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

On Wednesday, September 2, 2020, the Centers for Medicare and Medicaid Services (CMS) issued the <u>Hospital Inpatient Prospective Payment System (IPPS) final rule</u>. The rule contains several issues of interest to the field of radiation oncology, including New Technology Add-On Payments (NTAP) for technologies involving radiation treatment delivery; a finalized policy involving Medicare Advantage market-based payment rates to inform future Medicare rates; continuation of the Low Wage Index Hospital Policy; and a finalized policy change related to Medical Residents affected by Residency Program or Teaching Hospital closure.

Due to the public health emergency, CMS is waiving its typical 60-day delay in the effective date of the final rule and adopting a 30-day delay. Therefore, the effective date of the final rule is October 1, 2020.

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

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 the 2021 IPPS proposed rule, CMS considered several applications for new technology add-on payments and sought public comment for further information to determine whether these applications met the NTAP criteria.

CMS specifies three criteria for a new medical service or technology to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

In the 2021 IPPS final rule, CMS presented 22 NTAP applications for 2021, of which 16 were approved. CMS provided determinations in response to the following NTAP applications for services related to the delivery of radiation therapy in the inpatient setting:

GammaTileTM

In the 2021 IPPS final rule, CMS finalized that GammaTileTM still does not meet the substantial clinical improvement criteria for approved NTAP. Specifically, they assert that the applicant does not provide statistical data or meta-analyses that demonstrates significant efficacy of GammaTileTM when compared to conventional radiation therapy.

GammaTileTM is a brachytherapy technology for use in the treatment of patients 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 GammaTileTM is biocompatible and is left in the body permanently without the need for future surgical removal.

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A NTAP application for GammaTileTM initially appeared in the 2020 IPPS proposed rule. At the time, CMS determined GammaTileTM did not meet the criteria for new technology add-on payments specifically because the applicant was not able to satisfy the third criteria for NTAP and present GammaTileTM as a substantial clinical improvement over existing therapies. CMS indicated that there was no statistically significant data that supported the GammaTileTM NTAP application.

AZEDRA NTAP Status Proposed to be Extended through 2021

Every year, CMS reviews the status of technologies previously approved for NTAP and determines whether to continue the NTAP status. In the 2021 IPPS final rule, CMS finalizes the extension of the new technology add-on payments for AZEDRA® for 2021. Using the maximum new technology add-on payment criteria of 65 percent, the maximum new technology add-on payment amount for a case involving AZEDRA® will remain at \$98,150. for 2021.

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 extends new technology add-on payments for an additional year only if the three-year anniversary date of the product's entry into the U.S. market occurs in the latter half of the upcoming fiscal year. According to the Agency, the beginning of that period for AZEDRA® was July 30, 2018, the date it was approved by the FDA, which qualifies it for an extension through 2021.

Medicare Advantage Market-Based Payment Rates to Inform Future Medicare Rates CMS currently uses hospital charge master data to inform rates for both hospital inpatient and outpatient services. In the 2021 IPPS final rule, CMS is finalizing, with a modification, its proposal to require hospitals to report market-based payment rate information, specifically median payer-specific negotiated charges, in their Medicare cost report by Medicare Severity-Diagnosis Related Group (MS-DRG). The proposed rule would have applied this requirement to the negotiated rates of both Medicare Advantage (MA) plans and third-party payers, but the final rule only applies to MA plans.

CMS asserts that by reducing its reliance on hospital chargemaster data, it can adjust Medicare payment rates so that they reflect the relative market value for inpatient services and items. Hospitals will be required to report the median payer-specific negotiated charge for each MA organization for cost reporting periods ending on or after January 1, 2021. According to CMS, because the collection of MA charge data aligns with requirements under the Hospital Price Transparency rule, it does not represent an added administrative burden. CMS proposes to use this information to change the methodology for calculating the IPPS MS-DRG relative weights to reflect market-based pricing.

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This new data collection requirement is expected to inform a MS-DRG relative weight methodology that the Agency plans to implement in 2024. The relative weight will be calculated using the ratio of the single-weighted average standardized median MA organization payer specific negotiated charge for each MS-DRG across hospitals to the single national weighted average standardized median MA organization payer-specific negotiated charge across all MS-DRGs. By calculating this ratio establishing relativity, the weights would reflect the resources used with respect to discharges classified within the MS-DRG.

In an effort to ensure a transparent process, CMS commits to providing an opportunity for the public to review the market-based data collected for purposes of establishing the new MS-DRG weight methodology. Additionally, the Agency remains open to making modifications and refinements to the market-based methodology through rulemaking prior to the 2024 effective date. While CMS is currently not considering a phase-in of the new methodology, the Agency may consider it in future rule making.

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. The change increases the wage index values for certain hospitals with low wage index values in a budget neutral manner through an adjustment applied to the standardized amounts for all IPPS hospitals, as well as by changing the calculation of the rural floor. 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. For 2021, CMS maintained this policy and finalized the wage index value at the 25th percentile, which equates to 0.8465 for 2021. CMS will continue to achieve budget neutrality by adjusting the standardized amount.

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

In the 2021 IPPS final rule, CMS is finalizing 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. In the proposed rule, displaced residents were identified as 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 at the closing hospital or program but for the fact that they were on approved leave. The proposed policy change expanded 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.

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In the 2021 IPPS final rule, CMS is modifying the definition of "displaced to include a resident who is accepted into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program."

The 2021 IPPS final rule can be downloaded from the Federal Register at:

https://www.federalregister.gov/documents/2020/09/18/2020-19637/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

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

https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page

For a fact sheet on the 2021 IPPS final rule, please visit:

https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0