Experience With Medicare’s New Technology Add-On Payment Program

The NTAP program is striking a balance between timely payment for new technology and Medicare spending.

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ABSTRACT: We describe the new technology add-on payment (NTAP) program used by the Centers for Medicare and Medicaid Services (CMS) to provide additional payment for breakthrough technologies in the Medicare hospital inpatient prospective payment system (IPPS). We also evaluate spending under the program. Our findings suggest that the criteria established by the CMS to limit qualifying technologies, combined with an improvement in overall payment adequacy for the new technologies that qualify for NTAPs, may represent important steps toward improving value in Medicare. [Health Affairs 27, no. 6 (2008): 1632–1641; 10.1377/hlthaff.27.6.1632]

Since the inception of the inpatient prospective payment system (IPPS), it has been a challenge to maintain a payment and classification system that accounts for new technologies.1 Under the IPPS, Medicare pays hospitals a fixed, prospectively determined amount for each inpatient hospitalization based on Medicare severity diagnosis-related groups (MS-DRGs). Each MS-DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that MS-DRG. These fixed, prospective payments encourage hospitals to operate efficiently but also put hospitals at risk for higher costs associated with changes in technology, since new technologies are typically introduced without adjustments to the payment levels.2 (Conversely, hospitals are in a beneficial position when changes in technology result in lower costs.) Breakthrough medical technologies whose benefits are realized over a period of months or years can be a particular concern because adoption of the innovation might be in the public interest, but the full incremental cost might be incurred during the...
hospitalization when payment levels do not adequately reflect costs. Without appropriate payment to the hospital at the point of use, technologies that provide value to patients and the health care system over time might not be available to patients.

Although the CMS annually revises the MS-DRGs using data from inpatient claims submitted for inpatient services rendered to Medicare beneficiaries, the MS-DRG classifications and weights are generally based on data from claims for inpatient services provided two fiscal years before the fiscal year in which they will be used. This can create a two-to-three-year delay between the market introduction of a new technology and the recalibration of MS-DRG weights to reflect its added cost. During this period, hospitals that adopt the new technology may experience financial losses.

**Medicare’s New Technology Add-On Payment Program**

In 2000, Congress took steps to ensure that Medicare beneficiaries would have timely access to new, breakthrough technologies that, absent any additional payments, would be inadequately paid for under the existing DRG amount. Section 533 of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Benefits Improvement and Protection Act (BIPA) of 2000 mandated an additional payment that “recognize[s] the costs of new medical services and technologies under the [inpatient] payment system.” The intent of the additional payments was to bridge the recalibration delay by providing a temporary payment mechanism for the use of new technologies in addition to the DRG payment amount the hospital would otherwise receive. The new technology add-on payments (NTAPs) were to be provided until the CMS had inpatient claims data for MS-DRG rate setting that reflected the added costs of the new technology.

In 2001, the CMS used its discretionary authority provided under the statute to issue regulations specifying a process and criteria for granting NTAPs. The program definitions established by the CMS provide that only new technologies meeting specific cost thresholds and demonstrating substantial clinical improvement over existing services would qualify for an NTAP. The CMS also established specific limits to the additional payments made under the NTAP program to ensure that Medicare and hospitals would share in the financial risk of providing costly new technologies.

Additional modifications to the underlying statute enacted in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 required the CMS to update the criteria in 2004. As the NTAP program has evolved, Congress has provided pressure to expand access to new technology, while the CMS has used its authority granted in the statute to establish regulatory criteria requiring that new technologies meet certain criteria to qualify for NTAPs.

- **Eligibility criteria.** Today, for a technology to be eligible for an NTAP, it must meet the following three conditions: the technology must be new, which the CMS
generally defines as within two to three years following Food and Drug Administration (FDA) approval or market introduction, if later; the existing MS-DRG payment for the service involving the technology must be inadequate as demonstrated by meeting thresholds calculated annually by the CMS; and the technology must be a substantial clinical improvement over existing services.5

To determine if the new technology meets the latter requirement, the CMS uses the following set of criteria published in regulation: (1) The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. (2) The technology offers the ability to diagnose a medical condition in a patient population where that condition is currently undetectable or diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient. (3) Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are reduced mortality rate with use of the device; reduced rate of device-related complications; decreased rate of subsequent diagnostic or therapeutic interventions (for example, because of a reduced rate of recurrence of the disease process); decreased number of future hospitalizations or physician visits; more rapid resolution of the disease or treatment process because of use of the device; decreased pain, bleeding, or other quantifiable symptoms; and reduced recovery time. Also, because the NTAP program is for operating costs, the new technology must not be a capital-related expense.6

■ Determination of NTAP amount. For technologies that meet the eligibility criteria and receive CMS approval, the determination of the NTAP amount is based on the cost to hospitals for the new technology. The NTAP amount is calculated distinctly for each eligible discharge that includes the technology, and NTAPs are made only when the estimated cost of the case exceeds the payment that would otherwise be made to the hospital (excluding outlier payments but including higher payments resulting from medical education, serving a high proportion of low-income patients, and adjustments for area wage differences).

The NTAP amount is equal to the lesser of 50 percent of the amount by which the total covered costs of the case exceed the MS-DRG payment, or 50 percent of the costs of the new technology.7 The NTAP formula established by the CMS requires Medicare and hospitals to share in the financial risk of providing costly new technologies. The NTAP limit—which is linked to the price of the technology as reported by manufacturers to the CMS—is established by the CMS when it publishes findings on new technology applications in the IPPS annual final rule.

■ Budget-neutrality requirement. When first enacted in BIPA, the NTAP program was required by law to be budget-neutral. Amounts projected to be spent on NTAPs were to be offset by a corresponding decrease in the standardized amounts used to determine payments for discharges across all MS-DRGs, thus holding over-
all spending under the IPPS constant. The budget-neutrality requirement was a cause of concern among hospitals since additional payments for new technology would be financed by reductions in all other MS-DRG payments to hospitals. Congress amended the NTAP provision in MMA both to remove the requirement that the NTAP be budget-neutral and to lower the cost threshold for new technologies to qualify for add-on payments. The Congressional Budget Office (CBO) estimated that the program modifications established in MMA would increase Medicare inpatient payments by $0.5 billion over ten years beginning with technologies eligible for fiscal year 2005. Since Congress eliminated the budget-neutrality requirement, hospitals have advocated for more expansive application of the NTAP program.

Examples Of The NTAP Policy At Work

Below are three examples of the NTAP policy for cases involving a technology with an estimated cost of $5,000 in an MS-DRG that reimburses $30,000.

■ Example 1: case where no NTAP is paid. Assume that the charges for a particular case are $20,000. After applying the hospital’s cost-to-charge ratio, the cost of the case is estimated at $10,000. Since the cost ($10,000) is less than the MS-DRG payment ($30,000), no NTAP is provided.

■ Example 2: case where the maximum NTAP amount is paid. Assume that the cost of the case is estimated to be $50,000. Since the cost of the case is greater than the MS-DRG payment, an NTAP is made. To determine the amount of the NTAP, compare 50 percent of the excess costs not covered by the MS-DRG payment ($10,000) to 50 percent of the cost of the new technology ($2,500). Since 50 percent of the cost of the new technology is less than 50 percent of the excess costs, the NTAP amount would equal $2,500. Therefore, the total payment to the hospital would equal $32,500.

■ Example 3: case where the NTAP equals 50 percent of the excess cost not covered by the MS-DRG. Assume that the total cost of the case is $31,000. The NTAP amount would be equal to 50 percent of the excess cost not covered by the MS-DRG payment ($500) since it is less than 50 percent of the new technology cost ($2,500). Therefore, the total payment to the hospital would equal $30,500.

Experience With The NTAP Program

Applicants for NTAPs submit a formal request, including a full description of the clinical applications of the new technology and the results of clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, along with cost data to demonstrate that the technology meets the cost threshold establishing that the current MS-DRG payment is inadequate. The CMS then provides opportunities for public comment, including a town hall meeting (required by MMA) to discuss whether the new technology represents a substantial clinical improvement or advancement, and publication of discussion in the annual IPPS proposed rule, which is subject to public notice and comment.
The applications. Since the inception of the NTAP program in 2001, the CMS has received twenty-eight unique applications for consideration of NTAPs. Of the submitted applications, eight were found not to be “new” under the program requirements, one had not received FDA approval, and one did not meet the cost criterion. Of the eighteen remaining applications, seven were found not to provide a substantial clinical improvement, and seven were approved for NTAPs. At the time of this writing, the remaining four applications were under review at the CMS for NTAPs in FY 2009.

The seven approved technologies are (1) drotrecogin alpha (activated) protein for the treatment of severe sepsis associated with acute organ dysfunction, (2) bone morphogenetic proteins for spinal fusion, (3) cardiac resynchronization therapy with defibrillation (CRT-D), (4) bilateral deep brain stimulation for the treatment of Parkinson's disease, (5) rechargeable implantable spinal cord stimulators for chronic pain, (6) endovascular graft repair of the thoracic aorta, and (7) interspinous process decompression system for lumbar spinal stenosis.

The claims and their financial impact. Using the Medicare Provider Analysis and Review (MedPAR) limited data set for the federal fiscal years when technologies were eligible to receive NTAPs, we identified claims where the new technologies were used. Claims were identified with the combinations of International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes specified for each eligible technology as outlined in the Federal Register. For each identified claim we calculated the NTAP amount. The sum, mean, standard deviation, and median NTAP amounts were calculated for each technology.

The CMS estimates the maximum financial impact for each NTAP-eligible technology and publishes the estimates in the proposed and final IPPS rules. The CMS projects maximum financial impact based on the maximum NTAP amount and the expected volume utilization of the new technology (Exhibit 1). We compared the actual spending under the NTAP program (as estimated by the sum of the NTAP amounts of identified claims) to the annual CMS projections.

With the exception of bone morphogenetic proteins for spinal fusion, the CMS did not spend the maximum expected amount on each technology approved for NTAP. There are two possible sources of lower-than-expected spending: the projected use of the new technologies and NTAP amounts paid. In calculating the maximum financial impact, the CMS assumed that the majority of hospitals using the new technologies approved for NTAPs would receive the maximum NTAP available. However, analysis of the NTAP amounts paid demonstrates that the NTAP amounts are highly variable.

Only two of the seven technologies’ median NTAP equals the maximum NTAP available (Exhibit 2). There is also high within-technology variation in the NTAP amounts (Exhibit 3). The variation demonstrates not only the underlying variation in hospital costs and DRG payments, but also the variation in hospital coding and charging practices.
Discussion Of Results

The NTAP program has improved payment for breakthrough medical technologies that increase costs during the hospital stay. The median and mean NTAP amounts show that the actual costs per case exceed the MS-DRG payments. Without the additional payment amounts, many hospitals would have incurred financial losses as a result of using the new technology.

The NTAP program has also resulted in both lower overall Medicare spending than projected by the CMS and high within-technology variation in the NTAP amounts. One potential explanation for this finding is that the NTAP amounts are dependent upon hospital charges adjusted to costs. To determine whether the costs of a case with an approved new technology should receive an add-on payment (and, if so, how much), the CMS uses billed charges for the case and estimates costs from those charges by applying the hospital operating cost-to-charge ratio. If the estimated costs of the case exceed the actual DRG payment for the case (excluding outlier payments), the hospital will receive an NTAP.

EXHIBIT 1

<table>
<thead>
<tr>
<th>Technology</th>
<th>Year(s) eligible</th>
<th>Projected¹</th>
<th>Actual¹</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drotrecogin alpha (activated)</td>
<td>FY 03 FY 04</td>
<td>74.8</td>
<td>12.1</td>
<td>–62.7</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>84.8</td>
<td>26.6</td>
<td>–58.2</td>
</tr>
<tr>
<td>Bone morphogenetic proteins for spinal fusion</td>
<td>FY 04 FY 05</td>
<td>4.4</td>
<td>10.7</td>
<td>6.3</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>12.2</td>
<td>18.7</td>
<td>6.5</td>
</tr>
<tr>
<td>Cardiac resynchronization therapy with defibrillation</td>
<td>FY 05</td>
<td>341.0</td>
<td>128.1</td>
<td>–212.9</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>341.0</td>
<td>128.1</td>
<td>–212.9</td>
</tr>
<tr>
<td>Implantable neurostimulator for deep brain stimulation</td>
<td>FY 05 FY 06</td>
<td>11.9</td>
<td>1.2</td>
<td>–10.7</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>24.7</td>
<td>2.3</td>
<td>–22.4</td>
</tr>
<tr>
<td>Rechargeable implantable neurostimulator</td>
<td>FY 06 FY 07</td>
<td>6.0</td>
<td>0.9</td>
<td>–5.1</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>12.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endovascular graft repair of the thoracic aorta</td>
<td>FY 06 FY 07</td>
<td>16.6</td>
<td>9.0</td>
<td>–7.6</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>33.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interspinous process decompression system</td>
<td>FY 07 FY 08</td>
<td>9.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: See below.


³ Data for fiscal years 2007 and 2008 were unavailable at the time of analysis.
Previous research has demonstrated that hospitals’ charging practices and mark-ups on supplies (including implanted medical devices) can vary for a number of reasons, such as payer mix, utilization, market forces, and the cost of supplies. Distortions in payment for the types of high-cost technologies that meet the CMS cost threshold to merit additional payment to qualify for an NTAP could be due to the problem known as “charge compression.” Charge compression occurs when hospitals mark up low-cost items proportionately more than they do high-cost items, but the CMS’s payment methodology assumes a uniform mark-up rate when estimating costs from billed charges.

The use of a single, uniform cost-to-charge ratio to derive costs from charges results in underestimating the cost of the high-cost items and overestimating the cost of lower-cost items. Variations across hospitals in charge mark-ups and cost estimates for cases that include qualifying new technologies may contribute to the skewed NTAP distribution across hospitals. In particular, it may be a contributing factor to why the two NTAPs with the lowest maximum payment amounts were the only products where the median actual NTAP levels equaled the maximum allowable amount. Costs for cases involving other higher-cost NTAPs may have

### EXHIBIT 2


<table>
<thead>
<tr>
<th>Technology</th>
<th>Year(s) eligible for NTAP</th>
<th>N</th>
<th>Maximum add-on payment ($)</th>
<th>Mean ($) ± SD</th>
<th>Median ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drotrecogin alpha (activated)</td>
<td>FY 03–FY 04</td>
<td>9,803</td>
<td>3,400</td>
<td>2,709 ± 1,288</td>
<td>3,400</td>
</tr>
<tr>
<td>Bone morphogenetic proteins for spinal fusion, b</td>
<td>FY 04–FY 05</td>
<td>7,724</td>
<td>-a</td>
<td>2,424 ± 2,371</td>
<td>1,955</td>
</tr>
<tr>
<td>Cardiac resynchronization therapy with defibrillation</td>
<td>FY 05</td>
<td>33,700</td>
<td>16,263</td>
<td>3,802 ± 4,972</td>
<td>1,163</td>
</tr>
<tr>
<td>Bilateral implantable neurostimulator for deep brain stimulation</td>
<td>FY 05–FY 06</td>
<td>483</td>
<td>8,285</td>
<td>4,838 ± 3,282</td>
<td>5,601</td>
</tr>
<tr>
<td>Rechargeable implantable neurostimulator, c</td>
<td>FY 06–FY 07</td>
<td>153</td>
<td>9,320</td>
<td>5,796 ± 3,609</td>
<td>6,977</td>
</tr>
<tr>
<td>Endovascular graft repair of the thoracic aorta, c</td>
<td>FY 06–FY 07</td>
<td>1,764</td>
<td>10,599</td>
<td>5,093 ± 4,457</td>
<td>4,449</td>
</tr>
<tr>
<td>Interspinous process decompression system, d</td>
<td>FY 07–</td>
<td>-d</td>
<td>4,400</td>
<td>-d</td>
<td>-d</td>
</tr>
</tbody>
</table>

**SOURCE:** Authors’ calculations based on data from the Medicare Provider Analysis and Review (MedPAR) limited data set, 1 October 2002–30 September 2006.

- There were two different maximum NTAP amounts in fiscal years 2004 and 2005.
- The maximum add-on payment and criteria for receiving the payment differs between fiscal years 2004 and 2005.
- Based on 1 October 2005–30 September 2006 MedPAR data; data for 1 October 2006–30 September 2007 were not available at the time of this analysis.
- Data for fiscal year 2007 were unavailable at the time of analysis.
been underestimated as a result of charge compression, possibly leading to artificially reduced NTAP levels.

Policy Implications

- **NTAP criteria limit qualifying technologies.** Through regulatory provisions, the CMS has structured the NTAP program criteria to ensure that only a subset of new technologies qualifies. Most notably, application of the criterion of substantial clinical improvement enables the CMS to find that only medical technologies proven to be an advance over existing technologies can qualify for an NTAP. This criterion has been criticized for lacking clarity. In recent inpatient payment regulations, the CMS has sought public comments to make the process more predictable and transparent. Although comments have been submitted, the CMS has chosen to retain its flexibility.

  While “flexibility” can be viewed as “lacking clarity,” it may be important for the CMS to retain discretion, given the evolution of clinical and economic evidence over time and the range of technologies and disease states involved. For example, the CMS may appropriately require less extensive clinical data when considering whether to approve a new treatment option for patients with a potentially fatal and previously untreatable condition.

- **Technologies that have qualified have continued to be of proven value.** Although new technologies must exceed cost thresholds set for each MS-DRG to qualify for an NTAP, cost-effectiveness analyses related to the technology are not a requirement for an NTAP. However, independent of NTAP, cost analyses have been published on all technologies receiving NTAPs. As is typical with cost analyses, much of the research has been completed and published after the technologies were introduced and the NTAPs were granted. The application of the clinical evaluation
criteria that require the technology to be a substantial clinical improvement over existing services could be serving as a reasonable proxy for value while also allowing timely reimbursement to breakthrough technology.

- **Addressing charge compression will help ensure accurate payment.** Although the problem of charge compression may be skewing payments, the CMS has proposed steps to address this issue over the long run. Specifically, the CMS has proposed to add a cost center to the hospital cost report to ensure that the costs and charges for relatively inexpensive medical supplies are reported separately from the costs and charges of more expensive implantable devices. The addition of a new cost center for implantable devices has been supported by the major hospital associations, CMS consultant reports, the Medicare Payment Advisory Commission (MedPAC), and the medical technology industry. These steps will help to ensure appropriate MS-DRG assignment and payment when the NTAP expires.

- **Some argue that NTAP amounts should be increased.** The NTAP program is structured to ensure shared risks for the costs of new technology; however, hospitals and others have argued that the maximum payment amounts provide an inadequate level of support to hospitals to cover the costs of a new technology. Raising the payment standard from 50 percent to 80 percent would be consistent with other mechanisms (such as outlier payments) in which there is shared risk for factors or costs extending beyond hospitals’ direct control. This increase in payment would improve payments for all hospitals receiving NTAPs greater than zero. However, without evidence that inadequate NTAP amounts are posing a barrier to the adoption of qualifying medical technologies (which is outside the scope of this paper), neither the CMS nor Congress has acted to increase the maximum payment amount.

Further research on the NTAP program is necessary to fully understand its impact on hospitals and the adoption of medical technologies. Most important, research is needed to quantify the benefit of the NTAP program in providing timely access to clinically meaningful technologies to Medicare beneficiaries.

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**NOTES**

5. CMS, “Medicare Program: Changes to the Hospital IPPS and FY 2004 Rates,” Federal Register 68, no. 148 (2003): 45385–45393. The MS-DRG thresholds are determined annually by the CMS and are equal to the geometric mean standardized charge of all cases in a particular MS-DRG plus the lesser of 75 percent of the national adjusted operating standardized payment amount (increased to reflect charges instead of costs) or 75 percent of one standard deviation of mean charges by MS-DRG.


14. CMS, “Medicare Program: Changes to the Hospital IPPS and FY 2008 Rates.”


17. CMS, “Medicare Program: Proposed Changes to the Hospital IPPS and FY 2009 Rates.”