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Inpatient Prospective Payment System (IPPS) 2023 Final Rule
Summary of Issues Impacting Radiation Oncology

On Monday, August 1, 2022, 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:

- New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2023
- 2021 MedPAR data and FY 2020 HCRIS for analyzing MS-DRG changes and determining MS-DRG relative weights
- Reclassification of Laser Interstitial Thermal Therapy (LITT) MS-DRG
- Permanent Cap on Wage Index Decreases
- Low Wage Index Value Hospital Policy Maintained
- PPS-Exempt Cancer Hospital (PCH) Quality Reporting (PCHQR) Program
- Medicare Promoting Interoperability Program
- Health Equity
- Hospital Inpatient Quality Reporting (IQR) Program

The effective date of the final rule is October 1, 2022.

New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2023

Each year in the IPPS proposed rule, CMS presents its evaluation and analysis of New Technology Add-on Payment (NTAP) applications. The Agency does not issue application decisions 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 decision making that will appear in the IPPS 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. 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) represents a substantial clinical improvement over existing services or technologies.

AZEDRA NTAP Status to be Discontinued

In FY 2020, Progenics Pharmaceuticals, Inc. submitted an NTAP application 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.

In the IPPS final rule, CMS confirmed that for FY 2023, AZEDRA® will no longer be considered new as its three-year anniversary date (May 21, 2022) will occur prior to April 1, 2023.

FY 2023 NTAP Applications

While there were no NTAP applications related to the delivery of radiation therapy included in the 2023 IPPS proposed rule, there were a number of applications associated with systemic chemotherapy and immunotherapy that were of interest:

CARVYKTI™

Janssen Biotech, Inc., submitted a successful NTAP application for CARVYKTI™ (ciltacabtagene autoleucel). CARVYKTI™ is an autologous chimeric-antigen receptor (CAR) T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. The NTAP for a case involving the use of CARVYKTI™ will be $289,532.75 for FY 2023.

The following NTAPs were withdrawn prior to the issuance of the final rule, as they did not receive FDA approval or clearance in time to be considered:

Lifileucel

- Iovance Biotherapeutics submitted an NTAP application for lifileucel. According to the company, lifileucel is a proprietary, one-time autologous Tumor Infiltrating Lymphocytes (TIL) cell-based therapy for the treatment of unresectable or metastatic melanoma.

Mosunetuzumab

- Genentech, Inc. submitted an NTAP application for Mosunetuzumab. According to the company, Mosunetuzumab is an investigational drug that is anticipated to be a novel first-in class therapy for the treatment of any non-Hodgkin lymphoma (NHL).

Teclistamab

- Johnson & Johnson submitted an NTAP application for Teclistamab for FY 2023. Teclistamab is a bispecific antibody (bsAb) that is intended to bind CD3 on T cells and B cell maturation antigen (BCMA) on myeloma cells in the treatment of relapsed or refractory multiple myeloma.

2021 MedPAR data and FY 2020 HCRIS for analyzing MS-DRG changes and determining MS-DRG relative weights

In evaluating MS-DRG changes and setting MS-DRG relative weights, CMS has relied on claims data captured in the Medicare Provider Analysis and Review (MedPAR) file and cost report data captured in the Hospital Cost Reporting Information System (HCRIS) file. In a traditional year, for rate setting purposes, CMS would use data that captures claims from discharges that occurred for the fiscal year that is two years prior to the fiscal year addressed in the rulemaking. For FY 2022, in light of the COVID-19 public health emergency, CMS used FY

2019 MedPAR claims data rather than FY 2020 MedPAR data. For FY 2023, however, CMS will return to its historical practice of using the most recent data available, including FY 2021 MedPAR claims and FY 2020 cost report data, with certain modifications to its usual rate-setting methodologies to account for the anticipated decline in COVID-19 hospitalizations of Medicare beneficiaries at IPPS hospitals as compared to 2021.

Reclassification of Laser Interstitial Thermal Therapy (LITT) MS-DRG
In the 2022 IPPS Final Rule, CMS finalized the reassignment of 31 ICD-10-PCS procedure codes describing Laser Interstitial Thermal Therapy (LITT) of various body parts to more clinically appropriate MS-DRGs. For FY 2023, CMS received requests from LITT technology manufacturers (Medtronic and Monteris® Medical) to reverse the MS-DRG reassignment for the ICD-10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ) from the MS-DRGs for peripheral, cranial nerve and other nervous system procedures (MS-DRGs 040, 041, and 042) back to the MS-DRGs for craniotomy and endovascular procedures (MS-DRGs 023, 024, 025, 026, and 027). ASTRO supported the reassignment in its IPPS proposed rule comment letter.

In the final rule, rather than pursuing the recommended reclassification, CMS is reclassifying LITT procedures under the MS-DRGs in connection with the creation of new procedure codes to describe LITT. As discussed in the proposed rule, the entities requesting the reversal of the MS-DRG reassignment concurrently applied to the ICD-10 Coordination and Maintenance Committee for a reclassification of LITT procedures from the Radiation Therapy section of ICD-10-PCS to the Medical and Surgical section, which was approved after the IPPS proposed rule was released. Under its established process for determining the MS-DRG assignment for newly approved procedure codes, CMS determined that potential assignments and designations for LITT would align with those for the procedure codes describing Destruction of the respective anatomic body site (instead of the codes describing LITT from the Radiation Therapy section of ICD-10-PCS).

Permanent Cap on Wage Index Decreases
CMS adjusts the IPPS standardized amounts for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level and updates the wage index annually based on a survey of wages and wage-related costs of short-term, acute care hospitals. In last year's comments for the FY 2022 IPPS Proposed Rule, a 5% cap policy to prevent large year-to-year variations in wage index values was recommended. As such, for FY 2023 and subsequent years, CMS proposed to apply a 5% cap on any decrease to a hospital's wage index from its wage index in the prior fiscal year, regardless of the circumstances causing the decline. Additionally, this proposal would be applied in a budget-neutral manner through a national adjustment to the standardized amount.

CMS is finalizing this proposal in the 2023 final rule. That is, under this policy, a hospital's wage index will not be less than 95% of its final wage index for the prior FY. CMS is also applying this wage index cap policy in a budget-neutral manner through a national adjustment to the standardized amount.

Low Wage Index Value Hospital Policy Maintained

In the 2020 IPPS Final Rule, CMS adopted a policy to increase the wage index values for certain hospitals with low wage index values (below the 25th percentile) and decrease the wage index values for hospitals above the 75th percentile (to maintain budget neutrality). Low wage index value hospitals received an increase of half of the difference between each individual hospital's wage index value and the 25th percentile wage index value. A similar methodology was used to reduce the wage index value for hospitals above the 75th percentile wage index value, thus keeping the policy budget neutral.

At the time, CMS indicated the policy would be effective for at least four years, beginning in FY 2020, so that employee compensation increases implemented by these hospitals would have time to be reflected in the wage index calculation. For FY 2023, the Agency will continue the low wage index hospital policy and will continue to do so in the budget neutral method.

PPS-Exempt Cancer Hospital (PCH) Quality Reporting (PCHQR) Program

PCHs are required to report to CMS certain quality measures (but there is no financial impact to PCH Medicare payment if a PCH does not participate). In the FY 2023 IPPS Proposed rule, CMS proposed that the Agency may promptly remove a measure from the program without rulemaking if the Agency believes continued use of a measure raises specific patient safety concerns and proposed to begin public display of the following measures:

- 30-Day Unplanned Readmissions for Cancer Patients
- Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
- Proportion of Patients Who Died from Cancer Not Admitted to Hospice
- Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
- Proportion of Patients Who Died from Cancer Admitted to Hospice for Less than Three Days

In the FY 2023 IPPS final rule, CMS is:

- Finalizing that it will begin public display of the 30-Day Unplanned Readmissions for Cancer Patients Measure (PCH-36) and the four end-of-life measures (PCH-32, PCH-33, PCH-34, and PCH-35);
- Adopting and codifying a patient safety exception into the measure removal policy; and
- Acknowledging comments received from stakeholders on the request for information in the proposed rule regarding the potential future adoption of two digital National Healthcare Safety Network (NHSN) measures: the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure.

Medicare Promoting Interoperability Program

CMS is finalizing several proposed changes to the Medicare Promoting Interoperability program. Specifically, the Agency is:

(1) Requiring the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure while maintaining the associated points at 10 points beginning with the EHR reporting period in CY 2023;
(2) Expanding the Query of PDMP measure to not only include Schedule II opioids but also Schedule III and IV drugs beginning with the CY 2023 EHR reporting period and are adding exclusions;
(3) Adding a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective, beginning with the CY 2023 EHR reporting period;
(4) Modifying the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Antibiotic Resistance (AUR) measure in addition to the current four required measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) beginning with the CY 2024 EHR reporting period;
(5) Consolidating the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective, requiring the reporting of the active engagement option selected for the measures under the objective beginning with the CY 2023 EHR reporting period, and modifying the amount of time spent at the option 1 level of active engagement (pre-production and validation) to one EHR reporting period beginning with the CY 2024 EHR reporting period;
(6) Modifying the scoring methodology for the Medicare Promoting Interoperability Program beginning in CY 2023;
(7) Instituting public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period;
(8) Removing regulation text for the objectives and measures in the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 and adding new paragraph (f) beginning in CY 2023; and
(9) Adopting two new eCQMs in the Medicare Promoting Interoperability Program's eCQM measure set beginning with the CY 2023 reporting period, two new eCQMs in the Medicare Promoting Interoperability Program's eCQM measure set beginning with the CY 2024 reporting period, and modifying the eCQM data reporting and submission requirements to increase the number of eCQMs required to be reported and the total number of eCQMs to be reported beginning with the CY 2024 reporting period, which is in alignment with the eCQM updates finalized for the Hospital IQR Program.

Health Equity

Social Determinants of Health Diagnosis Codes – Request for Information

CMS sought comments on how it can foster the documentation and reporting of the diagnosis codes describing social and economic circumstances (social determinants of health) to reflect

each health care encounter and improve the reliability and validity of the coded data, including efforts to advance health equity more accurately.

Some commenters, including ASTRO, stated that while the documentation and reporting of SDOH diagnosis codes is important to address health care inequities, the collection of this data may place significant burden on facilities and providers.

No final decision was made following this request for information, and CMS stated that it will take the commenters' feedback into consideration in future policy development.

Hospital Inpatient Quality Reporting (IQR) Program
CMS finalized the adoption of ten new measures:

1. Hospital Commitment to Health Equity
2. Screening for Social Drivers of Health
3. Screen Positive Rate for Social Drivers of Health
4. Cesarean Birth
5. Severe Obstetric Complications
6. Hospital-Harm—Opioid-Related Adverse Events
7. Global Malnutrition Composite Score
8. Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty
9. Medicare Spending Per Beneficiary
10. Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty

CMS is also refining two measures that are currently part of the Hospital IQR Program measure set beginning with the FY 2024 payment determination: Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA measure and Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction measure.

<u>Electronic Clinical Quality Measure (eCQM) and Hybrid Measures</u>
In the final rule, CMS is modifying the eCQM validation policy to increase the submission requirement from 75% to 100% of the requested medical records to successfully complete eCQM validation beginning with the FY2025 payment determination period. The Agency also is modifying the eCQM reporting and submission requirements to increase eCQM reporting from four (one mandatory and three self-selected) to six (three mandatory and three self-selected) beginning with the CY2024 reporting period.

Finally, CMS will remove the zero denominator declarations and case threshold exemptions policies for hybrid measures beginning with the FY2024 reporting period.

The 2023 IPPS final rule can be downloaded from the Federal Register at:
https://public-inspection.federalregister.gov/2022-16472.pdf

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For a fact sheet on the 2023 IPPS final rule, please visit:
https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective