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) 2027 Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP) Virtual Town Hall Meeting

Wednesday, December 10, 2025

******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_ln3u54LYTNi01B_Faqc6kw
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: 161 359 4055
Passcode: 089822

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 2027 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 NTAP@cms.hhs.gov

9:00-9:05am: **Welcome** and **Meeting Overview** from the Division of New Technology

9:05-9:20am: **COBENFY™ (xanomeline and trospium chloride) –** a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, for the treatment of schizophrenia in adults

Presenters: Greg Mattingly, MD
Associate Clinical Professor, Psychiatry,
Washington University School of Medicine
St. Charles Psychiatric Associates

Kabir Toor
Senior Director, HEOR Consulting at Lumanity

9:20-9:35am: **RAPIBLYK™ (landiolol) –** an intravenous beta-adrenergic blocker with rapid action and high selectivity for β1 cardio-receptors for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter, lowering heart rate with reduced side effects in critically ill patients

Presenters: Dr. Jason Katz MD, MHS, FAHA, FACC, FHFSA
NYU Langone Cardiology Associates

9:35-9:50am: **GAMIFANT® (emapalumab-lzsg) –** an interferon gamma (IFNγ)-blocking antibody for the treatment of adult and pediatric patients with hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS

Presenters: Lynes Torres Cartularo, PhD
Associate Medical Director, Immunology North America
Sobi

9:50-10:15am: **BREAK**

10:15-10:30am: **narsoplimab-wuug –** a fully human monoclonal antibody designed to treat and alleviate the consequences of transplant-associated thrombotic microangiopathy (TA-TMA) by inhibiting MASP-2 and blocking lectin pathway activation; preventing inflammation and providing anticoagulant effects, while preserving the functions of the complement system

Presenters: Miguel-Angel Perales, MD
Chief, Adult Bone Marrow Transplantation Service
Memorial Sloan Kettering Cancer Center

10:30-10:45am: **Waskyra (etuvetidigene autotemcel) –** an autologous gene therapy composed of (CD)34+ hematopoietic stem and progenitor cells, enriched and transduced ex vivo with a lentiviral vector encoding the human *WAS* gene, for the treatment of Wiskott-Aldrich syndrome (WAS).

Presenters: Dr. Francesca Ferrua, MD, PhD
Pediatric Immunohematology and Bone Marrow Transplantation Unit, San Raffaele-Telethon Institute for Gene Therapy (SR-Tiget), IRCCS San Raffaele Scientific Institute, Milan, Italy

10:45-11:00am: **ZEVASKYN™ (prademagene zamikeracel) –** an autologous cell sheet-based gene therapy for adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)

Presenters: Sarah Abdelwahab, MD, MBA
Executive Medical Director, Head of Clinical Development
Abeona Therapeutics

Sara Melton
Executive Director, Market Access
Abeona Therapeutics

11:00am-11:15am: **clemidsogene lanparvovec-sngl** – an investigational, one-time, AAV9-based gene therapy carrying a full-length IDS gene that is designed to enable the production of I2S enzyme following one-time infusion into the cerebrospinal fluid for the treatment of Mucopolysaccharidosis II (MPS II; Hunter syndrome), a rare lysosomal storage disorder

Presenter: Robert Crozier, PhD
Sr. Director, Medical Affairs
NS Pharma

11:15am-12:00pm: **BREAK – LUNCH**

12:00-12:15pm: **Orca-T –** an allogeneic stem cell and T-cell immunotherapy composed of cellular infusions of highly purified regulatory T-cells, hematopoetic stem cells and conventional T-cells sourced from the peripheral blood of an 8/8 HLA-matched donor, under evaluation for the curative treatment of multiple hematologic malignancies

Presenter: J. Scott McClellan, MD, PhD
Chief Medical Officer
Orca Bio

12:15-12:30pm: **tabelecleucel (tab-cel) –** an allogeneic Epstein-Barr virus (EBV)-specific T-cell immunotherapy under investigation as monotherapy for treatment of patients with EBV-positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy, including an anti-CD20 containing regimen.

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

12:30-12:45pm: **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 2027 applications and on the town hall presentations) **must be sent to CMS via email to NTAP@cms.hhs.gov with the subject line: "Town Hall Comment: (insert technology name)". All comments must be received by Monday, December 15, 2025 (5 p.m. EST).**