

Inpatient Prospective Payment System (IPPS) 2022 Proposed Rule Summary of Issues Impacting Radiation Oncology

On Tuesday, April 27, 2021 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 request for information on closing the health equity gap; proposed New Technology Add-On Payments (NTAP) for new services and technologies for FY 2022; repeal of private payer MS-DRG relative weight data to inform future Medicare rates; continuation of the Low Wage Index Value Hospital Policy; PPS-Exempt Cancer Hospital Quality Reporting Program, Medicare Promoting Interoperability Program, and the Hospital Inpatient Quality Reporting Program.

Comments in response to the rule are due June 28, 2021.

Closing the Health Equity Gap – Request for Information

As part of an effort across CMS to evaluate appropriate initiatives to reduce health disparities, the agency is requesting information on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, providers, and patients.

For purposes of this rule, CMS is using the definition of “equity” used in Executive Order 13985, issued on January 25, 2021: “the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.”

Specifically, CMS is requesting information on three areas:

1. Future potential stratification of quality measure results by race and ethnicity;
2. Improving demographic data collection; and
3. The potential creation of a Hospital Equity Score to synthesize results across multiple social risk factors.

CMS notes plans for additional requests for information on health equity in the future.

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2022

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.

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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) costly such that the applicable DRG rate is inadequate; and 3) represents a substantial clinical improvement over existing services or technologies.

AZEDRA NTAP Status Proposed to be Extended through 2022

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 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) occurred in the second half of 2021, CMS continued new technology add-on payments for 2021.

Under the 2022 Proposed Rule, CMS is proposing to use FY 2019 MedPAR data instead of FY 2020 data for FY 2022 rate setting in situations where the FY 2020 data was significantly impacted by the COVID-19 public health emergency. The agency believes it would be appropriate to allow for a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022. Therefore, AZEDRA® would receive another one-year extension under this proposal.

The agency seeks comments on its proposal to provide for a one-year extension of new technology add-on payments for FY 2022 for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

New NTAP Applications

While there were no new NTAP applications related to the delivery of radiation therapy included in the 2022 IPPS proposed rule, there were a number of applications associated with systemic chemotherapy and immunotherapy:

- Amivantamab
Johnson & Johnson submitted an application for new technology add-on payments for 2022 Amivantamab, which is used for the treatment of metastatic non-small cell lung cancer (NSCLC). Amivantamab is a bispecific monoclonal antibody that can inhibit the epidermal growth factor receptor (EGFR) and c-MET tyrosine kinase signaling pathways known to be involved in the pathogenesis of NSCLC.

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- Breyanzi® (lisocabtagene maraleucel)
Juno Therapeutics (a Bristol-Myers Squibb Company) submitted an application for new technology add-on payment for 2022 for Breyanzi®. Breyanzi® is a CD19-directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy that is comprised of individually formulated CD8 (killer) and CD4 (helper) CAR T-cells, and it is indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after at least two prior therapies.
- Ciltacabtagene autoleucel
Janssen Biotech, Inc., submitted an application for new technology add-on payments for 2022 for ciltacabtagene autoleucel. Ciltacabtagene autoleucel 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.
- COSELA (trilaciclib)
G1 Therapeutics submitted an application for new technology add-on payments for Trilaciclib. COSELA (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).
- ABECMA® (idecabtagene vicleucel)
Celgene Corporation (a wholly owned subsidiary of Bristol-Myers Squibb), submitted an application for new technology add-on payment for ABECMA® (idecabtagene vicleucel) for 2022. ABECMA® is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell immunotherapy for the treatment of adult patients with relapsed or refractory (RR) multiple myeloma (MM) (RRMM) who have received at least four prior therapies.
- Lifileucel
Iovance Biotherapeutics submitted an application for new technology add-on payments for lifileucel for 2022. Lifileucel is a one-time autologous Tumor Infiltrating Lymphocytes (TIL) cell-based therapy being studied for effectiveness in solid tumors.
- Tecartus™ (brexucabtagene autoleucel)
Kite Pharma submitted an application for new technology add-on payment for 2022 for Tecartus™ (brexucabtagene autoleucel). Tecartus™ is a CD19 directed genetically modified autologous T-cell immunotherapy for the treatment of adult patients with relapsed and refractory (r/r) mantle cell lymphoma (MCL).
- ZEPZELCA™ (lurbinectedin)
Jazz Pharmaceuticals submitted an application for new technology add-on payments for ZEPZELCA™ for 2022. ZEPZELCA™ is an alkylating drug indicated for the treatment

of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

2019 MedPAR data and FY 2018 HCRIS file 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 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, the data that CMS would analyze, in normal circumstances, would be from FY 2020. In light of the COVID-19 public health emergency, CMS is proposing to use FY 2019 MedPAR claims data rather than FY 2020 MedPAR data.

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

CMS uses hospital charge master data to inform rates for both hospital inpatient and outpatient services. To reduce its reliance on hospital charge masters, last year the agency finalized a rule that would require hospitals to report market-based payment rate information in their Medicare cost report for periods ending on or after January 1, 2021. CMS proposed using this information to change the methodology for calculating the IPPS MS-DRG relative weights to reflect market-based pricing. The agency specifically asked that hospitals report the median payer-specific negotiated charge that the hospital negotiated with Medicare Advantage organizations and third-party payers by Medicare Severity-Diagnosis Related Group (MS-DRG).

While this proposal did not directly impact radiation oncology practices, ASTRO was concerned that a similar methodology could potentially be applied in the Hospital Outpatient setting. However, in the 2022 Proposed Rule, CMS is proposing to repeal this policy and not move forward with the use of payer-specific negotiated charge data.

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 2022, the agency will continue the low wage index hospital policy and will continue to do so in the aforementioned budget neutral method.

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

CMS is proposing removing the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology measure beginning with the FY 2024 program year. The Agency has concluded it is no longer feasible to implement the measure due to recent changes by the measure steward. The measure steward has decided to revert to a previous version of the measure that requires a plan of care to address any, rather than just moderate-severe, pain and will no longer maintain the specifications for this measure as it is currently used in the PCHQR Program.

The Agency is proposing to adopt the COVID-19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the FY 2023 program year and for subsequent years. CMS believes it is important to require that PCHs report their rates of vaccination in order to assess whether they are taking steps to limit the spread of COVID-19, and to help sustain the ability of U.S. hospitals to continue serving their communities throughout the COVID-19 Public Health Emergency (PHE) and beyond. PCHs would be required to report data on the measure for the fourth quarter of CY 2021 (that is, from October 2021 through December 2021).

Medicare Promoting Interoperability Program

CMS is proposing the following changes to the Medicare Promoting Interoperability Program, which are consistent with the policies finalized for MIPS eligible clinicians in the CY 2021 [Physician Fee Schedule Final Rule](#):

- Maintain the Electronic Prescribing Objective’s Query of Prescription Drug Monitoring Program (PDMP) measure as optional, while increasing its available bonus from five points to 10 points for the EHR reporting period in CY 2022. As a result, the maximum total points available for the Electronic Prescribing Objective would increase to 20 points for CY 2022.
- Add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation to the HIE objective as an optional alternative to the two existing measures beginning with the EHR reporting period in CY 2022.
- Modify the Provide Patient’s Electronic Access to Their Health Information measure to establish a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, beginning with the EHR reporting period in CY 2022;

**Proposed Performance-Based Scoring Methodology
 EHR Reporting Period in CY 2022**

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and <i>Reconciling</i> Health Information	20 points
	<i>OR</i>	

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Health Information Exchange (alternative)	Health Information Exchange Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 4 measures: <ul style="list-style-type: none"> • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting 	10 points
	Report one of the following measures: <ul style="list-style-type: none"> • Public Health Registry Reporting • Clinical Data registry Reporting 	5 points (bonus)

The Agency is also recommending the continuation of the EHR reporting period of a minimum of any continuous 90-day period for new and returning eligible hospitals and critical access hospitals (CAHs) for CY 2023 and to increase the EHR reporting period to a minimum of any continuous 180-day period for new and returning eligible hospitals and CAHs for CY 2024. The Agency believes that by increasing the EHR reporting period in CY 2024, eligible hospitals, CAHs, and vendors will have time to plan in advance, build upon, and utilize investments already made within their infrastructure. Additionally, the Agency believes that increasing the EHR reporting period in CY 2024 is important for the continued improvement of interoperability and health information exchange by producing more comprehensive and reliable data for patients and providers, which are key goals of the Medicare Promoting Interoperability Program.

The Agency has proposed the removal of the attestation statements number 2 (focusing on CEHRT implementation) and number 3 (specific use) from the Promoting Interoperability Program’s prevention of information blocking requirement.

Finally, given the widespread success of participating hospitals, CMS is proposing to increase the minimum required score for the objectives and measures to be considered a meaningful EHR user from 50 to 60 points.

Hospital Inpatient Quality Reporting (IQR) Program

CMS is proposing to adopt five new measures:

1. Maternal Morbidity Structural Measure
2. Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure
3. COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure
4. Hospital Harm-Severe Hypoglycemia eCQM
5. Hospital Harm-Severe Hyperglycemia eCQM

Additionally, the Agency is proposing to remove five measures:

1. Death Among Surgical Inpatients with Serious Treatable Complications
2. Exclusive Breast Milk Feeding

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3. Admit Decision Time to ED Departure Time for Admitted Patients
4. Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM
5. Discharged on Statin Medication eCQM

Certified Electronic Health Records Technology (CEHRT)

CMS is proposing that, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data. In May 2020, the Office of the National Coordinator for Health Information Technology (ONC) finalized additional updates to the 2015 Edition in the 21st Century Cures Act Final Rule, including an e-prescribing standard required for alignment with other CMS programs.

The 21st Century Cures Act final rule finalized updates to a number of certification criteria, which are currently associated with objectives and measures under the Promoting Interoperability Program, as well as criteria that are included in the 2015 Edition Base EHR¹ definition. In general, ONC finalized that health IT developers have until May 2, 2022 to make technology certified to these updated criteria available to their customers. During this time, developers are expected to continue supporting technology certified to the prior version of certification criteria for use by their customers.

In general, health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated criteria available to their customers, plus the additional three-month period during which ONC will exercise enforcement discretion around compliance dates finalized in the 21st Century Cures Act final rule in response to the COVID-19 PHE. As a result, where the 21st Century Cures Act final rule requires health IT developers to make technology meeting new and updated certification criteria available by May 2, 2022, developers taking advantage of enforcement discretion would be permitted to delay making updated certified technology available until August 2, 2022. *After this date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.*

Health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to implementing updates, and healthcare providers participating in QPP may use such technology for the purposes of these programs while working with health IT developers to implement updates in a manner that best meets their needs. Several certification criteria were removed because they are already in widespread use, including medications, medication allergies and smoking status. A new criterion, “electronic health information export,” was established. This new criterion requires a certified health IT module to electronically export all electronic health information (EHI) that can be stored at the time of certification by the product of which the health IT module is a part. A

¹ 2015 Edition Base EHR means an electronic record of health-related information on an individual that:
(1) Includes patient demographic and clinical health information, such as medical history and problem lists; (2) Has the capacity: (i) To provide clinical decision support; (ii) To support physician order entry; (iii) To capture and query information relevant to health care quality; (iv) To exchange electronic health information with, and integrate such information from other sources; and (3) Has been certified to the certification criteria adopted by the Secretary.

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health IT developer of a certified health IT products, which, at the time presented for certification, electronically stores EHI must certify such products to this new criterion and make these products available to their customers by May 2, 2023. However, the new EHI Export criterion is not included in the Base EHR definition, and it is not associated with any objectives or measures in the Promoting Interoperability Programs.

Advancing to Digital Quality Measurement Request for Information:

The Agency included a request for information regarding the modernization of quality measurement to digital quality measurement. The Agency is asking for specific comments on plans to modernize its quality measurement enterprise, including:

- Clarifying the definition of digital quality measures.
- Using the Fast Healthcare Interoperability Resources (FHIR®) standard for eCQMs that are currently used in the various quality programs.
- Standardizing data required for quality measures for collection via FHIR-based Application Programming Interfaces (APIs).
- Leveraging technological opportunities to facilitate digital quality measurement.
- Better supporting data aggregation.
- Developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.

The proposed rule (CMS-1752-P) can be downloaded from the Federal Register at:

<https://www.federalregister.gov/public-inspection/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

More information regarding the 2022 IPPS can be found at the following link:

<https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipp-pps-proposed-rule-home-page>

For a fact sheet on the proposed rule (CMS-1752-P), please visit:

<https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipp-pps-and-long-term-care>