



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient
Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020**

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

1. Technology Name:

AZEDRA® (iobenguane I 131) injection, for intravenous use

2. Manufacturer Name:

Progenics Pharmaceuticals, Inc.

3. Trade Brand of Technology:

The trade brand name of AZEDRA® (iobenguane I 131) was approved by the U.S. Food and Drug Administration (FDA) on July 30, 2018.

4. Brief Description of Service, Device or Drug:

AZEDRA® (iobenguane I 131) (AZEDRA) was approved by the FDA on July 30, 2018, as the first and only drug indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. The FDA granted AZEDRA Orphan Drug Designation for the treatment of neuroendocrine tumors on January 18, 2006, and Fast Track designation on March 8, 2006. AZEDRA also received Breakthrough Therapy designation from the FDA on July 26, 2015.

AZEDRA, a very high specific activity radiopharmaceutical, delivers tumor destructive power and potentially avoids harmful side effects that typically result from the use of a low specific activity product. AZEDRA targets an ultra-orphan patient population that previously had no available FDA-approved treatment option. The drug contains a small molecule that specifically targets neuroendocrine tumors (such as pheochromocytoma and paraganglioma) and, when labeled with a radioisotope, can be used as an imaging agent as well as for therapy.

AZEDRA is manufactured using a novel, proprietary platform called Ultratrace®, which allows the drug to be manufactured from a solid phase precursor. This unique manufacturing process is designed to prevent unlabeled or “cold” iobenguane from being carried through the manufacturing process to the final formulation, yielding a drug product with very high specific activity. The unprecedented use of Ultratrace in the production of iobenguane I 131 radiotherapy, i.e., AZEDRA, resulted in a new drug that can efficiently, effectively, and safely deliver therapy to patients who, if left untreated, experience debilitating clinical symptoms and high mortality rates.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:

Caplacizumab

2. Manufacturer Name:

Sanofi

3. Trade Brand of Technology:

Sanofi has suggested the brand name of CABLIVI®; however, the brand name may change upon FDA approval.

4. Brief Description of Service, Device or Drug:

Caplacizumab (ALX-0081) is a humanized bivalent Nanobody consisting of two identical building blocks joined by a tri alanine linker. Nanobodies represent a novel therapeutic class of proteins derived from the heavy chain variable domains that occur naturally in heavy chain immunoglobulins from Camelidae. In terms of sequence and structure, they have a high degree of homology to human immunoglobulin heavy chain variable region domains. Caplacizumab is intended to treat adults with acquired thrombotic thrombocytopenic purpura (aTTP) through immediate and direct inhibition of the microclot formation responsible for the significant mortality and morbidity associated with this disease. According to the submitted Prescribing Information, Caplacizumab is to be used in patients 18 years of age and older experiencing an episode of aTTP, as it reduces the frequency of TTP-related death, recurrence of TTP, and refractory disease.

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

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: Brachytherapy planar source, pladium-103
2. Manufacturer Name: CivaTech Oncology
3. Trade Brand of Technology: CivaSheet®
4. Brief Description of Service, Device or Drug: CivaSheet is an implantable, lowdose rate polymer-encapsulated brachytherapy device that is configured as an array of radioactive palladium-103 sources embedded within a flexible, membrane-like bioabsorbable substrate. The CivaSheet sources feature embedded gold shielding, giving the device an active and inactive side. The shielding enables physicians to safely deliver an aggressive dose of radiation in immediate proximity to healthy tissues. CivaSheet is applied intraoperatively; it can be cut and is conformable, and thus can be customized, during the surgery, to the tumor cavity of the patient.

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

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: fosfomycin for injection
2. Manufacturer Name: Nabriva
3. Trade Brand of Technology: CONTEPO
4. Brief Description of Service, Device or Drug:

CONTEPO™ (fosfomycin for injection) is a potentially first-in-class epoxide intravenous (IV) antibiotic in the United States with a broad spectrum of bactericidal Gram-negative and Gram-positive activity, including activity against Extended-spectrum β -lactamase (ESBL)-producing Enterobacteriaceae as well as many other contemporary multi-drug resistant, or MDR, organisms that threaten hospitalized patients. If approved, CONTEPO would offer a potential first-line treatment for complicated urinary tract infections (cUTI) suspected to be caused by MDR pathogens in the United States

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:
 - Vascular Conduit Solution
2. Manufacturer Name:
 - Somahlution, LLC
3. Trade Brand of Technology:
 - DuraGraft® Vascular Conduit Solution
4. Brief Description of Service, Device or Drug:
 - DuraGraft, an endothelial damage inhibitor is a one-time intraoperative treatment designed to prevent vascular graft disease and failure and reduce the clinical complications associated with graft failure. These complications include myocardial infarction and repeat revascularization.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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. 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.

Note: This application contains confidential, commercial information exempt from disclosure under Exemption 4 of FOIA.

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

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: tagraxofusp, SL-401
2. Manufacturer Name: Stemline Therapeutics, Inc.
3. Trade Brand of Technology: ELZONRIS
4. Brief Description of Service, Device or Drug:

SL-401 is a targeted therapy for the treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN). SL-401 is a recombinant protein targeted at CD123 and administered via infusion.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: **Erdafitinib**
2. Manufacturer Name: **Johnson & Johnson Health Care Systems, Inc., on behalf of Janssen Oncology, Inc.**
3. Trade Brand of Technology: **Erdafitinib does not yet have a designated trade brand.**
4. Brief Description of Service, Device or Drug: **Erdafitinib is an oral drug proposed for the second-line treatment of adult patients with locally advanced or metastatic urothelial carcinoma whose tumors exhibit certain fibroblast growth factor receptor (FGFR) genetic alterations as detected by an FDA-approved test, and who have disease progression during or following at least one line of prior chemotherapy including within 12 months of neoadjuvant or adjuvant chemotherapy.**

Erdafitinib is an oral pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer. FGFRs are a family of receptor tyrosine kinases which may be upregulated in various tumor cell types and may be involved in tumor cell differentiation and proliferation, tumor angiogenesis, and tumor cell survival.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: **apalutamide**
2. Manufacturer Name: **Johnson & Johnson Health Care Systems Inc., on behalf of Janssen Products LP**
3. Trade Brand of Technology: **ERLEADATM**
4. Brief Description of Service, Device or Drug: **ERLEADA™ (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castrationresistant prostate cancer (NM-CRPC), a type of prostate cancer that continues to grow despite treatment with hormone therapy (medical or surgical) that lowers testosterone levels (castration-resistant) and has not spread to other parts of the body (non-metastatic). ERLEADA works by blocking the effect of androgens, a type of hormone, on the tumor. These androgens, such as testosterone, can promote tumor growth. ERLEADA is administered orally, once daily. ERLEADA is the first FDA-approved treatment for patients with NM-CRPC, a small but important clinical state within the spectrum of prostate cancer. It was approved on 14 February 2018 based on data from the SPARTAN study, including the novel endpoint of metastasis free survival (MFS), the primary endpoint of the study. Delaying metastases, or extending MFS, may delay symptomatic progression, morbidity, mortality, and healthcare resource utilization. Metastases are a major cause of complications and death among men with prostate cancer. ERLEADA provides an effective option with a demonstrated safety profile to a subset of patients with prostate cancer, where previously no approved treatments were available, and the standard approach was ‘watch and wait’/observation.**

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

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: **Esketamine**
2. Manufacturer Name: **Johnson & Johnson Health Care Systems Inc., on behalf of Janssen Pharmaceuticals, Inc.**
3. Trade Brand of Technology: **Esketamine does not yet have a designated trade brand.**
4. Brief Description of Service, Device or Drug: **Esketamine nasal spray is a glutamate receptor modulator being developed for an indication of treatment-resistant depression. The antidepressant action of esketamine is hypothesized to be mediated by increased glutamate release resulting in downstream neurotrophic signaling facilitating synaptic plasticity, thereby bringing about rapid and sustained improvement in people with treatment-resistant depression (TRD) which is defined as Major Depressive Disorder in adults who have not responded adequately to at least two different antidepressants of adequate dose and duration to treat the current depressive episode. Through glutamate receptor modulation, esketamine is thought to help restore connections between brain cells in people with TRD. Esketamine nasal spray will be self-administered by patients under the supervision of health care professionals.**

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:

gilteritinib

2. Manufacturer Name:

Astellas Pharma US, Inc.

3. Trade Brand of Technology:

XOSPATA

4. Brief Description of Service, Device or Drug:

Astellas anticipates gilteritinib to be FDA approved for the treatment of adult patients who have relapsed or refractory Acute Myeloid Leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. Currently, there are no FLT3-targeting agents approved for the treatment of relapsed or refractory FLT3 mutation-positive (FLT3mut+) AML. Gilteritinib is a small molecule FMS-like tyrosine kinase 3 (FLT3) inhibitor. It has been demonstrated to inhibit FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3, including FLT3 internal tandem duplication (ITD), tyrosine kinase domain mutations (TKD) FLT3-D835Y and FLT3-ITD-D835Y, and it induces apoptosis in leukemic cells expressing FLT3-ITD. FLT3 is a member of the class III receptor tyrosine kinase family that is normally expressed on the surface of hematopoietic progenitor cells, but is overexpressed in the majority of acute myeloid leukemia (AML) cases.

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

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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. Brief Description of Service, Device or Drug: Customized permanent cesium-131 brain implant with brachytherapy sources in collagen matrix

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:

Imipenem, cilastatin, and relebactam (IMI/REL) for injection for intravenous use

2. Manufacturer Name:

Merck

3. Trade Brand of Technology:

As of the submission of this application, the trade/brand name has not yet been determined.

4. Brief Description of Service, Device or Drug:

IMI/REL is a fixed dose combination of imipenem/cilastatin (IMI), a β -lactam (BL) antibacterial (specifically, a carbapenem), and relebactam (REL), a novel β -lactamase inhibitor (BLI). It is anticipated that when approved, IMI/REL will be indicated in patients 18 years of age and older with (a) complicated intra-abdominal infections caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available and (b) complicated urinary tract infections, including pyelonephritis, caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:

imlifidase

2. Manufacturer Name:

Hansa Medical AB

3. Trade Brand of Technology:

Trade name Idefirix has been conditionally accepted by the FDA.

4. 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.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: Jakafi® (ruxolitinib)
2. Manufacturer Name: Incyte Corporation
3. Trade Brand of Technology: Jakafi® (ruxolitinib)
4. Brief Description of Service, Device or Drug:

Jakafi® (ruxolitinib) is an oral kinase inhibitor that inhibits Janus-associated kinases 1 and 2 (JAK1/JAK2), a pathway that has been shown in pre-clinical and clinical studies to reduce graft versus host disease (GVHD).

The results of a prospective REACH1 study, as well as other independent prospective and retrospective studies, demonstrate the potential of Jakafi to meaningfully improve the outcomes of allo-HSCT in patients with acute GVHD who have had an inadequate response to corticosteroids, and further underscore the promise of JAK inhibition to advance the treatment of this potentially-devastating condition.

Incyte is seeking an approval of a sNDA application for Jakafi for the treatment of patients with acute GVHD who have had an inadequate response to corticosteroids with Orphan Drug and Breakthrough Therapy designations. It is anticipated that Jakafi will receive FDA approval in advance of the July 1, 2019 deadline.

GVHD BACKGROUND:

Allogeneic hematopoietic stem cell transplantation (allo-HSCT) represents a potentially curative treatment option for several high-risk or relapsed hematologic malignancies, as well as for certain non-malignant hematologic disorders. Despite the increasing use of allo-HSCT and advances in methodology, outcomes remain suboptimal. Major barriers to successful outcomes include relapse of the underlying malignancy and transplant-related complications. Acute GVHD, a serious complication of allo-HSCT that results when activated donor T cells attack host tissues, occurs in 30-70% of patients, depending on donor characteristics, conditioning regimen, and prophylaxis, and represents a significant source of morbidity and mortality, accounting for up to one-third of the deaths in these patients. Many acute GVHD diagnoses occur in the first few months post-transplant, sometimes while the patient is still hospitalized from the allo-HSCT and often after initial discharge. Approximately 40% of patients with acute GVHD are readmitted to the hospital.

Systemic corticosteroids are used as conventional first-line therapy for grade II to IV GVHD, however, only 40-60% of acute GVHD patients respond to systemic steroids and many of these responses are not durable. There are no FDA-approved treatments for acute GVHD, including for those patients who have had an inadequate response to corticosteroids.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:

Supersaturated Oxygen (SSO₂) Therapy

2. Manufacturer Name:

TherOx, Inc.

3. Trade Brand of Technology:

DownStream® System

4. Brief Description of Service, Device or Drug:

Supersaturated Oxygen (SSO₂) Therapy is a novel therapy designed to ameliorate progressive myocardial necrosis by minimizing microvascular damage in AMI patients following percutaneous intervention with coronary artery stent placement. SSO₂ Therapy is an adjunctive cardiac catheterization laboratory (cath lab) initiated procedure with superoxygenated blood delivered via a catheter to the left main coronary artery (LMCA) in a patient with acute myocardial infarction (AMI) after successful percutaneous intervention (PCI) with stenting has been performed.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name: **T2Bacteria Test Panel**
2. Manufacturer Name: **T2 Biosystems, Inc.**
3. Trade Brand of Technology: **T2Bacteria® Panel**
4. Brief Description of Service, Device or Drug:

The T2Bacteria® Panel is the first and only FDA-cleared, direct from blood bacteria pathogen identification test that does not require blood culture. The T2Bacteria Test Panel is a multiplex diagnostic panel that detects five major bacterial pathogens associated with sepsis directly from whole blood in 3-5 hours instead of 1-6 days for the current standard of care (blood culture) with an overall sensitivity of 90% and overall specificity of 98%.

The T2Bacteria Panel runs on the T2Dx Instrument, an easy-to-use, bench-top diagnostic instrument that utilizes developments in magnetic resonance and nanotechnology to detect pathogens directly in whole blood, plasma, serum, saliva, sputum and urine at limits of detection as low as one colony forming unit per milliliter. It is capable of running a broad range of diagnostic tests and is fully automated from patient sample input to result, eliminating the need for manual work flow steps such as pipetting that can introduce risks of cross-contamination. To perform a diagnostic test, the patient sample tube is snapped onto our disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into the T2Dx, which automatically processes the sample and then delivers a diagnostic test result. The T2Dx is a Class II medical device that received de novo 510(k) clearance from the FDA on September 22, 2014

The T2Bacteria Panel's ability to detect bacterial pathogens directly in whole blood, and its speed to result (3-5 hours), coupled with its superior sensitivity as compared to blood culture, helps reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which helps reduce side effects for patients, lowers hospital costs and potentially counteracts the growing resistance to antimicrobial therapy. The T2Bacteria Panel is designed to identify bacterial pathogens commonly not covered by broad-spectrum antibiotic drugs. Overall, the T2Bacteria Panel provides identification of infectious bacterial species faster than any other diagnostic method available to clinicians today, and thus enables rapid administration of species-specific antimicrobial therapies to reduce patient length of stay and substantially improve clinical outcomes.

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

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



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2020

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

1. Technology Name:

Venetoclax tablets

2. Manufacturer Name:

AbbVie Inc.
North Chicago, IL 60064

3. Trade Brand of Technology:

VENCLEXTA®

4. Brief Description of Service, Device or Drug:

VENCLEXTA is an oral BCL-2 inhibitor. The target indication for VENCLEXTA is for the treatment of newly diagnosed patients with acute myeloid leukemia who are ineligible for intensive chemotherapy, in combination with a hypomethylating agent or in combination with low-dose cytarabine. VENCLEXTA has Food and Drug Administration-approved indications for the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, who have received at least one prior therapy. VENCLEXTA is available in 10, 50, and 100 mg tablets and is self-administered.

Data provided in this application or in the tracking form, is proprietary, is a trade secret or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act. Such data are the property of AbbVie, Inc. and may not be used, divulged or otherwise disclosed without the express written consent of AbbVie, Inc.

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

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