Medical Device Policies In Hospital IPPS

New Technology Winners & Losers, No New DRGs, LITT & N95 Masks

The Centers for Medicare and Medicaid Services (CMS) released the final FY 2023 hospital inpatient rule (IPPS) that contains medical device payments and policies (here). Pay to inpatient hospitals will be +3.3% (proprietary hospitals), with +2.6% 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 implanting a permanent 10% cap on year-to-year declines in the relative weights of MS-DRG beginning with FY 2023 relative weights.

- **CMS is reclassifying Laser Interstitial Thermal Therapy (LITT) procedures in connection to create new procedure codes (brain tumors).** LITT is an emerging technique to treat primary and metastatic brain tumors. The procedure codes below will be deleted Oct. 1, 2022: Procedure Codes associated with this final rule (describing LITT of the brain) are assigned to MS-DRGs 025, 026 and 027

- **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 approved 4 NTAP applicants under the Tradition Pathway for FY 2023**. Carvykti (JNJ), Darzalex Faspro (JNJ), Hemolung RAS (ALung Technologies), Livtencity (TAK)

  - **(+) CMS approved 6 technologies 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), Thoraflex Hybrid Device (Terumo Aortic), 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. (unchanged from proposed)

  - **(-) 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). (Remained unchanged from proposed)

  - **(-) 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). (unchanged from proposed)

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  - **(-) Contepo (NBRV) will lose its conditional NTAP approval for 2022 & 2023.** Contepo is an epoxide antibiotic in development as a first-line treatment for complicated UTIs. It did not receive FDA marketing authorization, therefore no NTAP will be made for cases involving the use of CONTEPO for FY 2022, and CONTEOP is therefore not eligible for the continuation of NTAP for FY 2023.

- **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. In CY 2023 OPPS/ASC proposed rule, CMS discussed the proposal for making payment adjustments for additional resource costs of domestic NIOSH-approved surgical N95 respirators. No final decision has been made.

- **CMS received many 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 has stated that they will take these comments into consideration for future rule making but have not implemented anything as of right now.

- **UP NEXT/OUR TAKE:** The CMS final rule improved final rates by 100bps. CMS finalized a +3.3% update for proprietary hospitals (versus 2.3% proposed). The tech and DRG policies are largely inline with expectations.

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