



**Fiscal Year (FY) 2024 Inpatient Prospective Payment System (IPPS) New
Technology Add-on Payment (NTAP) Virtual Town Hall Meeting**

Wednesday, December 14, 2022

*****Please click this URL to join.*****

https://cms.zoomgov.com/webinar/register/WN_7jRB-QQCS-6O5PoAzAZWYw

Or join by phone:

Dial: US: +1 833 568 8864 (Toll Free)

Webinar ID: 160 592 9875

Passcode: 027677

Each presentation is allotted 10 minutes, plus 5 minutes for questions and answers. Please note that while we will do our best to adhere to this schedule, times are subject to change.

FY 2024 NTAP Town Hall Agenda (all times shown are in EST)

- 8:30-9:00am: **Virtual Arrival:** CMS will start the meeting promptly at 9am EST. Attendees experiencing technical issues during the virtual town hall meeting may contact us at NewTech@cms.hhs.gov
- 9:00-9:05am: **Welcome and Meeting Overview** from the Division of New Technology
- 9:05-9:20am **Opening Remarks** Jason Bennett, Director
Technology, Coding, and Pricing Group
Centers for Medicare & Medicaid Services
- 9:20-9:30am: **Public comment(s): Richard Price**
Senior Vice President, Payment and Health Care
Delivery, Head of Research,
AdvaMed
- 9:30-9:45am: **GLOFITIMAB** - a novel full-length, fully humanized, T-cell engaging bispecific antibody with a novel 2:1 structure with a proposed indication for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after 2 or more prior therapies.
- Presenter: Dr. Michael Dickinson**

- 9:45-10:00am: **epcoritamab** - a full-length CD3 x CD20 bispecific antibody for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL).
- Presenter: Jon Ukropec, PhD**
- 10:00-10:15am: **SeptiCyte® RAPID** - a gene expression assay, with sample to answer turnaround time of approximately 60 minutes. The SeptiCyte® RAPID test generates a score that falls within one of four discrete Interpretation bands based on the increasing likelihood of sepsis.
- Presenter: Roy Davis MD, PhD, MHA**
- 10:15-10:30am: **VEST** – an external support device which can be fitted over the saphenous vein when used as a bypass conduit in coronary artery bypass grafting (CABG) surgery.
- Presenter: Dr. Daniel Goldstein**
Department of Cardiovascular and Thoracic Surgery,
Montefiore Medical Center
- 10:30-10:45am: **Break**
- 10:45-11:00am: **SER-109** – an oral microbiome therapeutic candidate for the treatment of recurrent *Clostridioides difficile* (*C. diff*) infection (rCDI) as part of a two-pronged treatment approach to repair the microbiome.
- Presenter: Robert Stevens, PharmD**
Vice President and Head, Medical Affairs
Seres Therapeutics
- 11:00-11:15am: **RBX2660** - an investigational, nonantibiotic, broad consortium microbiota-based live biotherapeutic suspension expected to reduce recurrence of *Clostridioides difficile* (*C. difficile*) infection (CDI) in adults following antibiotic treatment for recurrent *C. difficile* infection (rCDI), inclusive of the first recurrence.
- Presenter: Dr. Paul Feuerstadt**
- 11:15-11:30am: **omidubicel** - the first patient-specific advanced cellular therapy donor source for allogeneic hematopoietic cell transplant (HCT) for patients with hematologic malignancies.
- Presenter: Ronit Simantov, MD**
Chief Medical Officer and Chief Scientific Officer, Gamida Cell

- 11:30-11:45am: **TERLIVAZ (terlipressin)** - a V1 receptor agonist that is thought to increase renal blood flow in patients with hepatorenal syndrome (HRS).
- Presenter: Dr. Khurram Jamil**
Vice President for Hepatology at Mallinckrodt Pharmaceuticals
- 11:45am-12:30pm: **Lunch**
- 12:30-12:45pm: **HEPZATO™ KIT**- a drug/device combination product, consisting of melphalan hydrochloride and the Hepatic Delivery System (HDS), for the treatment of patients with unresectable primary and metastatic tumors in the liver.
- Presenter: Dr. Johnny John**
Senior Vice President Clinical Development and Medical Affairs
- 12:45-1:00pm: **elranatamab** - a heterodimeric humanized full-length bispecific antibody against BCMA and CD3 that allows the direct targeting of cytotoxic T cells to tumor cells. BCMA is an ideal cell surface target for multiple myeloma.
- Presenters: Caroline Hoang, PhD**
US Medical Affairs Hematology Team Lead, Pfizer Oncology
Alex Schepart, PharmD
US Medical Director, Hematology, Pfizer Oncology
- 1:00-1:15pm: **Spevigo®** - a humanized monoclonal immunoglobulin G1 antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36 receptor (IL36R) for the treatment of generalized pustular psoriasis (GPP) flares in adults.
- Presenter: Arash Mostaghimi, M.D., M.P.A., M.P.H.**
Assistant Professor of Dermatology, Harvard Medical School
Director, Inpatient Consultation Service, Department of Dermatology Brigham and Women's Hospital
- 1:15-1:30pm: **Sabizabulin** - an oral, novel microtubule disruptor for treatment of severe SARS-CoV-2 infection in hospitalized patients with moderate to severe COVID-19 at high risk for Acute Respiratory Distress Syndrome (ARDS) and death.
- Presenter: Tara L. Gonzales, MD**
Vice President, Medical Affairs Infectious Diseases Franchise, Veru Inc.
- 1:30-1:45pm: **Break**

- 1:45-2:00pm: **TECVAYLI™ (teclistamab)** - a bispecific BCMA-directed CD3 T-cell engager for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy.
- Presenter: Jessica Fowler, PhD**
Group Medical Director, US Medical Affairs Lead,
Bispecifics
- 2:00-2:15pm: **NexoBrid™** - a concentrate of proteolytic enzymes (enriched in bromelain) for non-surgical eschar removal (debridement) in adult patients with deep partial thickness (DPT) and/or full thickness (FT) thermal burns.
- Presenters: Brad Rubin**
Fangting Yu
Dr. James Boron
- 2:15-2:30pm: **DuraGraft** - an intraoperative vein-graft treatment and endothelial damage inhibitor used during CABG surgery that protects the vascular endothelium of harvested vascular grafts against ischemic injury that occurs following graft harvesting.
- Presenter: Steve Brooks, M.D.**
Chief Medical Officer
Marizyme, Inc
- 2:30-2:45pm: **VANFLYTA® (quizartinib)** – a kinase inhibitor for use in combination with chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD) positive.
- Presenter: Albert Fliss, PhD**
Director of Oncology at Daiichi Sankyo
- 2:45-3:00pm: **Break**
- 3:00-3:15pm: **MOSUNETUZUMAB** – a full-length, humanized, immunoglobulin G1 (IgG1) bispecific antibody that is designed to concomitantly bind CD3 on T cells and CD20 on B cells with a proposed indication for the treatment of adults with R/R follicular lymphoma (FL) who have received at least 2 (≥ 2) prior systemic therapies.
- Presenter: Dr. Matthew Matasar**

3:15-3:30pm: **lovotibeglogene autotemcel (lovo-cel)** - an investigational, one-time, autologous gene therapy being evaluated for the treatment of sickle cell disease (SCD).

Presenter: Jennifer Leiding, MD
Medical Director

3:30-4:00pm: **CYTALUX (pafolacianine)** - the first targeted intraoperative molecular imaging agent that illuminates ovarian cancer in real time, enabling the detection of more cancer for resection; and
CYTALUX (pafolacianine) - the first targeted intraoperative molecular imaging agent that illuminates lung cancer in real time, enabling the detection of more cancer for resection.

Presenters: Bert Slade, MD
Michael Ebright, MD
Tim Biro, RPh
Tommy Lee, MSHS

4:00-4:15pm: **XENOVIEW (hyperpolarized Xenon 129)** – an diagnostic signaling agent for oral inhalation used in conjunction with chest MRI for evaluation of lung ventilation.

Presenters: Bastiaan Driehuys, PhD
Professor of Radiology
Chase S. Hall, MD
Assistant Professor, Pulmonary, Critical Care and Sleep Medicine
Associate Director, Interstitial Lung Disease and Rare Lung Disease Clinic, SOM-Kansas City The University of Kansas Hospital
Dr. Joe Mammarappallil, MD
Radiology General Radiology
Duke University Hospital
Fergus Gleeson (RTH) OUH
Professor of Radiology
Head of Academic Radiology | Director of the Oxford Imaging Trials Unit
Divisional Director for the Oxford University Hospitals NHS Trust

4:15-4:30pm **Wrap-up and Conclusion for Day 1**

Public Comments on Substantial Clinical Improvement: Comments for consideration in the IPPS proposed rule related to the substantial improvement criterion for NTAP (including comments on the FY 2024 applications and on the town hall presentations) **must be sent to CMS via email to newtech@cms.hhs.gov** with the subject line: “Town Hall Comment: (insert technology name)”. **All comments must be received by 5:00 p.m. EST on Thursday, December 22, 2022.**