CAPITOL STREET

April 11, 2023

Hospital Inpatient 2024 New Tech Add On

Cell & Gene, Breakthrough Device Coverage (TCET) Not Addressed Here & Up Next

Relevant Companies

Late on April 10th, CMS issued the proposed IPPS and LTCH payment rules (here). These are rates and policies that start FY 2024 (Oct 1, 2023). Comments are due by June 9, 2023. Final rates will be released on or around August 1, 2023.

Our Take & Next Up

There is a high bar for NTAP designation. We will see the final determinations for the 19 new + 19 alternative pathway NTAP coverage determinations for 2024 in the final IPPS rule (on or around August 1). Several cell therapies are expected to lose NTAP designation in 2024. For cell therapies with similar indications and mechanism, CMS appears to use the earlier approval date for NTAP purposes. NTAP applications for cell therapies may be increasingly difficult in the future as a result. TCET guidelines will be released in April, and we expect a much more limited pathway compared to the previous Medicare Coverage of Innovative Technology (MCIT).

Key Points

CMS will provide a + 2.8% proposed 2024 pay bump to all hospitals. Urban hospitals will have a +2.8% bump and rural hospitals will receive a +3.3% bump. See page 1383 of the rules for an impact analysis table of proposed changes to the IPPS.

MED TECH & CELL/GENE THERAPY

Transitional Coverage for Emerging Technologies (TCET) is not addressed in this rule, as expected, and will likely be released by CMS in the next few weeks. As a reminder, CMS is expected to release TCET guidelines in April, likely in a separate rule. We predict that automatic enrollment is unlikely and the pathway is expected to have additional data generation requirements for manufacturers.

Rare disease, cell & gene therapy NTAP coverage is not included in the FY24 rule, as we expected, and should be out later this year. Earlier, we previewed how CMS could address inpatient payment issues for rare diseases treatments, including in-hospital formulary access for high-cost, low volume therapies. CMS continues to tout equity initiatives and we may still see CMS address high-cost inpatient drugs in the future. Solutions that were solicited by CMS largely address drug payment issues through modifying or creating a new DRG, orphan drug specific proposals are also possible.

NEW TECH ADD ON PAYMENTS

19 new alternative pathway products are being proposed for NTAP approval (e.g., Breakthrough, QIDP, or LPAD approval). Alternative NTAPs are expected to cost CMS $264 M for FY 2024.

4WEB Medical Ankle Truss System & Total Ankle Talar Replacement (**4WEB Medical**), Aveir AR Leadless Pacemaker (**ABT**), Canary Tibial Extension with CHIRP System (**ZBH**), Ceribell Delirium Monitor & Ceribell Status Epilepticus Monitor (**Ceribell**), EchoGo Heart Failure 1.0 (**Ultromics**), LimFlow System (**LimFlow**), Nelli Seizure Monitoring System (**Neuro Events Labs**), Phagenyx System (**Phagenesis**), SAINT Neuromodulation System (**Magnus Medical)**, Selux NGP System (**Selux Diagnostics)**, DETOUR System (**Endologix**), TOPS System (**Premia Spine**), Transdermal GFR Measurement System utilizing Lumitrace (**MediBeacon**), REZZAYO (**CDTX)**, DefenCath (**CorMedix**), SUL-DUR **(ETTX**),

19 new traditional products are also currently being reviewed for NTAP approval. CMS has not yet determined if any traditional products will meet NTAP criteria.

CYTALUX (**On Target Labs**), DuraGraft (**Marizyme**), Elranatamab **(PFE**), epcoritamab (**GMAB**), glofitamab (**Genentech**), Lunsumio (**Genentech**), NexoBrid (**VCEL**), Omidubicel (**GMDA**), REBYOTA (**Ferring Pharma**), Sabizabulin (**Veru**), SeptiCyte RAPID **(Immunexpress**), SER-109 (**Seres Therapeutics**), SPEVIGO (**BIPI**), TERLIVAZ (**MNK**), TECVAYLI (**JNJ**), VANFLYTA (**Daiichi Sankyo**), VEST (**VGS**), XENOVIEW (**Polarean**).

11 products will keep their NTAP designation.

Intercept, Rybrevant (JNJ), StataGraft (MNK), Hemolung Respiratory Assist System (ALung), aprevo Intervertebral Body Fusion Device for transforaminal lumbar interbody fusion (Carlsmed), Livtencity (Takeda), Thoraflex Hybrid Device (Terumo Aortic), ViviStim (MicroTransponder), GORE TAG Thoracic Branch Endoprosthesis (Gore Medical), Cerament G (BONESUPPORT), iFuse Bedrock Granite Implant System (SIBN). 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.

15 products will lose their NTAP designation as their 3-year anniversary date will occur before April 1, 2024.

CARVYKTI (JNJ), a multiple myeloma cell therapy, was determined to be substantially similar to ABECMA (BMY), another cell therapy for multiple myeloma (also in FY 2023 final rule). Both will lose their NTAP designation in FY 2024 as the newness period for both was determined to be March 26, 2021 (based on the FDA approval of ABECMA). Other products that are expected to lose their NTAP designation include cell therapies Tecartus (GILD) and Veklury (GILD).

Additional NTAP designations set to expire: Zepzelca (JAZZ). aScope Duodeno (Ambu), Caption Guidance (Caption Health), aprevo Intervertebral Body Fusion Device for lateral interbody fusion & anterior lumbar interbody fusion (Carlsmed), Cosela (GTHX), ShockWave C2 IVL System (SWAV), ABECMA (BMY), Harmony Transcatheter Pulmonary Valve System (MDT), Fetroja (Shionogi), Recarbrio (MRK), DARZALEX FASPRO (JNJ), Hemolung Respiratory Assist System (RAS) for COVID-19 treatment (ALung).

CMS is proposing an FDA application completion requirement for NTAPs starting in FY 2025. CMS could require NTAP applicants for technologies that are not FDA authorized to have a complete and active FDA market authorization application request at the time of NTAP application submission, and CMS is also proposing to move the FDA approval deadline from July 1 to May 1. CMS noted that many applicants who apply for NTAPs prior to submitting an FDA marketing authorization have information missing from their applications, which will not become available until after submission to FDA.

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