

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) 2018**

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

1. Technology Name: Replacement Heart Valve
2. Manufacturer Name: LivaNova Canada Corp.
3. Trade Brand of Technology: Perceval Sutureless Heart Valve
4. Brief Description of Service, Device or Drug: The Perceval bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

For the complete application requirements, please see the instructions at
http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage--.

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1. Technology Name:

Andexanet Alfa

2. Manufacturer Name:

Portola Pharmaceuticals Inc.

3. Trade Brand of Technology:

AndexXa™

4. Brief Description of Service, Device or Drug:

Andexanet Alfa is a recombinant, modified, and truncated human Factor Xa protein. It is being developed as a direct antidote for both Factor Xa inhibitors (e.g., rivaroxaban, apixaban, and edoxaban) and indirect Factor Xa inhibitors (e.g., enoxaparin and fondaparinux). Andexanet Alfa is expected to be the first and only antidote available to treat patients receiving an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation.

A Biologics License Application for Andexanet Alfa was submitted for review by the U.S. Food and Drug Administration (FDA) in November 2015. Andexanet Alfa has been granted Orphan Drug Designation, Breakthrough Therapy Designation, and has undergone Priority Review by the FDA. In August 2016, the FDA responded and requested additional information related to manufacturing and the inclusion of edoxaban and enoxaparin in the label. Portola and the FDA are working closely together to resolve the outstanding questions. It is anticipated that andexanet alfa will be approved by the FDA to meet the newness criterion.

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1. Technology Name: **EDWARDS INTUITY Elite™ valve system**
2. Manufacturer Name: **Edwards Lifesciences**
3. Trade Brand of Technology: **EDWARDS INTUITY Elite™ Valve System**
4. Brief Description of Service, Device or Drug: **The device is a bovine pericardial aortic bioprosthetic valve with a novel balloon expandable stainless steel frame and a textured sealing cloth. It has a Rapid Deployment mechanism that allows the valve to be deployed and secured using only 3 non-pledgeted sutures versus the 12-18 pledgeted sutures used when implanting a traditional non-rapid deployment valve.**

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1. Technology Name:

Implantable System for Remodulin®

2. Manufacturer Name:

- Medtronic plc
- United Therapeutics

3. Trade Brand of Technology:

Implantable System for Remodulin®

4. Brief Description of Service, Device or Drug:

The Implantable System for Remodulin® (ISR) is a new and innovative therapy designed to improve patient care for Pulmonary Arterial Hypertension (PAH) patients.

This fully implantable system consists of four elements: the Medtronic drug delivery pump, the Medtronic implantable intravascular catheter, the pump programmer, and the FDA-approved drug Remodulin®.

Remodulin (treprostinil) is currently delivered via an external (wearable) pump either intravenously or subcutaneously. Intravenous delivery is associated with the risk of serious bloodstream infections and sepsis. Subcutaneous delivery is associated with infusion site pain and adverse reactions, which can be intolerably severe. More generally, an external pump interferes with a patient's quality of life. For instance, patients must follow a strict hygiene regimen and are restricted from common activities such as bathing and swimming.

The ISR allows patients to receive Remodulin therapy with a lower rate of safety concerns and an improved quality of life impact compared to the current external delivery systems.

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1. Technology Name:

Bezlotoxumab

2. Manufacturer Name:

Merck & Co., Inc

3. Trade Brand of Technology:

ZINPLAVA™

4. Brief Description of Service, Device or Drug:

ZINPLAVA is a human monoclonal antibody indicated for reducing *Clostridium difficile* infection (CDI) recurrence in adults who are receiving antibacterial drug treatment for CDI and who are at high risk for CDI recurrence. ZINPLAVA is not indicated for the treatment of the presenting episode of CDI and is not an antibacterial drug. ZINPLAVA is administered during Standard of Care (SOC) antibacterial drug treatment for CDI.

ZINPLAVA specifically binds to and neutralizes *Clostridium difficile* (*C. difficile*) toxin B, an exotoxin that contributes to the gut tissue damage and immune system effects that underlie the symptoms of CDI.

ZINPLAVA for injection will be supplied as a 1000 mg/40 mL (25 mg/mL) solution in a single-dose vial. The recommended dose is 10 mg/kg administered as an IV infusion over 60 minutes as a single dose.

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1. Technology Name: GammaTile™
2. Manufacturer Name: IsoRay Medical, Inc. and GammaTile, LLC
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
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1. Technology Name: axicabtagene ciloretreleucel
2. Manufacturer Name: Kite Pharma, Inc.
3. Trade Brand of Technology: Not yet confirmed. Investigational name: KTE-C19.
4. Brief Description of Service, Device or Drug: When approved by the FDA, KTE-C19 will represent the only FDA-approved treatment for patients with chemorefractory aggressive B-cell non-Hodgkin's lymphoma (NHL) and for those who are ineligible for autologous stem cell transplant (ASCT).

KTE-C19 is the first engineered autologous cellular immunotherapy comprised of CAR T cells that recognizes CD19 expressing cancer cells and B cells and which has demonstrated efficacy in chemorefractory, aggressive B-cell NHL in a multi-centered clinical trial. Its mechanism of action is distinct and unique from any other cancer drug or biologic that is currently approved for the treatment of aggressive B-cell NHL, namely single-agent or combination chemotherapy regimens.

KTE-C19 is a single infusion engineered autologous T cell immunotherapy administered intravenously, by which a patient's own T cells are harvested and engineered ex vivo by retroviral transduction of a chimeric antigen receptor (CAR) construct encoding an anti-CD19 CD28/CD3-zeta. The anti-CD19 CAR T cells are expanded and infused back to the patient. These T cells can recognize and eliminate CD19 expressing target cells. The antigen CD19 is a protein expressed on the cell surface of B-cell lymphomas and leukemias. KTE-C19 binds to CD19 expressing cancer cells and normal B cells. These normal B cells are considered to be non-essential tissue, as they are not required for patient survival. This binding leads to the activation and expansion of CAR T cells followed by cytotoxicity against CD19 expressing target cells.

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1. Technology Name:

Intraoperative vascular graft treatment

2. Manufacturer Name:

Somahlution, Inc.

3. Trade Brand of Technology:

DuraGraft® Vascular Graft Treatment

4. Brief Description of Service, Device or Drug:

DuraGraft is a one-time intraoperative treatment designed to prevent vascular graft disease and failure and reduce the clinical complications associated with graft failure. It is formulated into a solution that is used during standard graft handling, flushing and bathing steps

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1. **Technology Name:** STELARA[®] (ustekinumab) for intravenous infusion
2. **Manufacturer Name:** Janssen Biotech
3. **Trade Brand of Technology:** STELARA[®]
4. **Brief Description of Service, Device or Drug:**

Drug (biological): STELARA[®] is a human interleukin-12 and -23 antagonist indicated for the treatment of adult patients with:

- moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy. (1.1)
- active psoriatic arthritis (PsA), alone or in combination with methotrexate. (1.2)
- moderately to severely active Crohn's disease (CD) who have
 - failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or
 - failed or were intolerant to treatment with one or more TNF blockers

Please note: This new technology add-on application addresses the use of STELARA[®] for intravenous infusion associated with this most recent FDA indication. This is a new indication—and an entirely different route of administration—than previous versions of the product.

STELARA[®] for intravenous infusion is used to provide induction dose. It is administered intravenously using weight-based tiers:

Initial IV dosing of STELARA[®]		
Patient Weight at the time of dosing	Dose	Number of 130 mg STELARA[®] vials
≤ 55 kg	260 mg	2
> 55 kg to ≤ 85 kg	390 mg	3
> 85 kg	520 mg	4

Maintenance dosing is 90 mg subcutaneous injection 8 weeks after the initial IV dose, then every 8 weeks.

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1. Technology Name: Cytarabine and Daunorubicin Liposome for Injection.
2. Manufacturer Name: Celator Pharmaceuticals, Inc., a direct subsidiary of Jazz Pharmaceuticals, Inc.
3. Trade Brand of Technology: The proposed trade name, VYXEOS™, is conditionally approved by the FDA and is subject to confirmation upon approval of the NDA.
4. Brief Description of Service, Device or Drug: If approved by the FDA, VYXEOS will represent the only new treatment for adult patients with acute myeloid leukemia (AML) to improve overall survival since cytarabine and daunorubicin were approved over 40 years ago. VYXEOS has been granted Breakthrough Therapy Designation and Fast Track Designation. It has also been granted Orphan Drug Designation for the treatment of acute AML.

VYXEOS is specifically designed with the proprietary, novel CombiPlex® technology platform to deliver and maintain the optimized 5:1 molar ratio of cytarabine and daunorubicin encapsulated within a nano-scale liposome to be delivered to the bone marrow and preferentially taken up by leukemic cells. Maintenance of the synergistic drug ratio cannot be achieved with conventional forms of the two separate drugs, cytarabine and daunorubicin, regardless of how they may be dosed or scheduled. The evidence has shown that (1) *in vitro* VYXEOS is taken up intact by the cell and releases cytarabine and daunorubicin at their synergistic ratios resulting in well-coordinated pharmacology of the two drugs and the most effective synergistic ratio at the site of tumor; (2) encapsulation maintains the synergistic ratios, reduces degradation, and minimizes the impact of drug transporters and the effect of known resistant mechanisms; and (3) VYXEOS provides prolonged exposure of cytarabine and daunorubicin in the bone marrow and animal models show the sustained delivery leads to improved efficacy and death of tumor cells. VYXEOS will be the first and only approved fixed combination of cytarabine and daunorubicin and is designed to uniquely control the exposure using a nano-scale drug delivery vehicle. In addition, in a Phase 3 clinical study, Vyxeos demonstrated statistically significant improvements in survival in patients with high-risk AML compared to the conventional 7+3 free drug dosing. VYXEOS (CPX-351) is administered as a 90 minute intravenous infusion on days 1, 3, and 5 (induction therapy) as compared to the 7+3 free drug dosing which consists of two individual drugs administered on different days, including 7 days of continuous infusion.

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