

Inpatient Prospective Payment System (IPPS) 2021 Proposed Rule Summary of Issues Impacting Radiation Oncology

On Monday, May 11, 2020 the Centers for Medicare and Medicaid Services (CMS) issued the Inpatient Prospective Payment System (IPPS) [proposed rule](#), containing several issues of interest to the field of radiation oncology, including: a proposed policy involving the collection of private payer MS-DRG relative weights to inform payment methodology changes; New Technology Add-On Payments (NTAP) for technologies involving radiation treatment delivery; technical clarification of the alternative pathway for the FDA's Breakthrough Devices Program; continuation of the Low Wage Index Hospital Policy; a proposed policy change related to Medical Residents affected by Residency Program or Teaching Hospital closure; and waiver of the 60-day delayed effective date for the Final Rule. Comments in response to the rule are due July 10, 2020.

Private Payer MS-DRG Relative Weight Data to Inform Future Medicare Rates

CMS currently uses hospital charge master data to inform rates for both hospital inpatient and outpatient services. To reduce its reliance on hospital charge masters, the Agency is proposing to require hospitals to report market-based payment rate information in their Medicare cost report for periods ending on or after January 1, 2021. CMS proposes to use this information to change the methodology for calculating the IPPS MS-DRG relative weights to reflect market-based pricing.

In the proposed IPPS, the Agency is specifically asking that hospitals report the median payer-specific negotiated charge that the hospital has negotiated with Medicare Advantage organizations and third-party payers by Medicare Severity-Diagnosis Related Group (MS-DRG). CMS is considering adopting this policy in the 2021 IPPS Final Rule and seeks comments on the potential methodology change.

While this proposal does not directly impact radiation oncology practices, ASTRO is concerned that a similar methodology could potentially be applied in the Hospital Outpatient Setting.

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2021

Each year in the proposed rule, CMS addresses the applications for new technology add-on payments under the IPPS by presenting its evaluation and analysis of the applications. The Agency does not generally make proposals in the rule, but rather describes any concerns it may have regarding whether a technology meets the criteria for payment as a new technology and seeks additional information as needed for use in making a decision on the applications in the final rule.

A new medical service or technology may be considered for NTAP, if the DRG prospective payment rate is inadequate based on the estimated costs incurred with respect to services delivered involving a new medical service or technology. In order to secure a new technology add-on payment, the new medical service or technology must demonstrate that it is 1) new; 2)

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costly such that the applicable DRG rate is inadequate; and 3) represents a substantial clinical improvement over existing services or technologies. The following application was received for services related to the delivery of radiation therapy in the inpatient setting:

GammaTile™

In FY 2020, GT Medical Technologies, Inc. submitted an application for GammaTile™, which is a brachytherapy technology for use in the treatment of patients who have been diagnosed with brain tumors. The technology uses cesium-131 radioactive sources embedded in a collagen matrix that are designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of brain tumors. The GammaTile™ is biocompatible and is left in the body permanently without need for future surgical removal.

In the 2020 IPPS final rule, CMS finalized that GammaTile™ did not meet the criteria for new technology add-on payments. CMS was unable to make a determination that GammaTile™ technology represented a substantial clinical improvement over existing therapies. From the analysis provided during public comment, CMS indicated that there was no statistically significant data that supported the GammaTile™ NTAP application. In the FY 2021 IPPS proposed rule, GT Medical Technologies, Inc again submitted an application for new technology payments, and the agency is seeking comment on whether the GammaTile™ meets the NTAP criterion.

IMFINZI® (durvalumab)

AstraZeneca PLC submitted an application for new technology add-on payments for IMFINZI® for 2021. IMFINZI® is a selective, high-affinity, human IgG1 monoclonal antibody (mAb) that blocks programmed death-ligand 1 (PD-L1) binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity. IMFINZI® has multiple indications but is applying for new technology add-on payments for IMFINZI® in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). The agency is seeking comment on whether the IMFINZI® meets the NTAP criterion.

TECENTRIQ® (atezolizumab)

Genentech, Inc. submitted an application for new technology add-on payments for TECENTRIQ® for 2021. According to Genentech, Inc, TECENTRIQ® is a programmed death-ligand 1 (PD-L1) blocking antibody with four different oncology indications, including one in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). The agency is seeking comment on whether the TECENTRIQ® meets the NTAP criterion.

AZEDRA NTAP Status Proposed to be Extended through 2021

Every year, CMS reviews the status of technologies approved for NTAP and determines whether or not to continue NTAP status. In FY 2020, Progenics Pharmaceuticals, Inc. submitted an application for new technology add-on payments for AZEDRA® (iobenguane Iodine-131). AZEDRA® is a drug solution formulated for intravenous use in the treatment of patients with iobenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and

paraganglioma. These are rare tumors with an incidence of approximately 2 to 8 people per million per year.

CMS considers the beginning of the newness period to commence when AZEDRA® was approved by the FDA, which was on July 30, 2018. CMS extends 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 upcoming fiscal year. Since the 3-year anniversary date of the entry of AZEDRA® into the U.S. market (July 30, 2021) will occur in the second half of 2021, CMS is proposing to continue new technology add-on payments for 2021. CMS is also proposing that the maximum new technology add-on payment for cases involving AZEDRA remain at \$98,150. CMS is inviting public comments whether to continue new technology add-on payments for AZEDRA® for 2021.

Technical Clarification to the Alternative Pathway for the FDA Breakthrough Devices Program

In the 2020 IPPS final rule, CMS finalized a new NTAP pathway for transformative new devices. This new approach recognized devices that are part of the Federal Drug Administration's (FDA) Breakthrough Devices Program and receive FDA marketing authorization. These devices are considered new and are not required to meet the requirement that it substantially improves, relative to the existing technologies, the diagnosis or treatment of Medicare beneficiaries. This new approach applies to applications beginning October 1, 2020.

Additionally, the Agency finalized modifications to the NTAP payment methodology. If the costs of care exceed the Diagnosis Related Group (DRG) payment, then Medicare will 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 cost of the case exceeded the DRG payment. This represents an increase from the existing add on amount of 50 percent, which many commenters felt did not adequately reflect the cost of many expensive therapies.

In the 2021 IPPS, CMS addresses public concern with respect to the "marketing authorization" required for purposes of approval under the alternative pathway for transformative new devices. Specifically, CMS is addressing concern that technology would meet the marketing authorization requirement so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program.

To address this potential confusion, CMS clarifies existing policy that a new medical device under the alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program. Specifically, with regard to the eligibility criteria, CMS is proposing to amend the regulations to state that "A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation."

Continuation of the Low Wage Index Hospital Policy

In the 2020 IPPS final rule, CMS finalized policies 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 doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor.

CMS addressed concerns regarding disparities between high and low wage index hospitals as a result of the application of the current Medicare Wage Index system and finalized an increase in the wage index values for hospitals with a wage index below the 25th percentile and a decrease in the wage index values for hospitals with index values above the 75th percentile. CMS also finalized an increase in the wage index value for hospitals below the 25th percentile by half of the difference between each individual hospital's wage index value and the 25th percentile wage index value. A similar methodology is used to reduce the wage index value for hospitals above the 75th percentile wage index value, thus keeping the proposal budget neutral.

In addition, CMS modified the "rural floor" policy which dictated that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that same state. The Agency finalized the decision to remove the wage data of urban hospitals that have been reclassified as rural from the rural floor methodology.

CMS stated that this policy is effective for at least four years, beginning in 2020, and includes a transition period, which caps the decrease at 5 percent, for hospitals that experience a significant decrease in the hospital wage index for the first two years. Therefore, CMS will continue this policy in 2021. Based on the data for this proposed rule, the 25th percentile wage index value across all hospitals would be 0.8420. To offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, CMS is proposing to apply the budget neutrality adjustment in the same manner as applied in FY 2020, as a uniform budget neutrality factor applied to the standardized amount.

Proposed Policy Change Related to Medical Residents Affected by Residency Program or Teaching Hospital Closure

CMS is proposing policy changes related to closed teaching hospitals and residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and to foster seamless Medicare indirect medical education and direct graduate medical education funding. Currently, displaced residents include those who are physically training in the hospital or program on the day of or day prior to closure and those who would be at the closing hospital or program but for the fact that they were on approved leave. The proposed policy change would expand the existing definition of "displaced" resident to include those who leave a program after closure is publicly announced; those residents assigned to and training at planned rotations at other hospitals; and medical students or would-be fellows who matched into GME programs at the closing hospital or program but have not yet started training. These proposed policies would provide greater flexibility for the residents to transfer while the hospital

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operations or residency programs were winding down and would allow funding to be transferred for certain residents who are not physically at the closing hospital/closing program.

Waiver of the 60-day Delayed Effective Date for the Final Rule

Due to the significant devotion of resources to the COVID-19 response, CMS is waiving the 60-day delay in the effective date of the final rule and replacing it with a 30-day delay in the effective date of the final rule. CMS ordinarily provides a 60-day delay in the effective date of final rules after the date it is issued. However, due to CMS prioritizing efforts in support of containing and combatting the COVID-19 public health emergency, the work needed to complete the IPPS payment rule will not be in accordance with the usual schedule. Thus the Agency is adding 30 days in order to complete the work needed on this payment rule.

The proposed rule (CMS-1735-P) can be downloaded from the Federal Register at:

<https://www.federalregister.gov/documents/2020/05/29/2020-10122/medicare-programshospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

More information regarding the 2021 IPPS can be found at the following link:

<https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-proposed-rule-homepage#Proposed>

For a fact sheet on the proposed rule (CMS-1735-P), please visit:

<https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute>