

FY 2024 Proposed Rule Summary

Inpatient Prospective Payment System (IPPS)

April 19, 2023

On April 10, 2023, the Centers for Medicare and Medicaid Services (CMS) issued the proposed rule for fiscal year (FY) 2024 Inpatient Prospective Payment System (IPPS). The full document is located here: <https://www.federalregister.gov/public-inspection/2023-07389/medicare-program-proposed-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals>. The format of the following information is intended to serve as a summary of the proposed changes and readers are encouraged to view the document in its entirety for further details.

Payment Rates

Under the Inpatient Prospective Payment System (IPPS) CMS sets rates for most, excluding those defined by law, acute care hospital inpatient stays. The base payment rates are established based on the patient's diagnosis and severity of illness. The hospital will receive one payment for the case per the assigned classification of the patient at discharge. IPPS uses Medicare Severity Diagnosis-Related Groups (MS-DRGs) classification system for determining the corresponding payment rate. Rates assigned to the MS-DRGs are required to be updated annually based on several factors related to the price for goods and services used by the hospitals to treat Medicare beneficiaries as well as other factors, all known as the "market basket."

Proposed FY 2024 Payment Rates

Beginning with a base rate, CMS applies other factors which when calculated determine the overall payment for the patient's care per their diagnosis and severity of illness relative to the geographic location of the hospital. For FY 2024, which begins October 1, 2023, CMS is proposing to increase payment rates for hospitals that have successfully participated in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users by approximately 2.8 percent. This is reflected in the projected hospital market basket update of 3.0 percent and a 0.2 percent reduction of the productivity adjustment.

Claims Data

When calculating the payment rates for FY 2024, CMS utilizes the most recently completed claims data which is two years prior. For FY 2024, CMS is proposing to return to the use of most recent claims data when calculating and setting rates for the upcoming fiscal year, this means utilizing FY 2022 claims data for the upcoming payment period.

Based on proposed payment changes CMS projects the operating payment rate increase with the other proposed changes to IPPS payment polices will be approximately \$2.7 billion. Proposed changes in uncompensated care payments, new technology add-on payments, and capital payments offset the increased operating payments (\$3.2 billion) and will decrease IPPS payments by approximately \$0.466 billion from FY 2023.

Low Wage Index

CMS is proposing to continue the low wage index hospital policy implemented in FY 2020, and effective for at least 4 years, to account for disparities between high wage and low wage hospitals. This adjustment to standardized amounts for all hospitals over the 4-year time period allows for employee compensation increases implemented by the hospitals to be appropriately reflected in the calculation for payment.

Severity Level Changes for ICD-10-CM Z Codes Describing Homelessness

Health equity is a focus of the current Administration and a goal in understanding and recognizing the impact homelessness has on resources in the acute inpatient hospital setting. In response to the President's January 20, 2021, Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,"

CMS is proposing to change the severity level designation of social determinants of health (SDOH) diagnosis codes Z59.00 (*Homelessness, unspecified*), Z59.01 (*Sheltered homelessness*) and Z59.02 (*Unsheltered homelessness*) describing homelessness from non-complication or comorbidity (NonCC) to complication or comorbidity (CC) for FY 2024. To do this, CMS is seeking feedback on how to support the reporting of ICD-10-CM diagnosis codes to describe each healthcare encounter, ensure it is accurate and appropriately describes the social and economic circumstances.

Non-O.R. Procedures and O.R. Procedures

Different from ICD-10-CM, which is used to identify the diagnosis of the patient, ICD-10-PCS (procedural classification system) are the codes reported by the hospital on the claim to represent the services provided for inpatient procedures. ICD-10-PCS codes are alphanumeric and identify the general procedure by type, body system, procedure objective, specific body part, procedure approach and device use. Unlike the CPT® codes used by physicians to report the services performed, the individual ICD-10-PCS codes are not separately tied to reimbursement. Instead, they map to a DRG, and reimbursement is tied to the MS-DRG.

ICD-10-PCS codes are either designated as a non-O.R. procedure or not designated as an O.R. procedure. For each procedure that is classified as an O.R. procedure, it is further classified as either extensive or non-extensive. For each procedure that is classified as non-O.R. procedure, it is further classified as either affecting the MS-DRG assignment or not affecting the MS-DRG assignment.

CMS is proposing to allow additional time for claims data to stabilize prior to selecting the timeframe to analyze for this review. CMS received requests regarding changing the designation of specific ICD-10-PCS procedure codes from non-O.R. to O.R. procedures.

Replaced Devices Offered without Cost or with a Credit

In FY 2008 CMS implemented the policy to reduce reimbursement to a hospital for device placement for certain MS-DRGs where the implantation of the device subsequently failed or was recalled. At that time, CMS reduced the amount paid to the hospital when they received a credit equal to 50 percent or more of the cost of the device. In FY 2012 this was clarified to mean if a hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly. For FY 2024 CMS is proposing to delete 6 MS-DRGs (222, 223, 224, 225, 226, and 227) and add MS-DRGs 275 (*Cardiac Defibrillator Implant with Cardiac Catheterization and MCC*) and new MS-DRGs 276 and 277 (*Cardiac Defibrillator Implant with MCC, and without MCC, respectively*), and reassign the subset procedures from MS-DRGs 222-227 to 275-277.

Proposed Changes to the Hospital Readmissions Reduction Program

Under the Hospital Readmissions Reduction Program, Medicare payments under IPPS for discharges may be reduced for certain excess readmissions. For FY 2024, CMS is not proposing any changes, and refers readers to the FY 2023 finalized changes to this program.

Proposed Changes for the Hospital Value-Based Purchasing (VBP) Program

The Hospital VBP Program was created to provide value-based incentive payments in a fiscal year to hospitals based on their performance on measures established in a performance period for such fiscal year. For FY 2024, CMS is proposing the following:

- Updates to the Medicare Spending Per Beneficiary (MSPB) Hospital Measure beginning in FY 2028;
- Updates to the Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning in FY 2030;
- Adoption of the Severe Sepsis and Septic Shock: Management Bundle measure in the Safety Domain beginning in FY 2026;
- Adoption of a health equity scoring change for rewarding excellent care in underserved populations beginning in FY 2026;
- Technical updates to the administration of the HCAHPS Survey measure under the Hospital VBP Program beginning in FY 2027; and
- Modification of the Total Performance Score (TPS) maximum to be at 110, such that the TPS numeric score range would be 0 to 110 in order to allow top-performing hospitals the opportunity to receive the additional health equity bonus points under the proposed health equity scoring change.

In the FY 2019 final rule, CMS finalized eight measure removal factors for the Hospital VBP program. CMS is proposing to codify these eight measure removal factors at 42 CFR 412.164(c) of their regulations, as well as the policies for updating measure specifications and retaining measures. CMS is also requesting feedback on potential additional future changes to the Hospital VBP Program scoring methodology that would address health equity.

Hospital-Acquired Condition (HAC) Reduction Program

Section 1186 of the Act establishes an incentive to reduce the number of hospital-acquired conditions (HACs) by a 1 percent payment reduction to applicable hospitals, effective October 1, 2014. This adjustment applies to hospitals which rank in the worst performing 25 percent of all applicable hospitals (compared to the national average) of acquired conditions during the specified period and all hospital discharges for the specified year.

CMS is proposing not to add or remove any measures from the HAC Reduction Program. CMS is proposing to establish a validation reconsideration process for hospitals who fail data validation beginning in FY 2025 and modification of the validation targeting criteria for extraordinary circumstances exceptions (ECEs) beginning in FY 2027. CMS is seeking comments on potential future measures to adopt in the HAC Reduction Program that would address patient safety and health equity.

Add-On Payments for New Services and Technologies for FY 2024

New Applications

Each year CMS reviews applications received per the deadline for new technology requesting an add-on payment to the DRG. There are specific criteria which must be met in order to qualify for the additional payment:

- (1) the medical service or technology must be new;
- (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and
- (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

Newness Criterion

The newness criterion, technology is no longer considered “new” for the purposes of the add-on payment if it is substantially like one or more existing technologies, even if it recently received FDA approval or clearance. In addition, if it has been on the market for more than 2 to 3 years, it is no longer considered “new”.

To differentiate how CMS defines what is new technology and the criteria it must meet to evaluate if potentially like existing technology CMS created the following guidelines. If technology meets all the following it is considered similar to existing technology and not “new” for an add-on payment:

- (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome;
- (2) whether a product is assigned to the same or a different MS-DRG; and
- (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population.

Cost Criterion

The second criterion is related to cost. CMS will evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS-DRGs if the new medical service or technology occurs in many different MS-DRGs). CMS does provide access to the data files utilized for this analysis.

Applicants are expected to submit a significant sample of data to demonstrate the technology meets the high-cost threshold. The sample size is expected to be significant to allow for CMS to be able to do an initial validation and analysis of the data.

Substantial Clinical Improvement Criterion

The third and final criterion is the technology must represent an advancement that significantly improves the diagnosis or treatment relative to already existing technologies. Some of the criteria which may support the clinical improvement include:

- The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;
- The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a

medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

- The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or
- The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources with the United States or elsewhere may be sufficient to establish the improvement.
- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

For FY 2024, CMS is proposing to continue the add-on payment for 10 technologies and discontinue add-n payments for 15 new technologies.

Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2023	Coding Used to Identify Cases Eligible for NTAP
1 Intercept® (PRFC)	05/05/2021	10/1/2021	5/05/2024	86 FR 45149 through 45150 86 FR 67875 87 FR 48913	\$2,535.00	30233D1 or 30243D1 in combination with one of the following D62, D65, D68.2, D68.4 or D68.9
2 Rybrevant™	05/21/2021	10/1/2021	05/21/2024	86 FR 44988 through 44996 87 FR 48913	\$6,405.89	XW033B7 or XW043B7
3 StrataGraft®	06/15/2021	10/1/2021	06/15/2024	86 FR 45079 through 45090 87 FR 48913	\$44,200.00	XHRPXF7
4 aprevo® Intervertebral Body Fusion Device	6/30/2021 (TLIF)	10/1/2021	6/30/2024 (TLIF)	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913	\$40,950.00	XRGA0R7 or XRGA3R7 or XRGA4R7 or XRGB0R7 or XRGB3R7 or XRGB4R7 or XRC0R7 or XRC3R7 or XRC4R7 or XRGD0R7 or XRGD3R7 or XRGD4R7
5 Hemolung Respiratory Assist System (RAS)	11/15/2021 (other)	10/1/2022	11/15/2024 (other)	87 FR 48937 through 48948	\$6,500.00	5A0920Z without U07.1*

6	Livtency™	12/2/2021	10/1/2022	12/2/2024	87 FR 48948 through 48954	\$32,500.00	XWODX38 or XWOG738 or XW0H738
7	Thoraflex Hybrid Device	04/19/2022	10/1/2022	04/19/2025	87 FR 48974 through 48975	\$22,750.00	X2RX0N7 in combination with X2VW0N7
8	ViviStim	04/29/2022	10/1/2022	04/29/2025	87 FR 48975 through 48977	\$23,400.00	X0HQ3R8
9	GORE TAG Thoracic Branch Endoprosthesis	05/13/2022	10/1/2022	05/13/2025	87 FR 48966 through 48969	\$27,807.00	O2VW3DZ in combination with O2VX3EZ
10	Cerament® G	05/17/2022	10/1/2022	05/17/2025	87 FR 48961 through 48966	\$4,918.55	XW0V0P7
11	iFuse Bedrock Granite Implant System	05/26/2022	10/1/2022	05/26/2025	87 FR 48969 through 48974	\$9,828.00	XNH6058 or XNH6358 or XNH7058 or XNH7358 or XRGE058 or XRGE358 or XRGF058 or XRGF358

*As discussed in the following section, we are proposing to discontinue new technology add-on payments for COVID-19 Hemolung RAS cases.

Table II.P.-02: Proposed Discontinuation of Technologies Approved for FY 2023 New Technology Add-on Payments 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 onto U.S. Market	Previous Final Rule Citations
1	TECARTUS®	7/4/2020	10/1/2021	7/4/2023	86 FR 45090 through 45104 87 FR 48913
2	VEKLURY®*	7/1/2020*	10/1/2021	7/1/2023*	86 FR 45104 through 45116 87 FR 48909 through 48914
3	Zepzelca™	6/15/2020	10/1/2021	6/15/2023	86 FR 45116 through 45126 87 FR 48912 through 48913
4	aScope® Duodeno	7/17/2020	10/1/2021	7/17/2023	86 FR 45133 through 45135 87 FR 48912 through 48916
5	Caption Guidance™	9/15/2020	10/1/2021	9/15/2023	86 FR 45135 through 45138 87 FR 48911 through 48913
6	aprevo® Intervertebral Body Fusion Device	12/3/2020 (ALIF and LLIF)	10/1/2021	12/3/2023 (ALIF and LLIF)	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913
7	Cosela™	2/12/2021	10/1/2021	2/12/2024	86 FR 45008 through 45017 87 FR 48912 through 48913
8	ShockWave C2 Intravascular Lithotripsy (IVL) System	2/12/2021	10/1/2021	2/12/2024	86 FR 45151 through 45153 87 FR 48913
9	ABECMA®	3/26/2021	10/1/2021	3/26/2024	86 FR 45028 through 45035 87 FR 48911 through 48925
10	Harmony™ Transcatheter Pulmonary Valve (TPV) System	03/26/2021	10/1/2021	3/26/2024	86 FR 45146 through 45149 87 FR 48913
11	Recarbrio™ (HABP/VABP)	6/4/2020	10/1/2021	6/4/2023	86 FR 45157 through 45158 86 FR 67874 87 FR 48914
12	Fetroja® (HABP/VABP)	9/25/2020	10/1/2021	9/25/2023	86 FR 45156 through 45157 86 FR 67876 87 FR 48913
13	DARZALEX FASPRO®	01/15/2021	10/1/2022	01/15/2024	87 FR 48925 through 48937
14	CARVYKTI™	03/26/2021**	10/1/2022	03/26/2024	87 FR 48920 through 48925
15	Hemolung Respiratory Assist System (RAS)	04/22/2020 (COVID-19)	10/1/2022	04/22/2023 (COVID-19)	87 FR 48937 through 48948

*See discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48909 through 48914).

** As discussed in the FY 2023 IPPS/LTCH PPS final rule, because we determined that CARVYKTI™ is substantially similar to ABECMA®, we consider the beginning of the newness period for CARVYKTI™ to be March 26, 2021, which is the date that ABECMA® received FDA marketing authorization (87 FR 48925).

Applications for Alternative Pathway for Breakthrough Devices

DETOUR System by Endologix, Inc.

Endologix, Inc. applied for new technology add-on payment for the DETOUR System for FY 2024. Per the applicant, the DETOUR System is a fully percutaneous approach to femoral-popliteal bypass. Under fluoroscopic guidance, a TORUS Stent Graft System is deployed from the popliteal artery into the femoral vein, and from the femoral vein into the superficial femoral artery (SFA) in a continuous, overlapping fashion through two independent anastomoses. The applicant stated the intended result is a large lumen endograft bypass, that delivers unobstructed, pulsatile flow from the SFA ostium to the popliteal artery.

The DETOUR System received Breakthrough Device designation from FDA on September 2, 2020, for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. Endologix is seeking premarket approval from FDA for the same indication and plans to make the DETOUR System available on the market immediately upon FDA approval.

CMS believes the Cost criterion has been met for the DETOUR System. Endologix, Inc. has not provided a cost for the DETOUR System but will be required to prior to the final rule publication. CMS is inviting comments if there is support for the approval of the DETOUR System for the add-on payment for new technology based on cost criterion for FY 2024.

Submitting Comments

CMS is accepting comments on this proposed ruling, file **CMS-1785-P, no later than 5 p.m. EDT on June 9, 2023**. Electronic comments can be submitted at <http://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.