Coastal Carolinas Health Alliance
Medicare Update: Day 1

FY2022 IPPS Updates, Medical Necessity, Utilization Review, and other Medicare Updates

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Presented By

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Learning Objectives

- At the completion of this educational activity, the learner will be able to:
- Discuss CMS rate setting changes for 2022 and how they affect New Technology
- Identify proper post-acute care transfer rule coding for home health transfers
- Review two situations where a physician certification applies to an inpatient stay

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Agenda

- FY2022 IPPS Payment Updates
  - Outlier, wage index, and other payment factors, including correction notice updates
    - Policy to use 2019 data and impact on payment factors
    - Repeal of rate setting methodology
    - Uncompensated care payments
  - New Technology drugs and devices for 2022
    - Policy to continue expiring new technologies
    - Correction notice updates
  - New Covid-19 Treatment Add-on Payments (NCTAP) policies
  - Major MS-DRG grouping changes
  - Suppression of certain quality factors and impact on payment
- Questions

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Agenda

- Transfers and Post-Acute Care Transfers
  - Updated guidance in Special Editions and revised Manual
  - OIG focus on home health transfers
- Repeal of MCIT and 'Reasonable and Necessary" rule incorporating private insurance

BREAK

- Regroup on Utilization Review
  - Certification requirements for long stays, outliers, and no available SNF bed
  - Short stay review guidance from reversal of IPO list elimination
    - QIO Short Stay Reviews and audit strategies and exemption from denial
  - Observation as basis of admission and the inpatient level of care myth
  - OIG's reviews and observation outliers
  - Leveraging self-denials to save UR resources

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FY2022 IPPS Payment Updates

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Source Authority

- IPPS final rule is effective October 1 each year
  - FY 2022 IPPS Proposed Rule
    - *86 Fed. Reg. 25070–25790*
  - FY 2022 IPPS Final Rule
    - *86 Fed. Reg. 44774–45615*
  - FY2022 IPPS Final Rule, correction and correcting amendment
    - *86 Fed. Reg. 58019–58039*
  - FY2022 IPPS Final Rule, correction (to the correction and correcting amendment)
    - *86 Fed. Reg. 67874–67876*
  - FY 2022 IPPS Tables
    - CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/index.html
      - Click on the link on the left side of the screen titled, “FY 2022 IPPS Final rule Home Page” or “Acute Inpatient—Files for Download.”

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FY2022 Payment Updates

- CMS finalized their proposal to use FY2019 data (from prior to the PHE) for rate setting purposes for FY2022 to more closely approximate the expected FY2022 inpatient hospital utilization
  - Ordinarily the best available full year of data to approximate the expected FY 2022 inpatient hospital utilization would be data from FY 2020
  - Unfortunately, the FY 2020 data reflects changes in inpatient hospital utilization driven by the PHE, prompting CMS to use FY 2019 data instead
  - This affected calculation of the relative weights and the length of time new technology will qualify for additional payment, among other factors

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CMS Reverses Direction on MS-DRG Relative Weight Policy

- CMS currently uses chargemaster (gross) rates to calculate MS-DRG relative weights
  - This requires CMS to first reduce average gross charges for all discharges assigned to the same MS-DRG to costs by multiplying them by national average cost-to-charge ratios
  - Based upon concerns that this methodology may result in inflated payment rates, in the FY 2021 IPPS final rule
    - CMS changed the methodology for calculating future relative weights, shifting from gross charges to market-based information for FY 2024 and beyond
    - To obtain relevant market-based information, CMS also mandated that hospitals report median payer-specific negotiated charges (by MS-DRG) which the hospital negotiated with Medicare Advantage (MA) payers on their Medicare cost reports for cost reporting periods ending on and after January 1, 2021

CMS Reverses Direction on MS-DRG Relative Weight Policy

  - Since these payer-specific negotiated charges are for the same service packages that hospitals are already required to make public under Hospital Price Transparency rules, CMS assumed any additional burden would be minimal
  - When CMS realized that hospitals' administrative burden would increase by approximately 64,000 hours, it reversed its decision and repealed both
    - Its prior decision to implement a market-based MS-DRG relative weight methodology effective for FY 2024 and beyond, and
    - The mandate for hospitals to report median negotiated charges for cost reporting periods ending on or after January 1, 2021
  - As a result, CMS will continue using the existing cost-based MS-DRG relative weight methodology to set Medicare payment rates for IPPS inpatient stays for FY 2024 and beyond

Payment Factors: Final FY 2022 Operating Standard Amount (OSA)

Overall 2.5% increase to IPPS operating rates

Summary

+2.7% – Market basket increase

-0.7% – ACA multifactor productivity reduction

+2.0% -- Adjusted market basket update before coding/documentation adj

+0.5%* – Coding and documentation adjustment

2.5%** – Adjusted market basket update after coding/documentation adj

*This adjustment, however, does not appear to be factored into the % increases to the IPPS operating payment, as reflected in the respective labor and non-labor related OSAs set out in Tables 1A and 1B

**Assuming hospital met IQRP and EHR (MPIP) requirements

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Payment Factors: OSA Adjustments

- For FY 2022, a hospital is only eligible for the **full 2.0% increase** to the OSA if it meets both the IQRP **and** EHR requirements.
  - If a hospital fails to meet both quality program requirements, it may be subject to the following additional payment adjustments:
    - A hospital that fails to meet EHR requirements **but** does meet IQRP requirements is subject to a 3/4 reduction to the full MBU (2.7% x 75%) or -2.025% in addition to the MFP adjustment (-0.7%), resulting in a **-0.025% increase**
    - A hospital that fails to meet IQRP requirements **but** is a meaningful EHR user is subject to a 1/4 reduction to the MBU (2.7 x 25%) or -0.675% in addition to the MFP adjustment (-0.7%), resulting in an **increase of 1.325%**
    - A hospital that fails to meet **both** IQRP **and** meaningful EHR user requirements is subject to a reduction of -2.7% to the full MBU (2.7%), in addition to the MFP adjustment (-0.7%), resulting in a **-0.7% increase**

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FY 2022 PERCENTAGE INCREASES FOR THE IPPS OPERATING PAYMENT

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Increase	2.7	2.7	2.7	2.7
Failed to submit quality data	0	0	-0.675	-0.675
Failed to meet EHR requirements	0	-2.025	0	-2.025
MFP adjustment	-0.7	-0.7	-0.7	-0.7
% increase to OSA	2.0	-0.025	1.325	-0.7

Payment Factors: Adjustments to Hospital-Specific Rates

- For FY 2022, the hospital-specific rates for sole community hospitals (SCH, based on highest rate from 1982, 1987, 1996, or 2006) and Medicare dependent hospitals (MDH, based on highest rate from base years 1982, 1987, or 2002) will be subject to the same OSA adjustments as those that apply to other IPPS hospitals
  - In particular, SCHs and MDHs are subject to applicable reductions for failure to meet IQRP and/or EHR requirements

Payment Factors: Wage Index

- Applicable wage indices for all urban and state-wide rural CBSAs are set out in Tables 3 to the FY 2022 IPPS final rule
  - The first step in calculating the MS-DRG operating payment for a specific hospital discharge is to wage-index adjust the labor-related portion of the hospital's OSA
  - Each year CMS determines what the respective labor-related portion of the OSA will be for IPPS hospitals, depending upon whether the hospital's wage index is greater than or equal to (or less than) 1
    - For those hospitals with a wage index greater than 1, the labor-related portion will be 67.6%, which is a downward adjustment from 68.3% in FY 2021
    - For those hospitals with a wage index of 1 or less, the labor-related portion will remain at 62%

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Wage Index adjustments

- For each FY, CMS determines the average hourly labor cost for all hospitals within a geographic region referred to as a core-based statistical area (CBSA) and compares that to the national average hourly labor cost (1.00) for all hospitals across the country
  - If labor costs in a CBSA exceed the national average, the WI will be greater than 1, resulting in an upward adjustment to the hospital's operating payments
  - If the labor costs in a CBSA are less than the national average, the WI will be less than 1, resulting in a downward adjustment to the hospital's operating payments
  - Hospitals in urban CBSAs tend to have a higher WI, and those in rural CBSAs tend to have a lower WI, creating significant disparity

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Wage Index Adjustments

- Under the FY 2020 IPPS final rule, CMS implemented the following changes, to be effective for at least 4 years, beginning in FY 2020
  - Adjustments increasing the WI of hospitals with a WI value below the 25th percentile, beginning with FY 2020
    - CMS will increase the WI of hospitals with a WI value below the 25th percentile WI value for a FY by half the difference between the otherwise applicable final WI value for that hospital and the 25th percentile WI value for that FY
  - A budget neutrality adjustment to the operating standardized amount applied across all IPPS hospital
  - To ease the effect of the transition on hospitals with higher wage indices, a 5-percent cap for FY 2020 on any decrease in a hospital's WI from its final WI for FY 2019

Wage Index Adjustments

- This policy will continue to be effective for two more years, including FY 2022, to allow employee compensation increases sufficient time to be reflected in the hospital's WI calculation
  - For FY 2022, however, CMS will continue to place a 5% cap on any decrease in a hospital's wage index from the hospital's FY 2021 wage index **only** for those hospitals that received a transition extension in FY 2021
  - For purposes of the low wage index hospital policy, for FY 2022, the 25th percentile wage index value across all hospitals is 0.8437
  - The FY 2022 wage index values under this policy are based on data collected from Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2018

Wage Index Adjustments

- Other wage-index related policies for FY 2022 include
  - Reinstatement of the imputed floor wage index policy for all-urban states effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date
    - This policy will not, however, be applied in a budget neutral manner, and
  - Continuation of certain ongoing wage-index adjustment policies (rural floor, state frontier floor and outmigration adjustment based on commuting patterns of hospital employees) without change

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Payment Factors: DSH Adjustments

- The DSH adjustment to the operating IPPS payment applies to hospitals that service a significantly disproportionate share of low-income patients, including
  - Patients entitled to Part A by reason of disability, and
  - Patients not entitled to Part A but eligible for Medicaid

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Payment Factors: DSH Adjustments

- For FY 2022, the DSH adjustment to the IPPS operating payment has two components
  - A per-discharge adjustment of 25% of what the DSH adjustment would have been under the prior calculation **PLUS**
  - An additional uncompensated care payment that is the product of three factors
    - CMS' estimate of 75% of estimated DSH payments for 2022, based on the old calculation (**$10,488,564,546.74**)
    - An adjustment of **68.57%**, to account for changes in uninsured and under-insured patients,
    - The **hospital's %** of uncompensated care compared to uncompensated care for all DSH hospitals (**$7,192,008,709.70**)
      - CMS will use FY 2018 Worksheet S-10 cost report data in the calculation of hospital's % of uncompensated care for all hospitals except IHS, Tribal and Puerto Rico hospitals

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Payment Factors: IME Adjustments

- For FY 2022, CMS is proposing to continue to pay an additional amount added to each operating IPPS payment to hospitals with an approved residency program
  - This add-on payment, referred to as the operating IME adjustment, is designed to cover the higher indirect medical costs of teaching hospitals
  - The percentage varies for each hospital, depending on the ratio of residents to eligible inpatient beds
- For FY 2022, the formula multiplier will remain 1.35
  - CMS estimates an increase in IPPS payment of 5.5 percent for every 10% increase in resident/bed ratio

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Payment Factors: Capital Standard Federal Rate (CSFR)

Overall 0.8% increase to FY 2022 IPPS capital rate
Summary

+1.1% – Capital input price index (CIPI)*
0.0% – Intensity
0.0% – Case-mix adjustment factors:
(Real across DRG change of .5% minus
Projected case-mix change of .5%)
0.0% – Effect of FY 2020 reclassification and recalibration
-0.3% – Forecast error correction

Total +0.8%

*The CIPI represents the FY 2018-based CIPI

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Payment Factors: CSFR

- For FY 2022, CMS is increasing the national capital Federal rate from $466.21 (FY 2021) to **$472.60**, based upon
  - The 0.8% increase to the IPPS capital rate

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Payment Factors: Outlier Calculation Factor Update

- For FY 2022, CMS confirmed the following factors for outlier calculation
  - The "fixed loss amount" for FY 2022 will be **$30,988**
    - The "fixed-loss amount" is the dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment
  - The "outlier fixed-loss cost threshold" for FY 2022 will be the sum of the following amounts
    - IPPS rate for the MS–DRG
    - Any IME and empirically justified Medicare DSH payments
    - Any estimated uncompensated care payment
    - Any add-on payments for new technology
    - The FY 2022 "fixed loss amount" (**$30,988**)

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Payment Factors: Outlier Calculation Factor Update

- In FY 2022, hospitals will only be eligible to receive an additional outlier payment for losses in **excess** of the outlier fixed-loss cost threshold
  - There is no recovery for the fixed-loss amount ($30,988)
- Costs of the case are determined by multiplying the total billed charges by the inpatient CCRs
- The marginal cost factor is the percentage of the excess of the costs of the case over the "fixed-loss cost threshold" that will determine the amount of outlier payment, if any
  - For FY 2022, CMS is continuing to apply a marginal cost factor, in general, of 80%
    - 90% for burn MS-DRGs 927, 928, 929, 933, 934, and 935

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New Technology under the IPPS

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Expanding Access to New Technologies

- CMS' focus on unleashing innovation in healthcare technology was based upon concern that Medicare's existing payment system was unable to keep up with the rapid pace of advancement in medical science
- This led to CMS making certain changes to existing payment policies by
  - Increasing the new technology add-on payment (NTAP), which provides hospitals with additional payments for cases with high costs involving new technologies
  - Modernizing payment policies for medical devices that meet FDA's Breakthrough Devices designation
  - Finalizing policies to remove barriers for new antimicrobial therapies and other drugs
- In the FY 2022 IPPS final rule, CMS is also extending new COVID-19 treatment add-on payments (NCTAP) through the end of the FY in which the PHE ends (currently September 30, 2022)

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Expanding Access to New Technologies

- Under the IPPS, as part of each FY final rule, certain new technologies are approved for NTAP
  - An NTAP is in addition to the standard MS-DRG payment and is designed to cover the cost of new technologies that generally must meet the following 3 requirements:
    - The new technology must be new and not substantially similar to an existing technology,
    - The cost of the new technology must be great enough that the otherwise applicable MS-DRG payment would be inadequate, and
    - The new technology must demonstrate substantial clinical improvement over existing technologies
  - In general, NTAP is granted for a maximum of 3 years
    - For FY2022, some NTAP were extended an additional year based on CMS payment policy due to available data for FY2020 due to the COVID-19 PHE

Expanding Access to New Technologies

- For dates of service on or after October 1, 2019 (FY 2020),
  - CMS increased the NTAP payment generally to the lesser of
    - 65% (rather than 50%) of the amount by which the costs of the case exceed the standard MS-DRG payment, or
    - 65% (rather than 50%) of the costs of the new medical service or technology
  - For certain new antimicrobial therapies, CMS increased the NTAP payment to the lesser of
    - 75% of the amount by which the costs of the case exceed the standard MS-DRG payment, or
    - 75% of the costs of the new medical service or technology

Alternative Pathway for Breakthrough Devices

- Beginning with NTAP applications for **FY 2021**, CMS implemented an alternative pathway for new medical devices that
  - Are part of the FDA's Breakthrough Devices Program (BDP), and
  - Have received FDA marketing authorization **by July 1 preceding** the beginning of the FY (October 1) for which they seek NTAP
- Under this pathway, two of the current NTAP requirements would be effectively waived
  - Devices would be assumed to be new and not substantially similar to an existing technology and would not have to demonstrate substantial clinical improvement over existing technologies
  - The breakthrough devices would only need to meet the ***cost*** criterion to receive NTAP

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Alternative Pathway for Antimicrobial Products

- Beginning with NTAP applications for **FY 2021**, CMS also implemented an alternative pathway for new antimicrobial therapies which
  - Treat drug-resistant infections, and
  - Have received a Qualified Infectious Disease Products (QIDP) designation and marketing authorization from the FDA
- Under this pathway, the following rules apply
  - As with breakthrough devices, QIDP would only need to meet the ***cost*** criterion to receive NTAP
    - Their NTAP would continue to be based on a marginal cost factor of 75%
  - Antimicrobial drug resistant ICD-10-CM diagnosis codes will continue to be designated as CCs, generally resulting in higher MS-DRG assignment and payment

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Alternative Pathway for Limited Population Pathway for Antibacterial and Antifungal Drugs

- Beginning with NTAP applications for **FY 2022**, CMS is expanding the alternative new technology add-on payment pathway for QIDPs to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway).
  - For applications received for NTAP for FY 2022 and subsequently, if an antimicrobial product is approved through FDA's LPAD pathway, it will only need to meet the ***cost*** criterion to receive NTAP

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FY IPPS Approval Date for QIDP and LPAD NTAP

- Beginning with FY 2021, CMS may grant conditional approval for otherwise qualifying products under the QIDP or LPAD, subject to the technology receiving FDA marketing authorization **by July 1 of the FY** for which application was made
  - In that case, NTAP will only be paid for discharges beginning in the quarter following FDA authorization
    - For example: In order to receive NTAP during FY 2022, a qualifying product would have to receive FDA marketing authorization by July 1, 2022, and NTAP would be paid only for discharges during the last quarter of FY 2022

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New Technologies for FY2022

- For FY 2022, 40 technologies will be eligible to receive NTAP
  - CMS is continuing NTAP for all 23 of the technologies receiving NTAP in FY 2021
    - 10 remain within their newness period for FY 2022
    - CMS is using its exceptions and adjustments authority during the PHE to provide a one-year extension for the remaining 13 technologies that are no longer new
  - CMS also approved or (conditionally approved) 17 new technologies for FY 2022
- CMS estimates that FY 2022 Medicare spending on NTAP will be approximately $1.5 billion, nearly a 77% increase over FY 2021 spending
- Two correction notices were published that made significant corrections to the payment limit amounts or qualifying codes for new technologies for FY2022
  - A complete list of new technologies, with qualifying codes and payment add-ons, including corrections is included as an attachment at the end of the presentation.

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New COVID Treatment Add-on Payments (NCTAP)

- In FY 2021, CMS also established the NCTAP to cover the costs of cutting edge COVID-19 therapies provided to hospital inpatients during the PHE
- Because CMS anticipates there will be inpatient cases of COVID-19 beyond the end of the PHE, CMS is extending the NCTAP for eligible COVID-19 products through the end of the FY in which the PHE ends, which is designed to
  - Mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, and
  - Minimize any potential payment disruption immediately following the end of the PHE

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New COVID Treatment Add-on Payments (NCTAP)

- Qualifying cases:
  - Case must include a drug or biological authorized to treat COVID-19 by the FDA, including through an emergency use authorization (EUA)
  - Products currently approved according to the CMS NCTAP website:
    - Beginning 8/23/20, COVID-19 convalescent plasma
    - Beginnig 10/22/20, remdesivir (Veklury®)
    - Beginning 11/19/20, baricitinib (Olumiant®) in combination with remdesivir (Veklury®)
  - See the CMS NCTAP website (https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap) for coding details for eligible cases
  - Case must be eligible for the 20% increase to the DRG weight for individuals diagnosed with COVID-19
  - The operating costs of the case must exceed the IPPS operating payment, including the 20% add on payment

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New COVID Treatment Add-on Payments (NCTAP)

- NCTAP payment amount
  - NCTAP payments are the **lesser** of
    - (1) **65%** of the operating outlier threshold for the claim or
    - (2) **65%** of the amount by which the costs of the case exceed the standard DRG payment, including the CARES Act 20% payment

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New COVID Treatment Add-on Payments (NCTAP)

- CMS did not finalize its proposal to discontinue the NCTAP for discharges on or after October 1, 2021, for a product that is approved for NTAP beginning in FY 2022
  - Instead, hospitals will be eligible to receive both a NCTAP and the traditional NTAP for qualifying inpatient stays through the end of the FY in which the PHE ends
    - The amount of the NCTAP, however, will be reduced by the amount of the NTAP
  - Currently one product qualifies for both NTAP and NCTAP
    - VEKLURY® (remdesivir, a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as SARS-CoV-2 (COVID-19))

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MS-DRG Updates

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MS-DRGs

- Payment under the IPPS is based upon the MS-DRG to which the case is assigned
  - List of MS-DRGs is published as Table 5 to annual IPPS final rule
  - MS-DRGs are grouped into one of 25 "MDCs" based on organ/body system or nature of disease or injury
  - Every discharge is assigned to only one MS-DRG
    - Each MS-DRG is assigned a relative weight reflecting "estimated relative cost of hospital resources" for cases assigned to that MS-DRG

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MS-DRGs

- Factors driving MS-DRG assignment
  - Principal DX (UB-04, FL 67)
  - Secondary DXs that rise to the level of CCs or MCCs (UB-04, FLs 67A-Q)
    - Some secondary DXs are considered CC exclusions when present with certain principal DXs, and are **not** considered in MS-DRG assignment in those cases
    - Hospital acquired conditions (HACs) that arise during that stay are **not** considered in MS-DRG assignment
  - Procedures performed during that stay (UB-04, FLs 74, 74a-e)
  - Gender and discharge status
- **Identification, documentation and reporting of all relevant factors is essential for appropriate MS-DRG assignment and payment**

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MS-DRGs

- For cases with the same principal diagnosis and principal procedure, there may be as many as three separate payment groups:
  1. A base DRG with no additional secondary diagnosis that increases resource use
  2. A slightly higher paying DRG with at least one secondary diagnosis designated as a complication or comorbidity **(CC)** that increases resource use
  3. An even higher paying DRG with at least one secondary diagnosis designated as a major CC **(MCC)** that significantly increases resource use

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MS-DRGs

- CMS is required to annually update the MS-DRGs to which cases will be assigned, as well as their respective payment rates, to account for changes in the prices of goods and services used by hospitals to treat Medicare patients
  - In doing so, CMS considers the patient specific factors noted above and other related operating and capital costs (e.g., labor, utilities, land)
  - This annual update is known as the hospital market basket update (MBU)
- The best resource on MS-DRG assignment is the *MS-DRG Definitions Manual*
  - For ordering information on the *MS-DRG Definitions Manual*, see http://solutions.3m.com/wps/portal/3M/en_US/3MHIS/HealthInformationSystems/products-services/product-list/definition-manuals/

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MS-DRGs

- As part of this ongoing refinement process, CMS applies the following criteria to determine if the creation of a new NonCC, CC or MCC subgroup within a base MS–DRG is warranted:
  - A reduction in variance of costs of at least 3 percent;
  - At least 5 percent of the patients in the MS–DRG fall within the NonCC, CC, or MCC subgroup;
  - At least 500 cases are in the NonCC, CC, or MCC subgroup;
  - There is at least a 20-percent difference in average costs between subgroups; and
  - There is a $2,000 difference in average costs between subgroups
- All 5 criteria must be met to create a new subgroup

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MS-DRGs

- The following tables reflect the finalized severity levels under Version 39 of the ICD-10 MS-DRGs for FY 2022
  - Table 6I. — Complete MCC List--FY 2022
  - Table 6I.1—Additions to the MCC List--FY 2022
  - Table 6I.2—Deletions to the MCC List--FY 2022
  - Table 6J. — Complete CC List--FY 2022
  - Table 6J.1—Additions to the CC List--FY 2022
  - Table 6J.2—Deletions to the CC List--FY 2022

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MS-DRG Changes: CAR-T

- In FY 2021, CMS created new **MS-DRG 018 (Chimeric Antigen Receptor [CAR] T-cell Immunotherapy)** for cases that include procedures describing CAR T-cell therapies
- For FY 2022, CMS finalized the following related proposals:
  - To continue to assign listed procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC MS–DRG 018,
  - To modify the title of Pre-MDC MS–DRG 018 to **"Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies"** to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies, and
  - To continue to apply an adjustment of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018

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20% Increase to COVID-19 MS-DRGs

- For an individual diagnosed with COVID-19 during the PHE, the CARES Act directs DHHS to increase the weighting factor of the discharge MS-DRG by 20 percent to determine the IPPS operating payment
- Discharges of an individual diagnosed with COVID-19 must be identified by either of the following ICD-10-CM diagnosis codes:
  - B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020, or
  - U07.1 (COVID-19) for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE

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20% Increase to COVID-19 MS-DRGs

- Effective for admission on/after 9/1/20, claims eligible for 20 percent increase require a positive COVID-19 laboratory test documented in the MR
  - Positive tests must be based only on results of viral testing (i.e., molecular or antigen), consistent with CDC guidelines
  - Test may be performed either during, or prior to, the hospital admission
    - If prior to admission, must generally be performed within 14 days of admission
  - OIG has indicated it will be auditing COVID-19 cases, beginning with admissions on/after 9/1/20

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20% Increase to COVID-19 MS-DRGs

- CMS may conduct post-payment medical review to confirm the presence of a positive COVID-19 laboratory test
  - If no test is contained in the MR, the additional payment resulting from 20 percent increase in MS-DRG relative weight will be recouped
  - If hospital diagnoses patient with COVID-19 per ICD-10-CM guidelines, but does not have positive test result in MR, it can decline, at the time of claim submission, the additional 20% payment to avoid recoupment
- See most recent revision of SE20015 for more details
  - Also applies to hospital-specific payment rates for sole community hospitals (SCHs) and Medicare dependent hospitals (MDHs) and per diem transfer payments

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IPPS Quality Update

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Interoperability and Meaningful Quality Measures

- In the FY 2022 IPPS final rule, CMS made a number of changes to the following programs:
  - Medicare Promoting Interoperability Program (MPIP), formerly referred to as the Electronic Health Record (EHR) Program
  - Hospital Inpatient Quality Reporting Program (HIQRP)
  - Hospital Readmissions Reduction Program (HRRP)
  - Hospital Value-Based Purchasing Program (HVBPP)
  - Hospital-Acquired Condition (HAC) Reduction Program (HACRP)

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MPIP

- CMS established the MPIP to encourage eligible professionals, hospitals, and critical access hospitals (CAH) to adopt, implement, upgrade, and demonstrate meaningful use of CEHRT.
  - IPPS hospitals that fail to meet their MPIP/EHR requirements are subject to a three-fourths reduction in their IPPS market basket update

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MPIP

- CMS is finalizing the following changes to the MPIP:
  - Continuing the EHR reporting period of any continuous 90-day period for new and returning eligible hospitals/CAHs for CY 2023 (continuous 180-day period for CY 2024)
  - Maintaining the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing bonus from 5 to 10 points for EHR reporting period in CY 2022
  - Adding a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation as an optional alternative to the two existing measures beginning with EHR reporting period in CY 2022
  - Requiring reporting a "yes" on four of the existing Public Health and Clinical Data Exchange Objective measures or requesting the applicable exclusion(s)
  - Adding a new measure to the Protect PHI objective that requires eligible hospitals and CAHs to attest to having completed an annual assessment of SAFER Guides beginning with EHR reporting period in CY 2022
  - Removing attestation statements 2 and 3 from MPIP's prevention of information blocking requirement

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MPIP

- Increasing minimum required score for objectives and measures from 50 points to 60 points (out of 100 points) to be considered a meaningful EHR user
- Adopting two new eCQMs to the MPIP's eCQM measure set, beginning with reporting period in CY 2023 and removing three eCQMs from the measure set, beginning with reporting period in CY 2024, in alignment with eCQM updates being finalized for HIQRP

- CMS is not, however, finalizing two of its proposals:
  - To remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436) in alignment with HIQRP
  - To modify the Provide Patients Electronic Access to Their Health Information measure by requiring eligible hospitals and CAHs to ensure that PHI remains available to the patient (or their representative)

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HIQRP

- The HIQRP is a pay-for-performance quality program that reduces payment to an IPPS hospital that fails to meet applicable requirements for timely and reliable reporting of key clinical measures
  - Hospitals that fail to meet HIQRP reporting requirements are subject to a one-fourth reduction in their market basket update under the IPPS
- CMS is finalizing the adoption of five new measures:
  - A new structural measure—Maternal Morbidity Structural Measure—beginning with shortened reporting period from October 1, 2021 through December 31, 2021 affecting CY 2021 reporting period/FY 2023 payment determination
  - The Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure in a stepwise fashion, beginning with voluntary reporting period from July 1, 2022 through June 30, 2023, followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting FY 2026 payment and subsequently

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HIQRP

- The COVID-19 Vaccination Coverage among Health Care Personnel (HCP) measure, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting CY 2021 reporting period/FY 2023 payment determination and quarterly reporting beginning with FY 2024 payment and subsequently
- Two medication-related adverse event eCQMs, beginning with CY 2023 reporting period/FY 2025 payment determination
  - Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e)
  - Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e)

- CMS is also finalizing the removal of three measures:
  - The Exclusive Breast Milk Feeding (PC-05) (NQF #0480), beginning with FY 2026 payment determination
  - The Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) (NQF #0497), beginning with FY 2026 payment determination
  - The Discharged on Statin Medication eCQM (STK-06) (NQF #0439), beginning with the FY 2026 payment determination

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HIQRP

- Finally, CMS is finalizing its proposal that, beginning with CY 2023 reporting period/FY 2025 payment determination, hospitals will be required to use certified EHR technology (CEHRT) that has been updated consistent with the 2015 Edition Cures Update and supports the reporting requirements for all available eCQMs
  - Hybrid measures will also be required to comply with the same certification requirements as eCQMs

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HRRP

- The HRRP is a pay-for-performance quality program that reduces payment to an IPPS hospital for a discharge to account for excess readmissions for selected conditions
  - When hospital has excess readmissions during the applicable period (July 1, 2017 - June 30, 2020 for FY 2022 payment), CMS will reduce the hospital's base operating DRG payments up to 3% for *all* discharges during that payment year to account for excess readmissions for selected conditions during the applicable period
  - A readmission occurs when a patient is discharged from an initial index hospital and admitted to the same or a different hospital within 30 days of discharge.
    - CMS does not count certain patients (e.g., discharge AMA, under 65) or readmissions (e.g., transfers, planned readmissions) for purposes of determining the number of excess readmissions.

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HRRP

- CMS is finalizing the following policies for the HRRP:
  - Adopting a cross-program measure suppression policy for the duration of the public health emergency for COVID-19
  - Suppressing the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2023 program year
  - Modifying the remaining five condition-specific readmission measures (acute myocardial infarction [AMI], heart failure [HF], Pneumonia [PN], elective total hip arthroplasty [THA] or total knee arthroplasty [TKA], chronic obstructive pulmonary disease [COPD]) to exclude COVID-19 diagnosed patients from the measure denominators, beginning with the FY 2023 program year
  - Using the MedPAR data that aligns with the applicable period for FY 2022 (July 1, 2017 through June 30, 2020)
  - Adopting automatically the use of MedPAR data corresponding to the applicable period beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary
  - Updating the regulatory text to reflect the renaming of the Hospital Compare website, which is now referred to as Care Compare

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HVBPP

- The HVBPP is a pay-for-performance quality program that provides value-based incentive payments to an eligible IPPS hospital that meets or exceeds certain performance standards, resulting in an increase to the hospital's base operating DRG payments
  - A hospital's eligibility for and amount of incentive payments is based on its FY Total Performance Score (TPS), which is the **higher** of two scores for each measure:
    - Improvement: comparing a hospital's performance during a base year to its performance during the performance period
    - Comparison to peers: comparing a hospital's performance against that of its peers during the performance period
  - Because the HVBPP is budget neutral, these incentive payments are funded by a prescribed percentage reduction (currently 2%) to total base operating DRG payments of all eligible participating hospitals

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HVBPP

- CMS is finalizing the following proposals for the HVBPP:
  - To establish for the duration of the COVID-19 PHE a measure suppression policy to ensure that hospitals are neither rewarded nor penalized based on circumstances caused by the PHE
  - To suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Medicare Spending Per Beneficiary (MSPB), and the five current CDC National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures for the FY 2022 program year
  - To suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia (PN) Hospitalization (MORT-30-PN) measure for the FY 2023 program year
  - To remove the Patient Safety and Adverse Events Composite (CMS PSI 90) measure beginning with the FY 2023 program year (which will continue to be included in the HACRP) because the costs associated with the measure outweigh the benefit of its use in the program

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HVBPP

- Because of suppression of measures in all but the Clinical Care Domain, CMS believes calculating a TPS for hospitals using only data from the remaining measures would not result in a fair national comparison
- Instead, CMS is finalizing the following proposals:
  - To award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (two percent)
  - To update the baseline periods for certain measures affected by the Extraordinary Circumstances Exception (ECE) granted in response to the COVID-19 PHE and make related technical updates to terminology used in the HVBPP regulations

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HACRP

- The HACRP is a pay-for-performance quality program designed to reduce the number of HACs that arise during an inpatient stay in an IPPS hospital
  - HACs are specified high-cost and/or high-volume conditions CMS determines to be reasonably preventable
  - Under the HACRP, CMS reduces the sum of the adjusted operating and capital DRG payments for each discharge from an applicable hospital by 1%
  - An applicable hospital is a hospital in the top quartile of hospitals with the highest number of HACs reported during the applicable periods
    - The applicable periods for FY 2022 are the following:
      - For CMS PSI-90, the 24-month performance period is July 1, 2018 - June 30, 2020
      - For the five CDC NHSN HAI measures, the 24-month performance period is January 1, 2019 - December 31, 2020

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HACRP

- Beginning in FY 2023, the applicable period for both the CMS PSI 90 and CDC NHSN HAI measures will be the 24-month period beginning one year after the start of the applicable period for the previous program year
- In the FY 2022 IPPS final rule, CMS is also clarifying its ECE policy and finalizing the following three proposals:
  - To adopt a cross-program measure suppression policy for the duration of the PHE for COVID-19
  - To apply that measure suppression policy to suppress certain program data from the HACRP for FYs 2022, 2023, and 2024
  - To update the regulatory text to reflect that the Hospital Compare website has been renamed and is now referred to as Care Compare

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Transfers and Post-Acute Care Transfers

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Post Acute Care Transfer (PACT) DRGs

- PACT Rule applies to
  - Specified MS-DRGs
    - For FY2022, there are 280 PACT MS-DRGs (designated on Table 5 of the IPPS rule)
      - 42 of these are Special Pay PACT MS-DRGs subject to special payment calculation (designated on Table 5 of the IPPS rule)
  - Transfers to applicable settings
    - Non-IPPS Hospitals or distinct parts (IRF, IPF, LTAC, children's, cancer
    - SNF, but not swing bed, for skilled care, whether or not covered or paid by Medicare
    - HHA for related care within 3 days of discharge
    - Hospice (effective FY2019)

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Post Acute Care Transfer (PACT) DRGs

- PACT Payment
  - Normal payment calculation is based on a per diem, calculated by dividing the DRG payment by the GMLOS
    - 2 per diems are paid for the first day of the stay and 1 per diem for each other day
    - Payment is capped at the full MS-DRG payment
    - Note: full payment is made as long as the length of stay is within 1 day of the GMLOS
  - Special payment calculation to account for procedural costs at the beginning of the stay for specified MS-DRGs
    - ½ the total DRG payment plus ½ a per diem for the first day of the stay and ½ a per diem for each other day

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OIG reports on PACT

- Prior Audits related to PACT
  - 10/1999 – 9/2000 - $61 million overpayments
  - 10/2002 – 9/2005 - $24.8 million overpayments
  - 1/2009 – 9/2012 - $19.5 million overpayments – edits not working properly
- November 2019 Audit
  - 1/2016 – 12/2018 - $54.4 million overpayment
  - 83% were followed by a claim for Home Health
  - OIG identified hospitals can override automatic edits with condition codes for HH claims
- August 2020 Audit
  - 10/2015 – 9/2017 - $267 million overpayment
  - Audit focused on inpatient claims with a HH claim within 3 days of discharge
  - 147 errors of 150 claims reviewed
  - Recommended legislative action to make all HH discharged defined as “related”

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CMS Responded

- SE20025, December 1, 2020
  - Short review of the PACT and Condition Code 42 and 43 without details on their use
- SE21001, February 22, 2021
  - Reviewed discharges, acute care transfers, and PACT
  - Special section on transfers to home with home health
- Transmittal 10952, August 19, 2021, replaced with 11189 January 12, 2022
  - Revised Medicare Claims Processing Manual, Chapter 3 § 40.2.4

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CMS Responded

- Medicare Claims Processing Manual, Chapter 3 § 40.2.4
  - Clarified acute care transfer occurs when:
    - Transfer to another IPPS hospital for related care
    - Admitted to another IPPS hospital on same day after leaving against medical advice
    - Admitted to another IPPS hospital on the same day as discharge, unless unrelated
    - Transfer to a non-participating hospital that would otherwise be eligible to be paid under IPPS
    - Transfer to a Critical Access Hospital (CAH)
  - Added all discharge status codes for planned readmissions
  - Added hospice discharges to the PACT section
  - A new section on discharges where the patient receives home health

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PACT rules related to HH

- Rules related to PACT and discharges to Home Health
  - PACT applies when a patient is admitted to HH
    - Within three days of discharge
      - Condition code 43 may be reported if the HH care is related to the inpatient hospital services but no HH services are furnished within 3 days of the hospital discharge
    - For continuing care related to the condition or diagnosis the individual received inpatient hospital services
      - Condition code 42 may be reported if the patient is discharged to home with HH, but the continuing care is not related to the condition or diagnosis for which the patient received inpatient hospital services
      - The PACT applies to resumption of HH services in place prior to the inpatient stay
    - Claims reported with condition codes 42 or 43 do not trigger PACT payment

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PACT rules related to HH

- Rules related to PACT and discharges to Home Health
  - Claims systems review all LIDOS on HH claims for services within 3 days after the IPPS discharge date
    - OIG found CMS edits were not complete and not applied consistently
  - If a hospital learns the PACT should apply (i.e., HH care was related or provided within 3 days) the hospital should submit an adjustment claim

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Repeal of MCIT and "Reasonable and Necessary" Rule

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Repeal of Regulation Defining "Reasonable and Necessary"

- January 14, 2021, CMS published a final rule:
  - To adopt a regulatory definition of reasonable and necessary and
  - Medicare Coverage of Innovative Technology (MCIT)
- Reasonable and Necessary
  1. Safe and effective
  2. Not experimental or investigational
  3. Appropriate for Medicare patients, including the duration and frequency considered appropriate for the item or service, in terms of whether it is:
     - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
     - Furnished in a setting appropriate to the patient's medical needs and condition;
     - Ordered and furnished by qualified personnel;
     - One that meets, but does not exceed, the patient's medical need; and
     - At least as beneficial as an existing and available medically appropriate alternative

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Repeal of Regulation Defining "Reasonable and Necessary"

- What's was new in the proposal
  - Current definition of reasonable and necessary is addressed in Program Integrity Manual
  - As alternative to criteria in #3 a service would be appropriate for Medicare patients if it is ***covered in the commercial insurance market***, except where evidence supports there are clinical differences between Medicare beneficiaries and commercially insured individuals
    - A commercial market analysis would be initiated if an item or service fails to fulfill factors in #3
    - Seeking comment on most appropriate sources for commercial coverage policies, limitations or subsets such as number of enrollees or plan type (HMO, PPO, etc.), majority of plans or plurality
    - Would be deferred to MACs to "tailor restrictions" based on what they observe in the commercial market in LCD or claim by claim determinations
    - Admit it could expand or narrow coverage

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Repeal of Regulation Defining "Reasonable and Necessary"

Medicare Coverage of Innovative Technology (MCIT)

- Provides coverage for devices designated an FDA Breakthrough Device and are market authorized
- FDA Breakthrough Device:
  - Device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or condition
  - Meets one of these criteria
    - Represents a breakthrough technology, or
    - No approved/cleared alternative exists, or
    - it offers advantages over existing alternatives, or
    - availability is in the best interest of patients

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Repeal of Regulation Defining "Reasonable and Necessary"

Medicare Coverage of Innovative Technology (MCIT)

- Coverage would begin immediately upon market authorization, unless there is no Medicare benefit category or it is excluded from coverage
  - Purpose is to eliminate coverage uncertainty between FDA market auth and finalization of an NCD or LCD
  - Coverage for use consistent with the FDA approved/cleared indication for use and does not include off-label use
  - Continues up to 4 years, after which CMS will issue NCD for coverage or non-coverage or defer to MAC discretion to develop LCD or claim by claim
  - Can cover devices that received breakthrough designation prior to the effective date of the rule if the device is placed after the effective date of the rule

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Repeal of Regulation Defining "Reasonable and Necessary"

Regulatory delays and repeal timeline:

- January 14, 2021: Final Rule published by CMS prior to the change of administration adopting new reasonable and necessary definition (R&N) and MCIT
- January 20, 2021: 60 day "Regulatory Freeze Pending Review" delayed implementation of R&N/MCIT rule
- March 17, 2021: Interim Final Rule with Comment Period effective March 12 delayed R&N/MCIT rule until May 15 and opened a 30-day comment period
- May 18, 2021: Final Rule effective May 14 delayed R&N/MCIT rule until December 15
- September 15, 2021: Proposed Rule to repeal R&N/MCIT rule with 30-day comment period
- November 15, 2021: Final Rule repealing R&N/MCIT effective December 15, 2021

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Regroup on Utilization Review

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Medicare Inpatient Certification Requirements

Certification is required as a condition of payment for certain cases under Part A

- For PPS hospitals, Medicare requires certification for two distinct situations:
  - Cases 20 days in length, by the 20th day
  - Outlier, if no 20-day certification, by the date the hospital requests outlier payment
- For Critical Access Hospitals (CAH), a "good faith" certification that the patient will be transferred or discharged within 96 hours, by one day before the claim
- Inpatient psychiatric facilities (IPFs) have separate certification and recertification requirements for each admission
  - See 42 *CFR* 424.14, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 4 § 10.9, Medicare Benefit Policy Manual, Chapter 2 § 30.2.1
- Inpatient rehabilitation facilities (IRFs) have additional pre-screening and initial evaluation requirements

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Medicare Inpatient Certification Requirements

IPPS Certification requirements

- Certifying physician includes
  - Attending/admitting physician;
  - Surgeon responsible for a major procedure; OR
  - Staff physician on behalf of a NPP, after reviewing case and must enter full certification
- Format
  - Forms, notes or records reflected required elements, sign by the physician along with a separate signed statement the services are, were or continue to be medically necessary; OR
  - Separate form redocumenting all elements and a statement that the services are, were or continue to be medically necessary

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Medicare Inpatient Certification Requirements

IPPS Certification requirements

- Elements of the certification
  - The reason for continued hospitalization for inpatient medical treatment or diagnostic testing (extended stay) or the special or unusual services resulting in cost outlier
  - The estimated time the patient requires hospitalization, if before discharge, or the actual time the patient was hospitalized if after discharge (outlier)
  - Plans for post discharge care, if appropriate

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Medicare Inpatient Certification Requirements

CAH certification

- "Good faith" certification that the patient may "reasonably be expected to be discharged or transferred to another hospital within 96 hours
  - A CAH must maintain an average annual length of stay of 96 hours, but any individual stay longer than 96 is payable as long as the physician is able to make a good faith certification
  - Time spent in outpatient care does not count toward the 96 hours
  - During the PHE, CMS waived the 96-hour requirement
- If the physician cannot make or refused to make the "good faith" certification, the CAH cannot be reimbursed for any portion of the admission
  - CMS has announced that effective October 1, 2017 their contractors will make the 96-hour certification a low priority during medical review absent concerns of fraud, waste, and abuse
  - CMS also stated the OIG and Dept of Justice will continue reviews and enforcement because the requirement is statutory and cannot be removed by CMS

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Medicare Inpatient Certification Requirements

Certification of continued hospitalization if no SNF bed is available

- Continued inpatient hospitalization is covered if
  - The patient requires skilled care at a SNF
  - No SNF bed is available at a participating SNF
  - The physician certifies the need for continued hospitalization on that basis
  - The physician (?) continues to make placement efforts
- Coverage ends when
  - A bed becomes available at a participating SNF
  - The patient no longer needs SNF care
  - The patient exhausts their Part A inpatient hospital benefit days
- "Alternate placement days can count toward three-night requirement for SNF coverage

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Medicare Inpatient Certification Requirements

Certification of continued hospitalization if no SNF bed is available does not apply in CAHs or small rural hospitals with swing beds to "swing" the patient to SNF

- Normally, swing beds are limited to rural hospitals with less than 100 beds
- At a CAH, paid at cost basis similar to other CAH services
- At a PPS hospital, paid under the SNF PPS – requires submission of information for the PDPM payment groups under the SNF PPS
  - Difficult for hospitals who don't typically bill SNF PPS to bill correctly

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Medicare Inpatient Certification Requirements

During the PHE, CMS also expanded the ability of large and urban hospitals to offer “swing bed” services for patients they are unable to find placement in a SNF

- Requirements
  - The SNF swing beds can’t be used for acute level care
  - The hospital must comply with all non-waived CoPs
  - Be consistent with the state emergency preparedness plan
- Hospital must attest to CMS
  - They have made a good faith effort to exhaust all other options
  - There are no SNFs within the hospital’s catchment area currently willing to accept or able to take patients because of the COVID-19 PHE
  - The hospital meets the waiver eligibility requirements
  - They have a plan to discharge patients as soon as practicable when a SNF bed becomes available or the PHE ends, whichever is earlier

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Short Stay Audits

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Audit Strategy

History of CMS audits for short stays (i.e., less than two midnights)

- Prior to 10/1/13 – RACs did inpatient medical necessity reviews
- 10/1/13 – 10/1/15 – MACs audit compliance with new policies for admission (the two midnight rule), orders and certification adopted 10/1/13
- 10/1/15 – 5/8/19 QIOs conduct short stay audits
  - From May to September of 2016, CMS paused QIO audits and instructed the QIOs to re-audit certain claims and pay other denied claims due to poor quality of the audits
  - 5/8/19 CMS paused audits due to changes in QIO jurisdictions causing delays with other regulatory functions of the QIOs – intended to restart third quarter 2019
- 4/2021 – Livanta received sole contract to audit short stays
  - Livanta posted a schedule for monthly audits beginning 10/4/21, but few details on how they would conduct audits

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Audit Strategy

Livanta has announced:

- Reviews will consist of 30 claims within a rolling 3- month period
- Records are submitted via esMD, DSM, or e-LiFT
- Before denying payment, the hospital will be provided an opportunity for discussion through a faxed letter
  - If the hospital does not respond the MAC and beneficiary will be notified of the denial
  - If the hospital responds, the “response” is taken into consideration when making the final determination
- A summary report with all findings will be issued for educational purposes
  - Educational one-on-one teleconferences will be scheduled when results indicate a need for education

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Audit Strategy

Audit strategy adopted for CY2021 for procedures removed from the IPO list

- Services removed from IPO list in 2020 (i.e., THA) - 42 *CFR* 412.3(d)(2)(i)
  - Exempt from denial (but not audit) for 2 years (CY2020 and CY2021)
- Services removed from IPO list in 2021 and later - 42 *CFR 412.3(d)(2)(ii)*
  - Exempt from denial (but not audit) for ***an indefinite period*** until data shows procedure is more commonly performed on an outpatient basis (i.e., more than 50% of the time)
    - Determination is based on Medicare claims data
    - ***Evaluated on a yearly basis*** and CMS will "revisit in rulemaking whether and when an exemption for a procedure should be ended" (CY2021 OPPS Final Rule, 85 Fed. Reg. 86119)

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Audit Strategy

Audit strategy amended for CY2022 based on reversal of the policy to eliminate the IPO list

- CMS amended 42 *CFR* 412.3 (d)(2)(i) to indicated services removed from the IPO list on or after January 1, 2020 would be exempt for 2 years
- CMS failed to amended 42 *CFR* 412.3(d)(2)(ii), adopted in 2021, and it still provides for an exemption for procedures removed on or after January 1, 2021 until the procedure is more commonly performed on an outpatient basis
  - This would seem to override the prior section r/t on or after January 1, 2020, even though CMS' stated intention in the CY2022 OPPS Final Rule in amending (d)(2)(i) was to implement a 2 year exemption period

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Audit Strategy

During exemption period, contractors

- Will continue medical review of short stays for procedures removed from the IPO List
  - Medical necessity of the procedure; and
  - Medical necessity for the site of service
- Will not deny cases for the incorrect site of service (i.e., noncompliance with the two-midnight rule)
  - Will provide education to the provider for the noncompliant claims
  - Will not be used for referral to RAC for non-compliance reviews
  - RAC will not conduct site of service reviews
- CMS reserved the right to conduct audits if there is evidence of fraud or abuse

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Audit Strategy

CMS regarding the exemption:

> …Whether a procedure has an ***exemption or not***, does not change what site-of-service is medically necessary or appropriate for an individual beneficiary. Providers are still expected to use their ***complex medical judgment to determine the appropriate site of service*** for each patient and to bill in compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and site-of-service claim denials. (CY2022 OPPS Final Rule, 86 Fed. Reg. 63739)

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Audit Strategy

CMS regarding the exemption:

Old language:

…The ***indefinite exemption*** will help hospitals and clinicians become used to the ***availability of payment*** under both the hospital ***inpatient and outpatient*** setting for procedures removed from the IPO list. (CY2021 OPPS Final Rule, 85 Fed. Reg. 86120)

New language:

…we explained that it was our belief that the ***2-year exemption*** from referrals to RACs, RAC patient status review, and claim denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures ***eligible to be paid under either the IPPS or the OPPS***, while avoiding potential adverse site-of-service determinations. (CY2022 OPPS Final Rule, 86 Fed. Reg. 63739)

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Audit Strategy

And don't forget about the 2-Midnight Presumption

…for services removed from the IPO list, ***under the 2-Midnight presumption***, inpatient hospital claims with lengths of stay greater than ***2 midnights after admission*** will be ***presumed to be appropriate*** for Medicare Part A payment and would ***not be the focus of medical review*** efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. (CY2021 OPPS Final Rule, 85 Fed. Reg. 86115, CY2022 OPPS Final Rule, 86 *Fed. Reg*. 63738)

Translation: inpatient lengths of stay of 2 days or greater are effectively 'exempt' from audit

- This is independent of the list of procedures removed from the inpatient only list and exempt from denial, but not audit

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Audit Strategy

And we might get some help from CMS:

> …in the future, we ***plan*** to provide ***information on appropriate site of service selection*** to support physicians' decision-making. We note that these considerations will be for ***informational or educational purposes*** only and will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting. (CY2021 OPPS Final Rule, 85 Fed. Reg. 86088)

Although 2022 seems less certain:

> …In the future, we ***may*** provide additional ***educational material*** regarding considerations for the ***selection of site-of-service*** for a procedure to support physicians' decision making. We note that this additional information will be for ***informational or educational purposes only*** and will not be intended to prohibit payment of procedures that were previously included on the IPO list in the outpatient setting. (CY2022 OPPS Final Rule, 86 *Fed. Reg.* 63740)

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Outpatient Observation and the Myth of Inpatient Level of Care

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Outpatient Services and the 2-Midnight Rule

Let's let CMS tell it in their own words:

- From the 2021 OPPS Final Rule (85 Fed. Reg. 86114), "B. Medical Review of Certain Inpatient Hospital Admissions…"

> …for purposes of determining whether the ***2-Midnight benchmark is met*** and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including ***the total time spent receiving hospital care***—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving ***outpatient services, such as observation services, treatments in the emergency department, and procedures*** provided in the operating room or other treatment area.

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Outpatient Services and the 2-Midnight Rule

Let's let CMS tell it in their own words:

- From the 2021 OPPS Final Rule (85 Fed. Reg. 86114), "B. Medical Review of Certain Inpatient Hospital Admissions…"

> …while the ***time the beneficiary spent as an outpatient*** before the admission order is written is not considered inpatient time, it ***is considered during the medical review*** process for purposes of determining whether the ***2-Midnight benchmark*** was met. Pg. 742 of the display copy.
>
> …because ***time spent as an outpatient should be considered*** in determining whether there was a reasonable expectation that the ***hospital care*** would span 2 or more midnights.

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Outpatient Services and the 2-Midnight Rule

But this has been CMS' message from the start

> …if the beneficiary has already ***passed 1 midnight as an outpatient observation patient*** or in routine recovery following outpatient surgery, the physician should consider the 2-midnight benchmark met if he or she expects the beneficiary to ***require an additional midnight in the hospital.*** This means that the decision to admit becomes easier as the time approaches the second midnight, and beneficiaries in medically necessary hospitalizations ***should not pass a second midnight prior to the admission order being written.*** (FY2014 IPPS Final Rule, 78 Fed. Reg. 50946)

> …Because we expect that this revision ***should virtually eliminate the use of extended observation***, we also anticipate it will concurrently limit beneficiary cost-sharing for outpatient services. (FY2014 IPPS Final Rule, 78 Fed. Reg. 50946)

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Outpatient Services and the 2-Midnight Rule

But what about an inpatient level of care, doesn't the patient need to meet inpatient level of care?

> …we ***do not refer to "level of care"*** in guidance regarding hospital inpatient admission decisions. Rather, we have consistently provided physicians with the aforementioned ***time-based admission framework*** to effectuate appropriate inpatient hospital admission decisions. (FY2014 IPPS Final Rule, 78 Fed. Reg. 50945)

> …the beneficiary's required ***"level of care" is not part of the guidance regarding hospital inpatient admission*** decisions. Rather, we provide physicians with a 2-midnight admission framework to effectuate appropriate inpatient hospital admission decisions. (FY2014 IPPS Final Rule, 78 Fed. Reg. 50947)

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Outpatient Services and the 2-Midnight Rule

So where does that leave us?

- Covered outpatient services (such as observation, ED and outpatient procedures) should be counted towards the two-midnight rule
  - Documentation must show the services as ***covered, hospital level of care***
  - Observation can be problematic because of patients receiving non-covered/custodial care
- The patient ***never needs to meet an inpatient level of care***, as specified by third party criteria, to meet the two-midnight benchmark for Medicare
- Part A payment is appropriate (and inpatient admission) based ***solely on a medically necessary outpatient / observation*** level of care that last two midnights
  - Remember that an inpatient admission order is required to bill inpatient Part A

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Outpatient Services and the 2-Midnight Rule

- Non-covered care has to be excluded from the 2-Midnight determination
  - Failure to identify non-covered observation time could lead to inappropriate orders for inpatient care
  - Systematic inclusion of non-covered observation time could lead to accusation of gaming or abuse and loss of the 2-Midnight Presumption (presumption of coverage for two night stays)
  - The OIG is beginning to focus on non-covered observation resulting in inappropriate outlier payments – discussed below

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Outpatient Services and the 2-Midnight Rule

Observation not covered if:

- It is provided for the convenience of the patient/family/physician
  - Patients waiting for a ride, waiting for a transfer or waiting because of delays in care may fall in this category
  - Manual guidance seems to indicate that care provided to avoid inconvenience that affects the patient's health may be considered in determining care provided toward 2-midnight benchmark

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Outpatient Services and the 2-Midnight Rule

Observation not covered if:

- It's bundled into other care (i.e., already reported as part of other care)
  - Standard preparation for diagnostic/ surgical/ therapeutic services
  - Post op monitoring during standard recovery period
  - Monitoring incident to other diagnostic/ surgical/ therapeutic services
    - This may include colonoscopy, PICC line placement, chemotherapy, injections/infusions that require active monitoring
    - Note that this was the issue in at least one OIG audit report this year, and specifically called out by the OIG

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Outpatient Services and the 2-Midnight Rule

Observation not covered if:

- It is not reasonable and necessary (i.e., not medically necessary at a hospital)
  - Patients with placement issues or no safe discharge may fall in this category
  - Consider providing the patient an ABN
  - More than 48 hours generally considered not medically necessary – but CMS implemented MUE of 72 hours?
    - If 48 hours are ***medically necessary*** patient should have been admitted ***under the 2-midnight benchmark***

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Outpatient Services and the 2-Midnight Rule

What About Safe Discharge?

- Hospitals are required to provide discharge planning:
  - Determining appropriate post-hospital discharge destination
  - Identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination
  - Beginning the process of meeting the patient's identified post-discharge needs

BUT

Medicare ***only pays for***

medically necessary ***hospital*** care

and specified post discharge care

(***skilled nursing, home health, hospice***)

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Outpatient Services and the 2-Midnight Rule

What does that mean?

Hospitals have a responsibility to plan
for and make a safe discharge for the patient

BUT

Medicare doesn't have to pay for it

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Recent OIG Audit Activity Related to Observation

OIG Audits of outlier payments related to observation

- February 2020: CHI St. Vincent Infirmary
  - Audit was focused on outpatient outlier payments
  - Among many other problems, in review of 120 claims the OIG found 14 claims that overcharged for observation time, one claim did not have a physician order
  - Overpayment $362,999 – did not delineate portion attributable to outlier payments for observation overcharges

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Recent OIG Audit Activity Related to Observation

OIG Audits of outlier payments related to observation

- September 2020: Baylor, Scott and White – College Station
  - Audit focused on outpatient outlier payments
  - 30 claims found with overcharged observation time: 24 claims where observation was charged instead of extended recovery; 6 claims where observation was billed while other outpatient services were being performed
  - "College Station stated that it does not perform utilization review for observation services less than 24 hours."
  - Overpayments $189,276 – did not delineate portion attributable to observation

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OIG Audit Activity

OIG Audits, oh and….

- Short Stay Audits were added to the OIG Work plan in November 2020:
  - "While the OIG previously stated that it would not audit short stays after October 1, 2013, this serves as notification that the OIG will begin auditing short stay claims again, and when appropriate, recommend overpayment collections."

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OIG Audit Activity

And that's scary because…

- December 2020: Providence Medical Center
  - General compliance audit
  - Found 13 claims alleged to not comply with 2-midnight rule
  - Hospital response:
    - Cases met 2-Midnight Presumption
    - Cases were 2 midnights in length complying with the 2-midnight rule
    - Contractor incorrectly applied a standard of the "inpatient care is indicated when a patient can only be safely managed in an inpatient setting"
  - OIG's response:
    - We are not bound by the 2-Midnight Presumption
    - The contractor "***assured us*** that its determinations were based on the regulatory requirements"

Leveraging Self-Denials

Comparing Self-Denials (CCW2) and CC44

Payment for inpatient cases "not appropriate for Part A payment" fundamentally changed October 1, 2013:

Prior to October 1, 2013

- Condition code 44 (changing the patient to outpatient) was ***the only way*** to get full payment under Part B
- Very limited *inpatient* part B payment

After October 1, 2013

- Self-denials allowed expanded inpatient part B payment to get full payment under Part B in most cases

So why use ***self-denial (CCW2)*** vs. ***CC44*** billing?

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Comparing Self-Denials (CCW2) and CC44

Self-denial (CCW2) and CC44 are both used when:

- The attending physician writes an inpatient order
- UR indicates the patient is not appropriate for/does not qualify for inpatient Part A payment

Both Self-denial (CCW2) and CC44:

- Require review by UR committee representative under UR CoP
- Use CPT/HCPCS codes for billing
- Are paid under Part B through OPPS
- Trigger co-insurance for the patient under Part B rules

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Comparing Self-Denials (CCW2) and CC44

- What is the difference between self-denial (CCW2) and CC44?

	Self-Denial (CCW2)	CC44
UR Determination	Any time **after** discharge	**Before** discharge
Notice	**Within two days** of determination	**Before** discharge
Patient status	**Outpatient** (TOB 13X) and/or **Inpatient** (TOB 12X)	**Outpatient** (TOB 13X)
Attending Physician	Concurrence **not required**, only offer opportunity to give input	Concurrence **required**
Payable	All covered services (except some nursing ancillary services for some hospitals/cases – more later)	All covered services

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Case Study 1

- Patient presents at 8 a.m. for total knee arthroplasty
- The procedure is scheduled as an inpatient procedure and the physician writes an inpatient order prior to the procedure
- At 1 p.m. UR determines inpatient Part A payment is inappropriate because the physician did not reasonably expect the patient to stay two midnights
- Condition Code 44 procedures are followed and patient is changed to outpatient at 3 p.m.
- Patient stays overnight and is discharged after a normal course of care at 4 p.m. the next day

How would this case be billed and paid?

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Case Study 1

How would this case be billed and paid?

- The total knee arthroplasty is billed on an outpatient claim (TOB 131) with CC44 and paid OPPS rate ($12,593)

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Case Study 2

- Patient presents at 8 a.m. for total knee arthroplasty
- The procedure is scheduled as an inpatient procedure and the physician writes an inpatient order prior to the procedure
- Patient stays overnight and is discharged after a normal course of care at 4 p.m. the next day
- After discharge, UR determines inpatient Part A payment is inappropriate because the physician did not reasonably expect the patient to stay two midnights
- UR CoP procedures for self-denial are followed

How would this case be billed and paid?

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Case Study 2

How would this case be billed and paid?

- The total knee arthroplasty is billed on an inpatient Part B claim (TOB 121) with CCW2 and paid OPPS rate ($12,593)

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Case Study 3

- Patient presents at 8 a.m. for total knee arthroplasty
- The physician anticipates sending the patient home the following day if all goes well overnight, but nevertheless orders inpatient care at 3 p.m.
- Patient stays overnight and is discharge after a normal course of care at 4 p.m. the next day
- After discharge, UR determines inpatient Part A payment is inappropriate because the physician did not reasonably expect the patient to stay two midnights

How would this case be billed and paid?

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Case Study 3

How would this case be billed and paid?

- The total knee arthroplasty is billed on a regular outpatient claim (TOB 131) and paid OPPS rate ($12,593)
  - No Condition Code 44 or W2 because the pacemaker was provided on an outpatient basis and is being billed on an outpatient basis
- If any billable services occurred after 3 p.m. on first day, the hospital could bill them on an inpatient Part B claim (TOB 121) (after first filing the provider liable claim (TOB 110))
  - ***Caution:*** The C-APC payment for total knee arthroplasty is an **encounter-based payment** (i.e., payment for the full encounter) – a separate inpatient Part B claim could lead to inappropriate additional payment/patient co-insurance

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Case Studies 1, 2, 3 - Overview

- Payment for surgical cases is the same for:
  - Condition code 44 – *single claim*

    OR
  - Self-denial billed with CCW2 on inpatient Part B claim (order before procedure) – *two claims*

    OR
  - Self-denial billed on an outpatient Part B claim (order after procedure) – *single claim*

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Case Study 4

- Patient presents to ED at 5 a.m. and is placed in observation at 8 a.m.
- Physician orders inpatient status at 8 p.m. that night
- Patient is discharged at 12 p.m. the next day

How would this case be billed and paid if UR review occurs
before discharge (CC44) or
after discharge (CCW2)?

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Case Study 4

Payment is the same in both cases:

	Before Discharge (CC44): UR day 2, 8 a.m., order and status changed day 2, 10 a.m.		After discharge (CCW2): UR conducted post discharge	
	Billed	Paid	Billed	Paid
ED VISIT	131/CC44	$2283*	131	$2283*
OBSERVATION	131/CC44 14 hours** (8 a.m. – 8 p.m., 10 a.m. – 12 p.m.)	As part of the Observation C-APC	131 12 hours (8 a.m. – 8 p.m.)	As part of the Observation C-APC

*Observation C-APC, includes payment for most services in the encounter

** Assumes hours can be combined on a single line

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Case Study 5

- Patient presents to ED at 5 a.m. and is placed in observation at 8 a.m.
- Physician orders inpatient status at 1 p.m. that afternoon
- Patient is discharged at 12 p.m. the next day

How would this case be billed and paid if UR review occurs
before discharge (CC44) or
after discharge (CCW2)?

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Case Study 5

Payment is the same in both cases:

	Before Discharge (CC44): UR day 2, 8 a.m., order and status changed day 2, 10 a.m.		After discharge (CCW2): UR conducted post discharge	
	Billed	Paid	Billed	Paid
ED VISIT	131/CC44	$73 – $522*	131	$73 – $522*
OBSERVATION	131/CC44 7 hours (8 a.m. – 1 p.m., 10 a.m. – 12 p.m.)	As part of the ED Visit	131 5 hours (8 a.m. – 1 p.m.)	As part of the ED Visit

*Includes payment for diagnostics. Advanced diagnostics (MRI, CT) and drug administration paid separately, with some difference in the billable services depending on when they are provided – discussed later

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Case Study 6

- Patient presents to ED at 5 a.m. and is placed in observation at 8 a.m.
- Physician orders inpatient status at 3 p.m. that afternoon
- Patient is discharged at 12 p.m. the next day

How would this case be billed and paid if UR review occurs
before discharge (CC44) or
after discharge (CCW2)?

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Case Study 6

Payment is the same in both cases:

	Before Discharge (CC44): UR day 2, 8 a.m., order and status changed day 2, 10 a.m.		After discharge (CCW2): UR conducted post discharge	
	Billed	Paid	Billed	Paid
ED VISIT	131/CC44	$2283*	131	$73 – $522
OBSERVATION	131/CC44 9 hours** (8 a.m. – 3 p.m., 10 a.m. – 12 p.m.)	As part of the Observation C-APC	131 7 hours (8 a.m. – 3 p.m.)	As part of the ED visit

*Observation C-APC, includes payment for most services in the encounter

** Assumes hours can be combined on a single line

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Case Studies 4, 5, 6 - Overview

- Payment difference between self-denial (CCW2) and CC44 for medical cases is difficult to predict, dependent on:
  - Hours of observation before inpatient order is written
  - Hours of observation after UR determination/change in status
    - Assuming observation can be combined on a single line
  - Differences in billable services
  - Differences in payable/packaged services when billed on a single claim vs. two claims

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Back to the Original Question

So why use ***self-denial (CCW2)*** vs. ***CC44*** billing?

- Self-denials(condition code W2)
  - Easier/less time consuming for UR staff and physician advisors
  - More complicated for billing staff
    - Thoughtful claim submission can avoid excess claims/effort and maintain same payment as CC44
- Condition Code 44
  - More difficult/time consuming for UR staff and physician advisors
  - Simpler for billing/claims staff

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Three types of Inpatient Part B

There are three situations where Inpatient Part B billing is used, which can cause confusion:

- Admission ***not reasonable and necessary*** for part A payment (TOB 12X with ***CCW2***)
  - Payment for all service normally payable on outpatient Part B claim, including surgery, except those requiring outpatient status (ED, Obs) which are billable on TOB 131
- ***No eligibility*** for Part A or ***exhaustion*** of Part A benefits (TOB 12X ***no CCW2***)
  - Very limited payment available for diagnostics, therapy, other selected services
    - No payment for surgery
- ***Preventative services*** (TOB 12X ***no CCW2***)
  - There is no Part A benefit for preventative services so they are billed to Part B

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Inpatient Part B Claims (12X with CCW2)

Guidance/Resources for inpatient Part B billing with CCW2

- Special Edition *MLN Matters* article SE1333
- *Medicare Benefit Policy Manual*, Chapter 6 § 10.1 “Reasonable and Necessary Part A Hospital Inpatient Claim Denials”
- *Medicare Claims Processing Manual*, Chapter 4 § 240 “Inpatient Part B Hospital Services”
- *Medicare Claims Processing Manual,* Transmittal 3106, revising Chapter 4§240

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Inpatient Part B Claims (12X with CCW2)

Three claims ***may*** need to be submitted in Inpatient Part B/ CCW2 cases:

1. Part B outpatient claim (TOB 13X)
   - For all services before the inpatient order
     - ED visit
     - Observation
     - Surgery
     - Diagnostic tests
   - No Condition Code required
   - May be the ***only claim*** in many cases – discussed below

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Inpatient Part B Claims (12X with CCW2)

Three claims ***may*** need to be submitted in Inpatient Part B/ CCW2 cases:

2. "Provider liable" claim (TOB 110) – original or adjusted
   - Occurrence Span Code M1 with the inpatient dates of service
   - Must post in claims history before 12X will process
     - Can not maintain Part A and Part B claims simultaneously
   - Only required if billing 12X inpatient part claim

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Inpatient Part B Claims (12X with CCW2)

Three claims ***may*** need to be submitted in Inpatient Part B/ CCW2 cases:

3. Part B inpatient claim (TOB 12X)
   - For services after the inpatient order
   - Condition Code W2
     - Allows ***different set of revenue codes*** than 12X claims without CCW2
   - Treatment Authorization Code: A/B Rebilling
   - Remarks: NTE*ADD*ABREBILLING12345678901234-99999999~
     - 12345678901234 = document control number for inpatient denial
     - 99999999 = date of last adjudication (if contractor denial)
   - Do not include services normally included in the inpatient room rate (***routine services***) as defined by the provider

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Inpatient Part B Claims (12X with CCW2)

OPPS currently has an encounter-based payment methodology

- If a C-APC is paid on the outpatient part B (13X) claim, it may not be appropriate to bill inpatient part B (12X)
  - E.g., ED visit + 8 hrs of observation = C-APC for obs
  - E.g., surgery performed before an inpatient order

OR

- If a C-APC is paid on the inpatient part B (12X) claim, may not be appropriate to bill outpatient part B (13X)
  - E.g., major surgery after the inpatient order

Simplifies the billing process in most cases and maintains full encounter-based payment and single co-insurance for patient

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Implementing Self-Denials

Steps for self-denial reviews

- UR staff identifies a case for review
  - Notifies HIM and business office to hold coding/billing
  - The case is added to agenda for periodic review meeting (i.e. weekly, bi-weekly, semi-weekly) with UR physician
  - Attending physician is notified/invited to provide their views
- Review meeting occurs where determination is finalized
- Notice of determination is sent to
  - HIM/business office
  - Patient
  - Attending physician
- Sample policy available on request

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Implementing Self-Denials

Review meeting:

- Standards for inpatient reviews/determinations:
  - Patient stays less than two nights after the inpatient order: apply **2-midnight benchmark** or **case-by-case** review
  - Patient stays two nights after the inpatient order: apply **2-midnight presumption - CAUTION**
- Documentation of review/determination
  - No required format specified by CMS
  - Sample format available on request

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Implementing Self-Denials

Other considerations

- Timing of review
  - Limit is just short of one year to allow for billing within one-year timely filing limit
  - Closer to patient's discharge encourages efficiencies in review, lessens impact of revenue cycle
- UR communication with HIM/business office is vital to avoid recoding/rebilling

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Implementing Self-Denials

Notice to the patient within 2 days

- No specified required content for notice to patient
  - Consider informing them about impact on co-insurance and deductible
  - Provide number for them to call with questions
  - Sample patient notice letter available on request

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Thank you!

Questions?

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Attachment A

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
ZEMDRI™ (Plazomicin) (Next-generation aminoglycoside antibiotic for multi-drug resistant gram-negative bacteria) Extended One Year	XW033G4 or XW043G4	$4,083.75 (75% add-on limit)	83 *Fed. Reg.* 41326-34, 83 *Fed. Reg.* 49837; 84 *Fed. Reg.* 42190-191; 85 *Fed. Reg.* 58613
AndexXa™ (Andexanet alfa) (Reversal of anti-coagulation of Xarelto and Eliquis or life-threatening or uncontrolled bleeding) Extended One Year	XW03372 or XW04372	$18,281.25	83 *Fed. Reg.* 41355-62; 83 *Fed. Reg.* 49837; 84 *Fed. Reg.* 42193-194; 85 *Fed. Reg.* 58614-615
AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution (treatment of iobenguane avid malignant and/or recurrent and/or unresectable metastatic pheochromocytoma and paraganglioma (PPGL) Continued from FY2021	XW033S5 or XW043S5	$98,150	84 *Fed. Reg.* 42194-201; 85 *Fed. Reg.* 58615
CABLIVI® (caplacizumab-yhdp) (inhibits microclot formation in acquired thrombotic thrombocystopenic purpura) Extended One Year	XW013W5 or XW033W5 or XW043W5	$33,215	84 *Fed. Reg.* 42201-208; 85 *Fed. Reg.* 58615
ELZONRIS™ (tagraxofusp, SL-401) (targeted treatment of blastic plasmacytoid dendritic cell neoplasm) Extended One Year	XW033Q5 or XW043Q5	~~$125,448.05~~ $144,116.04	84 *Fed. Reg.* 42231-42237; 85 *Fed. Reg.* 58615-616
Balversa™ (Erdafitinib) (second-line treatment for locally advanced or metastatic urothelial carcinoma) Continued from FY2021	XW0DWL5	$3,563.23	84 *Fed. Reg.* 42237-242; 85 *Fed. Reg.* 58616
SPRAVATO (Esketamine) (nasal spray for treatment-resistant depression) Extended One Year	XW097M5	$1,014.79	84 *Fed. Reg.* 42247-256; 85 *Fed. Reg.* 58616-617

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
XOSPATA® (gilteritinib) (treatment of relapsed or refractory acute myeloid leukemia (AML)) Extended One Year	XW0DXV5	$7,312.50	84 *Fed. Reg.* 42256-260; 85 *Fed. Reg.* 58617
JAKAFI™ (Ruxolitinib) (oral kinase inhibitor treating acute graft-versus-host disease (GVHD)) Continued from FY2021	XW0DXT5	~~$4,096.21~~ $4475.38	84 *Fed. Reg.* 42265-273; 85 *Fed. Reg.* 58617-618
T2Bacteria® Panel (T2 Bacteria Test Panel) (aids in the diagnosis of bacteremia, a precursor for sepsis Extended One Year	XXE5XM5	$97.50	84 *Fed. Reg.* 42278-288; 85 *Fed. Reg.* 58618
ContaCT (a radiological computer-assisted triage and notification software system, analyzing CTAs of the brain and notifying neurovascular specialists of suspected large vessel occlusions) Extended One Year	4A03X5D	$1,040	85 *Fed. Reg.* 58625-636
Eluvia™ Drug-Eluting Vascular Stent System (a drug-eluting stent for the treatment of lesions in the femoropopliteal arteries) Extended One Year	X27(H,J,K,L)385, X27(H,J,K,L)395, X27(H,J,K,L)3B5, X27(H,J,K,L)3C5,	$3,646.50	85 *Fed. Reg.* 58645-658
Hemospray® Endoscopic Hemostat (for hemostasis of nonvariceal gastro-intestinal bleeding) Extended One Year	XW0G886, XW0H886	$1,625.00	85 *Fed. Reg.* 58665-672
IMFINZI ® (durvalumab) and TECENTRIQ ® (atezolizumab) (programmed death-ligand 1 (PD-L1) blocking antibodies for the treatment of patients with extensive-stage small cell lung cancer) Extended One Year	XW03336, XW04336, XW033D6, XW043D6	$6,875.90	85 *Fed. Reg.* 58672-684
Soliris ® (eculizumab) (for treatment of neuromyelitis optica spectrum disorder who are anti-aquaporin-4 antibody positive) Continued from FY2021	XW033C6, XW043C6	$21,199.75	85 *Fed. Reg.* 58684-689
SpineJack ® System (an implantable fracture reduction system, for use in the reduction of painful osteoporotic vertebral compression fractures) Extended One Year	XNU0356, XNU4356	$3,654.72	85 *Fed. Reg.* 58689-701

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
BAROSTIM NEO ® System (for the improvement of symptoms of heart failure for patients who remain symptomatic despite treatment with guideline-directed medical therapy) Continued from FY2021	0JH60MZ, with 03HK3MZ or 03HL3MZ	$22,750	85 *Fed. Reg.* 58716-58717
The Optimizer ® System (QFV) (for the treatment of chronic heart failure in patients with advanced symptoms with normal QRS duration and not indicated for cardiac resynchronication therapy) Continued from FY2021	0JH60AZ, 0JH63AZ, 0JH80AZ, 0JH83AZ	$14,950	85 *Fed. Reg.* 58720-721
Cefiderocol (Fetroja) (a B-lactam antibiotic for the treatment of complicated urinary tract infections (cUTI) Continued from FY2021	XW03366, XW04366	$7,919.86 (75% add-on limit)	85 *Fed. Reg.* 58721-723
NUZYRA® for injection (omadacycline) (a tetracycline class antibacterial for treatment of specific infections) Extended One Year	XW033B6, XW043B6	$1,552.50 (75% add-on limit)	85 *Fed. Reg.* 58725-727
RECARBRIO™ (a fixed dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel B-lactamase inhibitor (BLI) for complicated urinary tract infections (cUTI)) Continued from FY2021	XW033U5, XW043U5	$3,532.78 (75% add-on limit)	85 *Fed. Reg.* 58727-729
XENLETA (a pleuromutilin antibacterial agent, a first treatment from a novel class of antibiotics for community-acquired bacterial pneumonia) Continued from FY2021	XW03366, XW04366, XW0DX66	$1,275.75 (75% add-on limit)	85 *Fed. Reg.* 58729-732
ZERBAXA® (a combination of ceftolozane, a cephalosporin antibacterial; and tazobacam, a b-lactamase inhibitor (BLI) for treatment of specified infections) Continued from FY2021	XW03396, XW03496	$1,836.98 (75% add-on limit)	85 *Fed. Reg.* 58732-733
RYBREVANT™ (amivantamab, for the treatment of metastatic non-small cell lung cancer (NSCLC). New FY2022	XW033B7, or XW043B7	$6,405.89	86 *Fed. Reg.* 44988-996

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
COSELA™ (trilaciclib, used to decrease the incidence of chemo-therapy-induced myelosuppression in adult patients administered prior to a certain treatment for extensive-stage small cell lung cancer((ES-SCLC) New for FY2022	XW03377, or XW04377	$5,526.30	86 *Fed. Reg.* 45008-17
ABECMA® (idecabtagene vicleucel, a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR)T-cell immunotherapy for relapsed or refractory multiple myeloma and is a 5th line plus treatment) New for FY2022	XW033K7, or XW043K7	$272,675.00*	86 *Fed. Reg.* 45028-35; * as corrected in 86 *Fed. Reg.* 58032
StrataGraft™ Skin Tissue, a viable bioengineered, regenerative skin construct (BRSC) for treatment of severe thermal burns. New for FY2022	XHRPXF7	$44,200.00	86 *Fed. Reg.* 45079-90
TECARTUS® (brexucabtagene autoleucel, a CD19 directed genetically modifier autologous T-cell immunotherapy for relapsed and refractory mantle cell lymphoma, a form of CAR-T. New for FY2022	XW033M7, or XW043M7	$259,350*	86 *Fed. Reg.* 45090-104; * as corrected in 86 *Fed. Reg.* 58033
VEKLURY® (remdesivir, a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as SARS-CoV-2 (COVID-19)) New for FY2022	XW033E5, or XW043E5	$2,028.00	86 *Fed. Reg.* 45104-116
ZEPZELCA (lurbinectedin, a marine derived, synthetic antineoplastic compound for treatment of metastatic small cell lung cancer (SCLC) with disease progression on chemotherapy) New for FY2022	XW03387, or XW04387	$8,622.90	86 *Fed. Reg.* 45116-126
Aprevo™ (an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures for spinal deformity, custom made from patient CT scans New for FY2022	XRG(A,B,C,D)0R7 XRG(A,B,C,D)3R7 XRG(A,B,C,D)4R7	$40,950.00 *	86 *Fed. Reg.* 45127-133; * as corrected in 86 *Fed. Reg.* 67875

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
aScope Duodeno (a sterile, single-use endoscope for endoscopy and endoscopic treatment of the upper gastrointestinal tract) New for FY2022	XFJB8A7, or XFJD8A7	$1,715.59[1]	86 *Fed. Reg.* 45133-135
EXALT™ Model D Single-Use Duodenoscope (a single-use, flexible duodenoscope for diagnostic and therapeutic treatment of the pancreaticobiliary system during ERCP) New for FY2022	XFJB8A7, or XFJD8A7	$1,715.59[1]	86 *Fed. Reg.* 45138-140
Caption Guidance™ (an artificial intelligence (AI) guided medical imaging acquisition software system for cardiac ultrasound images, providing real-time guidance during transthoracic echocardiography) New for FY2022	X2JAX47	$1,868.10	86 *Fed. Reg.* 45135-138
Harmony™ Transcatheter Pulmonary Valve System (a bioprosthetic heart valve from porcine pericardial tissue for treatment of congenital heart disease) New for FY2022	02RH38M	$26,975.00	86 *Fed. Reg.* 45146-149
INTERCEPT Fibrinogen Complex (PRCFC) (a blood product for treatment of fibrinogen deficiency-related bleeding, including massive hemorrhage) New for FY2022	30233D1, or 30243D1 reported with ICD-10-CM codes D62*, D65, D68.2, D68.4* or D68.9*	$2,535.00	86 *Fed. Reg.* 45149-150; * as corrected in 86 *Fed. Reg.* 67875
Shockwave C2 Intravascular Lithotripsy System (for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting) New for FY2022	02F03ZZ, 02F13ZZ, 02F23ZZ, or 02F33ZZ	$3,666.00	86 *Fed. Reg.* 45151-153

[1] The preamble text established a payment limit of $1,715.59, however, the table on 86 *Fed. Reg.* 45585 shows a payment limit of $1,715.58. The limit in the table appears to be an error based on other corrections in the correction notice of October 20, 2021 which corrected the amount in the table to match the amount discussed in the preamble text for other services, however, the amounts for aScope Duodeno and EXALT™ Model D Single-Use Duodenoscope were not corrected.

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
CONTEPO™ (fosfomycin)[2] (an intravenous epoxide antibiotic for treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis), if FDA marketing authorization by July 1, 2022 New for FY2022	XW033K5, or XW043K5	$2,625.00[3] (75% add-on limit)	86 *Fed. Reg.* 45154-155
FETROJA® (cefiderocol) (an injectable siderophore cephalosporin for hospital-acquired bacterial pneumonia/ ventilator- associated bacterial pneumonia New for FY2022	XW033A6, or XW043A6 * reported with ICD-10-CM codes Y95 and J14, J15.0, J15.1, J15.5, J15.6, or J15.8; OR J95.851 and B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89	$8,579.84** (75% add-on limit)	86 *Fed. Reg.* 45156-157; * as corrected in 86 *Fed. Reg.* 67875; ** as corrected in 86 *Fed. Reg.* 58032
RECARBRIO™ (imipenem, cilastatin, and relebactam) (a novel b-lactamase inhibitor for treatment of hospital acquired bacterial pneumonia/ ventilator associated bacterial pneumonia caused by susceptible Gram-negative bacteria) New for FY2022	XW033U5, or XW043U5 *reported with ICD-10-CM codes Y95 and J14, J15.0, J15.1, J15.5, J15.6, or J15.8 for HABP ; OR XW033A6 or XW043A6 reported with ICD-10-CM codes J95.851 and B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89 for VABP	$9,577.00** (75% add-on limit)	86 *Fed. Reg.* 45157-159; * as corrected in 86 *Fed. Reg.* 58023; further corrected in 86 *Fed. Reg.* 67875; ** as corrected in 86 *Fed. Reg.* 58032

[2] Approval conditioned on FDA approval by July 1, 2022 and NTAP will begin the quarter following the date of FDA authorization.

[3] Contepo™ is a QIDP with payment limit of 75%. The preamble text for Contepo™ established a payment limit of $2,625.00, which is 75% of the cost per case of $3,500, however the table on 86 *Fed. Reg.* 45585 shows a payment limit of $2,275 or 65% of the calculated cost per case, which appears to be an error. The payment limit was corrected for two other newly added QIDP drugs with the same error, however, the amount for Contepo in the table was not corrected.