



**Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) New
Technology Add-on Payment (NTAP) Virtual Town Hall Meeting**

Tuesday, December 14, 2021

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

<https://cms.zoomgov.com/j/1613772191?pwd=cTFmVC9Fa1hWZ1FmN0hEdzViZXVOZz09>

Or join by phone:

Dial: US: +1 669 254 5252 or +1 646 828 7666 or 833 568 8864 (Toll Free)

Webinar ID: 161 377 2191

Passcode: 354717

Each presentation is allotted 15 minutes, including any time for questions and answers. Please note that while we will do our best to adhere to this schedule, times are subject to change.

FY 2023 NTAP Town Hall Day 1 Agenda (all times shown are in EST)

- 8:30-9:00am: **Meeting Registration:** Registration for attendees not presenting at the meeting is not required. However, attendees that would like to receive emailed notifications in the event of CMS technical issues during the virtual town hall meeting may contact us at NewTech@cms.hhs.gov
- 9:00-9:05am: **Welcome** 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
- 9:20-9:25am: **Meeting Overview** from the Division of New Technology
- 9:25-9:35am: **Public comment(s): Richard Price**
Senior Vice President
AdvaMed
- 9:35-9:50am: **TERLIVAZ® (terlipressin)** - an investigational drug for the treatment of Hepatorenal Syndrome Type 1 (HRS-1).

Presenter: Khurram Jamil, MD
Vice President Hepatology
Mallinckrodt Pharmaceuticals

9:50-10:05am: **UPLIZNA®**– a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) for adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Presenter: Kristina Patterson, MD
Medical Director – Neuroimmunology, Medical Affairs
Horizon Therapeutics

10:05-10:20am: **RBX2660** – a nonantibiotic, broad consortium microbiota-based live biotherapeutic suspension that reduces 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
Assistant Clinical Professor of Medicine
Yale University School of Medicine
Attending Gastroenterologist PACT-Gastroenterology Center

10:20-10:35am: **REGEN-COV™** a combination of two monoclonal antibodies (also known as REGN10933 and REGN10987, respectively) designed to block infectivity of SARS-CoV-2, the virus that causes COVID-19.

Presenter: Dr. Ernesto Oviedo-Orta
Infectious Disease Lead | General Medicine Franchise
Senior Director | Medical Affairs
Regeneron Pharmaceuticals, Inc

10:35-10:50am: **Darzalex Faspro®** - a subcutaneous formulation of daratumumab, a CD38-directed cytolytic antibody, indicated for the treatment of systemic light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients. Darzalex Faspro® is also approved for multiple indications for

treatment of patients with multiple myeloma (MM), from newly diagnosed (NDMM) to relapsed/refractory MM (RRMM).

Presenters: Annelore Cortoos, MD

Thomas Lin, MD PhD

10:50-11:05am: **Break**

11:05-11:20am: **Treosulfan** - a new chemical entity currently under FDA review through a New Drug Application with a proposed indication for use as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients older than one year with acute myeloid leukemia (AML) or with myelodysplastic syndrome (MDS).

Presenter: Mark Fosdal DHSc, PA-C
Director of Scientific Communications

11:20-11:35am: **teclistamab** - a full-sized bispecific antibody with two distinct binding regions: one that binds CD3 on T cells and another that binds BCMA on myeloma cells, to treat multiple myeloma.

Presenter: Kathleen Gray, PhD

11:35-11:50am: **Spesolimab** - a humanized antagonistic monoclonal immunoglobulin G1 antibody for the treatment of flares in adult patients with generalized pustular psoriasis (GPP).

Presenter: Howard Rogers, M.D. Ph.D.

11:50-12:05pm: **Narsoplimab**— a fully human monoclonal antibody targeting mannan-binding lectin serine protease 2 (MASP-2), the effector enzyme of the lectin pathway of the complement system, for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy.

Presenter: Dr. Miguel-Angel Perales
Chief, Adult Bone Marrow Transplantation Service
Memorial Sloan Kettering Cancer Center

12:05-1:05pm: **Lunch**

1:05-1:20pm: **mosunetuzumab** -a bispecific, humanized monoclonal antibody BTCT4465A, with an antigen-recognition site for the T-cell surface antigen CD3, and the other for the B-cell tumor-associated antigen (TAA).

for the treatment of adults with relapsed or refractory follicular lymphoma and who have received at least 2 prior systemic therapies.

Presenter: Dr. Matthew Matasar, MD
Medical Director
MSK Bergen

1:20-1:35pm: **XENOVIEW™** - a drug/device combination drug used in conjunction with chest magnetic resonance imaging (MRI) for MRI lung diagnostics.

Presenters: Bastiaan Driehuys, PH.D
Duke University School of Medicine
Department of Radiology

Talissa Altes, MD
University of Missouri Hospital
Radiology Chair

Yuh-Chin Tony Huang, MD
Duke University School of Medicine
Pulmonary, Allergy, and Critical Care Medicine

1:35-1:50pm: **Hemolung Respiratory Assist System (RAS)** - provides partial ventilatory lung support independent of the lungs as an alternative or supplement to invasive mechanical ventilation.

Presenter: Steven A. Conrad, MD, PhD

1:50-2:05pm: **ISS500** - a medical device intended to treat acute ischemic stroke patients in a 24-hour window from stroke onset. The ISS500 utilizes a miniature implant to stimulate the SPG to increase cerebral collateral blood flow in the affected hemisphere and reduce disability of the patient.

Presenter: Jeffrey Saver, MD. FAAN, FAHA
Director, UCLA Comprehensive Stroke and Vascular
Neurology Program
SA Vice-Chair and Professor of Neurology, DGSOM

2:05-2:20pm: **maribavir** - an orally bioavailable anti-cytomegalovirus (CMV) compound for the treatment of post-transplant patients with CMV in solid organ transplant (SOT) or hematopoietic cell transplant (HCT).

Presenters: Dr. Roy Chemaly
Professor of Medicine
Chief Infection Control Officer
Director, Clinical Virology Research

Department of ID/IC/EH
UT MD Anderson Cancer Center
Director, Medical Affairs
Regenerative Medicine
Mallinckrodt Pharmaceuticals

2:20-2:35pm: **ciltacabtagene autoleucel** - an autologous chimeric-antigen receptor T cell (CAR-T) therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma.

Presenters: **Gregory Ursino, MD**
Doctor of Medicine
Group Medical Director
Janssen Pharmaceuticals

Tonia Nesheiwat, PharmD
Executive Director, Medical Affairs
Legend Biotech

Susan Zabierowski
Director IECT Medical Affairs
Janssen Pharmaceuticals

2:35-2:50pm: **lifileucel** - an autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for the treatment of patients with unresectable or metastatic melanoma.

Presenter: **Amod Sarnaik, MD**
Surgical Oncologist
Department of Cutaneous Oncology, the Immunology
Program and the Melanoma Center of Excellence
H. Lee Moffitt Cancer Center

2:50-3:05pm: **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 2023 applications and on the town hall presentations) **must be sent to CMS via email to newtech@cms.hhs.gov. All comments must be received by 5:00 p.m. EST on Monday, December 27, 2021.**