

Medical Device Policies In Hospital IPPS

Technology Add-On Winners & Losers, No New DRGs, LITT & N95 Masks

The Centers for Medicare and Medicaid Services (CMS) released the proposed FY 2023 hospital inpatient rule (IPPS) that contains medical device payments and policies ([here](#)). Pay to inpatient hospitals will be +2.3% (proprietary hospitals), with +1.4% pay for all Medicare-eligible hospitals. New polices and pay start Oct 1, the beginning of FY 2023.

- **CMS will add no new MS-DRGs for 2023.** This will maintain the number of MS-DRGs at 767 for FY23. CMS is also considering changes to MS-DRG relative weights with a proposed 10% cap on decreases in an MS-DRG relative weight from one fiscal year to the next.
- **CMS is considering reclassifying laser interstitial thermal therapy (LITT) procedures in connection with a proposal to create new procedure codes.** LITT is an emerging technique to treat primary and metastatic brain tumors.
- **New technologies add-on (NTAP) policies ~ Impacts Biopharma and MedTech, emerging therapies.** NTAPs are extended for another year for products ending in 2H 2023, which is standard CMS policy. The extension will only apply if the 3-year anniversary date of the product's entry occurs after April 1, 2023. See highlights below:
 - **(+) CMS is considering 13 new NTAP applications.** Carvykti (JNJ), Darzalex Faspro (JNJ), Teclistamab (JNJ), Hemolung RAS (ALung Technologies), Lifileucel (Iovance), Livtencity (TAK), Mosunetuzumab (ROG), Narsoplimab (Omeros), Spesolimab (BIPI), Terlivaz for injection (MNKKQ), Treosulfan (MEDXF), Uplizna (HTI-DAC/HZNP), Xenoview (Polarean).
 - **(+) There are also 13 new applications being reviewed under the “alternative” NTAP pathway (e.g., Breakthrough, QIDP, or LPAD approval).** CERAMENT G (BONESUPPORT AB), GORE TAG Thoracic BranchEndoprosthesis (W.L. Gore and Associates), iFuse Bedrock Granite Implant System (SIBN), LigaPASS 2.0 PJK Prevention System (MDT), Magnus Neuromodulation System with SAINT Technology (Magnus Medical), Nelli Seizure Monitoring System (Neuro Event Labs), Phagenyx System (Phagenesis), Precision TAVI Coronary Obstruction Module (DASI Simulations), Thoraflex Hybrid Device (Terumo Aortic), TOPS System (Premia Spine), VITARIA System (LIVN), ViviStim Paired VNS System (MicroTransponder), DefenCath and heparin (CorMedix).
 - **(+) 15 products will keep their NTAP designation from 2022.** Tecartus (GILD), Veklury (GILD), Zepzelca (JAZZ), aScope Duodeno (Ambu), Fetroja (SGIOY), Recarbrio (MRK) will keep their NTAP designation, despite their 3-year anniversary occurring in 2023.
 - **(-) 11 products will lose their NTAP designation as their 3-year anniversary date will occur prior to April 1, 2023.** Affected products include Balversa (JNJ), Jakafi (INCY), Barostim neo system (CVRX), Recarbrio (MRK), Soliris (ALXN), Xenleta (NBRV), Zerbaxa (MRK), Azedra, Exalt model D (BSX), and Fetroja (SGIOY).
 - **(-) All 13 products that received a one-year extension in 2022 will be discontinued in 2023.** FY 2022 1-year extension discontinued, is negative but perhaps for expected for manufacturers. Products impacted include Cablivi (SNY), Elzonris (Stemline), AndexXa (AZN), Spravato (JNJ),

T2 Bacteria Panel (TTOO), Eluvia (BSX), Hemospray (Cook), Imfinzi (AZN) / Tecentriq (ROG), SpineJack (SYK), Xospata (ALPMY), and Nuzyra (PRTK).

- **(+/-) Contepo (NBRV) may lose its conditional NTAP approval for 2022 & 2023.** Contepo is an epoxide antibiotic in development as a first-line treatment for complicated UTIs. It must receive FDA marketing authorization before July 1, 2022, to receive NTAP payments for 2022. If it fails to meet the deadline NBRV is risking FY22 & FY23 payments as NBRV did not apply for a 2023 NTAP.
- **N95 cost impact & solutions for hospitals in a (future) pandemic/variant.** CMS recognizes that hospitals may incur additional costs when purchasing wholly domestically produced NIOSH-approved surgical N95 respirators and is seeking comment on the appropriateness of payment adjustments under the IPPS and OPSS that would account for any such additional costs. CMS is considering such payment adjustments to apply to 2023 (and potentially subsequent years). This rule outlines two possible frameworks to do so, and seeks comment on these or other frameworks.
- **CMS is soliciting comments on social determinants of health (SDOH) diagnosis codes & whether that may improve the ability to recognize severity of illness,** complexity of service, and/or utilization of resources under the MS-DRGs. CMS is also interested in receiving feedback on how the agency might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.
- **OUR TAKE / NEXT STEPS:** We will learn about the fate of the 13 new + 13 alternative pathway device NTAP applications & coverage for 2023 CMS reimbursement in the final IPPS rule (on or around August 1). We do not see other new/different medical device technology policies between now and final rule.