

CMS Proposes Several Changes to Reimbursement for Transformative Medical Technologies

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Key Points

- In recent proposed rulemaking, the Centers for Medicare and Medicaid Services (CMS) make several significant recommendations that incentivize innovation and break down patient barriers to accessing cutting-edge medical technology.
- CMS proposes a more expansive approach to how the agency assesses “substantial clinical improvement” for purposes of determining whether a new medical technology merits a new technology add-on payment (NTAP) under the Medicare Inpatient Prospective Payment System.
- CMS also proposes to develop an alternative pathway to receive an NTAP payment for medical technologies that are part of the Food and Drug Administration (FDA) Breakthrough Device Program.

On April 23, 2019, CMS issued its FY 2020 hospital inpatient prospective payment system (IPPS) proposed rule (IPPS Proposed Rule).¹ The IPPS Proposed Rule addresses many critical Medicare coding, coverage and reimbursement issues, including new medical technology that offers improved solutions for patients but that might add to the cost of a medical procedure or treatment. Under the IPPS Proposed Rule, CMS suggests several changes to how the agency grants new technology add-on payments under IPPS and similar transitional pass-through payments under the outpatient equivalent, the Outpatient Prospective Payment System (OPPS).

- **First**, CMS proposes to recalibrate how it analyzes and appraises “substantial clinical improvement” for determining which medical technology merits IPPS add-on payments and OPPS transitional pass-through payments.
- **Second**, CMS proposes to eliminate the substantial clinical improvement criteria for medical technology participating in the FDA Breakthrough Device Program.
- **Third**, CMS seeks comments on a proposal to increase the value of the IPPS new technology add-on payment.

CMS’ proposed revisions would likely result in increased payment for new and transformative medical technology and would also provide a mechanism for swift uptake in these settings. These policies reflect a shift in the agency’s approach,

Contact Information

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signaling support for more and better patient access. CMS is moving in the same direction as the FDA and consistent with Congressional intent in establishing the **Breakthrough Pathway** in the 21st Century Cures Act, as further outlined below.

Appropriate Substantial Clinical Improvement Criteria

CMS examines several factors when determining whether new medical technology should receive an **NTAP** under the IPPS or a **transitional pass-through payment** under the OPSS. Among these factors are the technology's novelty, the technology's cost and whether the technology represents a "**substantial clinical improvement**" over existing technology.

"Substantial clinical improvement" is at the core of criteria used to evaluate a technology that is the subject of an application for an NTAP payment or transitional pass-through payment.² Currently, CMS' NTAP payment application looks to the following when analyzing whether a new medical technology represents a "substantial clinical improvement:"

- Whether the medical technology offers a treatment option for a patient population unresponsive to or ineligible for current available treatments.
- Whether the medical technology offers the ability to diagnose a condition in a patient population (a) where that condition is currently undetectable or (b) earlier than allowed by currently available methods.
- Whether use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments.

CMS reviews similar criteria requested on the OPSS transitional pass-through application as well.³

In the IPPS Proposed Rule, **CMS seeks comments on changes to the IPPS and OPSS substantial clinical improvement criterion.** CMS has solicited feedback on the following:

- What role should substantial clinical improvement play without **discouraging appropriate utilization of new medical technologies**?
- How should CMS determine which existing technologies are **appropriate comparators to new technologies**?
- More specificity on **types of evidence or study designs considered by CMS** in evaluating substantial clinical improvement?
- **What is the appropriate data to demonstrate** whether the use of technology substantially improves clinical outcomes relative to existing technologies?
- What **types of study designs, criteria or methodologies** could a new technology use to demonstrate substantial clinical improvement?
- Are there certain technically or ethically **challenging designs** for specific medical technologies and should that be more explicitly reflected in the regulations?
- Should potential limitations related to **cross-trial comparisons** with existing therapies be more explicitly reflected in the regulations?
- Can CMS **infer substantial clinical improvement** under certain circumstances (e.g., technical or financial challenges to study accrual)?

- Should the data be focused on the **Medicare population**?
- What **clinical outcomes and patient reported measures** should be assessed?
- Should CMS consider evidence regarding the **off-label use** of a new technology?

For add-on payment applications and transitional pass-through payment applications received beginning in FY 2020 for IPPS and CY 2020 for OPPIs, respectively, CMS is considering adopting regulatory changes to the substantial clinical improvement criteria. Namely, **CMS is seeking comments on whether the agency should adopt the following policy changes:**

- Adopt a policy explicitly specifying that an applicant can meet “substantial clinical improvement” if it demonstrates that new technology would be **broadly adopted** among applicable providers and patients.
- Adopt a definition of the term **“substantially improves”** meaning that the new technology has demonstrated positive clinical outcomes that are different from existing technologies, including that improvement may always be demonstrated by comparison to existing technology.
- Adopting a policy that the relevant information for purposes of a finding of substantial clinical improvement **does not require a peer-reviewed journal article.**
- Adopting a policy that the substantial clinical improvement criterion may be met regardless of the size of the subset patient population where improvement is shown.
- Adopting a policy specifying that “substantially improves” can be met through real-world data and evidence, but that such evidence is not required. This could include decreased mortality rate; reduction in length of stay; reduced recovery time; reduced complications; decreased subsequent interventions; reduction in adverse events; decreased future hospitalizations; more rapid resolution of treatment; improvement in daily living or quality of life.
- Adopting a policy that addresses that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology.

Proposed Alternative Pathway for Transformative New Devices

Also in its IPPS Proposed Rule, **CMS proposes a new pathway for transformative medical technology seeking an add-on payment under the IPPS.** Specifically, CMS proposes that for applications received for IPPS new technology add-on payments for FY 2021 and beyond:

- If a medical device is **part of the FDA’s Breakthrough Device Program** (i.e., designated by FDA to be a breakthrough device) and has received FDA marketing authorization, the device would be considered new and not substantially similar to an existing technology.
- For these transformative devices, because the technology may lack sufficient evidence to show substantial clinical improvement at the time of FDA marketing

authorization, CMS proposes that the device does not need to show substantial clinical improvement to qualify for the add-on payment.

The current breakthrough pathway for devices was established in 2016 by the 21st Century Cures Act (“Cures”), in an effort to facilitate timely access for U.S. patients for devices that would represent a “breakthrough” in diagnosis or treatment. However, Cures did not address coverage and reimbursement of these new, breakthrough devices. Congress modeled the regulatory program for breakthrough devices on the breakthrough pathway for drugs. As enacted, the program is available to qualifying devices that will go through the premarket approval (PMA), *de novo*, or 510(k) pathways. To qualify, a device must demonstrate that it provides for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition, and meets one of the following criteria:

- It represents a breakthrough technology
- It has no approved or cleared alternative
- It offers significant advantages over existing approved or cleared alternatives, including “the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care . . . , or establish long-term clinical efficiencies”
- Its availability is in the best interest of patients.⁴

Breakthrough devices granted priority review are not guaranteed a faster review than nonbreakthrough devices, though they are prioritized in the agency’s review queue and assigned additional review resources. As directed by Cures, the FDA issued guidance on the Breakthrough Device Program, and finalized its policies in December of 2018. Among other things, the guidance details the scope of the program, agency interactions with sponsors of a breakthrough-designated device (including “sprint meetings,” intended to address specific issues and testing protocols), and clinical trial considerations for breakthrough devices.

In addition to proposing a specific pathway for FDA Breakthrough Devices, CMS has also asked for public comments on the following:

- How should CMS compare the risks (i.e., risk of adverse events or negative outcomes) vs. the benefits (i.e., facilitate beneficiary access to transformative new medical devices; mitigate potential delayed access to innovation and adoption) of the proposed pathway?
- CMS also asks whether the newness period under the proposed alternative payment pathway should be limited to a period of time sufficient for the evidence base to develop to the point where a substantial clinical improvement determination can be made. For example, one to two years after approval, depending on whether the transformative new medical device would be eligible for a third year of new technology add-on payments. CMS also notes that the newness period for a transformative new medical device cannot exceed three years.

Proposed Revision to Add-On Payment Calculation

Finally, **CMS proposes increasing the amount of the IPPS new technology add-on payment.** Currently, CMS bases new technology add-on payments on the cost to the

hospital for the new medical technology. Under 42 C.F.R. § 412.88, if the costs of the discharge exceed the full diagnosis-related group (DRG) payment, Medicare makes an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical technology or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

The agency notes that feedback has indicated this calculation does not reflect the true costs of new medical technology and dissuades innovation. Accordingly, CMS has solicited comments on a proposed increase in the amount to the lesser of: (1) **65 percent** of the costs of the new medical technology; or (2) **65 percent** of the amount by which the costs of the case exceed the standard DRG payment.

¹ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page.html>.

² 42 C.F.R. § 412.87(b); 42 C.F.R. § 419.66(b). 42 C.F.R. § 412.87(b)(1); *see also* 42 C.F.R. § 419.66(c).

³ *See id.*

⁴ For a more in-depth discussion of the Breakthrough Device Program, as enacted by Cures, see Akin Gump's Health Industry Alert, "Key Implications of the 21st Century Cures Act for Medical Devices," <https://www.akingump.com/en/news-insights/key-implications-of-the-21st-century-cures-act-for-medical.html>.

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