FY 2023 Proposed Rule Summary

Inpatient Prospective Payment System (IPPS)

April 26, 2022

On April 18, 2022, the Centers for Medicare and Medicaid Services (CMS) issued the proposed rule for fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS). The full document is located here: https://www.federalregister.gov/public-inspection/2022-08268/medicare-program-hospital-inpatient-prospective-payment-systems-quality-programs-and-medicare. The format of the following information is intended to serve as a summary to 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 2023 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 2023, which begins October 1, 2022, 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 2.7 percent. This reflects the projected hospital market basket update of 3.1 percent, a 0.4 percent reduction of the productivity adjustment, and the 0.5 percent increase required by previous MACRA (Medicare Access and CHIP Reauthorization Act of 2015) legislation.

Claims Data

When calculating the payment rates for FY 2023, CMS would typically utilize the most recently completed claims data which is two years prior. For FY 2023, this would mean utilizing data from FY 2021 (October 1, 2020 – September 30, 2021). Due the impact COVID-19 has had on hospitals and inpatient services and those hospitals will continue to have admissions related to COVID-19; CMS is proposing to use FY 2021 data for ratesetting with modifications to account for the anticipated decline in COVID-19 IPPS hospitalizations. CMS is also seeking comments on an alternative for ratesetting, using FY 2021 data for FY 2023 MS-DRG relative weights without proposed modifications.

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.

Cap to Wage Index Changes

CMS is also proposing to put a permanent cap of 5 percent related to wage index decreases. If a hospital's wage index were to decrease it could not be more than 95 percent from its final wage index in the previous year, this would be applied for subsequent years until the full reduction is implemented.

Based on these proposed payment changes CMS projects the operating payment rate increase with the other proposed changes to IPPS payment polices will be approximately $1.6 billion. Proposed changes in uncompensated care payments, new technology add-on payments, and capital payments will decrease IPPS payments by approximately $0.8 billion from FY 2022.

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 addressing requests that were received regarding changing the designation of specific ICD-10–PCS procedure codes from non-O.R. to O.R. procedure or changing the designation from O.R. procedure to non-O.R. procedure. Parameters include whether the procedure would typically require the resources of an operating room; whether it is an extensive or a nonextensive procedure; and to which MS-DRGs the procedure should be assigned.

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 2023 CMS is not proposing to add any additional MS-DRGs to the policy for replaced devices offered without cost or with a credit. They are proposing to continue the current list of MS-DRGs.

Add-On Payments for New Services and Technologies for FY 2023

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 similar to 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 similar to existing technology CMS created the following guidelines. If technology meets all of 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 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 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.

The following are new technology add-on payment applications outlined in the FY 2023 IPPS proposed rule which may include technologies utilized or beneficial to interventional radiology.

GORE® TAG® Thoracic Branch Endoprosthesis (TBE)

W.L. Gore and Associates, Inc., submitted an application for new technology add-on payments for the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) device for FY 2023. According to the applicant, the GORE® TAG® TBE device is a modular device consisting of three components, each of which is pre-mounted on a catheter delivery system for treatment of thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection:

- Aortic component
- Side branch component
- Optional Aortic Extender Component

According to GORE, the GORE® TAG® TBE device was granted designation under the Expedited Access Pathway (EAP) by FDA (and is therefore considered part of the Breakthrough Devices Program by FDA) on July 17, 2015, for endovascular repair of descending thoracic aortic and aortic arch for patients who have appropriate anatomy. GORE anticipates receiving premarket approval of the GORE® TAG® TBE device as a Class III device from FDA in Spring 2022 with a proposed indication for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who have adequate iliac/femoral access, and eligible proximal aorta, left subclavian, or distal landing zones (isolated lesion patients only).

Since the indication for which GORE anticipates receiving premarket approval is included within the scope of the EAP designation, it appears that the proposed PMA indication is appropriate for new technology add-on payment under the alternative pathway criteria.

From a coding perspective, GORE identified a combination of two existing ICD-10-PCS codes to accurately report this procedure: 02VW4EZ (Restriction of thoracic aorta, descending with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach) and 02VX4EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach). Because the TBE device includes two anatomic regions, the descending thoracic aorta and the thoracic aortic arch, both procedure codes are necessary to accurately report the use of this device.

Based on the preliminary information received by GORE at the time of this proposed rule, the per patient anticipated hospital cost of the GORE® TAG® TBE device is $42,780. CMS stated this cost information may be updated in the final rule based on revised or additional information. If CMS approves this new technology add-on payment in the final rule, the maximum new payment for a case involving the GORE® TAG® TBE device would be $27,807 for FY 2023 (65% of the average cost of the technology). Public comments are requested on whether this technology meets cost criterion, subject to the technology receiving FDA marketing approval corresponding to the EAP designation by July 1, 2022.

Polarean, Inc. and The Institute for Quality Resource Management XENOVIEW (hyperpolarized Xenon-129 [HP 129Xe] gas for inhalation)

Polarean, Inc. and The Institute for Quality Resource Management ("Polarean") submitted an application for new technology add-on payments for XENOVIEW (hyperpolarized Xenon-129 [HP 129Xe] gas for inhalation). Per the applicant, XENOVIEW is a gas blend used in chest magnetic resonance imaging (MRI) that is processed to consist of 89% Helium, 10% Nitrogen, and 1% Xenon. The blend of gases is supposed to allow for "*high resolution 3-dimensional (3-D) images of the lungs and assessment of the lungs' functional status when inhaled by a patient during a pulmonary MRI scan.*"

Polarean did indicate they are awaiting FDA approval and the isotopic properties used by XENOVIEW make this different from Traditional MRI. They also stated it cannot be compared to other technologies as it varies making it a technology without a MS-DRG it could be assigned to but would most likely be used by those in MS-DRGs 190-192 for COPD and 2020-203 for bronchitis and pneumonia. In the application to CMS Polarean stated based on these elements XENOVIEW meets the newness criterion.

CMS believes the technology is similar to other MRI technology, uses similar mechanisms to inhaled gases and is inviting comments whether the mechanism of action for XENOVIEW is different than other mechanisms for diagnosis and assessment for certain lung abnormalities.

The applicant supported through various data they believed the cost criterion was met in their application. CMS is inviting comments on the cost criterion and whether some patients will be without complications and major complications and able to handle additional radiation exposure such as from SPECT/CT or high-resolution CT, or nephrotoxicity from MRI.

Polarean provided several studies to support the substantial clinical improvement criterion; however, CMS indicated they have concerns. The applicant stated XENOVIEW offers treatment for patients unresponsive to or ineligible for other treatments, but XENOVIEW is a diagnostic test, not a treatment. The studies presented did not support the statement it benefits populations of patients who have a medical condition that cannot currently be detected earlier than current methods. Lastly, to the statements the technology when used in MRI will lead to actionable treatment decisions, CMS questioned the single case report with a single patient to base this on and concerns to generalize this to a whole population.

Submitting Comments

CMS is accepting comments to this proposed ruling, file **CMS-1771-P, no later than 5 p.m. EDT on June 17, 2022**. Electronic comments can be submitted at http://www.regulations.gov. Follow the instructions under the "submit a comment" tab.