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MedTech Policies in Final Inpatient Rule

Blood Cancer Therapies Receive New NTAPs, Cell Therapy NTAPs Expire

Relevant Companies

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CMS issued the final IPPS and LTCH payment rules (here). These are payment rates and policies that would be for FY 2024 (starts Oct 1, 2023) that contains medical device payments and policies, including final NTAP designations.

Our Take & Next Up

Under new traditional NTAPs, the biggest winners are various antibody therapies for blood cancers. These included EPKINLY (GMAB) & COLUMVI (Genentech), Lunsumio (Genentech), TECVAYLI (JNJ). Myriad MedTech companies also received designation. Several cell therapies (JNJ, BMY, GILD) will lose NTAP designation in 2024, in line with the proposed rules. For cell therapies with similar indications and mechanisms, CMS will use the earlier approval date for NTAP purposes and CMS has commented that they will not consider the first sale of a product, only the availability date when considering newness. CMS will not extend NTAP for an additional year due to lack of uptake. This means that while a documented delay may help a product get an NTAP late, it will not extend NTAP add-on if there is a commercialization delay after it receives the designation. See other new NTAP designations below.

Key Points

CMS will provide a +3.8% 2024 pay bump to all proprietary hospitals (THC, UHS, HCA, CYH, others). Government and voluntary hospitals will receive a +3% bump. Urban hospitals will have a +3.1% bump and rural hospitals will receive a +3.5% bump. Payment updates are slightly better than proposed (+2.8%, or 100 bps) due to an increased market basket. See page 2014 of the rules for the impact analysis table.

12 new alternative pathway products received NTAP (new tech add-on) approval (e.g., Breakthrough, QIDP, or LPAD approval). Alternative NTAPs are expected to cost CMS $305 M for FY 2024. Total estimated payments for new technologies

that are part of the Breakthrough Device program are approximately $87 M for FY 2024. QIPD is a qualified infectious disease product and LPAD is a limited population antibacterial drug.

They are as follows: Taurolidine/heparin (CRMD), REZZAYO (CDTX), XACDURO (INVA), Aveir AR Leadless Pacemaker (ABT), Aveir Leadless Pacemaker (Dual-Chamber) (ABT), Canary Tibial Extension with CHIRP System (ZBH), Ceribell Status Epilepticus Monitor (Ceribell), EchoGo Heart Failure 1.0 (Ultromics), Phagenyx System (Phagenesis), SAINT Neuromodulation System (Magnus Medical), TOPS System (Premia Spine), DETOUR System (Endologix).

8 new products received traditional NTAP approval. Prior to the final rule, 12 traditional applicants withdrew their application, and 3 technologies (1 alternative and 2 traditional) did not meet the July 1 deadline for FDA approval or clearance of the technology and are therefore ineligible for consideration. Traditional NTAPs are expected to cost CMS $59 M for FY 2024.

They are as follows: CYTALUX for lung and ovarian (On Target Labs), EPKINLY (GMAB) & COLUMVI (Genentech), Lunsumio (Genentech), REBYOTA (Ferring Pharmaceuticals) & VOWST (MCRB), SPEVIGO (BIPI), TECVAYLI (JNJ), and TERLIVAZ (MNK).

11 products will keep their NTAP designation. This is expected to cost CMS $131 M in total payments. 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.

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

15 products will lose their NTAP designation as proposed. Impacted products include CARVYKTI (JNJ), a multiple myeloma cell therapy, which was determined to be substantially like ABECMA (BMY), another cell therapy. Both will lose their NTAP designation in FY 2024. Other products that are expected to lose their NTAP designation include cell therapies TECARTUS (GILD) and VEKLURY (GILD). See table on page 413 for full list of discontinued products.

CMS finalizes FDA application completion requirement for NTAPs starting in FY 2025 (as proposed). CMS will 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 will move the FDA approval deadline earlier from July 1 to May 1. CMS noted the challenge of reviewing a product that has not yet been submitted to FDA due to lack of preliminary info.

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