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) 2026 Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP) Virtual Town Hall Meeting

*Wednesday, December 11, 2024*

******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/j/1602368041?pwd=2L5dahOQQeTyL0UdCpJmsaXzjlOQri.1
After registering, you will receive a confirmation email with information about joining the webinar.
*Or join by phone:*
*Dial: US: +1 833 435 1820 (Toll Free)*
***Webinar ID:*** 160 236 8041
***Passcode:*** 545176

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 2026 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: **NTAP – Opening Remarks, Observations, and Helpful Tips**

**Presenters:** CMS NTAP Team

9:20-9:35am: **Aucatzyl® (obecabtagene autoleucel) –** a CD19-directed autologous chimeric antigen receptor (CAR) T cell therapy with tumor burden-guided dosing designed to improve persistence and reduce immune-mediated toxicity, under investigation for treatment of adult relapsed/refractory B-cell Acute Lymphoblastic Leukemia

**Presenter:** Bijal D. Shah, MD, MS
Dept. of Malignant Hematology
H. Lee Moffitt Cancer Center & Research Institute

9:35-9:50am: **IMDELLTRA™ (tarlatamab-dlle) –** Bispecific T-cell Engager (BiTE®) molecule that binds the antigen DLL3 expressed on the surface of SCLC cells and CD3 expressed on the surface of T cells causing T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells for the treatment of 2L+ extensive-stage small cell lung cancer (ES-SCLC)

**Presenters:** Catherine Chan, PharmD, U.S. Medical Lead, Small Cell Lung Cancer, Amgen

Amanda Struckhoff, PhD, U.S. Clinical Research Senior Medical Scientist, Small Cell Lung Cancer, Amgen

9:50-10:05am: **DuraGraft® –**a vascular conduit solution used during coronary artery bypass grafting surgery (CABG) in adult patients to protect the vascular endothelia of harvested vascular grafts during the ischemic graft storage interval

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

Catherine J. Pachuk, Ph.D.
Chief Scientific Officer, Executive VP

10:05-10:30am: **BREAK**

10:30-10:45am: **ATEV (acellular tissue engineered vessel-tyod) –**bioengineered, implantable blood vessel offering a new treatment option for adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible

**Presenter:** Laura Niklason MD, PhD
Founder and CEO, Humacyte

10:45-11:00am: **RYSTIGGO® (rozanolixizumab-noli) –** neonatal Fc receptor blocker for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive

**Presenter:** Angela Ting, PharmD
US Medical Strategic Value Lead
UCB, Inc.

11:00-11:15am: **Grafapex™ (treosulfan) –** conditioning agent used for allogenic hematopoietic stem cell transplantation which, if approved, will be the only FDA-approved conditioning agent for acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

**Presenter:** Mark Fosdal DHSc, PA-C,
Clinical Director at Medexus

11:15am-12:00pm: **BREAK – LUNCH**

12:00-12:15pm: **tabelecleucel –** non-genetically modified allogeneic, off-the-shelf, Epstein-Barr Virus (EBV)-specific T-cell immunotherapy under investigation as monotherapy for treatment of adult and pediatric patients 2 years of age and older with EBV positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at
least one prior therapy.

**Presenter:** Susan Prockop, MD
Program Director, Clinical and Translational Research
Outpatient Clinic Director
Hematopoietic Stem Cell Transplant Program
Attending Physician, Dana-Farber/Boston Children's Cancer and Blood Disorders Center
Associate Professor of Pediatrics, Harvard Medical School

12:15-12:30pm: **BREYANZI® (lisocabtagene maraleucel) –** CD19-directed, autologous CAR T-cell immunotherapy
comprised of individually formulated CD8 and CD4 CAR T-cells, for the treatment of adult patients with R/R CLL/SLL who have received ≥2 prior LOT including a BTKi and a BCL2i

**Presenter:** Peter Riedell, M.D.

Candice McCoy, Clinical Development Program Lead
Breyanzi Late Clinical Development Cell Therapy

12:30-12:45pm: **COBENFY™ (Xanomeline and trospium chloride) –** combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, for the treatment of schizophrenia in adults

**Presenter:** Ken Kramer, PhD

12:45-1:00pm: **Ziihera® (zanidatamab-hrii) –** investigational human epidermal growth factor receptor 2 (HER2)-directed bispecific antibody for the treatment of adults with previously treated, unresectable/metastatic HER2+(IHC3+) biliary tract cancer (BTC), as detected by an FDA approved test

**Presenter:** Robin Kate Kelley, MD
Professor of Clinical Medicine
Chair, Data and Safety Monitoring Committee,
Helen Diller Family Comprehensive Cancer Center
Co-Director of Clinical Research,
Division of Hematology and Oncology
University of California, San Francisco (UCSF)

1:00-1:15pm: **BREAK**

1:15-1:30pm: **TECELRA® (afamitresgene autoleucel)) –** melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy for the treatment of adults with unresectable or metastatic synovial sarcoma (SyS)
who have received prior chemotherapy, are HLA-A*02 subtype positive, and whose tumor expresses the MAGE-A4 antigen

**Presenter:** Sandra P. D'Angelo, MD
Sarcoma Medical Oncologist & Cellular Therapist,
Memorial Sloan Kettering Cancer Center

1:30-1:45pm: **Fibryga® (fibrinogen) –** human fibrinogen concentrate for: • fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency

**Presenters:** Adam Gerber, MD, PhD
Doctor of Medicine
PhD in Neuroscience and Physiology

Huub Kreuwel, PhD
PhD in Immunology and Cell Biology

1:45-2:00pm: **bentracimab –**investigational human monoclonal antibody fragment (Fab) designed to reverse the antiplatelet activity of ticagrelor, an oral P2Y12 platelet receptor inhibitor, in patients requiring nondeferrable surgery or invasive procedure and in patients experiencing major bleeding, in whom ticagrelor impairs normal hemostasis

**Presenter:** W. Frank Peacock, MD, FACEP, FACC, FESC
Professor, Vice Chair for Research
Henry JN Taub Department of Emergency Medicine
Baylor College of Medicine
Houston, Texas

2:00-2:15pm: **IntelliSep Test –** a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties, for use alongside clinical assessments and laboratory findings to aid in the early detection of sepsis with organ disfunction for adults presenting to the Emergency Department

**Presenter:** Dr. Hollis O'Neal
Louisiana State University Healthcare

2:15-2:30pm: **AURLUMYN™ (iloprost) –** prostacyclin mimetic for the treatment of severe frostbite in adults to reduce the risk of digit amputations

**Presenter:** Ken Zafren, MD, FACEP, FAAEM, FAWM
Clinical Professor and Attending Physician
Dept. of Emergency Medicine
Stanford University Medical Center
Dept. of Emergency Medicine
Alaska Native Medical Center, Anchorage AK

2:30-2:40pm: **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 2026 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 Monday, December 16, 2024 (5 p.m., EST).**