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

On April 18, 2022 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 modifications to existing New Technology Add-On Payments (NTAP) designations, as well as proposed FY 2023 NTAP designations for new services and technologies. The rule also proposes a reversion to historical two-year data periods for determining MS-DRG rate changes, a proposal to reclassify laser interstitial thermal therapy's (LITT) MS-DRG, and seeks to establish a permanent cap on wage index decreases and maintain the Low Wage Index Value Hospital policy to ensure rate stability. CMS proposes modifications to the PPS-Exempt Cancer Hospital (PCH) Quality Reporting (PCHQR) Program and Medicare Promoting Interoperability Program. Finally, this proposed rule includes overarching principles for measuring healthcare quality disparities across CMS quality programs and requests additional information related to the collection of data associated with social determinants of health that can be used to improve health equity.

Comments in response to the rule are due June 17, 2022.

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

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.

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 may be of interest:

# **CARVYKTI**<sup>TM</sup>

• Janssen Biotech, Inc., submitted an NTAP application for CARVYKTI<sup>TM</sup> (ciltacabtagene autoleucel). CARVYKTI<sup>TM</sup> 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. Janssen submitted an NTAP application for CARVYKTI<sup>TM</sup> for FY 2022 but withdrew the application prior to the issuance of the final rule.

#### 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, they are proposing to return to their historical practice of using the most recent data available, including FY 2021 MedPAR claims and FY 2020 cost report data, with certain proposed modifications to their usual rate-setting methodologies to account for the anticipated decline in COVID-19 hospitalizations of Medicare beneficiaries at IPPS hospitals as compared to 2021. They are also considering, as an alternative, to use FY 2021 data for purposes of FY 2023 rate-setting without the proposed modifications to their usual methodologies.

This change is notable given that historical claims data are also used in setting Hospital Outpatient Prospective Payment (HOPPS) rates. Due to the COVID-19 PHE, CMS chose to use CY 2019 claims data to set CY 2022 HOPPS rates. Given the proposal described above for the FY 2023 IPPS, ASTRO anticipates that the Agency will revert back to the traditional two-year look back for the CY 2023 HOPPS.

#### Proposed 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).

The requestors both noted the distinct clinical differences between the invasiveness of LITT, which involves instrumentation being placed deeply within the brain tissue, and the non-invasiveness of stereotactic radiosurgery (SRS) that does not involve entering the brain with instrumentation. The requestor also indicated LITT utilizes a different modality via direct thermal ablation compared to SRS, which utilizes externally generated ionizing radiation. CMS is seeking comment on possible MS-DRG reassignments for the requested procedure codes describing LITT. They are proposing to reassign the existing procedure codes describing LITT of the brain or brain stem (not other treatment areas) from MS-DRGs 040, 041, and 042 to MS-DRGs 025, 026, and 027 for FY 2023.

#### **Proposed 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 is proposing 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.

ASTRO encourages the Agency to adopt the application of a 5% cap on any decrease to a hospital's wage index from its wage index in the prior fiscal year as many hospitals are still recovin

#### 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 25<sup>th</sup> percentile) and decrease the wage index values for hospitals above the 75<sup>th</sup> 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 25<sup>th</sup> percentile wage index value. A similar methodology was used to reduce the wage index value for hospitals above the 75<sup>th</sup> 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 proposes to continue the low wage index hospital policy and will continue to do so in the budget neutral method. However, this proposal is subject to pending litigation and CMS may take a different approach in the final rule, depending on public comments or developments in the court proceedings.

## 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 is proposing 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 is also proposing 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

#### Medicare Promoting Interoperability Program

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

- Make the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure mandatory, expand the measure to include Schedule II, III, and IV drugs and maintain the 10 point maximum;
- Add a new Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure under the Health Information Exchange (HIE) Objective as a yes/no attestation measure as an optional alternative to the three existing measures under the HIE Objective;

- Add a new Antimicrobial Use and Resistance (AUR) Surveillance measure and require its reporting under the Public Health and Clinical Data Exchange Objective;
- Modify the eCQM reporting and submission requirements to increase eCQM reporting from four eCQMs (one mandatory and three self-selected) to six eCQMs (three mandatory and three self-selected); and
- Institute public reporting of certain Medicare Promoting Interoperability Program data;

The Agency is also proposing several scoring changes, including increasing the Public Health and Clinical Data Exchange Objective from 10 to 25 points and increasing the points associated with the Electronic Prescribing Objective from 10 to 20 points. CMS is also proposing to reduce the points associated with the Health Information Exchange Objective from 40 to 30 points and reduced the points associated with the Provide Patients Electronic Access to Their Health Information from 40 to 25.

Objective	Measure	Maximum Points	Required/Optiona	
Electronic	e-Prescribing	10 points	Required	
Prescribing	Query of PDMP*	10 points*	Required	
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points*	Required (eligible	
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points*		
	-OR-		hospital or CAH's	
	Health Information Exchange Bi-Directional Exchange	30 points*	choice of one of the	
	-OR-		three reporting	
	Enabling Exchange under TEFCA*	30 points*	options)	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points*	Required	
Public Health and Clinical Data Exchange	<ul> <li>Report the following five measures:*</li> <li>Syndromic Surveillance Reporting</li> <li>Immunization Registry Reporting</li> <li>Electronic Case Reporting</li> <li>Electronic Reportable Laboratory Result Reporting</li> <li>AUR Surveillance Reporting*</li> </ul>	25 points*	Required	
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (bonus)*	Optional	

#### TABLE IX.H.-04: PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2023

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

\*Signifies a proposal made in this FY 2023 IPPS/LTCH PPS proposed rule.

# Health Equity

Social Determinants of Health Diagnosis Codes - Request for Information

CMS is seeking 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.

## <u>Current Assessment of Climate Change Impacts on Outcomes, Care, and Health Equity –</u> <u>Request for Information</u>

CMS notes there is evidence that climate change disproportionately harms underserved populations (for example, racial and ethnic minority groups, indigenous people, members of religious minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, older adults, and rural populations). Long-term discrimination and disparities based on social determinants of health mean that these groups are often less equipped to withstand climate threats and are more susceptible to associated harm. Out of concern for the health of individuals, and to maintain uninterrupted operations in service of patients, the Agency believes the healthcare sector should more fully explore how to effectively prepare for climate threats. Because healthcare facilities also emit greenhouse gases (GHGs) that contribute to climate change and its impacts, CMS believes that they should study how best to reduce those emissions, as well.

In this request for information, CMS is seeking comment on how hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, and how they can support them in doing so.

# Hospital Inpatient Quality Reporting (IQR) Program

CMS is proposing 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

#### Electronic Clinical Quality Measure (eCQM) and Hybrid Measures

CMS is proposing to modify 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 is also proposing to

modify 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 is proposing to remove the zero denominator declarations and case threshold exemptions policies for hybrid measures beginning with the FY2024 reporting period.

The proposed rule (CMS-1771-P) can be downloaded from the Federal Register at: <u>https://www.federalregister.gov/public-inspection/2022-08268/medicare-program-hospital-inpatient-prospective-payment-systems-quality-programs-and-medicare</u>

More information regarding the 2022 IPPS Proposed Rule can be found at the following link: <u>https://www.cms.gov/newsroom/press-releases/cms-proposes-policies-advance-health-equity-and-maternal-health-support-hospitals</u>

For a fact sheet on the proposed rule (CMS-1771-P), please visit: <u>https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospitals-ltch-pps</u>