor (BLI), indicated in patients 18 years or older for the treatment of the following infections caused by designated susceptible microorganisms:

- Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
- Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis
- Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA and other antibacterial drugs, ZERBAXA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.



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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) 2021**

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

1. Technology Name:

ZULRESSO™ (brexanolone) injection for intravenous use

2. Manufacturer Name:

Sage Therapeutics, Inc.

3. Trade Brand of Technology:

ZULRESSO™ (brexanolone) 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)?

No, ZULRESSO is a drug.

B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP)?

No.

5. Brief Description of Service, Device or Drug:

ZULRESSO is the first drug ever approved by the FDA specifically for postpartum depression (PPD) and represents an important treatment option for adult women suffering from this serious condition that can be life threatening to the mother and her child. ZULRESSO is a clear, colorless solution supplied in single dose vials. ZULRESSO is also a sterile and preservative-free solution intended for dilution. It is supplied as 100 mg brexanolone in a 20 mL single dose vial (5 mg/mL). ZULRESSO is administered as a continuous intravenous (IV) infusion over a total of 60-hours requiring titration. ZULRESSO is a neuroactive steroid gamma-aminobutyric acid (GABA)<sub>A</sub> receptor positive modulator.