

CMS proposes changes to new-technology add-on payment amounts and criteria in the inpatient prospective payment system proposed rule for FY 2020

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On 23 April 2019 the Centers for Medicare & Medicaid Services (CMS) issued the inpatient prospective payment system (IPPS) and long-term care hospital (LTCH) prospective payment system [proposed rule](#) for fiscal year (FY) 2020 (Proposed Rule), to be published in the Federal Register on 3 May 2019. In addition to the annual updates made to the IPPS and the LTCH each year as part of this Proposed Rule, CMS also proposes or asks for information about a number of changes to the new technology add-on payments (NTAPs) under the IPPS, including:

- Changes to increase the calculated add-on payment for devices with NTAP designation.
- A new NTAP pathway for devices that are part of the U.S. Food and Drug Administration's (FDA) Breakthrough Devices Program.
- A request for comment on CMS' approach to reviewing the substantial clinical improvement criterion for NTAP or transitional pass-through payment applications under the IPPS and outpatient prospective payment system (OPPS), respectively.

These proposals are outlined further below.

Changes to NTAP amount

Currently, if the costs of discharge exceed the Medicare Severity Diagnosis Related Group (MS-DRG) payment, Medicare will make an add-on payment under the NTAP program equal to the lesser of:

1. "50% of the costs of the new medical service or technology"; or
2. "50% of the amount by which the costs of the case exceed the standard DRG payment."¹

In the Proposed Rule, CMS acknowledged hearing that the current policy "does not adequately reflect the costs of new technology," particularly in the context of "a new technology with an

¹ 42 C.F.R. § 412.88(a)(2).

unprecedented high cost," such as the chimeric antigen receptor (CAR) T-cell therapies.² For this reason, CMS is proposing to increase the NTAP amount to the lesser of:

1. "65% of the costs of the new medical service or technology"; or
2. "65% of the amount by which the costs of the case exceed the standard DRG payment."³

New NTAP pathway for breakthrough devices

Under current regulations, NTAPs are available under the IPPS for certain new medical services or technologies if they afford substantial clinical improvements over the use of previously available technologies, they are considered new, and they meet a cost criterion.⁴

The Proposed Rule would create an alternative pathway for NTAP eligibility for "transformative new devices" that are part of FDA's Breakthrough Devices Program and have received FDA marketing authorization.⁵ Under the Breakthrough Devices Program, eligible devices must meet one of the following criteria:

- They must "represent breakthrough technologies."
- There must be "no approved or clear alternatives."
- They must "offer significant advantages over existing approved or cleared alternatives . . ."
- Their availability must be "in the best interest of patients."⁶

Devices approved through the alternative pathway would not need to meet the newness or substantial improvement criterion under the existing NTAP pathway but must continue to meet the cost criterion.⁷ Consistent with the existing NTAP program, the period for NTAP eligibility under the new pathway would be at least two but no more than three years after data became "available reflecting the inpatient hospital code . . . assigned to the new technology . . ."⁸ The new pathway would be available for applications for NTAP for FY 2021 and after. CMS did not propose an alternative NTAP pathway for drugs.

Request for information (RFI) on substantial clinical improvement criterion

In the Proposed Rule, CMS issued an RFI on the NTAP substantial clinical improvement criterion.⁹ CMS also asked for feedback as part of this RFI for the same criterion for transitional pass-through payments for devices under the OPPI.¹⁰ CMS notes that "greater clarity regarding what would substantiate the requirements of this criterion would help the public, including innovators, better understand how CMS evaluates new technology applications for add-on payments and provide greater predictability about which applications will meet the criterion for substantial clinical improvement."¹¹ CMS therefore is asking for broad feedback on this criterion,

² 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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals, CMS-1716-P, [hereinafter Display Copy] at p. 739.

³ *Id.* at 740, 1512.

⁴ 42 CFR § 412.87.

⁵ Display Copy at 735-36, 1511.

⁶ *Id.* at 732-33.

⁷ *Id.* at 736, 1511.

⁸ *Id.* at 737, 1511.

⁹ *Id.* at 714-24.

¹⁰ *Id.*

¹¹ *Id.* at 720.

including, but not limited to, specific changes or clarifications that CMS might consider making to it and feedback on the process for approving NTAP applications.¹²

Additional proposals

In addition to the proposed changes to and requests for comment on the NTAP provisions outlined above, the Proposed Rule seeks to make certain additional changes, including, but not limited to:

- Proposing to "reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and decreasing the wage index values for certain hospitals with high wage index values."¹³
- Proposing to update how CMS estimates "the three factors used to determine uncompensated care payments" for disproportionate-share hospitals.¹⁴
- Clarifying changes to the Hospital Readmissions Reduction Program (HRRP) and Hospital-Acquired Condition (HAC) Reduction Program as well as the development of factors to use to decide when measures under either of these programs should be removed.¹⁵

Comments on the Proposed Rule are due by 5 p.m. EST on 24 June 2019.¹⁶

¹² *Id.* at 720-24.

¹³ *Id.* at 815-37.

¹⁴ *Id.* at 869-934.

¹⁵ *Id.* at 935-54; 983-1003.

¹⁶ *Id.* at 2.

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