

Inpatient Prospective Payment System (IPPS) 2020 Final Rule Summary of Issues Impacting Radiation Oncology

On Friday, August 2, 2019, the Centers for Medicare and Medicaid Services (CMS) issued the [Hospital Inpatient Prospective Payment System \(IPPS\) final rule](#). The rule contains several issues of interest to the field of radiation oncology, including finalized New Technology Add-On Payments (NTAP) for three technologies involving radiation treatment delivery; finalized changes to the criterion and payment for evaluating NTAPs, that will also be applied to Outpatient Prospective Payment System (OPPS) transitional pass-through payments for devices; and finalized modifications to the Medicare wage index. The final rule was published in the *Federal Register* on August 16, 2019 and will be implemented on October 1, 2019 (Federal FY 2020).

New Technology Add-On Payments (NTAP) for New Services and Technologies for 2020

In the 2020 IPPS proposed rule, CMS discussed that 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 discharges involving a new medical service or technology. CMS established that in order to secure a new technology add-on payment, the new medical service or technology must demonstrate that it is 1) new; 2) costly such that the applicable DRG rate is inadequate; and 3) a substantial clinical improvement over existing services or technologies.

In the 2020 IPPS final rule, CMS provided determinations in response to the following NTAP applications for services related to the delivery of radiation therapy in the inpatient setting:

AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution

Progenics Pharmaceuticals submitted an application for AZEDRA®, which 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.

After review of public comments, CMS finalized that AZEDRA® meets all three criteria for a new technology add-on payment. Cases involving the use of AZEDRA® will be identified by ICD-10-PCS codes XW033S5 and XW043S5. The applicant estimated an average total cost per patient of approximately \$151,000. For 2020, using the maximum new technology add-on payment of 65 percent, the add-on payment for a case involving AZEDRA® is \$98,150. CMS estimates the 2020 add-on payments at approximately \$39,269,000, based on 400 patients.

CivaSheet®

CivaTech Oncology, Inc. submitted an application for CivaSheet®, which is intended for use as brachytherapy for placement into a body cavity or tissue as a source for the delivery of radiation therapy. CivaSheet® may be used either for primary treatment or for the treatment of residual disease after excision of the primary tumor. It can also be used concurrently, or sequentially, with other treatment modalities, such as external beam radiation therapy or chemotherapy.

CivaTech asserts that CivaSheet® is the first low dose rate brachytherapy device designed specifically for the delivery of intraoperative radiation therapy.

In the 2020 IPPS final rule, CMS finalized that CivaSheet® does not meet the criteria for a new technology add-on payment. Due to limited data, CMS was unable to determine that the CivaSheet® represents a substantial clinical improvement over existing therapies. CMS expressed concern that the supporting data provided by both the applicants and through public comment did not include the necessary comparison data to other current treatments, nor any long-term follow-up data with comparisons to currently available therapies to support a finding that the CivaSheet® represented a new technology for the purposes of receiving the NTAP.

GammaTile™

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™ does not meet the criteria for new technology add-on payments. In the final rule, CMS continued to express concerns with respect to whether GammaTile™ meets the substantial clinical improvement criterion to be approved for a new technology add-on payment. From the data provided by the applicants during public comment, CMS indicated that there was no statistically significant data that supported the GammaTile™ NTAP application.

Evaluation of Substantial Clinical Improvement Criterion for IPPS NTAP and OPSS Transition Pass-Through Payments for Devices

In the 2020 IPPS proposed rule, CMS sought comment on the “substantial clinical improvement” criterion for evaluating applications for both the IPPS (NTAP) and the OPSS transitional pass-through payment for devices. Existing regulations provide that a new technology is an appropriate candidate for additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available.

The Agency recognized that additional clarity regarding the requirements associated with the “substantial clinical improvement” criterion will help the public better understand how CMS evaluates new technology applications for add-on payments and will provide greater predictability about which applications will meet the criterion. There were no clarifications regarding the substantial clinical improvement criterion provided in the final rule. CMS stated that it will continue to collect comments to inform future rule making.

New NTAP Pathway for Transformative New Devices

In the 2020 IPPS final rule, CMS finalized a new NTAP pathway for transformative new devices. This new approach recognizes 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 in Federal FY 2021 (October 1, 2020).

Additionally, the Agency finalized modifications to the NTAP payment methodology. If the costs of care exceed the Diagnosis Related Grouper (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.

Medicare Wage Index Disparities

In the 2020 IPPS proposed rule, CMS recognized concerns regarding disparities between high and low wage index hospitals as a result of the application of the current Medicare Wage Index system. To address these concerns in the final rule, the Agency is finalizing 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.

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 believes that the inclusion of these hospitals in the past has inflated Medicare wage index disparities between low and high wage hospitals.

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.

IPPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In the 2020 IPPS final rule, CMS finalized removing the External Beam Radiotherapy for Bone Metastases measure beginning in 2022. According to the Agency, the costs associated with the measure outweigh the benefit of its continued use in the program. CMS recognized ASTRO's

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concerns that the radiation treatment delivery CPT codes used for the measure, which were part of a re-specification after the measure was finalized, have required additional exclusions proving burdensome on PPS-Exempt Cancer Hospitals (PCHs). Additionally, the measure lost NQF endorsement in 2018 and is no longer being maintained by the measure steward.

CMS also finalized removing the (Hospital Consumer Assessment of Healthcare Providers and Systems) HCAHPS pain management questions effective October 1, 2019. The rationale for removal is concern among stakeholders that the questions might create incentives for providers to prescribe more opioids in order to achieve higher scores on the pain management dimension of the HCAPS measures tool. In light of the opioid epidemic, CMS finalized its decision to remove the measures out of an abundance of caution.

Hospital Inpatient Quality Reporting (IQR) Program

The Agency finalized one of two new opioid-related electronic clinical quality measures (eCQMs) in the IQR program beginning with the 2021 reporting period. The measures under consideration included: 1) Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e) and 2) Hospital Harm – Opioid Related Adverse Events eCQM. Both measures exclude patients with an active cancer diagnosis.

Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e)

CMS finalized that all hospitals participating in the IQR Program must report this eCQM. This measure calculates the portion of patients 18 and older who are prescribed two or more opioids at discharge, with the goal of identifying and monitoring patients at risk. Beginning with the 2022 reporting period/FY 2024 payment determination.

Hospital Harm–Opioid Related Adverse Events eCQM

CMS did not finalize this measure which assesses the proportion of an acute care hospitals patients with an opioid-related adverse event during an admission as indicated by the administration of naloxone. The measure was submitted for National Qualify Forum (NQF) review in spring 2019 and the Patient Safety Standing Committee voted not to move forward with an endorsement. The Agency will consider the NQF’s concerns and consider whether the measure should be changed for future use.

More information regarding the 2020 IPPS Final Rule can be found at the following link:

<https://www.federalregister.gov/documents/2019/08/16/2019-16762/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

A fact sheet on the 2020 IPPS Final Rule can be found at the following link:

<https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2020-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0>