DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-08-06
Baltimore, Maryland 21244-1850

Fiscal Year (FY) 2025 Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP) Virtual Town Hall Meeting

Wednesday, December 13, 2023

******Participants/Panelists,** please use your individualized link/participant ID to join.****
*****Public/attendees (not presenting)**, please click the following URL to register, before joining***
https://cms.zoomgov.com/webinar/register/WN_VZiw-fWBT8afVD7ySpstjQ
After registering, you will receive a confirmation email with information about joining the webinar.
Or join by phone:
Dial: US: +1 833 568 8864 (Toll Free)
Webinar ID: 161 326 5623
Passcode: 620954

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

FY 2025 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

9:20-9:35am: **Quicktome Software Suite (Quicktome Neurological Visualization and Planning Tool)** – Provides AI-enabled visualization and analysis of the human connectome and brain networks, leveraging diffusion-weighted MRI and/or resting-state fMRI scans.

Presenter: Michael Sughrue, MD

9:35-9:50am: **DuraGraft (Vascular Conduit Solution)** – First-in-class product used during coronary artery bypass grafting surgery (CABG) to protect the vascular endothelium of harvested vascular grafts during the ischemic graft storage interval.

Presenter: Steve S. Brooks, M.D.
Medical Director, Consultant to Marizyme

9:50-10:05am: **HEPZATO KIT (melphalan for injection/Hepatic Delivery System)** – Drug/device combination product consisting of melphalan and the Hepatic Delivery System (HDS), indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases.

Presenter: Dr. Johnny John
Senior Vice President Clinical Development and Medical Affairs

10:05-10:20am: **BREAK**

10:20-10:35am: **ELREXFIO™ (elranatamab-bcmm)** – A bispecific, humanized IgG2Δa kappa antibody, B cell maturation antigen (BCMA)-directed, CD3 T-cell engager for the treatment of adult patients with relapsed refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy including a PI, an IMiD, and an anti-CD38 mAb.

Presenter: Caroline Hoang, PhD
US Medical Affairs Hematology Team Lead
Pfizer Oncology

Alex Schepart, PharmD
US Medical Director, Hematology
Pfizer Oncology

10:35-10:50am: **TALVEY (talquetamab-tgvs)** – Bispecific CD3 T-cell engaging antibody with a novel target of GPRC5D, indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Presenter: Saurabh Patel, MD
Medical Director, Multiple Myeloma
Janssen Pharmaceutical Companies of Johnson & Johnson

10:50-11:05am: **lifileucel –** Investigational one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

Presenter: Peter A. Prieto, MD, MPH, CMQ, FACS, FSSO
Senior Vice President, Medical Affairs
Iovance Biotherapeutics, Inc.

11:05-11:20am: **RP-L201** – To be the first autologous hematopoietic stem cell (HSC)-based gene therapy for the treatment of severe Leukocyte Adhesion Deficiency-Type I (severe LAD-I) – a rare, hereditary, immunodeficiency disorder.

Presenter: Karen Anderson
Vice President, Head of Global Medical Affairs
Rocket Pharmaceuticals, Inc.

11:20-12:00pm: **BREAK – LUNCH**

12:00-12:15pm: **lovo-cel (lovotibeglogene autotemcel)** – Investigational, one-time autologous gene therapy for treatment of patients 12-years old or older with sickle cell disease (SCD) and a history of vaso-occlusive events, adding functional copies of a modified form of the β-globin gene to durably produce anti-sickling adult hemoglobin, and fundamentally impact SCD at the genetic level.

Presenter: Louise Mason, M.D., FRCP, FACP
Vice President, Medical Directors Office
bluebird bio, Inc.

12:15-12:30pm: **exagamglogene autotemcel (exa-cel)** – One-time, CRISPR/CAS9 modified autologous CD34+ hematopoietic stem & progenitor cell (HSPC) cellular therapy administered via stem cell transplant, intended to treat the underlying cause of sickle cell disease with recurrent vaso-occlusive crises (severe SCD) and transfusion dependent beta-thalassemia (TDT).

Presenters: Dr. Ali Mohamadi, MD
Vice President, US Medical Affairs
Vertex Pharmaceuticals

Scott McGoohan, JD
Executive Director, Policy and Alliance Development
Vertex Pharmaceuticals

12:30-1:00pm: **odronextamab** – Both applications (R/R DLBCL and R/R FL) – First and only novel, fully human CD20xCD3 bispecific antibody with an IgG4-based structure in B-cell non-Hodgkin lymphoma (B-NHL) created using Regeneron's proprietary Veloci-Bi® technology for the treatment of adults with relapsed or refractory follicular lymphoma (R/R FL), or relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) after receiving at least two prior systemic therapies.

Presenters: Srikanth Ambati
Sr Medical Director Clinical Sciences, Global Development, Regeneron Pharmaceuticals

1:00-1:10pm: **Wrap-up and Conclusion**

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 2025 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 Monday, December 18, 2023.**