MEDTECH INSIGHT
CITELINE COMMERCIAL

06 Jul 2021 | **News**

Proposed Changes To Medicare Seek To Extend Add-On Payments, Expand Program For Homebound Patients

by Brian Bossetta

US medical device makers could potentially benefit from a proposed rule that would extend add-on payments for their technologies due to the impacts of the COVID-19 pandemic.

In comments submitted to the US Centers for Medicare & Medicaid Services (CMS), industry and stakeholders expressed support for the agency's planned extension of new technology add-on payments (NTAP) for 14 products set to expire at the end of fiscal year 2021, which ends 30 September.

In its *proposed rule*, issued 27 April, CMS also plans to use data from fiscal year 2019 in determining whether to renew NTAP status – opting not to use data from 2020 because health care spending in the year was upended by the pandemic. (Also see "*US CMS Should Delay Adjustment In Pay For E/M Services Until COVID-19 Crisis Passes: Device Firms*" - Medtech Insight, 9 Oct, 2020.))

NTAP designation applied to a given device or technology lasts no more than three years, during which time the product is evaluated for continuation of the designation. That evaluation is based on three criteria: newness, cost, and clinical improvement. Using data from 2020 as part of that evaluation would not provide an accurate assessment of that technology, according to CMS, because the pandemic year was so unprecedented.

Additionally, the proposed rule seeks to extend the New Covid-19 Treatments Add-On Payment (NCTAP) program, which CMS created during the pandemic. NCTAP increased Medicare payments for certain COVID-19 treatments approved by the US Food and Drug Administration for emergency use.

NCTAP, established in November 2020, was to stay in place for the duration of the federally declared public health emergency (PHE). Now, the proposed rule would extend NCTAP beyond the PHE for products that are not approved for new technology add-on payment (NTAP) beginning in fiscal year 2022. It would also discontinue NCTAP for those products that are approved for new technology add-on payments.

CMS is also proposing to use 2019 data instead of 2020 data to set rates for the Inpatient Prospective Payment System (IPPS) – which is how Medicare pays hospitals for services provided to beneficiaries. The proposal was supported by the Association of American Medical Colleges (AAMC) which said in its submitted comments that 2019 data would provide a better overall approximation of the inpatient experience compared to 2020 data.

> *"The pandemic caused a significant disruption in inpatient hospital care during much of FY 2020." – The Medical Device Manufacturers Association.*

During the comment period on its proposed rule, which ended 28 June, CMS received feedback from across the health care spectrum, including from many device makers urging the agency to extend the eligibility for add-on payments.

The final rule is expected to be finalized and in effect by 1 October.

The Medical Device Manufacturers Association (MDMA)agreed with the decision to forego 2020 data stating that the pandemic "caused a significant disruption in inpatient hospital care during much of FY 2020, including a substantial increase in admissions related to respiratory conditions and a substantial decrease in non-respiratory admissions, the latter of which included many admissions for emergency and elective surgical care that represent a significant portion of overall medical technology utilization." In other words, this decrease in non-respiratory admissions resulted in substantially less data during the pandemic that would otherwise be used in assessing NTAP status.

MDMA also agreed with the AAMC that the inpatient experience for fiscal year 2022 is unlikely

to reflect the 2020 inpatient experience. "We support the decision to use data from pre-COVID for purposes in which more recent data would normally have been used," MDMA stated.

The association also expressed its support for the agency extending NTAP eligibility for the 14 technologies for which the payments were set to be discontinued in fiscal year 2022. In its comments, MDMA asked CMS to use its authority to adjust payments or make waivers to extend the eligibility period for all technologies eligible for NTAP during 2020 for an additional year.

"Due to government mandates to hospitals to restrict elective procedures, as well as general concerns among patients about seeking care, there was a significant decline in non-COVID related procedures and, as a result, a material adverse impact on the collection of data on the costs of current NTAP technologies during the public health emergency period," MDMA stated.

Abiomed, Inc., the developer and manufacturer of the Impella heart pump, also submitted comments in support of using pre-pandemic data referring to 2019 data as the "most representative data available due to the public health emergency."

T2 Biosystems, an in vitro diagnostic company, argued for extension of its diagnostic panels for direct-from-blood detection of sepsis-causing pathogens. The company requested the one-year extension for its T2 Bacteria Panel "in light of the unique circumstances for fiscal year 2022 rate setting."

The American Society for Radiation Oncology (ASTRO) also voiced support for using 2019 data, noting that, if approved, AZEDRA, a radiopharmaceutical drug administered intravenously to treat a certain type of adrenal gland cancer and a rare type of nerve cell tumor, would be extended for another year.

Outside of the 14 technologies being considered for NTAP extensions, CMS has received 21 new applications for NTAP via the traditional pathway, 12 new applications via the alternative pathway for breakthrough devices and three applications for NTAP via the alternative pathway for qualified infectious disease products.

Non-Profit Critical Of NTAP Concerning Antibiotics

Despite the support for extending the add-on payments from device makers, the Pew Charitable Trusts criticized NTAP, stating the program is insufficient "to adequately and sustainably reimburse developers of new antibiotic drugs" – which are often administered through medical devices.

David Hyun, project director, Antibiotic Resistant Project at Pew, recommended CMS implement the more significant reform articulated in the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act, under which CMS would reimburse

eligible inpatient Qualified Infectious Disease Product (QIDP) antibiotics separately from diagnosis-related groups (DRGs) while also requiring antibiotic stewardship and surveillance.

New antibiotics, Hyun argued, face a significant challenge immediately upon market entry, as hospitals and doctors appropriately use them only when absolutely needed to preserve potency for as long as possible and slow the development of resistance.

"Although NTAP may be beneficial for other new and much costlier treatments in other therapeutic areas, for antibiotics the administrative burden of submitting an additional reimbursement request can outweigh the financial benefit, especially for small or rural hospitals," Hyun stated. "These limitations may hinder NTAP from significantly affecting uptake of new antibiotics."

Rule Seeks To Expand Program Nationwide

The proposed rule would also expand nationwide the *home health value-based purchasing* (HHVBP) model while increasing Medicare payments to home health agencies by 1.7%, an increase of some $310m from 2021.

Introduced in 2016, the HHVBP initiative was designed to give Medicare-certified home health agencies (HHAs) incentives to give higher quality and more efficient care. Currently, HHVBP operates in nine states representing each geographic area of the country: Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington.

> ***"Homebound Medicare patients face a unique set of challenges and barriers to getting the care they need." – CMS Administrator Chiquita Brooks-LaSure.***

The proposed rule also adjusts payments for home infusion therapy, which involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home.

"Homebound Medicare patients face a unique set of challenges and barriers to getting the care they need," CMS Administrator Chiquita Brooks-LaSure said in a statement. "This proposed rule

would streamline service delivery and value quality over quantity – at a time when Americans need it most."

According to CMS, the HHVBP program has resulted in an average of 4.6% improvement in HHA quality scores and has saved Medicare roughly $141m per year since its implementation in 2016.

Agency Proposes Changes To Payment For Organ Acquisition

The proposed rule would also impact the collection of organs and human tissue, which the National Disease Research Interchange (NDRI) said would negatively affect breakthroughs in treatment. NDRI, funded in part by the National Institutes of Health (NIH), procures and distributes human organs and tissue for biomedical research.

Currently, Medicare covers certain donor-related costs such as testing, hospitalization, or operating room costs. Under its proposed rule, CMS would no longer recognize organs intended for research as counting toward Medicare organ acquisition costs and would apportion these costs to research organs, lowering the costs recoverable by transplant centers and other organ procurement entities.

The changes CMS is proposing, according to NDRI president and CEO Bill Leinweber and Mary J.C. Hendrix, chair of the board of directors, would dramatically discourage the use or acquisition of human tissues for biomedical research thus stifling medical breakthroughs by shifting organ and donor acquisition costs to research organizations in the form of significantly higher acquisition fees for research organs.

"It is impossible to overstate the importance of research organs as a vital resource to investigators. Progress with underlying etiology in addition to discovery and testing of treatments and cures for disease depends on the availability and accessibility of organs for research," Leinweber and Hendrix said.

The proposed CMS rule change, they argued, has the potential to halt advancement of biomedical research. "While research organs are not used for transplantation purposes, their use for research provides a tangible benefit to Medicare beneficiaries — one of the communities likely to receive the greatest benefits from groundbreaking medical research," they said.