CAPITOL STREET

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Hospital Inpatient 2025 MedTech Updates

SCD Gene Therapies, NTAP Updates

Relevant Companies

On April 10, 2024, CMS issued the proposed IPPS and LTCH payment rules (here). These are payment rates and policies that would be for FY 2025 (starts Oct 1, 2024). Comments are due by June 10, 2024. Final rates will be released on or around August 1, 2024.

⋙ Our Take & Next Up

Final determinations for the 11 new + 14 alternative pathway NTAP (new tech) determinations for 2025 (including gene therapy SCDs) will be in the final IPPS rule (around August 1). Several gene therapies are being reviewed for the traditional NTAP pathway. They face barriers to approval as the agency is questioning the clinical improvement profile, particularly for Lyfgenia (BLUE) which has a risk of insertional oncogenesis. We believe that CMS will finalize the enhanced NTAP percentage (75%) for gene therapies. CMS is also expected to discuss the estimated payment impact for 2025 from the sickle cell gene therapies in the final rule. Recall CMMI has a cell & gene demonstration for States (as a bloc) to contract with manufacturers via the Medicaid program. See below for technologies that CMS will be adding, subtracting and maintaining.

⋙ Key Points

14 new alternative pathway products are being proposed for NTAP approval (e.g., Breakthrough, QIDP, or LPAD approval). The majority of the applications (12) received Breakthrough Device designation. Alternative NTAPs are expected to cost CMS $172 M for FY 2025.

- Annalise Enterprise Computed Tomography Brain (CTB) Triage – OH (Annalise-Ai Pty), ASTar System (Q-linea), cefepime-taniborbactam (Venatorx Pharmaceuticals), 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), restor3d TIDAL Fusion Cage

(Restor3d), Symplicity Spyral Multi-Electrode Renal Denervation Catheter (MDT), Transdermal GFR Measurement System utilizing Lumitrace (MediBeacon), TriClip G4 (ABT), VADER Pedicle System (Icotec Medical), ZEVTERA (Basilea Pharmaceutica),

11 new traditional products are also currently being reviewed for traditional NTAP approval, including sickle cell therapies.

- Casgevy (VRTX & CRSP) & Lyfgenia (BLUE) are both currently being reviewed and could be considered as a single application due to similarity.
- The agency is asking for input on how Casgevy & Lyfgenia may differ from one another with respect to the substantial similarity and newness criteria. CMS is also questioning therapy substantial clinical improvement due to a small study population limiting the generalizability of submitted studies to a Medicare population, the short length of patient follow-up, among other limitations.

A proposed increase in NTAP reimbursement for gene therapies is included which is helpful. CMS is proposing to increase the NTAP percentage from 65% to 75% for a gene therapy that is indicated and used specifically for the treatment of sickle cell disease (SCD). Since establishing the new technology add-on payment, CMS has been cautious about increasing the new technology add-on payment percentage but made exceptions to address where payment was falling short. For example, in the FY 2020 IPPS/LTCH PPS final rule, CMS increased in the new technology add-on payment percentage for QIDPs from 65% to 75%. For NTAP approved SCD gene therapies, if the costs of a discharge exceed the full DRG payment, CMS is proposing to make an add-on payment equal to the lesser of: (1) 75% of the costs of the new medical service or technology; or (2) 75% of the amount by which the costs of the case exceed the standard DRG payment.

- **Other products being considered for the traditional pathway include**: DuraGraft (Marizyme), ELREXFIO (PFE), FloPatch FP120 (Flosonics Medical), HEPZATO KIT (Delcath System), Lantidra (CellTrans), AMTAGVI (IOVA), Quicktome Software Suite (Omniscient Neurotechnology), TALVEY (JNJ), Odronextamab (Regeneron).

23 products will keep NTAP designation. Thoraflex Hybrid Device (Terumo Aortic), ViviStim (MicroTransponder), GORE TAG Thoracic Branch Endoprosthesis (W.L. Gore & Associates), Cerament G (BONESUPPORT), iFuse Bedrock Granite Implant System (SIBN), CYTALUX (On Target Labs), EPKINLY (ABBV/GMAB) and COLUMVI (Genentech), Lunsumio (Genentech), REBYOTA (Ferring Pharma), SPEVIGO (BIPI), TECVAYLI (JNJ), TERLIVAZ (MNK), Aveir AR Leadless Pacemaker (ABT), Aveir Dual-Chamber Leadless Pacemaker (ABT), Ceribell Status Epilepticus Monitor (Ceribell), DETOUR System (Endologix), EchoGo Heart Failure 1.0 (Ultromics), Phagenyx System (Phagenesis), REZZAYO (CDTX), SAINT Neuromodulation System (Magnus Medical), TOPS System (Premia Spine), XACDURO (INVA), DefenCath (CRMD). 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 case exceed the standard MS-DRG payment.

7 products will lose their NTAP designation as their 3-year anniversary date will occur before April 1, 2025.

- **NTAP designations set to expire:** Intercept (CERS), Rybrevant (JNJ), StataGraft (MNK), Hemolung Respiratory Assist System (ALung), aprevo Intervertebral Body Fusion Device for transforaminal lumbar

interbody fusion (Carlsmed), Livtencity (Takeda), Canary Tibial Extension with Canary health Implanted Reporting Processor (CHIRP) system (ZBH).

NTAP newness start period changed to match the fiscal year start. To reduce confusion for applicants, CMS is proposing to use the start of the fiscal year, October 1, instead of April 1, to determine whether a technology is within its 2- to 3-year newness period. This change would be effective starting in FY 2026 for both new and already approved NTAPs and is aimed at reducing the uncertainty around NTAP end dates.

CMS is proposing to allow FDA marketing authorization hold status (will not be considered inactive) for the purpose of the NTAP application eligibility. As a reminder, in CY 2024, CMS finalized their proposal that a complete and active FDA application is required for NTAPs starting in FY 2025. Of the 16 applications received under the traditional pathway, one applicant was not eligible because it did not meet these requirements, and three applicants withdrew their application prior to the proposed rule.

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