2023 Oncology Coding Update

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The coding updates for 2023 were released by both the American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS). While there are not a significant number of coding updates, providers should understand the changes that were made. This column outlines coding changes specific to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM); Current Procedural Terminology (CPT®); and Healthcare Common Procedure Coding System (HCPCS) for services that may be provided by or related to the services of oncology specialties. Items in orange indicate changes for 2023.

Revised ICD-10-CM Guidelines

As these updates run on a fiscal year calendar, the following ICD-10-CM guidelines went into effect Oct. 1, 2022. Note: due to the change to a biannual update to diagnosis coding, additional updates are expected for implementation on April 1, 2023.

Many of the 2022 guideline updates focus on the need to code the diagnosis to the highest level of specificity. Language was added in several sections of the *ICD-10-CM Official Guidelines*, including:

Conventions for ICD-10-CM

- **Code assignment and clinical criteria.** The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis. If there is conflicting medical record documentation, query the provider.

Chapter 1: Certain Infectious and Parasitic Diseases (A00- B99), U07.1, U09.9

- **Documentation of Complications of Care.** Code assignment is based on the provider's documentation of the relationship between the condition and the care or procedure, unless otherwise instructed by the classification. The guideline extends to any complications of care, regardless of the chapter in which the code is located. Note: not all conditions that occur during or following medical care or surgery are classified as complications. There must be a cause-and-effect relationship between the care provided and the condition, and the documentation must support that the condition is clinically significant. It is not necessary for the provider to explicitly document the term "complication." For example, if the condition alters the course of the surgery as documented in the operative report, then it would be appropriate to report a complication code. Query the provider for clarification if the documentation is not clear as to the relationship between the condition and the care or procedure.

Chapter 2: Neoplasms (C00-D49)

- **Admission/Encounter for treatment of primary site.** If the malignancy is chiefly responsible for occasioning the patient admission/encounter and treatment is directed at the primary site, designate the primary malignancy as the principal/first-listed diagnosis. The only exception to this guideline is if the administration of chemotherapy, immunotherapy, or external beam radiation therapy is chiefly responsible for occasioning the admission/encounter. In that case, assign the appropriate **Z51-code** as the first-listed or principal diagnosis, and the underlying diagnosis or problem for which the service is being performed as a secondary diagnosis.
- Secondary malignant neoplasm of lymphoid tissue. When a malignant neoplasm of lymphoid tissue metastasizes beyond the lymph nodes, a code from categories C81 to C85 with a final character "9" should be assigned, identifying "extranodal and solid organ sites," rather than a code for the secondary neoplasm of the affected solid organ. For example, for metastasis of B-cell lymphoma to the lung, brain, and left adrenal gland, assign code C83.39, diffuse large B-cell lymphoma, extranodal and solid organ sites.

Chapter 5: Mental, Behavioral and Neurodevelopmental Disorders (F01-F99)

- Dementia. The ICD-10-CM classifies dementia (categories F01, F02, and F03) on the basis of the etiology and severity (unspecified, mild, moderate, or severe). Selection of the appropriate severity level requires the provider's clinical judgment and codes should be assigned only on the basis of provider documen-

tation (as defined in the *ICD-10-CM Official Guidelines for Coding and Reporting*), unless otherwise instructed by the classification. If the documentation does not provide information about the severity of the dementia, assign the appropriate code for unspecified severity. If a patient is admitted to an inpatient acute care hospital or other inpatient facility setting with dementia at one severity level and it progresses to a higher severity level, assign one code for the highest severity level reported during the stay.

Chapter 19: Injury, Poisoning, and Certain Other Consequences of External Causes (S00-T88)

- The occurrence of drug toxicity is classified in ICD-10-CM as follows. Underdosing refers to taking less of a medication than is prescribed by a provider or a manufacturer's instruction. Discontinuing the use of a prescribed medication on the patient's own initiative (not directed by the patient's provider) is also classified as an underdosing. For underdosing, assign the code from categories T36 to T50 (fifth or sixth character "6"). Documentation of a change in the patient's condition is not required to assign an underdosing code. Documentation that the patient is taking less of a medication than is prescribed or discontinued the prescribed medication is sufficient for code assignment.

Chapter 21: Factors Influencing Health Status and Contact with Health Services (Z00-Z99)

- Social determinants of health. Codes describing problems or risk factors related to social determinants of health (SDOH) should be assigned when this information is documented. Assign as many SDOH codes as are necessary to describe all the problems or risk factors. These codes should be assigned only when the documentation specifies that the patient has an associated problem or risk factor. For example, not every individual living alone would be assigned code Z60.2, Problems related to living alone.

Revised ICD-10-CM Codes

These codes continue to expand to allow for specificity with diagnosis coding. The following are highlights of ICD-10-CM coding changes for 2023.

Neoplasms (C00-D49)

- **C61** Malignant neoplasm of prostate. "Previous–Use additional code to identify" was replaced with "New—Use additional code, if applicable, to identify."
- Under **C84** Mature T/NK-cell lymphomas:
  - **C84.0** Mycosis fungoides. "Previous—Excludes1: peripheral T-cell lymphoma, not classified (C84.4-)" was replaced with "New—Excludes1: peripheral T-cell lymphoma, not elsewhere classified (C84.4-)."
  - **C84.4** Peripheral T-cell lymphoma. "Previous—C84.4 Peripheral T-cell lymphoma, not classified" was replaced with "New—**C84.4** Peripheral T-cell lymphoma, not elsewhere classified."
  - Note: The codes listed under **C84.4** for peripheral T-cell lymphoma are all adjusted as listed above from "not classified" to "not elsewhere classified." Only one example is included for brevity.
- **C94** Other leukemias of specified cell type:
  - **C94.6** Myelodysplastic disease, not classified. "Previous–C94.6 Myelodysplastic disease, not classified" was replaced with "New–**C94.6** Myelodysplastic disease, not elsewhere classified." "Myeloproliferative disease, not classified" was deleted. "Myelodysplastic/myeloproliferative neoplasm, unclassifiable" and "Myeloproliferative disease, not elsewhere classified" were added.

Other Disorders of Blood and Blood-Forming Organs (D70- D77)

- **D75** Other and unspecified diseases of blood and blood-forming organs.
  - **D75.8** Other specified diseases of blood and blood-forming organs.
    - **D75.82** Heparin induced thrombocytopenia (HIT). Use additional code, if applicable, for adverse effect of heparin (**T45.515-**):
      - **D75.821** for non-immune heparin-induced thrombocytopenia, non-immune HIT, and type 1 heparin-induced thrombocytopenia.
      - **D75.822** for immune-mediated heparin-induced thrombocytopenia, immune-mediated HIT, and type 2 heparin-induced thrombocytopenia.
      - **D75.828** for other heparin-induced thrombocytopenia syndrome, autoimmune heparin-induced thrombocytopenia syndrome, delayed-onset heparin-induced thrombocytopenia, and persisting heparin-induced thrombocytopenia.
      - **D75.829** for heparin-induced thrombocytopenia, unspecified.
    - **D75.84** for other platelet-activating anti-PF4 disorders for spontaneous heparin-induced thrombocytopenia syndrome (without heparin exposure), thrombosis with thrombocytopenia syndrome, and vaccine-induced thrombotic thrombocytopenia. Use additional code, if applicable, for adverse effect of other viral vaccine (T50.B95-).

A large section of codes was added to identify long-term drug therapy. As factors influencing health status, these codes are only added to the claim form if documented

in the encounter by the physician. If there is no documentation to support their use, the codes are not utilized.

Z79 Long term (current) drug therapy

- **Z79.63**, Long term (current) use of chemotherapeutic agent.
  - **Z79.630** Long term (current) use of alkylating agent for: Long term (current) use of chlorambucil, Long term (current) use of cisplatin, and Long term (current) use of cyclophosphamide.
  - **Z79.631** Long term (current) use of antimetabolite agent for: Long term (current) use of 5-fluorouracil, Long term (current) use of 6-mercaptopurine, Long term (current) use of cytarabine, and Long term (current) use of methotrexate.
  - **Z79.632** Long term (current) use of antitumor antibiotic for: Long term (current) use of bleomycin, Long term (current) use of doxorubicin, and Long term (current) use of mitomycin C.
  - **Z79.633** Long term (current) use of mitotic inhibitor for: Long term (current) use of paclitaxel, Long term (current) use of plant alkaloids, Long term (current) use of vinblastine, and Long term (current) use of vincristine.
  - **Z79.634** Long term (current) use of topoisomerase inhibitor for: Long term (current) use of etoposide, Long term (current) use of irinotecan, and Long term (current) use of topotecan.
  - **Z79.64** Long term (current) use of myelosuppressive agent for: Long term (current) use of hydroxyurea.
  - **Z79.69** Long term (current) use of other immunomodulators and immunosuppressants.
- **Z79.8**, other long term (current) drug therapy.
  - **Z79.84** Long term (current) use of oral hypoglycemic drugs. Excludes: long-term (current) use of injectable non-insulin anti-diabetic drugs (**Z79.85**).
  - **Z79.85** Long-term (current) use of injectable non-insulin antidiabetic drugs. Excludes: long term (current) use of insulin (Z79.4) and long term (current) use of oral hypoglycemic drugs (Z79.84).

Evaluation and Management Deleted Codes

In 2023, several codes were deleted for evaluation and management (E/M) services to align with the overhaul of "other" E/M services (i.e., inpatient, observation, and critical care). The following codes were deleted effective Jan. 1, 2023: **99217, 99218, 99219, 99220, 99224, 99225, 99226, 99241, 99251, 99318, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99339, 99340, 99343, 99354, 99355, 99356,** and **99357.**

E/M Revised Codes

Inpatient and observation visit codes are revised for 2023, the changes mirror those made for outpatient visits in 2021. Inpatient and observation codes are now based on medical decision making (MDM) or total time on date of encounter.

The following are the inpatient and observation visit codes for initial and subsequent patient visits.

Initial Visits

- **99221**: Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straight forward or low-level medical decision-making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.
- **99222**: Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level medical decision-making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.
- **99223**: Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high-level medical decision-making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.

Subsequent Visits

- **99231**: Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low-level medical decision-making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.
- **99232**: Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level medical decision-making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.
- **99233**: Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high-level medical decision-making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.

New Codes

As in 2021, CMS and AMA did not agree on the use and application of prolonged services with the new E/M guidelines. Due to this, the AMA has a CPT code and the HCPCS (CMS) has three codes for prolonged services, but only one specific to inpatient and observation services. When reporting,

the appropriate code will depend on the payer.

- **AMA CPT Code 99418**: Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time. (List separately in addition to the code of the inpatient and observation evaluation and management service.)
- **HCPCS Code G0316**: Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact. (List separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services.)

Nuclear Medicine Revised Codes

In 2023, the radiopharmaceutical localization codes were updated to expand more on the acquisition variances in the code levels/selections:

- **78803**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging.
- **78830**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging.
- **78831**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, chest and abdomen) or separate acquisitions (eg, lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days.
- **78832**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, chest and abdomen or separate acquisitions (eg, lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days.

Nuclear Medicine Category III Codes

Three codes were created for cardiac focal ablation utilizing radiation therapy for arrhythmia. Currently, there is little guidance or information on the application of these codes relative to other radiation therapy treatment delivery codes. CMS does not recognize these codes for payment in the outpatient setting; for physicians, these codes are contractor priced.

- **0745T**: Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance.
- **0746T**: Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan.
- **0747T**: Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia.

HCPCS Code Changes: Added Modifiers

- **JZ**: Zero drug amount discarded/not administered to any patient.
- **LU**: Fractionated payment of CAR T-cell therapy.
- **JG**: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.
- **TB**: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities.

HCPCS Code Changes: Added Codes

- **G0317**: Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact. List separately in addition to CPT codes **99306** and **99310** for nursing facility evaluation and management services. Do not report **G0317** on the same date of service as other prolonged services for evaluation and management **99358**, **99359**, and **99418**). Do not report **G0317** for any time unit less than 15 minutes.
- **G0318**: Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified

healthcare professional, with or without direct patient contact. List separately in addition to CPT codes **99345** and **99350** for home or residence evaluation and management services. Do not report **G0318** on the same date of service as other prolonged services for evaluation and management **99358**, **99359**, and **99417**). Do not report **G0318** for any time unit less than 15 minutes.

- **J1954:** Leuprolide acetate for depot suspension (lutrate), 7.5 mg
- **J9046:** Injection, bortezomib, (Dr. Reddy's), not therapeutically equivalent to j9041, 0.1 mg
- **J9048:** Injection, bortezomib (Fresenius Kabi), not therapeutically equivalent to j9041, 0.1 mg
- **J9049:** Injection, bortezomib (Hospira), not therapeutically equivalent to j9041, 0.1 mg
- **J9314:** Injection, pemetrexed (Teva) not therapeutically equivalent to J9305, 10 mg
- **J9393:** Injection, fulvestrant (Teva) not therapeutically equivalent to J9395, 25 mg
- **J9394:** Injection, fulvestrant (Fresenius Kabi) not therapeutically equivalent to j9395, 25 mg OI

CY 2023 HOPPS Final Rule Highlights

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CMS released its Hospital Outpatient Prospective Payment System (HOPPS) final rule[1] on Nov. 1, 2022, but it was not published in the Federal Register until later that week. This article outlines several key HOPPS changes and updates that impact oncology outpatient hospitals.[1] Note: the below payment impacts are outside the agency's authority to change:

- The 2 percent sequestration reduction was fully reimplemented on July 1, 2022, after suspension due to the COVID-19 public health emergency (PHE)
- The 4 percent reduction in payments due to the pay-as-you-go rule (PAYGO) begins Jan. 1, 2023. While this decrease is intended to recoup the economic relief provided as part of the federal government's COVID-19 response, there are rumblings that Congress will waive the PAYGO decrease. These reductions would apply to Medicare payments for each code and would be in addition to the payment policies finalized by CMS for calendar year (CY) 2023.

HOPPS Payment Rates

The Hospital Outpatient Prospective Payment System provides the regulatory information and payment rates for facility-based settings, outpatient hospitals, and ambulatory surgical centers. CMS proposed a 2.7 percent increase and, in the end, finalized a 3.8 percent increase to the Outpatient Department fee schedule. However, due to a Supreme Court ruling filed on June 15, 2022, related to the 340B Drug Discount Program, CMS had to adjust final payments for CY 2023 to account for the shift from average sales price (ASP) -22.5 percent to ASP +6 percent for certain drugs. This adjustment affected services differently, but most saw a decrease of 2 percent from the proposed rates. Specifically, some services decreased and will be reimbursed at a lower payment rate in CY 2023 than CY 2022, while other services saw an increase overall in CY 2022, which was less than the increase proposed. The big unknown is what the additional five years of payment adjustments (2018 to 2022) that CMS must make will do to future rate setting. The agency indicated that it is still working through how to distribute the payback of monies from the remaining five years, but it is likely that more reductions will follow.

Cancer Hospital Payment Adjustment

There are 11 designated cancer hospitals in the United States. CMS provides additional payments to these hospitals, which are a "hold harmless" amount, as they are exempt from payment under the Inpatient Prospective Payment System. Each year, CMS calculates the factor of payment above the annual finalized rate hospitals will receive. For CY 2023, CMS finalized its proposal to continue to use the CY 2021 and CY 2022 target PCR (pre-claim review) of 0.89 for the 11 designated cancer hospitals without modification.

Procedures Assigned to New Technology APC Groups for CY 2023

When new technology is assigned a billing code, it can be difficult for CMS to establish a payment rate because there is no claims data to determine utilization and cost by hospitals. Due to this, the agency created New Technology Ambulatory Payment Classifications (APCs), which are like pass-through payments for new drugs, biologicals, radiopharmaceuticals, and devices. The new technology is assigned to a temporary APC until claims data is available. Typically, this assignment is a minimum of two years, but it can be less if there is sufficient data available sooner. Once there is sufficient data, the new technology is moved to a clinically appropriate APC.

Scalp cooling is a fairly new technology that became effective July 1, 2021. It is used to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. The scalp cooling device is included in Medicare's national coverage determination (NCD) policy: **NCD 110.6** (scalp hypothermia during chemotherapy to prevent hair loss). The scalp cooling cap is classified as a supply and not paid separately under HOPPS.

CMS received comments that indicate there was substantial resource costs, ranging from $1,900 to $2,400, for calibrating and cap fitting for scalp cooling services. The Category III code **0662T** (scalp cooling, mechanical; initial measurement and calibration of cap) is billable once per chemotherapy session,

which CMS interprets to be once per course of chemotherapy. As scalp cooling was new under the CY 2022 HOPPS final rule, CMS finalized its assignment to **New Technology APC 1529** for CY 2023, with a national payment rate of $1,850.50.

Brachytherapy Sources

CMS finalized the use of costs derived from CY 2021 claims data to set the CY 2023 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator (SI) "U." Codes with SI "U" are not packaged into C-APCs (comprehensive APCs); the sources are paid separately, in addition to the brachytherapy insertion code in the hospital setting.

CMS will also continue to use recently established low-volume APCs (i.e., when there are fewer than 100 single claims) in CY 2021 for CY 2023 rate setting. When a brachytherapy source meets this criterion, CMS will use up to four years of claims data to establish a payment rate using the greatest of the arithmetic mean cost, median cost, or geometric mean cost. CMS finalized the designation of four brachytherapy sources' APCs as low-volume APCs for CY 2023.

Payments of Drugs, Biologicals, and Radiopharmaceuticals

CMS finalized the following payment policies for drugs, biologicals, and radiopharmaceuticals:

- Packaged drugs and biologicals estimated at a per-day administration cost less than or equal to $135, in CY 2022 this was set at less than or equal to $130.
- Continued separate payment for items with an estimated per-day cost greater than $135, except for diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure.
- Continued policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for those codes that describe the same drug or biological but in different dosages.
- Continued policy of making all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.
- Continued payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status based on ASP methodology, as CMS considers these to be drugs under HOPPS.
- For drugs or biologicals without sufficient data on sales price during the initial sales period, CMS will base payments on their wholesale acquisition cost (WAC) +3 percent.

The Inflation Reduction Act of 2022,[2] signed into law on August 16, 2022, includes a required temporary increase—8 percent (from 6 percent) of the reference biological's ASP— for the add-on payment of qualifying biosimilar biological products, beginning Oct. 1, 2022. This increase applies for a 5-year period, as required by the Act.

The Act also defines a qualifying biosimilar biological product as a biosimilar with an ASP that is not more than the ASP of the reference biological. For qualifying biosimilar biological products paid using an ASP as of Sept. 30, 2022, the 5-year period began on Oct. 1, 2022. For qualifying biosimilar biological products with first payments made using an ASP between Oct. 1, 2022, through Dec. 31, 2027, the 5-year period will begin on the first day of the calendar quarter during which the first payment is made.

This change, as well as others, are related to the Inflation Reduction Act, and implementation of these changes are not fully detailed within the HOPPS final rule.

CMS clarified that further details on the implementation of the Act are forthcoming and will be communicated through a vehicle other than its CY 2023 HOPPS final rule.

Manufacturer Refunds for Discarded, Single-Use Vial Amounts

Drugs and biologicals ("drugs") are administered to patients in varying amounts, and the amount administered is often less than the total amount in the product's vial or package. Some of these drugs are only available in single-dose vials or single-dose packages. The U.S. Food and Drug Administration (FDA)-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after the dose is administered must be discarded. Based on this FDA language, Medicare has established under Part B that the unused and discarded amount from a single-dose vial or single-dose package would be paid when reported on the claim with use of **modifier JW**, which is not for use with drugs that are not separately paid, such as drugs packaged into outpatient hospital services or other designated settings.

Due to the nature of these changes, CMS proposed to codify certain billing requirements within the CY 2023 Medicare Physician Fee Schedule (MPFS) proposed rule[3] for HOPPS and ambulatory surgical centers. CMS directed interested parties to the full description of the proposed changes via the MPFS rulemaking. Similarly, CMS directed readers interested in the policy's finalization to the CY 2023 MPFS final rule,[4] which is available on the CMS website. Highlights of the CY 2023 MPFS final rule can be found on pages 21 to 24.

In addition, after the CY 2023 proposed rule, the Inflation Reduction Act[2] was signed into law and includes sections 11101 and 11102, which relate to rebates by manufacturers of drugs covered under Part B and D. The Act specifies an effective date of January 1, 2023. Per CMS policy established on Jan. 1, 2017, providers are required to report the

amount of the administered drug on one claim line with the applicable HCPCS code and units, and the waste amount with the applicable drug code, number of wasted units, and **modifier JW** on a separate claim line. 2020 claims data support that Medicare paid nearly $720 million for discarded drug amounts billed with modifier JW under Part B for single-dose vials or single-dose packages. These payment amounts track with yearly totals between 2017 and 2019, which ranged from approximately $700 million to $750 million each year.

340B Drug Discount Program

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (not including drugs on pass-through payment status or vaccines) at the rate of ASP -22.5 percent—a significant reduction from the previous rate of ASP+6 percent. Since this payment policy was updated in CY 2018, there has been significant litigation, which has resulted in varying decisions, some which favored the plaintiff and some which favored the defendant (CMS). In response to those rulings, the payment policy for the 340B Drug Discount Program has had some back-and-forth adjustments between ASP+6 percent and ASP -22.5 percent. On June 15, 2022, the Supreme Court filed a decision in the *American Hospital Association v. Becerra case*.[5] The Supreme Court reversed the D.C. Circuit Court's decision, citing that the Department of Health and Human Services Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. The Supreme Court's decision involved payments for CYs 2018 and 2019, but it has implications for CY 2023.

Utilizing the separately paid line items with modifier "JG" in the CY 2021 claims available for HOPPS rate setting, which is the modifier used to identify drugs purchased under the 340B Drug Discount Program, the estimated payment differential would be an increase of approximately $1.96 billion in HOPPS drug payments. To ensure budget neutrality, CMS applied a decrease to HOPPS payments by factoring in a 0.9691 adjustment for a revised CY 2023 conversion factor of $85.585.

On Sept. 28, 2022, after the publication of the proposed CY 2023 HOPPS rule, the district court ruled on the first motion, vacating the 340B reimbursement rate for the remainder of CY 2022. CMS took steps to implement the court's ruling, which was clarified as a final judgement.

CMS is maintaining its requirement for 340B hospitals to report the "JG" and "TB" modifiers for informational purposes for CY 2023. The application of the modifiers will have no effect on payment rates. The presence of modifier "JG" on a claim indicates a drug is acquired under the 340B program, but it will not trigger a payment reduction and will only be used for informational purposes. Claims for 340B drugs and biologicals identified with modifier "JG" will be paid at the statutory default rate as non-340B drugs and biologicals. For CY 2023, CMS directs rural sole community hospitals, children's hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals to continue to report modifier "TB" on claim lines for drugs acquired through the 340B Program. All other 340B providers are directed to continue to bill the modifier "JG."

In response to a comment within the final rule for CY 2023, CMS states the following, "We note that while the original intent of this policy was not to benefit rural hospitals financially, we recognize that ending this policy means that payment rates for non-drug items and services will decrease, which will lead to lower total payments for all hospitals, including non-340B hospitals or hospitals that were exempt from the 340B payment policy for which the 340B policy had a positive financial effect…since the Supreme Court invalidated the previous payment rate of ASP -22.5 percent for 340B acquired drugs and biologicals, we must decrease other rates to offset the increase in 340B drug payment. We believe the best interpretation of the statute is to require budget neutrality across the program."[1]

References

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CY 2023 MPFS Final Rule Highlights

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CMS released its 2023 Medicare Physician Fee Schedule (MPFS)[1] on November 1, 2022, but it was not published in the Federal Register until later that week. This column outlines several of the key items for MPFS that impact oncology practices and providers.[1] Note: the below payment impacts are outside the agency's authority to change:

- The 2 percent sequestration reduction was fully reimplemented on July 1, 2022, after suspension due to the COVID-19 public health emergency (PHE)
- The 4 percent reduction in payments due to the pay-as-you-go rule (PAYGO) begins Jan. 1, 2023. While this decrease is intended to recoup the economic relief provided as part of the federal government's COVID-19 response, there are rumblings that Congress will waive the PAYGO decrease. These reductions would apply to Medicare payments for each code and would be in addition to the payment policies finalized by CMS for calendar year (CY) 2023.

MPFS Payment Rates

The Medicare Physician Fee Schedule provides the regulatory information and payment rates for physicians—across all care settings (facility and non-facility). In its final MPFS rule, CMS made some changes to what was proposed, for example, to the conversion factor, which is the value multiplied to the assigned relative value units (RVUs) of physician work, practice expense, and malpractice codes to determine payment. CMS finalized a conversion factor of $33.0607, a decrease of 4.5 percent from CY 2022 ($34.6062) and slightly less than what was proposed. CMS provided a breakdown of the payment impacts to each specialty to identify where changes will be the greatest (non-facility vs. facility). This breakdown only reflects the impact to estimated RVUs and does not reflect other changes, such as the 4.5 percent decrease to the conversion. Table 1, below, illustrates the estimated impact these RVU changes will have on oncology/hematology specialties.

CMS finalized updates to malpractice RVUs for next year; these were last updated in CY 2020 and are required to be updated every three years. Based on the malpractice

Table 1. CY 2023 MPFS Estimated Impact on Total Allowed Charges by Setting

SPECIALTY	TOTAL NON-FACILITY/ FACILITY	ALLOWED CHARGES (MILLIONS)	COMBINED IMPACT
Hematology/Oncology	TOTAL	$1,713	-1%
	Non-facility	$1,134	-2%
	Facility	$579	1%
Radiation oncology and radiation therapy centers	TOTAL	$1,615	-1%
	Non-facility	$1,545	-1%
	Facility	$69	-1%

or practice liability insurance data collected from all 50 states, CMS is changing the risk index values that are used to calculate the malpractice RVUs at the code level. Malpractice RVUs reflect the risk of the primary specialty assigned to the service to perform the service. For CY 2023, the risk index value for hematology/oncology will decrease from 0.765 to 0.743 for CYs 2023 to 2025, and the risk index value for radiation oncology will increase from 0.840 to 0.907 for CYs 2023 to 2025.

Evaluation and Management Changes

Effective Jan. 1, 2023, there will be updates to the next set of evaluation and management (E/M) codes. These codes are the "other E/M" visits (inpatient and observation visits, emergency department [ED], nursing facility, domiciliary or rest home, and home visits, including cognitive impairment assessment). While these codes exclude critical care services, they match the framework (medical decision-making or time-based) of the outpatient and office E/M visits that changed in 2021. CMS is moving forward with the AMA CPT Editorial Panel changes, with a few minor exceptions like coding for prolonged services. The agency did finalize amendment of its definitions for "initial" and "subsequent" in relation to E/M visits for inpatient services. CMS does not recognize subspecialties, as is outlined in the CPT manual, so CMS proposed the following language:

- An initial service would be defined as one that occurs when a patient has not received any professional services from a physician or other qualified healthcare professional or another physician or other qualified healthcare professional of the same specialty who belongs to the same group practice during the stay.
- A subsequent service would be defined as one that occurs when a patient has received any professional services from a physician or other qualified healthcare professional or another physician or other qualified healthcare professional of the same specialty who belongs to the same group practice during the stay.

CMS proposed three new Healthcare Common Procedure Coding System (HCPCS) codes to be used in place of the AMA-created CPT code **99418** for prolonged services: one code for hospital inpatient or observation care, one for nursing facilities, and another for home or residence. The code to be used with Medicare beneficiaries for prolonged services of inpatient time-based visits in 2023 is:

- **G3016:** Prolonged hospital inpatient or observation care E/M service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact. List separately in addition to CPT codes **99223**, **99233**, and **99236** for hospital inpatient or observation care E/M services. Do not report **G0316** on the same date of service as other prolonged services for E/M codes **99358**, **99359**, and **99418**. Do not report **G0316** for any time unit less than 15 minutes.

As with outpatient prolonged services, CMS did not agree with the AMA on how time was counted to meet the threshold for billing new codes. In addition, the prolonged service code **G0316** can only be used with the highest-level hospital inpatient or observation care visit codes (CPT codes **99223**, **99233**, and **99236**) when the time-based method is used.

The prolonged service period described by **G0316** begins 15 minutes after the total time (as established in the physician time file) for CPT codes **99223**, **99233**, and **99236** have been met. Additionally, CMS finalized that the G0316 prolonged code would be used for a 15-minute increment, and that the entire 15-minute increment must be completed to bill **G0316**.

Code **G0316** will apply to both face-to-face and non-face-to-face time spent on a patient's care within the survey timeframe. For CPT codes **99223** and **99233**, this would be time spent on the date of encounter. For CPT code **99236**, this would be time spent within three calendar days of the encounter.

CMS said that split (or shared) visits for new and established patients will be fully integrated in policy beginning in CY 2023 (a one-year delay) to allow full acquaintance and implementation of the other E/M visit changes.

Telehealth after the PHE

As of writing this article, the COVID-19 PHE is scheduled to end mid-January 2023. Any extension to the PHE would require the Secretary of the Department of Health and Human Services to notify the governors of each state with 60 days' notice and an extension is very likely. The provisions and waivers in response to the COVID-19 pandemic will continue for 151 days post the PHE's end.

CMS reiterated that any codes that are not part of the telehealth list of services identified as continuing permanently or temporarily as a Category 3 telehealth service will end on day 152 post-PHE. The services to be removed include:

- CPT code **77427** for radiation oncology physician management
- Initial inpatient E/M CPT codes **99221**, **99222**, and **99223**
- Audio-only CPT codes **99441**, **99442**, and **99443**.

Billing for telehealth services will return to pre-PHE guidelines, with some exceptions, and no longer require use of **modifier 95**; the appropriate place of service (POS) code (02 or 10) must be applied to process payment.

Another change: telehealth visits will no longer be allowed for patients in their homes or anywhere outside of an originating site other than the statutory exceptions for the diagnosis, evaluation, and treatment of mental health disorders, home dialysis, end-stage renal disease-related visits,

and the diagnosis, evaluation, and treatment of acute stroke symptoms.

CMS also addressed that there are certain types of services, when provided incident to the billing physician or practitioner, that require direct supervision. The agency reiterated that "...outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service." CMS has clarified that the "immediate availability" requirement means in-person (physical) availability—not virtual—in two different recent rulemakings (April 6, 2020, interim final rule with comment period and CY 2022 MPFS final rule).[2,3]

CMS also reminded stakeholders that after Dec. 31 of the year in which the PHE ends, the pre-PHE rules for direct supervision will apply. The agency is not making the temporary exception to allow immediate availability for direct supervision through virtual presence permanent. Instead, CMS is continuing to seek comments on whether to allow flexibility to meet the immediate availability requirement for direct supervision using real-time, audio/video technology. The agency also reminded stakeholders that supervising practitioners continue to be required to append the "**FR**" modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through real-time, audio and video telecommunications technology.

Manufacturer Refunds for Discarded Single-Use Vial Amounts

Drugs and biologicals ("drugs") are administered to patients in varying amounts, and the amount administered is often less than the total amount in the vial or package. Some of these drugs are only available in single-dose vials or single-dose packages. The U.S. Food and Drug Administration (FDA)-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after the dose is administered must be discarded. Based on this FDA language, Medicare has established, under Part B, that the unused and discarded amount from a single-dose vial or single-dose package would be paid when reported on the claim with use of **modifier JW**, which is not for use with drugs that are not separately paid, such as drugs packaged into outpatient hospital services or other designated settings.

CMS finalized enacting section 90004 of the Infrastructure Investment and Jobs Act[4] and provided details of how it plans to do this for the following areas:

- How discarded amounts of drugs are determined
- Defining which drugs are subject to refunds (and exclusions)
- When and how often CMS will notify manufacturers of refunds
- When and how often payment of refunds from manufacturers to CMS is required
- Refund calculation methodology (including applicable percentages)
- A dispute resolution process
- Enforcement provisions.

In addition, after the CY 2023 proposed rule, the Inflation Reduction Act was signed into law on August 16, 2022, which includes sections 11101 and 11102 relating to rebates by manufacturers for drugs covered under Part B and D.[5] The Act also specified an effective date of January 1, 2023. The details below were finalized:[5]

- Use of **modifiers JW** (drug amount discarded/not administered to any patient) and **JZ** (zero drug amount discarded/not administered to any patient) to identify discarded billing units of a billing and payment code to calculate the refund amount.
- For dates of service on or after Jan. 1, 2023, **modifier JW** will be required on claims for all single-dose container or single-use drugs when any amount is discarded, as part of the current policy.
- A six-month delay in the requirement to use the **JZ modifier** would allow healthcare providers sufficient time to incorporate necessary updates to their claims systems to report JZ data. If a provider cannot report the **JW** or **JZ modifiers** as required by Oct. 1, 2023, they should hold their claims until they are able to do so. Claims submitted without required modifier data will not be accepted.
- The definition for refundable single-dose container or single-use package drug would apply "to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a 'single-dose' container or 'single-use' package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a 'kit' that is intended for a single dose or single use."
- Excluded drugs would be radiopharmaceuticals, imaging agents, drugs requiring filtration during the drug preparation process, and drugs approved on or after the date of the Act's enactment (Nov. 15, 2021), for which payment under Part B has been made for fewer than 18 months.
- Exclusion of drugs requiring filtration during the drug preparation process specifically pertains to those drugs in which the dosing and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require any unused portion of the drug after the filtration process be discarded.
- While CMS did not finalize that initial reports be sent no later than Oct. 1, 2023, the agency finalized the proposed timeline for sending reports to manufacturers. The effective date of the provision remains Jan. 1, 2023, as required by the statute, and reports will be sent at each calendar quarter, beginning on or after this date.

- Refunds by drug manufacturers will be due no later than Dec. 31 of the year in which the report was delivered.
- Establishment of a dispute resolution process, civil monetary penalties, and periodic review of Part B medication claims to ensure **modifier JW**, **modifier JZ**, and discarded drug amounts are billed appropriately, as part of the already developed claims audit policy and process.

The Radiation Oncology Model

Due to the indefinite hold on the Radiation Oncology (RO) Model, CMS is evaluating the radiation oncology treatment delivery and image guidance (IGRT) G-codes. Specifically, the agency is looking to determine if current coding and payment policies for the services represented by the G-codes in the outpatient hospital setting can be adopted in the office-based setting. If any changes are made, they would be finalized through a rulemaking process like MPFS and HOPPS. OI

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