



Increasing Access to Innovative Antibiotics for Hospital Inpatients Using New Technology Add-On Payments: Frequently Asked Questions

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PROVIDER TYPES AFFECTED

This MLN Matters Article is for hospitals billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This MLN Matters Special Edition Article informs providers of changes made by the Centers for Medicare & Medicaid Services (CMS) to develop an alternative New Technology Add-On Payment (NTAP) to increase access to innovative antibiotics for hospital inpatients. SE20004 answers Frequently Asked Questions (FAQs) about NTAP.

BACKGROUND

Antimicrobial Resistance (AMR) represents an urgent clinical and economic crisis for the American health care system. Bacteria resistant to existing antibiotic drugs annually infect more than 2 million Americans, resulting in thousands of deaths. Seniors are uniquely vulnerable to AMR due to age-related immunosuppression and greater exposure to infection (from catheters or chronic disease).

A recent CMS internal analysis indicated that Medicare beneficiaries account for the majority of cases of both new diagnoses of drug-resistant infections and resulting deaths in United States hospitals. Drug resistance causes Medicare beneficiaries to spend hundreds of thousands of additional days in hospitals each year, costing taxpayers billions in additional health care costs annually. Note: For more information, see the CMS publication entitled, *Securing Access to Life-Saving Antimicrobial Drugs for American Seniors*, available at <https://www.cms.gov/blog/securing-access-life-saving-antimicrobial-drugs-american-seniors>.

CMS is committed to modernizing payment systems that secure access to medications for Medicare beneficiaries and all Americans. In August 2019, CMS finalized several reforms to secure access to antimicrobials in the short-term for Medicare beneficiaries, as well as to realign financial incentives to sustain innovation in the long-term. SE20004 uses a series of FAQs to educate hospitals on changes to the new NTAP policy for Qualified Infectious Disease Products (QIDPs).

What is the NTAP for inpatients?

Section 1886(d)(5)(K) of the Social Security Act authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. This provision provides for an additional payment to recognize the costs of new medical services and technologies under the hospital Inpatient Prospective Payment System (IPPS).

In general, to qualify for additional payments under this provision, a new technology must:

1. Represent a substantial clinical improvement
2. Be new and not substantially similar to an existing technology such that data reflecting the cost of new technology must not yet be available in the data used to determine the Medicare Severity Diagnosis-Related Groups (MS-DRGs) payment rates
3. Must be relatively costly such that the MS-DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87(b)). (Special eligibility criteria for the alternative pathway for certain transformative new devices and certain antimicrobial resistance products can be found in 42 CFR 412.87(c) and (d), respectively.)

What value does NTAP offer hospitals?

When a hospital uses a new technology that has qualified for NTAP, Medicare will make an additional payment to the hospital equal to the lesser of:

- 65 percent, or 75 percent for QIDPs, of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or
- 65 percent, 75 percent for QIDPs, of the difference between the full DRG payment and the hospital's estimated cost for the case.

Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS-DRG payment plus 65 percent (75 percent for QIDPs) of the estimated costs of the new technology or medical service.

A medical service or technology may continue to be considered "new" for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment

for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

How has NTAP been changed for QIDPs?

Starting in the Fiscal Year (FY) 2021 application cycle, CMS will consider QIDPs as new and not substantially similar to an existing technology, and it will not need to meet the requirement that it represent a substantial clinical improvement. Applicants will only need to demonstrate that the new antimicrobial meets the cost criterion in order to be eligible for NTAP.

In addition, beginning FY 2020, the NTAP payment amount for QIDPs was increased from 50 to 75 percent of the cost of the product (or the additional cost of the case, whichever is lower).

Why did CMS make this change?

Antimicrobial drugs are uniquely disadvantaged from being considered for an NTAP using the old criteria for two reasons:

1. Limitations on clinical trial design for antibiotics prevent innovators from developing the same initial level of evidence by the time of FDA approval
2. Misaligned incentives limit the use of a payment for new antibiotics in hospitals

To address payment issues, CMS developed an alternate NTAP pathway that does not require "newness" or "substantial clinical improvement" demonstration and also offers an increased payment. Limiting access to the payment increase to only QIDP drugs reflects the agency's awareness of the public health imperative for novel antibiotics. This reduces barriers to accessing the incentive while ensuring that payment systems reflect the value of new innovations.

How do hospitals bill technologies with NTAP?

A unique ICD-10-PCS code is needed in order to identify the use of the technology for purposes of receiving an NTAP. To ensure the claim receives the NTAP, hospital billing staff must include the unique code on the claim that identifies the technology with NTAP. MACs processing such claims will perform all calculations to determine the value of the NTAP payment for each specific case.

Typically, CMS assigns a special ICD-10-PCS code to a technology that is seeking NTAP status. These codes are assigned in Section "X" of the ICD-10-PCS classification and are often referred to as "Section X codes". (Note, not all approved new technologies have a Section X code, and may be assigned codes in another section of the ICD-10-PCS classification). Requests for Section X codes are handled in the same manner as all other ICD-10-PCS code requests as part of the ICD-10 Coordination and Maintenance (C&M) Committee process. (For additional information on the C&M Committee meeting process, see <https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings>.)

The final coding that will be used to identify a technology that receives an NTAP are specified in that Fiscal Year's Inpatient Prospective Payment System (IPPS) final rule, which can be found on the web at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>. In addition, the implementation instructions that typically accompany the IPPS final rule includes the coding used identify each technology approved for NTAP. For example, CR 11361 shows the technologies approved for NTAP for FY 2020 in the FY 2020 IPPS final rule. (See the related MLN Matters article at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/mm11361.pdf>.)

Are there any special hospital billing requirements for QIDPs with NTAP?

No, hospital billing staff must include the unique code identifying the QIDP on the beneficiary's claim form, which is the same way that other technologies with NTAP are billed.

How much will hospitals get paid for QIDPs with NTAP?

Payment for each case will vary because NTAP is limited to the lesser of two calculations. Specifically, for a QIDP, the NTAP is the lesser of:

1. 75 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or
2. 75 percent of the difference between the full DRG payment and the hospital's estimated cost for the case.

Unless the discharge qualifies for an outlier payment, for a QIDP with NTAP the additional Medicare payment is limited to the full MS-DRG payment plus 75 percent of the estimated costs of the new technology or medical service.

Hospitals do not need to perform any additional calculations. Your MAC will calculate the additional payment amount as part of processing the claim. Many third-party billing and payment software systems will inform hospitals of the expected payment for each case prior to filing the claim.

How will hospitals know which technologies qualify for NTAP?

Applicants, such as manufacturers must apply to CMS for NTAP consideration. CMS considers these applications on an annual cycle that coincides with Inpatient Prospective Payment System (IPPS) rules. In the proposed rule, CMS will discuss the applicants for that cycle and will request comments from external stakeholders about applicants. Final determinations will be included in the final rule released in August, including the appropriate billing codes hospitals should use on the claim to receive the NTAP. For example, CR 11361 shows the NTAP products discussed in the FY2020 final rule. (See the related MLN Matters article at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/mm11361.pdf>.) New NTAP products will be eligible for

NTAP beginning with discharges occurring on or after October 1 of the same year as the IPPS rulemaking.

What other steps has CMS taken to increase access to new antibiotics?

Starting with discharges on or after October 1, 2019 (FY 2020), CMS increased the severity level designation for the 18 ICD-10-CM diagnosis codes that describe antimicrobial drug resistance. The severity level increased from “non-CC” to “CC,” which stands for complications or comorbidities, the presence of which generally results in assignment to a higher severity MS-DRG due to the relatively higher resources associated with diagnoses with such designation.

By increasing payments for inpatient cases with drug resistance, CMS removes potential financial disincentives to antibiotic innovation and thus increases beneficiaries’ access to new antibiotics.

ICD-10-CM Diagnosis Codes Describing Antimicrobial Drug Resistance

ICD-10-CM Diagnosis Code	Code Description
Z16.10	Resistance to unspecified beta lactam antibiotics
Z16.11	Resistance to penicillins
Z16.12	Extended spectrum beta lactamase (ESBL) resistance
Z16.19	Resistance to other specified beta lactam antibiotics
Z16.20	Resistance to unspecified antibiotic
Z16.21	Resistance to vancomycin
Z16.22	Resistance to vancomycin related antibiotics
Z16.23	Resistance to quinolones and fluoroquinolones
Z16.24	Resistance to multiple antibiotics
Z16.29	Resistance to other single specified antibiotic
Z16.30	Resistance to unspecified antimicrobial drugs
Z16.31	Resistance to antiparasitic drug(s)
Z16.32	Resistance to antifungal drug(s)
Z16.33	Resistance to antiviral drug(s)
Z16.341	Resistance to single antimycobacterial drug
Z16.342	Resistance to multiple antimycobacterial drugs
Z16.35	Resistance to multiple antimicrobial drugs
Z16.39	Resistance to other specified antimicrobial drug

ADDITIONAL INFORMATION

See the CMS publication entitled, Securing Access to Life-Saving Antimicrobial Drugs for American Seniors, available at <https://www.cms.gov/blog/securing-access-life-saving-antimicrobial-drugs-american-seniors>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

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January 21, 2020	Initial article released.

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