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 Rule Summary

The Center for Medicare & Medicaid Services (CMS) at the Department of Health and Human Services (HHS) issued a proposed rule on April 23, 2019, which revises the Medicare hospital inpatient prospective payment systems (IPPS). The text of the proposed rule can be found here. A summary of the sections in the proposed rule relevant to hematology can be found below. The deadline for comments is June 24, 2019 at 11:59 pm EST.

I. Overview and Purpose of Rule

The proposed rule includes payment and policy changes to the IPPS for FY 2020 operating costs and capital-related costs of acute care hospitals and certain hospitals that are excluded from the IPPS (PPS exempt centers). The proposed rule includes revisions to the Outpatient Prospective Payment System (OPPS) transitional pass-through payment for devices and the IPPS new technology add-on payments (NTAP) as well as requests for feedback on the “substantial clinical improvement criterion” for NTAP. It also includes discussions on the MS-DRG 014 for allogeneic bone marrow transplant and a discussion regarding the development on a new MS-DRG for chimeric antigen receptor T-cell (CAR-T) therapies, as well as alternative payment models for future rulemaking.

II. Request for Information on the New Technology Add-on Payment and Transitional Device Pass-through Payment Substantial Clinical Improvement Criterion

CMS is requesting information on the “substantial clinical improvement criterion” used to evaluate technology in an application for a NTAP under IPPS or for the transitional pass-through payment for additional costs of innovative devices under OPPS. CMS is considering revising this criterion and requests public comment on the type of additional detail and guidance that would be useful for applicants and the general public. This feedback is intended to be used for potential future rulemaking.

CMS is also requesting comments on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that CMS might consider in the FY2020 IPPS final rule and in the CY2020 OPPS final rule. The goal of this feedback is for CMS to provide a better understanding of the approach taken when evaluating substantial clinical improvement.

III. Provisions related to NTAP for Breakthrough Devices

In furtherance of CMS’ commitment to addressing barriers to innovation in health care and ensuring access to “critical and life-saving new cures and technologies that improve beneficiary health outcomes,” CMS is developing an alternative pathway for inpatient NTAPs as part of FDA’s Breakthrough Devices program.
Specifically, for applications received for IPPS NTAPs for FY 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, the device would be considered new and not substantially similar to an existing technology for purposes of NTAP under the IPPS.

Based on the criteria applied under the FDA’s Breakthrough Devices Program, and since the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, CMS is also proposing that the medical device would not need to meet the requirement under 42 CFR 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

IV. Proposed revision to calculate the inpatient hospital NTAP

CMS describes the current statutory basis for calculating inpatient NTAPs, which is based on the cost to hospitals for the new medical service or technology. Earlier this year ASH suggested revisions to improve CAR-T reimbursement to CMS on the NTAP formula and the Society’s proposal is included in Appendix I. In response, CMS is proposing to modify the current NTAP formula as follows:

“Beginning October 1, 2019, if the costs of a discharge involving a new medical service or technology exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of:

(1) 65 percent of the costs of the new medical service or technology; or

(2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.”


In the fall of 2018, CMS held a town hall meeting to receive input on the proposed clinical improvement criterion for the FY 2020 new medical service and technology add-on payment applications before publishing the FY 2020 IPPS proposed rule. A summary of the previously submitted public comments on applications for the proposed technologies for FY 2020 NTAPs is included in the proposed rule. A more detailed summary of the discussion for KYMRIAH® and YESCARTA® is included below.

Novartis and Kite submitted separate applications for NTAPs for FY 2019 for KYMRIAH® and YESCARTA®, respectively. Both technologies are “CD-19-directed T-cell immunotherapies used for the purposes of treating patients with aggressive variants of non-Hodgkin lymphoma (NHL).” Novartis received FDA-approval on May 1, 2018 for KYMRIAH’s second indication, treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Kite received FDA approval on October 18, 2017 for the use of YESCARTA® indicated for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
Both KYMRIAH® and YESCARTA® meet the NTAP newness criterion, as they are the first CAR T-cell immunotherapies. In the FY 2019 IPPS final rule, CMS found that the two technologies are substantially similar and that it was appropriate to evaluate them on one application for NTAP under IPPS. For this reason, CMS chose to use the earliest market availability date for both products as the beginning of the newness period. CMS asked for additional input on this decision in the FY 2019 IPPS final rule for consideration in FY 2020, and continues to consider KYMRIAH® and YESCARTA® to be substantially similar products. CMS requests further public comment on the substantial similarity decision.

After considering the newness, costs, and substantial clinical improvement criteria, CMS approved the NTAPs for KYMRIAH® and YESCARTA® for FY 2019 with the newness period beginning November 22, 2017. Since the three-year period would end after the start of FY 2020, CMS is proposing to continue NTAP payments for all of FY 2020 and is requesting comment on this proposal.

CMS is proposing not to modify the current MS-DRG assignment for cases reporting CAR-T therapies for FY 2020 and is alternatively seeking comment on alternative payment models for CAR-T (see next section).

VI. Provisions related to MS-DRG for procedures involving CAR-T Cell Therapies

CMS received a request to create a new MS-DRG for procedures involving CAR T-cell therapies. The requestor stated that “creation of a new MS-DRG would improve payment for CAR T-cell therapies in the inpatient setting.” This rationale is based on data that shows while cases involving CAR T-cell therapy are currently eligible for NTAPs and outlier payments, providers continue to face significant financial losses. The requestor also suggested that CMS modify its existing payment mechanisms to use a cost to charge ratio (CCR) of 1.0 for charges associated with CAR T-cell therapy and suggested technical and operational changes related to CAR T-cell therapy, such as the development of unique CAR T-cell therapy revenue and cost centers for billing and cost reporting purposes. The agency did not include more details of these requests in the proposed rule. CMS plans to consider these technical and operational suggestions in the development of future billing and cost reporting guidelines and instructions.

CMS next discusses the relevant ICD-10 procedure codes, which became effective on October 1, 2017. In the FY 2019 IPPS final rule, CMS noted that they should collect more comprehensive clinical and cost data before considering assignment of a new MS–DRG to CAR-T therapies. CMS asked for comment on several issues that CMS raised on approaches for setting the relative weight when developing a new MS-DRG, including: (1) the most appropriate way to develop the relative weight of drug costs given the current variation in claims data; (2) if clinical trial cases should be excluded since drug costs are not included on these claims; (3) whether to use an appropriate portion of the ASP for the drugs to reflect the costs involved in treating patients with CAR-T; (4) whether it would be appropriate to geographically adjust the payment under a new MS-DRG; or (5) whether IME and DSH payments should be impacted for cases assigned to a new MS-DRG for CAR-T.

At this time, CMS proposes not to modify the current MS-DRG assignment for cases reporting CAR T-cell therapies for FY 2020. CMS specifically requests comments on potential alternative payment models for CAR-T, which would include the following considerations:

• Effect of payment model on patient access to care;
• Impact on incentives to lower drug prices; and
• How the effective dates of a payment methodology alternative might impact future participation in the payment model.

CMS is requesting comments on other payment alternatives, including but not limited to:

• Adjusting the CCRs used to calculate NTAPs for cases using KYMRIAH and YESCARTA, for example by using a CCR of 1.0, when determining outlier payments, when determining the new technology add-on payments, and when determining payments to PPS exempt centers for CAR T-cell therapies.
  o CMS had considered this approach in the FY 2019 IPPS proposed rule and is reconsidering it based on feedback from providers that provide CAR-T at both PPS and PPS-exempt centers.

• Eliminating the use of CCRs to calculate NTAP for cases involving KYMRIAH and YESCARTA and:
  o Making a uniform add-on payment equal to the maximum add-on payment, or 65 percent of the cost of the technology (in accordance with the proposed increase in the calculation of the NTAP amount), which would be $242,450; and/or
  o Using a higher percentage than the proposed 65 percent to calculate the maximum new technology add-on payment amount.

VII. Provisions related to Request for MS-DRG for Allogenic Bone Marrow Transplant

CMS received a request to create new MS-DRGs for cases that identify patients who undergo an allogeneic hematopoietic cell transplant (HCT) procedure. The request sought to create two new MS-DRGs for allogeneic related and allogeneic unrelated donor sources, in order to distinguish between the clinical and cost differences in the cases. The purpose of the request is to address the inadequate current payment for allogenic HCT cases, which is a barrier to patient access to care.

CMS included an analysis of data supplied by the requestor, as well as the agency’s own claims data from Fiscal Year 2018. Based on the analysis, CMS determined that the current MS-DRG assignment is appropriate for the cases in the MS-DRG for patients who undergo an allogeneic HCT procedure regardless of donor source. CMS noted that in considering new MS-DRGs, they do not consider reported revenue codes.

CMS’ clinical advisors support maintaining the current structure for MS-DRG 014 as it is clinically appropriate for classifying all patients. Therefore, CMS is not proposing to split MS-DRG 014 into two new MS-DRGs, as requested. However, CMS did review the billing instructions for stem cell transplantation in the Medicare Claims Processing Manual and found duplication in Section 90.3.1 and 90.3.3 of Chapter 3, which CMS will be revising as necessary to align the instructions in the Manual.

CMS also found that there are 8 procedure codes for autologous HCT procedures included in MS-DRG 014 that are not properly assigned to the MS-DRG (see table 1). Since further analysis showed that the frequency of these procedure codes being reported in MS-DRG 014 is low and the average cost of case reporting is more closely aligned with MS-DRGs 016 and 017, CMS proposes to reassign the following four procedure codes to MS-DRGs 016 and 017 for FY 2020 (see table 2). CMS considers the remaining four procedure codes to be clinically invalid procedures and should not be reported in claims data.
### TABLE 1

<table>
<thead>
<tr>
<th>ICD-10-PCS Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>30230X0</td>
<td>Transfusion of autologous cord blood stem cells into peripheral vein, open approach</td>
</tr>
<tr>
<td>30233X0</td>
<td>Transfusion of autologous cord blood stem cells into peripheral vein, percutaneous approach</td>
</tr>
<tr>
<td>30240X0</td>
<td>Transfusion of autologous cord blood stem cells into central vein, open approach</td>
</tr>
<tr>
<td>30243X0</td>
<td>Transfusion of autologous cord blood stem cells into central vein, percutaneous approach</td>
</tr>
<tr>
<td>30250X0</td>
<td>Transfusion of autologous cord blood stem cells into peripheral artery, open approach</td>
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<tr>
<td>30253X0</td>
<td>Transfusion of autologous cord blood stem cells into peripheral artery, percutaneous approach</td>
</tr>
<tr>
<td>30260X0</td>
<td>Transfusion of autologous cord blood stem cells into central artery, open approach</td>
</tr>
<tr>
<td>30263X0</td>
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APPENDIX I*

§ 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

   (i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);
   (ii) The payment determined under § 412.4(f) for transfer cases;
   (iii) The payment determined under § 412.92(d) for sole community hospitals; or
   (iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

(2) If the costs of the discharge (determined by applying the operating cost to charge ratios as described in § 412.84(h)) exceed the full DRG payment an additional amount equal to the lesser of:

   (i) 50\% 80 percent of the costs of the new medical service or technology; or
   (ii) 50\% 80 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b) Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50\% 80 percent of the estimated costs of the new medical service or technology.

*ASH’s proposal. This was not included in the IPPS proposed rule.