

Inpatient Prospective Payment System (IPPS) 2024 Proposed Rule Summary of Issues Impacting Radiation Oncology

On April 10, 2023, the Centers for Medicare and Medicaid Services (CMS) issued the Inpatient Prospective Payment System (IPPS) [proposed rule](#). The proposed rule updates the Medicare reimbursements under IPPS by 2.8% (a 3.0% market basket update with a -0.2% productivity adjustment).

Why it matters: While radiation therapy reimbursement is typically tied to the Medicare Physician Fee Schedule (MPFS) or the Hospital Outpatient Prospective Payment System (HOPPS), the IPPS proposed rule often includes items of interest to radiation oncology related to new technologies and quality reporting. It also provides a preview of policy proposals, which may appear in the MPFS and HOPPS proposed rules this summer.

Items of interest in the 2024 IPPS proposed rule include:

- New Technology Add-On Payments (NTAP) for New Services and Technologies
- Proposed Continuation of the Low Wage Index Hospital Policy
- Permanent Cap on Wage Index Decreases and Budget Neutrality Adjustment
- Proposed Modification to the Rural Wage Index Calculation Methodology
- PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
- Hospital Inpatient Quality Reporting (IQR) Program
- Medicare Promoting Interoperability Program
- Request for Information on Challenges Faced by Safety-Net Hospitals
- Proposed Changes to the Severity Level Designation for Z Codes Describing Homelessness

Comments in response to the IPPS proposed rule are due June 9, 2023.

Go deeper on the proposed rule below.

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 it 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 diagnosis related group (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.

For FY 2024, there are no NTAPS directly related to radiation oncology, but the following are of interest to cancer care, generally.

CYTALUX® (pafolacianine), two indications

An NTAP application was received for CYTALUX®, a targeted intraoperative molecular imaging agent that illuminates ovarian cancer in real time, enabling the detection of more cancer for resection. It is an optical imaging agent comprised of a folic acid analog conjugated with a fluorescent dye that binds to folate receptor positive cancer cells and illuminates malignant lesions during surgery. It is to be used with a near-infrared imaging system (NIR) cleared by the FDA for specific use with CYTALUX®.

An NTAP for CYTALUX® also was submitted for use in lung cancer.

Elranatamab

An NTAP application was received for elranatamab, a heterodimeric humanized full-length bispecific antibody against B-cell maturation antigen (BCMA) and cluster of differentiation CD3 which, if FDA approved, will potentially be used for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

According to the applicant, elranatamab is proposed to act through direct bridging of the BCMA cell-surface antigen and the extracellular CD3 subunit expressed on T-cells.

Epcoritamab

An NTAP application was received for epcoritamab, an investigational immunoglobulin G1 (IgG1) bispecific antibody which directly binds cluster of differentiation CD3 expressing T-cells and CD20 expressing B-cells to potentially induce activation and cytotoxic activity of the T-cells against the malignant B-cells in a process that is strictly dependent on epcoritamab binding to both targets. According to the applicant, epcoritamab may be an effective treatment for patients with relapsed/refractory (R/R) Non-Hodgkin's Lymphoma (NHL), and more specifically R/R Large B-Cell Lymphoma (LBCL) by co-opting the patient's own immune system to target the disease.

Glofitamab

An NTAP application was received for glofitamab, a novel full-length, fully humanized, T-cell engaging bispecific antibody with a novel 2:1 structure (two CD20 binding domains, one CD3 binding domain [2:1 structure]) for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more prior therapies. Per the applicant, glofitamab activates the patient's own immune system to eradicate malignant B-cells by simultaneously binding CD20 on malignant B-cells and CD3 on T-cells, bringing them into close proximity inducing proliferation and targeted killing of B-cells. The applicant stated that the novel 2:1 structure of glofitamab enables high-avidity, bivalent binding to CD20 that can result in activity against malignant B-cells even under low effector-to-target cells.

Lunsumio™ (mosunetuzumab)

An NTAP application was received for Lunsumio™ (mosunetuzumab), a novel, full-length, humanized, immunoglobulin G1 (IgG1) bispecific antibody that is designed to concomitantly bind CD3 on T cells and CD20 on B cells, in the treatment of adults with relapsed/refractory (R/R) follicular lymphoma (FL) who have received at least 2 (≥2) prior systemic therapies (also referred to herein as 3L+FL). The applicant further stated that target B cell killing occurs only upon simultaneous binding to both targets, as it is a conditional agonist. An NTAP application for mosunetuzumab was submitted for 2023 but was withdrawn by the applicant.

TECVAYLI™ (teclistamab-cqyv)

An NTAP application was received for TECVAYLITM (teclistamab-cqyv), a bispecific antibody approved for the treatment of multiple myeloma (MM), specifically adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-cluster of differentiation (CD)38 monoclonal antibody. The applicant stated that the structure of TECVAYLI™ is advantageous versus other bispecific platforms since its full size is designed to mimic naturally-occurring immunoglobulin G (IgG) antibodies. An NTAP application for teclistamab-cqyv was submitted for 2023 but was withdrawn by the applicant.

VANFLYTA® (quizartinib)

An NTAP application was received for VANFLYTA® (quizartinib), a kinase inhibitor intended to be indicated for use in combination with standard cytarabine and anthracycline induction chemotherapy and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is Feline McDonough Sarcoma (FMS)-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD) positive as detected by an FDA-authorized test. The applicant asserted that, while other treatments for FLT3 AML are available, VANFLYTA® is the only treatment to exclusively target the FLT3-ITD mutation, thereby inhibiting further downstream FLT3 receptor signaling and blocking FLT3-ITD-dependent cell proliferation. According to the applicant, VANFLYTA® also does not target other kinases; this may mean that patients experience fewer off-target effects when undergoing therapy with VANFLYTA®.

Proposed continuation of technologies approved for FY 2023 NTAPs still considered new for FY 2024 because 3-year anniversary date will occur on or after April 1, 2024:

Technology	Newness Start Date	NTAP Start Date	3-Year Anniversary Date of Entry into U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2023	Coding Used to identify Cases Eligible for NTAP
Rybrevant™ (drug used to treat adults with non-small	5/21/21	10/1/21	5/21/24	86 FR 44988 – 44996	\$6,405.89	XW033B7 or XW043B7

Inpatient Prospective Payment System (IPPS) 2024 Proposed Rule

Summary of Issues Impacting Radiation Oncology

cell lung cancer				87 FR 48913		
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Proposed discontinuation of technologies approved for FY 2023 NTAPs no longer considered new for FY 2024 because 3-year anniversary date will occur prior to April 1, 2024

Technology	Newness Start Date	NTAP Start Date	3-Year Anniversary Date of Entry into U.S. Market	Previous Final Rule Citations
TECARTUS® (cell-based gene therapy for the treatment of mantle cell lymphoma and acute lymphoblastic leukemia)	7/4/20	10/1/21	7/4/23	86 FR 45090 – 45104 87 FR 48913
Zepzelca™ (prescription medicine used to treat adults with small cell lung cancer)	6/15/20	10/1/21	6/15/23	86 FR 45116 - 45126 87 FR 48912 – 48913
Cosela™ (medication used to reduce the frequency of chemotherapy-induced bone marrow suppression)	2/12/21	10/1/21	2/12/24	86 FR 45008 – 45017 87 FR 48912 – 48913
ABECMA® (cell-based gene therapy to treat multiple myeloma)	3/26/21	10/1/21	3/26/24	86 FR 45028 – 45035 87 FR 48911 – 48925
DARZALEX FASPRO® (medication used for the treatment of adults with multiple myeloma)	1/15/21	10/1/22	1/15/24	87 FR 48925 – 48937

CAVYKTI™ (medication used for the treatment of adults with multiple myeloma that is not responding to treatment or has returned after treatment)	3/26/21	10/1/22	3/26/24	87 FR 48920 - 48925
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Proposed Continuation of the Low Wage Index Hospital Policy

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). 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.

At this time, only one year of relevant data is available to evaluate the impact of this policy, so the Agency proposes to wait until it has usable data from additional fiscal years before making any decision to modify or end the policy. Therefore, CMS proposes to continue the low wage index hospital policy (and the related budget neutrality adjustment) for FY 2024.

Permanent Cap on Wage Index Decreases and Budget Neutrality Adjustment

In the FY 2023 IPPS final rule, CMS finalized the wage index cap policy (and associated budget neutrality adjustment) for 2023 and subsequent years. It provides that a hospital’s wage index will not be less than 95% of its final wage index for the prior fiscal year (a 5% cap). This cap and associated budget neutrality adjustment will be applied for FY 2024.

Proposed Modification to the Rural Wage Index Calculation Methodology

The Agency’s current interpretation of the law and regulations is that hospitals that have reclassified as rural, as implemented in the regulations under 42 CFR § 412.103 (“§ 412.103 hospitals”), shall be treated the same as geographically rural hospitals for the wage index calculation. CMS proposes to include § 412.103 hospitals along with geographically rural hospitals in all rural wage index calculations, and to exclude “dual reclass” hospitals implicated by the hold harmless provision (those with simultaneous § 412.103 and Medicare Geographic Classification Review Board reclassifications). Changes to the rural wage index that affect the rural floor would be implemented in a budget neutral manner.

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

PCHs are required to report to CMS certain quality measures. In the FY 2024 proposed rule, CMS is proposing to add four new measures:

- Facility Commitment to Health Equity, beginning in the FY2026 program year;

- Screening for Social Drivers of Health, beginning in the FY2026 program year with voluntary reporting, and mandatory reporting in the FY2027 program year;
- Screen Positive Rate for Social Drivers of Health, beginning in the FY2026 program year with voluntary reporting, and mandatory reporting in the FY2027 program year; and
- Documentation of Goals of Care Discussions Among Cancer Patients, beginning with the FY2026 program year.

The Agency is proposing to modify the COVID-19 Vaccination Coverage among Health Care Personnel measure beginning with the FY2025 program year by replacing the term “complete vaccination course” with the term “up to date” in the definition. The Agency is also proposing to publicly report the Surgical Treatment Complications for Localized Prostate Cancer (PCH-37) measure beginning with data from the FY 2025 program year.

Hospital Inpatient Quality Reporting (IQR) Program

CMS is proposing the adoption of three new measures beginning with the CY 2025 reporting period:

1. Hospital Harm – Pressure Injury electronic clinical quality measure (eCQM) beginning with the CY 2025 reporting period/FY 2027 payment determination;
2. Hospital Harm – Acute Kidney Injury eCQM beginning with the CY 2025 reporting period/FY 2027 payment determination; and
3. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) eCQM

The Agency is proposing the modification of three current measures beginning with the Quarter 4 CY2023 reporting period:

1. Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with the FY 2027 payment determination to include both FFS and Medicare Advantage patients;
2. Hybrid Hospital-Wide All-Cause Readmission (HWR) measure beginning with the FY 2027 payment determination to include both FFS and Medicare Advantage patients; and
3. COVID-19 Vaccination among Healthcare Personnel (HCP) measure (see above).

The Agency is proposing the removal of three current measures beginning with the CY2024 reporting period:

1. Hospital-level Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2025-March 31, 2028 reporting period;
2. Medicare Spending Per Beneficiary (MSPB)—Hospital measure beginning with the CY 2026 reporting period; and
3. Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01)

The Agency is considering two attestation-based structural measures, the Geriatric Hospital measure and the Geriatric Surgical measure, to demonstrate that patient-centered care for aging

patient populations with multiple chronic conditions should be prioritized by hospitals. These attestation-based structural measures apply evidence-based, concrete, actionable steps to improve patient-centered care in the hospital inpatient setting for older adults. The measures incentivize team-based care organized around the geriatric patient to meet their unique needs. CMS is also considering a geriatric care hospital designation to be publicly reported on a CMS website. The designation would be based on a hospital's attestation to the Geriatric Hospital and Geriatric Surgical structural measures.

Medicare Promoting Interoperability Program

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

1. Amend the definition of "EHR reporting period for a payment adjustment year for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program, to define the electronic health record (EHR) reporting period in CY 2025 as a minimum of any continuous 180-day period within CY 2025;
2. Update the definition of "EHR reporting period for a payment adjustment year" for eligible hospitals such that, beginning in CY 2025, those hospitals that have not successfully demonstrated meaningful use in a prior year will not be required to attest to meaningful use by October 1st of the year prior to the payment adjustment year;
3. Modify the requirements for the Safety Assurance Factors for EHR Resilience (SAFER) Guides measure beginning with the EHR reporting period in CY 2024, to require eligible hospitals and CAHs to attest "yes" to having conducted an annual self-assessment of all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs;
4. Modify the way the Agency refers to the calculation considerations related to unique patients or actions for Medicare Promoting Interoperability Program objectives and measures for which there is no numerator and denominator; and
5. Adopt three new eQMs beginning with the CY 2025 reporting period for eligible hospitals and CAHs to select as one of their three self-selected eQMs: the Hospital Harm – Pressure Injury eCQM, the Hospital Harm – Acute Kidney Injury eCQM, and the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) eCQM.

Request for Information on Challenges Faced by Safety-Net Hospitals

As part of its efforts to advance health equity, the Agency is seeking feedback on the challenges faced by safety-net hospitals and potential approaches to help safety-net hospitals meet those challenges.

Proposed Changes to the Severity Level Designation for Z Codes Describing Homelessness

For FY 2024, CMS is proposing to change the severity level designation for social determinants of health (SDOH) diagnosis codes describing homelessness from non-complication or comorbidity (NonCC) to complication or comorbidity (CC). Consistent with its annual updates to account for changes in resource consumption, treatment patterns, and the clinical

characteristics of patients, CMS is recognizing homelessness as an indicator of increased resource utilization in the acute inpatient hospital setting.

Additionally, in furtherance of its goal of advancing health equity, the Agency continues to ask for feedback on how it can foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

The proposed rule (CMS-1785-P) can be downloaded from the Federal Register at:
<https://public-inspection.federalregister.gov/2023-07389.pdf>

For a fact sheet on the proposed rule (CMS-1785-P), please visit:
<https://www.cms.gov/newsroom/fact-sheets/fy-2024-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective>

The press release for the 2024 IPPS Proposed Rule can be found at the following link:
<https://www.cms.gov/newsroom/press-releases/cms-proposes-policies-improve-patient-safety-and-promote-health-equity>