



June 28, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1752-P
P.O. Box 8011
Baltimore, MD 21244-1850
Submitted via <http://www.regulations.gov>

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

Dear Administrator Brooks-LaSure,

The Society of Infectious Diseases Pharmacists (SIDP) welcomes the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital Prospective Payment System (LTCH PPS); Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program proposed rule (herein referred to as "proposed rule").

SIDP is an association of pharmacists and allied healthcare professionals dedicated to promoting the appropriate use of antimicrobial therapeutics. SIDP membership is comprised of 1,500 members in hospital, academic, industry, public health, and other practice settings across all 50 states and throughout the globe. The mission of SIDP is to advance infectious diseases pharmacy and lead antimicrobial stewardship to optimize the care of patients.

SIDP members work on the front lines of healthcare and combat the detrimental effects of antibiotic resistance to patient care daily. As anti-infective experts, we are often consulted to make recommendations for patients that have infections that are caused by pathogens for which there are few, or in some cases, no commercially available medications for treatment. Therefore, we recognize and

support the work that CMS is doing to create incentives for anti-infective development and rapid infectious diseases testing and respectfully submit comments on the proposed regulations that are part of the **New Technology Add on Payment (NTAP) program**.

In addition, to promoting appropriate anti-infective use, we also support and promote efforts to increase vaccination against infectious diseases to minimize individual disease burden and for the benefit of protecting and promoting public health. Therefore, **we also are providing comment on the COVID-19 vaccination coverage among healthcare professionals quality measure**.

Thank you in advance for your consideration of our comments. Please do not hesitate to reach out with questions to Thomas Dilworth, PharmD, BCPS, AQ-ID, SIDP Policy and Government Affairs Chairperson at thomas.dilworth@aah.org.

Sincerely,

Susan Davis

Susan Davis, PharmD, FIDP
President
Society of Infectious Diseases Pharmacists

Summary:

New Technology Add on Payments (NTAP)

This year's proposed rule published in May 2021 addresses the need for several incentives for antimicrobials and infectious diseases-related diagnostics. **SIDP commends CMS' support of novel antimicrobial products and infectious diseases-related diagnostic testing via NTAPs.**

CMS has adopted the use of NTAPs as a way to provide additional incentives to hospitals using new technologies. SIDP appreciates CMS' initiative to provide relief to hospitals and increase access to agents developed for multi-drug resistant organisms (MDROs) and extensively drug-resistant organisms (XDROs). We are however concerned that the extension period for NTAP (3 years) does not allow enough time for hospitals, including many smaller institutions and non-teaching hospitals (which may be slower to adopt these new technologies than academic medical centers), to benefit from the cost-saving incentives designed for these agents and diagnostics under the NTAP. The use of new antimicrobial therapeutics or infectious diseases diagnostics is often slow or delayed. Many hospitals have stewardship programs in place for these drugs and tests that serve as a natural check on the potential early overuse. For these reasons and others described herein, **SIDP strongly urges CMS to consider extending the duration eligibility of the new technology add-on payments from 3 to at least 5 years for antimicrobial and infectious diseases diagnostic products.**

The regulations and policies contained in the IPPS are critical to allow clinicians access to these therapies and diagnostics to effectively treat MDROs and XDRROs. **We commend CMS for the revisions to NTAP that allow Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) to be included under the same reimbursement as Qualified Infectious Disease Product (QIDP); capped at 75%.** We urge CMS to continue to improve upon this and other initiatives within the IPPS to increase anti-infective access, use, and ultimately production of these innovative agents. Alternative reimbursement structures, such as those proposed in the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act, should be considered to further reduce financial barriers to institutions treating patients who require these novel antimicrobials.

Finally, **SIDP encourages CMS to consider changes to improve the NTAP to ensure that it is achieving its original intent.** *The majority of SIDP members surveyed indicated that their hospital employers have not been able to successfully get reimbursed for the additional NTAP payment.* An analysis of Medicaid claims found only 130 U.S. hospitals filed NTAP claims for Vabomere® and Zemdiri® from Q4 2019 – Q3 2020. Of these hospitals, 10 filed 60% of the claims. Translated, this means that many hospitals are unable to realize the full value of the NTAP incentives for using newer infectious diseases diagnostics and antimicrobials. Barriers to NTAP utilization identified by SIDP membership include: unfamiliarity with the NTAP claims process, which is perceived to be complex; limits of QIDP eligibility; limits of the NTAP exclusivity period (mentioned earlier in the letter); limited return on investment for hospitals compared to more expensive therapeutics (e.g. CAR-T); and that reimbursement is paid to non-pharmacy cost-centers despite initial drug purchases by pharmacy. **We propose that CMS consider developing a more streamlined submission process, create a system that allows for better tracking of NTAP usage, and education on NTAP navigation, specifically for pharmacists and hospital billing departments, as this may be needed to increase awareness and utility.** Thoughtful consideration of how to make NTAP data more meaningful is warranted to better support innovation in this must needed therapeutic field.

Specific Section Comments

New Technology Add-On Payment Policy for Certain Antimicrobial Products

Page 25205 states:

“under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by the FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by the FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway.”

SIDP Comment: We support the expansion of alternative new technology add-on payment pathway for QIDPs to include antimicrobials approved through the LPAD pathway. We continue to support CMS’ exceptions for antimicrobial products approved through this pathway including all products considered new and not substantially similar to another product, and increased reimbursement cap from 65% of the cost of the new product or 65% of the amount by which the costs of the case exceed the MS-DRG payment to 75%.

Page 25206 states:

“Additionally, in the FY 2021 IPPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.”

SIDP comment: We commend CMS for this revision to allow QIDPs to receive NTAPs earlier, but as stated above, we urge CMS to consider extending the duration of eligibility for NTAPs from 3 years to a longer period, such as 5 years. NTAP is still a relatively new concept outside of academic medical centers and the adoption of these new agents is often slow or delayed. As previously stated, SIDP members (who are some of the primary professionals at a hospital engaged in the NTAP process) have stated that their hospitals have not been able to successfully obtain NTAP reimbursement. Reasons for this are multi-factorial and include a limited understanding of how to access reimbursement through the NTAP program and a delay in the time it takes clinicians to incorporate these antimicrobials into their practice. In addition, the commercial availability of a product can occur several months after FDA marketing authorization, so these products are disadvantaged by the NTAP eligibility linked to the product's FDA-approval date. Further, approved susceptibility testing methods are often not readily available at the time of drug availability, creating another barrier to uptake of new antimicrobials. A longer period of NTAP eligibility, in conjunction with other programs designed to support hospitals with the NTAP submission and reimbursement tracking, would help to further incentivize development in this area.

Proposed FY 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments

Page 25212 states:

“Therefore, in light of our proposal to use FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights, we believe it would be appropriate to allow for a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022. Accordingly, we are proposing to use our authority under section 1886(d)(5)(I) of the Act to provide for a one-year extension of new technology add-on payments for FY 2022 for those technologies listed in the table that follows.”

SIDP Comment: We applaud the one-year extension for ZEMDRI®, NUZYRA® for Injection and the T2Bacteria® Panel. As stated above, SIDP urges CMS to consider extending the duration of eligibility for NTAPs for ZEMDRI® following the slow uptake in use of this drug due to reasons

previously stated. Hospitals are just now beginning to use this drug and therefore, will not be able to benefit from this reimbursement incentive unless the period of eligibility is extended. SIDP urges CMS to consider extending the duration of eligibility for NTAPs for infectious diseases diagnostic products (e.g. the *T2Bacteria® Panel*) from 3 to 5 years.

Regarding the newness criterion for VEKLURY® page 25345-25346 states:

“With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted VEKLURY® is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor, and that there are no other antiretroviral therapies that have received an EUA or an approval from FDA to treat COVID-19.”

“With regard to the second criterion, whether the technology is assigned to the same or a different MS-DRG, the applicant asserted that as there no other antiretroviral therapies for the treatment of patients with COVID-19, VEKLURY® could not be assigned to the same MS-DRG as existing technologies.”

“With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted VEKLURY® represents a novel treatment option for patients with COVID-19 who are hospitalized.”

Regarding the substantial clinical improvement criterion for VEKLURY® page 25351-225352 states:

“We note that the articles submitted by the applicant in support of substantial clinical improvement used study designs that may be subject to bias, such as the adaptive and open label design.”

SIDP Comment: We agree with the applicant that VEKLURY® does not use a same or similar mechanism of action to achieve a therapeutic outcome and that there is no other antiretroviral therapy for the treatment of patients with COVID-19, that VEKLURY® could not be assigned to the same MS-DRG as existing technologies, and that VEKLURY® represents a novel treatment option for patients hospitalized with COVID-19. SIDP supports NTCAP for VEKLURY® as this agent is used as standard of care for the treatment of hospitalized patients with COVID-19.

Proposed FY 2022 Applications for New Technology Add-On Payments (Traditional Pathway) and New COVID-19 Treatments Add-on Payment (NCTAP)

Regarding the NTAP and NCTAP criteria for Olumiant® (baricitinib), CMS states on page 25292 and 25293:

“As previously discussed, under the regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible.”

“Qualifying inpatient cases involving the use of Olumiant®, in combination with VEKLURY®, are currently eligible for NCTAP beginning November 19, 2020, the date Olumiant® received EUA, through the end of the PHE.”

SIDP comment: We support CMS’ proposed decision to approve the NCTAP payment for Olumiant® (baricitinib).

COVID-19 Vaccination Amongst Healthcare Workers

Regarding the statements related to COVID-19 vaccination of healthcare professionals “We believe it is important to incentivize and track (healthcare professional) HCP vaccination in acute care facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of hospitals to continue serving their communities ...Therefore, we are proposing a new measure, COVID-19 Vaccination Coverage Among HCP....”

SIDP Comment: We support CMS’ proposed decision to adopt a measure that promotes COVID-19 vaccination across HCPs that includes financial incentives for compliance.