

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

On August 1, 2023, the Centers for Medicare and Medicaid Services (CMS) issued the [Hospital Inpatient Prospective Payment System \(IPPS\) final rule](#).<sup>1</sup> The final rule updates Medicare reimbursements under IPPS by 3.1% (3.3% IPPS hospital market basket update minus a statutorily required 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 final rule includes items of interest to radiation oncology:

- New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2024
- Continuation of the Low Wage Index Hospital Policy
- Permanent Cap on Wage Index Decreases and Budget Neutrality Adjustment
- 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
- Changes to the Severity Level Designation for Z Codes Describing Homelessness

The final rule takes effect on October 1, 2023.

*Go deeper* on the proposed rule below.

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### New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2024

Each year in the IPPS proposed rule, CMS presents its evaluation and analysis of New Technology Add-on Payment (NTAP) applications. 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.

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<sup>1</sup> CMS pays acute care hospitals (with a few exceptions specified in the law) for inpatient stays under the IPPS. Under IPPS, CMS sets base payment rates prospectively for inpatient stays generally based on the patient's diagnosis, the services or treatment provided, and the severity of illness. Subject to certain adjustments, a hospital receives a single payment for each case depending on the payment classification assigned at discharge. The classification system for IPPS is Medicare Severity Diagnosis-Related Groups (MS-DRGs).

In the FY 2024 final rule, CMS finalized its proposal to require NTAP applicants whose technology has not received FDA approval or clearance to have a complete and active FDA market authorization request at the time the NTAP application is submitted. Additionally, applicants must receive FDA approval or clearance by May 1 prior to the start of the FY for which the applicant is applying (this changes the deadline from July 1 to May 1).

For FY 2024, there were 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. CMS found that CYTALUX met the criteria for approval for NTAP for FY 2024. An NTAP for CYTALUX® also was submitted and approved for use in lung cancer as well.

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 CD38 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. FDA approval for elranatamab was not received before July 1, 2023, so it is not eligible for NTAP for FY 2024.

EPKINLY™ (Epcoritamab) and COLUMVI™ (Glofitamab)

An NTAP application was received for epcoritamab, an investigational immunoglobulin G1 (IgG1) bispecific antibody which 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).

An NTAP application also was received for glofitamab, a novel full-length, fully humanized, T-cell engaging bispecific antibody with a novel 2:1 structure which is used in the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more prior therapies.

CMS deemed both EPKINLY™ and COLUMVI™ substantially similar to each other and evaluated both as one NTAP application. After consideration of public comments and the application, CMS is approving both for NTAPs for FY 2024.

Lunsumio™ (mosunetuzumab)

An NTAP application was received for Lunsumio™ (mosunetuzumab), which is designed to treat adults with relapsed/refractory (R/R) follicular lymphoma (FL) who have received at least two prior systemic therapies. CMS determined that Lunsumio™ met the criteria for approval for NTAP for FY 2024.

TECVAYLI™ (teclistamab-cqyv)

An NTAP application was received for TECVAYLITM (teclistamab-cqyv) which is for the treatment of multiple myeloma (MM) in adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy. CMS determined that TECVAYLI™ met the criteria for approval for NTAP for FY 2024.

VANFLYTA® (quizartinib)

An NTAP application was received for VANFLYTA® (quizartinib) which is 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. However, VANFLYTA® did not receive FDA approval by July 1, 2023, so it is not eligible for NTAP for FY 2024.

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

<b>Technology</b>	<b>Newness Start Date</b>	<b>NTAP Start Date</b>	<b>Three-Year Anniversary Date of Entry into U.S. Market</b>	<b>Previous Final Rule Citations</b>	<b>Proposed Maximum NTAP Amount for FY 2023</b>	<b>Coding Used to identify Cases Eligible for NTAP</b>
Rybrevant™ (drug used to treat adults with non-small cell lung cancer)	5/21/21	10/1/21	5/21/24	86 FR 44988 – 44996  87 FR 48913	\$6,405.89	XW033B7 or XW043B7

*Discontinuation of technologies approved for FY 2023 NTAPs no longer considered new for FY 2024 because three-year anniversary date will occur prior to April 1, 2024*

<b>Technology</b>	<b>Newness Start Date</b>	<b>NTAP Start Date</b>	<b>Three-Year Anniversary Date of Entry into U.S. Market</b>	<b>Previous Final Rule Citations</b>
TECARTUS® (cell-based gene therapy for the treatment of mantle cell)	7/4/20	10/1/21	7/4/23	86 FR 45090 – 45104  87 FR 48913

Inpatient Prospective Payment System (IPPS) 2024 Final Rule

Summary of Issues Impacting Radiation Oncology

lymphoma and acute lymphoblastic leukemia)				
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
CARVYKTI™ (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

**Continuation of the Low Wage Index Hospital Policy**

CMS is finalizing its proposal to continue the low wage index hospital policy and the related budget neutrality adjustment. Because there is only one year of relevant data available, the

Agency will wait until it has more usable data from additional fiscal years before making any decision to modify or end the policy.

*Go deeper:* 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.

Depending on current litigation, CMS may have to revisit this policy in the future.

### **Permanent Cap on Wage Index Decreases and Budget Neutrality Adjustment**

CMS did not propose any changes to its policy, which applies a permanent cap on wage index decreases, but it received several comments expressing support for the policy. It also received several comments pointing out that the Agency is not required to make the policy budget neutral and urging reconsideration for how the policy is funded to implement it in a non-budget neutral manner. In the final rule, CMS notes that it will continue to apply the wage index cap in a budget neutral way, but that the budget neutrality adjustment will be updated, as appropriate, based on the final rule data.

*Go deeper:* 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).

### **Modification to the Rural Wage Index Calculation Methodology**

Beginning in FY 2024, CMS will include § 412.103 hospitals along with geographically rural hospitals in all rural wage index calculations and only exclude "dual reclass" hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) in accordance with the hold harmless provision at § 1886(d)(8)(C)(ii) of the Act.

*Go deeper:* The Agency's interpretation of the law and regulations was that hospitals that have been 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 proposed 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).

### **PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR)**

In the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR), CMS is finalizing its proposals to add four new measures and to modify an existing measure (see below). It is also finalizing the proposal to adopt a modified version of the COVID-19 Vaccination Coverage

among health care personnel (HCP) measure beginning with the FY 2025 program year. CMS is also finalizing its proposals to publicly report the Surgical Treatment Complications for Localized Prostate Cancer (PCH-37) measure beginning with data from the FY 2025 program year, and technical changes to the form and manner of the administration of the Hospital Consumer Assessment of Health Care Providers and Systems (HCAHPS) survey measure beginning with the FY 2027 program year.

*Go deeper:*

PPS-Exempt Cancer Hospitals (PCHs) are required to report to CMS certain quality measures. In the FY 2024 final rule, CMS is finalizing four new measures:

1. Facility Commitment to Health Equity, beginning in the FY2026 program year;
2. Screening for Social Drivers of Health, beginning in the FY2026 program year with voluntary reporting, and mandatory reporting in the FY2027 program year;
3. 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
4. Documentation of Goals of Care Discussions Among Cancer Patients, beginning with the FY2026 program year.

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

### **Hospital Inpatient Quality Reporting (IQR) Program**

CMS is finalizing its proposals to add three new measures in the IQR program, modify three existing measures, and to remove three measures (see below). Included in the changes is the addition of the “Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)” eCQM for the 2025 reporting period.

### **Medicare Promoting Interoperability Program**

CMS is finalizing several changes to the Medicare Promoting Interoperability Program:

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 1 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 sought feedback on the challenges faced by safety-net hospitals and potential approaches to help safety-net hospitals meet those challenges.

CMS received “many thoughtful and wide-ranging comments” in response to this RFI, including comments from organizations representing safety-net hospitals, state hospital associations, industry trade groups, health systems, and other interested parties. The Agency is expeditiously conducting an in-depth review of the comments it received.

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

CMS is finalizing the proposed change to 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) for FY 2024. With this, 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.

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The 2024 IPPS final rule can be downloaded from the Federal Register at:

<https://public-inspection.federalregister.gov/2023-16252.pdf>

For a fact sheet on the 2024 IPPS final rule, please visit:

[https://www.cms.gov/newsroom/fact-sheets/fy-2024-hospital-inpatient-prospective-payment-system-ipp-and-long-term-care-hospital-prospective-0?utm\\_campaign=%2BInsight%20-%202024%20IPPS%20Final%20Rule%20-%2008042023&utm\\_medium=email&utm\\_source=Eloqua](https://www.cms.gov/newsroom/fact-sheets/fy-2024-hospital-inpatient-prospective-payment-system-ipp-and-long-term-care-hospital-prospective-0?utm_campaign=%2BInsight%20-%202024%20IPPS%20Final%20Rule%20-%2008042023&utm_medium=email&utm_source=Eloqua)