CAPITOL STREET

July 31, 2025

2026 MedTech & Biopharma: Inpatient Hospital New Tech

No NTAP for BMY, JAZZ & TEAM Model Modified

Relevant Companies

Our Take & Next Up

Five (5) new traditional + twenty-two (22) alternative pathway NTAP (new tech) determinations for 2026 (including cell therapies) are finalized. The opportunity for incremental cell & gene therapy reimbursement may become increasingly difficult under NTAP as newer approvals do not qualify for the newness criteria despite their novel usages. CMS issued the final IPPS and LTCH payment rules (here) this evening after the close. Payment rates and policies are effective for FY 2026 (starts Oct 1, 2025).

CMS is not finalizing NTAP coverage for 9 products under the traditional pathway including COBENFY (BMY) and ZIIHERA (JAZZ). See below for full list.

Key Points

NEW TECH ADD ONS (NTAP)

22 new alternative pathway products are being finalized for NTAP approval (e.g., Breakthrough, QIDP, or LPAD approval). The majority of the applications received Breakthrough Device designation. Alternative NTAPs are expected to cost CMS $219 M for FY 2026.

- **CMS is not finalizing NTAP coverage for 7 products (withdrawn or did not meet May 1 approval/clearance deadline):** Dexcom G7 Hospital Continuous Glucose Monitoring (CGM) System (DXCM), DrugSorb-ATR Device (CytoSorbents), Nelli Seizure Monitoring System (Neuro Event Labs), PearlMatrix P-15 Peptide Enhanced Bone Graft (Cerapedics), Provizio SEM Scanner (Bruin Biometrics), Spur Peripheral Retrievable Stent System (Reflow Medical), Ventura Interatrial Shunt System (V-Wave).
- **CMS is finalizing NTAP coverage for 22 products**: 4WEB Medical ATS (4WEB Medical), AeroPace (Lungpacer(R) Medical), AGENT Paclitaxel-Coated Balloon Catheter (BSX), alfapump system (Sequana Medical NV), aprevo-C cervical interbody fusion device (Carlsmed), CERAMENT G (BONESUPPORT) for open fractures, Emily's Care Nourish Test System (Lactation Lab), Esprit BTK Everolimus Eluting Resorbable Scaffold System (ABT), EUROPA Posterior Cervical Fusion System (MiRus), iFuse TORQ TNT Implant System (SI-BONE), Merit Wrapsody Cell Impermeable Endoprosthesis (Merit Medical),

Minima Stent System (Renata Medical), MY01 Continuous Compartmental Pressure Monitor (MY01), Positive Blood Culture (PBC) Separator with Selux AST System (Selux Diagnostics), RECELL Autologous Cell Harvesting Device (AVITA Medical), restor3d TIDAL Fusion Cage (restor3d), ShortCut (Pi-Cardia), The WiSE CRT System (EBR Systems), TriVerity Test (Inflammatix), VITEK REVEAL AST System (bioMerieux), EMBLAVEO (ABBV), CONTEPO (Meitheal Pharmaceuticals).

5 new traditional products are also being finalized for traditional NTAP. Applicants must have received FDA marketing authorization by May 1, 2024.

- **CMS is not finalizing NTAP coverage for 1 cell therapy**: AUCATZYL (Autolus Therapeutics). As we previously noted (here), cell therapies will find it increasingly difficult to qualify for NTAP payments as novel therapies may fall short of newness criteria due to same/similar mechanisms of action. CMS will not approve NTAPs for products that are substantially similar to existing technologies. The agency uses the mechanism of action as one of their guiding criteria and we will see newer cell therapies fall short despite their novelty due to this limiting factor.
- **CMS is not finalizing NTAP coverage for 8 other products under the traditional pathway.** COBENFY (BMY), DuraGraft (Marizyme), FIBRYGA (Octapharma USA), IntelliSep Test (Cytovale), Neuroguard IEP (Contego Medical), RYSTIGGO (UCB), SYMVESS (Humacyte), ZIIHERA (JAZZ).
- **CMS is finalizing NTAP coverage for 2 cell therapies**. BREYANZI (BMY), TECELRA (ADAP).
- **CMS is finalizing NTAP coverage for 3 other products under the traditional pathway.** AURLUMYN (SERB Pharmaceuticals), GRAFAPEX (Medexus Pharma), IMDELLTRA (AMGN).

27 products will keep their NTAP designation. As a reminder, the add-on payment is lesser of (1) 65% of the costs of the new tech or (2) 65% of the amount by which the costs of the case exceed the standard MS-DRG payment. This percentage is increased to (1) 75% for Qualified Infectious Disease Products (QIDPs) or products approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway, or for gene therapies.

- **Current NTAP products**: CYTALUX (On Target Labs) for lung indication, EPKINLY (ABBV/GMAB) and COLUMVI (Genentech), Aveir AR Leadless Pacemaker (ABT), Aveir Dual-Chamber Leadless Pacemaker (ABT), Ceribell Status Epilepticus Monitor (Ceribell), DETOUR System (Endologix), DefenCath (CRMD), Phagenyx System (Phagenesis), REZZAYO (CDTX), TOPS System (Premia Spine), XACDURO (INVA), Annalise Enterprise Computed Tomography Brain (CTB) Triage – OH (Annalise-Ai Pty), ASTar System (Q-linea), Edwards EVOQUE Tricuspid Valve Replacement System (EW), GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (W.L. Gore & Associates), LimFlow System (LimFlow), Paradise Ultrasound Renal Denervation System (ReCor Medical), PulseSelect Pulsed Field Ablation (PFA) Loop Catheter (MDT), Symplicity Spyral Multi-Electrode Renal Denervation Catheter (MDT), TriClip G4 (ABT), VADER Pedicle System (Icotec Medical), ZEVTERA (Basilea Pharmaceutica), HEPZATO KIT (Delcath System), Casgevy (VRTX & CRSP) & Lyfgenia (BLUE).

15 products will lose their NTAP designation as their 3-year anniversary date will occur before April 1, 2026.

- **NTAP designations set to expire:** Thoraflex Hybrid Device (Terumo Aortic), ViviStim Paired VNS System (MicroTransponder), GORE TAG Thoracic Branch Endoprosthesis (W.L. Gore & Associates),

Cerament G (BONESUPPORT), iFuse Bedrock Granite Implant System (SIBN), CYTALUX (On Target Labs) for ovarian indication, Lunsumio (Genentech), REBYOTA (Ferring Pharma) and VOWST (Nestle Health Science), SPEVIGO (Boehringer Ingelheim), TECVAYLI (JNJ), TALVEY (JNJ), ELREXFIO (PFE), TERLIVAZ (MNK), EchoGo Heart Failure 1.0 (Ultromics), SAINT Neuromodulation System (Magnus Medical).

TEAM DEMO

CMS finalizes the 5-year mandatory Transforming Episode Accountability Model (TEAM) for surgeries. Finalized changes affect the participation of new hospitals, quality measure and assessment, the construction of target prices, the removal of certain health reporting elements, the broadening of the Skilled Nursing Facility (SNF) 3-Day Rule, and the removal of the Decarbonization and Resilience Initiative (DRI). These are largely finalized as proposed. Finalized include (but are not limited to):

- TEAM focuses on improving quality and reducing costs for 5 surgery procedures (here): Lower Extremity Joint Replacement, Surgical Hip Femur Fracture Treatment, Spinal Fusion, Coronary Artery Bypass Graft, and Major Bowel Procedure.
- Implementing a limited deferment period for certain hospitals.
- Linking Track 2 participation eligibility for hospitals with a Medicare Dependent Hospital (MDH) designation to the expiration of the MDH program.
- Adding the Information Transfer Patient Reported Outcome-based Performance Measure (Information Transfer PRO-PM) for TEAM outpatient episodes beginning in Performance Year 3.
- Applying a neutral quality measure score for TEAM participants with insufficient quality data.
- Broadening the Skilled Nursing Facility (SNF) 3-Day Rule Waiver to include swing bed arrangements.

As a reminder, TEAM was proposed under President Biden as a five-year, mandatory, episode-based payment model that is now blessed by Dr. Oz's CMS and will start in January 2026. Hospitals required to participate will be selected based on geographic regions from across the US. TEAM will have graduated risk through different participation tracks to accommodate different levels of risk and reward and allow participants to ease into full-risk participation. CMS anticipates TEAM participants and PAC providers, such as skilled nursing facilities and home health agencies, to form partnerships that share financial risk and collaborate on care design strategies.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com
202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET
