

WELCOME!

WE WILL BEGIN MOMENTARILY

2024 MEDICARE PFS AND OPPTS PROPOSED RULES: WHAT YOU NEED TO KNOW



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Cancer Care Delivery and Health Policy
Association of Community Cancer Centers

34,000+

multidisciplinary practitioners
from every discipline in oncology



CANCER PROGRAM LEADERSHIP

Hospital Presidents
CEOs, COOs, CMOs
Vice Presidents
Department Directors

ADMINISTRATION

Oncology Program and Practice
Administrators, Managers, and
Service Line Executives
Program Administrative Staff

SUPPORTIVE CARE STAFF

Social Workers
Patient Navigators
Financial Advocates
Palliative Specialists

THE ENTIRE TEAM

Genetic Counselors
Quality Officers
Data Manager/Registrars
Billers & Coders

CLINICIANS

Medical
Radiation
Surgical
Pharmacy

PATIENT CARE

Allied Physicians
Oncology Nurses
Nurse Practitioners
Physician's Assistants

1,700

Private Practices, Hospital Cancer Programs, Healthcare Systems, & Major Academic Centers Nationwide

FEDERAL REGISTER



HOPPS (Facilities = Hospitals and Ambulatory Surgical Centers)



MPFS (Physicians and Offices)

2024 HOPPS PROPOSED RULE

HOPPS PROPOSED PAYMENT RATES



2.8% increase to
Outpatient Department
(OPD) fee schedule



Total payments of
\$88.6 billion for CY
2024

CANCER HOSPITAL PAYMENT ADJUSTMENT

Proposed target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment

TABLE 4.—ESTIMATED CY 2024 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2024 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	43.9%
050660	USC Norris Cancer Hospital	30.2%
100079	Sylvester Comprehensive Cancer Center	41.9%
100271	H. Lee Moffitt Cancer Center & Research Institute	25.0%
220162	Dana-Farber Cancer Institute	41.1%
330154	Memorial Sloan-Kettering Cancer Center	56.9%
330354	Roswell Park Cancer Institute	19.1%
360242	James Cancer Hospital & Solove Research Institute	11.6%
390196	Fox Chase Cancer Center	22.1%
450076	M.D. Anderson Cancer Center	47.7%
500138	Seattle Cancer Care Alliance	39.4%

Payments of Drugs, Biologicals and Radiopharmaceuticals



CY 2024 & subsequent years – only re-propose policies when there are changes



340B Program Drugs paid ASP +6%



Policies – Pass-through status payments (new, expiring etc.) addressed only when changes are proposed. Continue APS+6%, WAC+3%, or AWP%

DRUGS, BIOLOGICALS & RADIOPHARMACEUTICALS

- Drugs & biologicals **proposed** to be packaged @ per day admin cost of \leq \$140
- Drugs & biologicals $>$ \$140 paid separately **except**
 - Diagnostic radiopharmaceuticals*
 - Contrast agents
 - Anesthesia drugs
 - Drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure
 - Drugs and biologicals that function as supplies or devices when used in a surgical procedure
- Drugs with no sufficient pricing data during initial sales period
 - **WAC+3% proposed for CY 2024**

DIAGNOSTIC RADIOPHARMACEUTICALS

To enhance beneficiary access, proposing & seeking comments:

- 1) Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of \$140;
- 2) Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold;
- 3) Restructuring APCs , including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals;
- 4) Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and
- 5) Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

BIOSIMILAR BIOLOGICAL PRODUCTS – IRA

Inflation Reduction Act (IRA)

- New biosimilars furnished before average sales price (ASP) data is available must have a payment limit set
- Limit not to exceed 103% WAC or 106% lesser of WAC or ASP
- Qualifying Biosimilar Product = a biosimilar product with an ASP less than the ASP of the reference biological for a calendar quarter during an applicable five-year period
- ASP+8% of the reference biological's ASP

CY 2024 Proposal

- Continue previous policies for biosimilars
- Except biosimilars from the threshold packaging policy when their reference biologicals are separately paid
 - Expects will promote use as a lower cost alternative
- If a reference product's per-day cost falls below the threshold packaging policy, all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold

BRACHYTHERAPY SOURCES

- Rates based on cost reports & claims utilization
- Very important to report correctly!
- Continuation of Low Volume APC

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed CY 2024 APC Cost
2632	Iodine I- 125 sodium iodide	0	---	\$61.83
2635	Brachytx, non-str, HA, P-103	21	\$98.73	\$60.86
2636	Brachy linear, non- str, P-103	1	\$89.34	\$57.15
2642	Brachytx, stranded, C- 131	76	\$99.92	\$100.65
2647	Brachytx, NS, Non- HDRIr-192	2	\$452.28	\$403.29
5244	Level 4 Blood Product Exchanges and Related Services	55	\$52,105.34	\$53,360.21
5494	Level 4 Intraocular Procedures	50	\$13,410.30	\$14,227.94
5495	Level 5 Intraocular Procedures	88	\$7,399.50	\$16,660.19
5496	Level 6 Intraocular Procedures	26	\$11,183.21	\$17,309.37
5881	Ancillary Outpatient Services When Patient Dies	91	\$7,701.96	\$13,576.10

SCALP COOLING – RATE CHANGE PROPOSAL

- Effective July 1, 2021
- Initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss
- Medicare’s National Coverage Determination (NCD) policy, NCD 110.6 (*Scalp Hypothermia During Chemotherapy to Prevent Hair Loss*)
 - Scalp cooling cap is classified as a supply and not paid separately under HOPPS
- Requests to establish payment – assigned to New Technology APC for CY 2024, decrease from 2023

CPT® Code	Long Descriptor	Proposed CY 2024 OPPS APC	Proposed CY 2024 National Rate
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	1514	\$1,250.50

EXCESSIVE RADIATION QUALITY MEASURE

- Most of the over 80 million CT scans performed each year in the U.S. are done as outpatient procedures
- Proposing - Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults electronic clinical quality measure (the Excessive Radiation eCQM)
- Measure Specifications include:
 - The measure numerator is diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category, as defined by body region and reason for the exam. Also included are CT scans with a noise value greater than a threshold specific to the CT category.
 - The measure denominator is all diagnostic CT scans performed on patients ages 18 and older during the one-year measurement period which have an assigned CT category, a size-adjusted radiation dose value, and global noise value.

TABLE 71: Proposed Progressive Increase in eCQM Reporting Beginning with the CY 2025 Reporting Period and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting Requirement
CY 2025 Reporting Period	Any quarter(s)	Voluntary
CY 2026 Reporting Period/CY 2028 Payment Determination	Two self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination	Four quarters (one calendar year)	Mandatory

340B DRUG PROGRAM SEPARATE PROPOSAL

- Released July 11, 2023
- Addresses payback from January 1, 2018 through September 27, 2022
- CMS considered the following ways to remedy the needed payment adjustments.
 - Make Additional Payments to Affected 340B Covered Entity Hospitals for 340B-Acquired Drugs from CY 2018 through September 27th of CY 2022 Without Proposing an Adjustment to Maintain Budget Neutrality
 - Full Claims Reprocessing from January 1, 2018 through September 27, 2022
 - Aggregate Hospital Payments from January 1, 2018 through September 27, 2022

PROPOSED REMEDY TO 340B HOSPITALS

One-time Lump Sum

- Easier than reprocessing claims
- Based on difference what was paid, ASP-22.5% & ASP+6%

Affected Claims

- 1,649 340B hospitals paid ~\$10.5 billion
- \$1.5 billion remedied 1/1/22-9/27/22
- \$9 billion remains
- Seeking comments on methodology

CMS to Direct MACs

- Hospital est. remedied payment \$10 million, already paid \$7.31 million, \$2.69 million lump sum
- Each MAC 60 calendar days to pay back after CMS direction
- Beneficiaries cannot be billed for additional cost sharing

ADDRESSING NON-DRUG SERVICES

Calculated Amount

Services SI J1, J2, P, Q1, Q2, Q3, R, S, T, U, V

Est. offset amount
\$7.8 billion

Adjustments

All providers (except new hospitals) decreased CF

3.09% reduction applied CY 2023

Timeline

January 1, 2025 – December 31, 2040 (i.e., est. 16 years)

0.5% reduction to CF

REQUEST COMMENTS – ESSENTIAL MEDICATIONS

- January 26, 2021 Executive Order 14001, “A Sustainable Public Health Supply Chain” kicked off focus on supply chains
 - Specifically pharmaceuticals and simple medical devices
- Recent data supports hospitals are estimated to spend more than 8.6 million personnel hours and \$360 million per year to address drug shortages
- Seeking comments on separate payment under IPPS – establish and maintain access to buffer stock of essential medicines to “foster a more reliable, resilient supply of these medicines”.
 - Payment would not be budget neutral
 - Separate payment under OPSS could be considered for future years
 - Factoring in domestic manufactured essential medicines costlier in US than sourced from other countries
- May expand to include in future years devices on FDA’s Critical Medical Device List (CMDL)
 - List is expected to be available end of 2023
- Comment Solicitation of Additional Considerations – includes multiple points for consideration such as, is 3-month supply appropriate amount, etc.

ESTABLISHING PAYMENT

Quantifying resource costs based on currently available info

CMS could apply IPPS shares consistent with methodology for NIOSH approved surgical N95 respirator payments

Based on contractual agreement with distributor or wholesaler and hospital to hold essential medicines, reported in aggregate in cost report, exclude cost of medicine itself

Payments made biweekly as interim lump sum to hospital and reconciled at cost report settlement – provider could ask for a different payment timeline to align with cost report schedule

Payments would be determined by MACs – based on current data and reviewed bi-annually for updates

3-month buffer stock for 86 essential medicines prioritized in report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*

AMENDING REGULATIONS

- Portion of regulations CMS is considering amending:
 - *“(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators, and for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines.”*
 - *“(11) A payment adjustment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines as specified in § 412.113.”*

2024 MPFS PROPOSED RULE

CALCULATING CONVERSION FACTOR

TABLE 102: Calculation of the CY 2024 PFS Conversion Factor

CY 2023 Conversion Factor		33.8872
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		33.0607
CY 2024 RVU Budget Neutrality Adjustment	-2.17 percent (0.9783)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		32.7476

Budget neutrality factor to maintain budget within +/- \$20 million

ESTIMATED SPECIALTY IMPACTS

CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty					
(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Hematology/Oncology	\$1,591	1%	0%	0%	2%
Radiation Oncology and Radiation Therapy Centers	\$1,552	0%	-2%	0%	-2%

*Column F may not equal the sum of columns C, D, and E due to rounding.

ESTIMATED IMPACT BY SETTING

(A) Specialty	(B) Total Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
Hematology/Oncology	<i>TOTAL</i>	\$1,591	2%
	<i>Non-facility</i>	\$1,037	1%
	<i>Facility</i>	\$554	2%
Radiation Oncology and Radiation Therapy Centers	<i>TOTAL</i>	\$1,552	-2%
	<i>Non-facility</i>	\$1,076	-2%
	<i>Facility</i>	\$476	-2%

NEW CODES 2024

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (CPT® codes 9X034 and 9X035)

Code	Description
9X034	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes
9X035	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes

- January 2023 RUC meeting, specialty societies noted the data reflected time estimates higher than the time specified in these time-based codes.
 - RUC concluded the survey results for these codes were incorrect and should be resurveyed for 2025.
- For CY 2024, CMS is proposing the RUC-recommended contractor pricing for codes 9X034 and 9X035.

DRUG WASTE



October 1, 2023 – JW and JZ modifiers required



Proposed - to require that drugs separately payable under Part B from single-dose containers, furnished by a supplier who is not administering the drug, would bill the drug with modifier JZ.

OFFICE/OUTPATIENT E/M VISIT COMPLEXITY ADD-ON

- Finalized 2021 in response to AMA E/M revisions
- Reported with all O/O E/M visits
 - But not with modifier 25 & minor procedures
- CAA 2021 moratorium until 2024
- CMS still believes code revisions do not account for complexity for certain types of care
- **G2211** (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*).

TELEMEDICINE VISITS



11 May 2023

PHE ended May 11, 2023

- As of May 12, 2023, all telemedicine visits must use HIPAA compliant technology



Jan. 2025

Telemedicine E/M visit CPT® codes in works for January 2025 from AMA



31 Dec. 2024

Use of real-time audio video visits thru December 31, 2024, for E/M codes

OTHER E/M FACTORS

- Split (or Shared) visits using time solely to determine substantive portion delayed until January 1, 2025

- CMS proposing to continue payment for CPT® codes 98966-98968 (telephone NPPs) extending the telehealth-related flexibilities provided to other audio-only services covered in the CAA 2023

- CMS is proposing to continue payment for telehealth services to the originating site

NEW CODES CHI, SDOH and PIN SERVICES

Focus on equity in and access of care

How social determinants of health (SDOH) impact the ability to diagnose or treat the patient

Trying to determine how to improve payment accuracy for additional time and resources

Payment for many activities currently included in payment for other services

Proposing to create new coding to identify & value from other services

COMMUNITY HEALTH INTEGRATION (CHI) SERVICES

- 2 new G codes, GXXX1 and GXXX2
- Performed by certified or trained auxiliary personnel, (i.e., community health worker (CHW)), incident to and under general supervision
- Furnished monthly, as medically necessary, once a CHI initiating E/M visit provided
- Practitioner must identify any SDOHs which significantly limit their ability to diagnose or treat the problem(s) addressed in the visit
- Excluded for inpatient, observation, emergency dept., or SNF visit - ongoing care is not provided
- Seeking comments on typical time spent per month furnishing CHI services to address SDOH & duration of months

GXXX1 - Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.
 - Conducting a person-centered assessment to understand patient’s life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.
 - Facilitating patient-driven goal-setting and establishing an action plan.
 - Providing tailored support to the patient as needed to accomplish the practitioner’s treatment plan.
- Practitioner, Home-, and Community-Based Care Coordination
 - Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).
 - Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient’s psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.
 - Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.
 - Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).
- Health education- Helping the patient contextualize health education provided by the patient’s treatment team with the patient’s individual needs, goals, and preferences, in the context of the SDOH need(s) and educating the patient on how to best participate in medical decision-making.
- Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.
- Health care access / health system navigation
 - Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.
- Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.
- Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.
- Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

GXXX2 – Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1)

SOCIAL DETERMINANTS OF HEALTH (SDOH)

- 1 new G code, GXXX5
- Risk assessment as part of comprehensive social history in relation to E/M visit
 - Proposed to be on same date as E/M
- Include a large set of factors:
 - Economic stability,
 - Education access and quality,
 - Healthcare access and quality,
 - Neighborhood and build environment,
 - Social and community context (factors such as housing, food, nutrition access, and transportation needs)

PROPOSED REQUIREMENTS

GXXX5 - *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months*

CMS outlines the required elements of the risk assessment to include:

- Administration of a standardized, evidence-based SDOH risk assessment tool tested and validated through research
- Includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.
 - Billing practitioners may choose to assess for additional domains if there are other prevalent or culturally salient social determinants in the community being treated by the practitioner.

PRINCIPAL ILLNESS NAVIGATION (PIN)

- 2 new G codes, GXXX3 and GXXX4
- Providing individualized help to the patient to identify appropriate practitioners and providers for care needs and support, and access necessary care timely, especially when the landscape is complex and delaying care can be deadly.
- Provided under general supervision following initiating E/M visit addressing a serious high-risk condition/illness/disease
- Excluded for inpatient, observation, emergency dept., or SNF visit - ongoing care is not provided
- To determine whether the proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code
- Seeking comments on the typical amount of time practitioners spend per month furnishing PIN services.
 - Also, the number of months for which practitioners furnish PIN services following an initiating visit.

CRITERIA FOR PIN VISITS

1. One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death;

- a) Examples of serious high-risk conditions/illness/disease include, but are not limited to, cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder.

2. The condition requires development, monitoring, or revision of a disease specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.

GXXX3 - *Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:*

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*
 - *Conducting a person-centered assessment to understand the patient’s life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*
 - *Facilitating patient-driven goal setting and establishing an action plan.*
 - *Providing tailored support as needed to accomplish the practitioner’s treatment plan.*
- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination*
 - *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).*
 - *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient’s psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*
 - *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*
 - *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*
- *Health education- Helping the patient contextualize health education provided by the patient’s treatment team with the patient’s individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access / health system navigation*
 - *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.*
 - *Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.*
- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4 – *Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3)*

CHI, SDOH, and PIN HIGHLIGHTS

Type of Visit	Excluded When Patient Visit is...	Initiating E/M Visit Required	Provided by Certified/Trained Auxiliary Staff (Incident to and under General Supervision)	Provided by Practitioner Performing E/M Visit	Proposed 2024 Nonfacility Rate	Proposed 2024 Facility Rate
Community Health Integration (CHI)	Inpatient/observation, emergency department (ED), or SNF	Yes	Yes	-	GXXX1 = \$78.92 GXXX2 = \$49.45	GXXX1 = \$48.79 GXXX2 = \$34.06
Social Determinants of Health (SDOH)	-	No, is part of E/M visit	-	Yes	GXXX5 = \$18.67	GXXX5 = \$8.84
Principal Illness Navigation (PIN)	Inpatient/observation, emergency department (ED), or SNF	Yes	Yes	-	GXXX3 = \$78.92 GXXX4 = \$49.45	GXXX3 = \$48.79 GXXX4 = \$34.06

DENTAL COVERAGE PROPOSALS

Codify to permit payment for certain dental services that are inextricably linked to, and substantially related and integral to, the clinical success of, other covered services

Payments for (A&B) dental or oral exam as part of comprehensive workup prior to Medicare –covered chemotherapy and CAR T-cell therapy for tx of cancer and administration of high-dose bone-modifying agents

Payments for (A&B) medically necessary diagnostic and tx services to eliminate oral or dental infection prior to, or with, chemotherapy and CAR T-cell therapy for tx of cancer, administration of high-dose bone-modifying agents, including many of the ancillary services inextricably linked.

Payments for (A&B) may be made for dental or oral exam performed as part of a comprehensive workup in either the inpatient or outpatient setting, and medically necessary diagnostic and tx to eliminate oral or dental infection prior to initiation of or during treatments for head and neck cancer, primary or metastatic regardless of site of origin, and regardless of initial modality of treatment.

SEEKING COMMENTS – DENTAL

- **CMS is seeking comments on following:**

- Whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore payable under Medicare Parts A and B.
- All components of proposal to cover work-up prior to treat cancer (chemo and CAR T-cell) and eliminate infections
- When chemo with radiation – coverage is not limited to only this combo and not when chemo alone or some other combo
- Proposals for CAR T-cell proposals
- Should other types of lymphodepleting medical services used for cancer treatment in addition to CAR T-cell also be paid – need specific info on types of therapies and how impacted by dental infections/conditions, when previously asked no comments received
 - Is quality of care impacted?
 - Better outcomes with less readmissions?
- Medication-related osteonecrosis of the jaw (MRONJ)

REFERENCES

1. Medicare and Medicaid Programs: Calendar Year 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, Medicare Shared Savings Program Requirements, etc., <https://public-inspection.federalregister.gov/2023-14624.pdf>
2. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; etc., <https://www.federalregister.gov/public-inspection/2023-14768/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>
3. Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 <https://www.federalregister.gov/documents/2023/07/11/2023-14623/medicare-program-hospital-outpatient-prospective-payment-system-remedy-for-the-340b-acquired-drug>

QUESTIONS



Federal Policy Update

- Inflation Reduction Act
- Medicare Multi-Cancer Early Detection (MCED) Screening Coverage Act
- Cancer Care Planning and Communications Act, H.R. 4414
- Drug Shortages

Inflation Reduction Act

- Caps Medicare beneficiaries' out-of-pocket spending by eliminating coinsurance above the catastrophic threshold in 2024.
- Places a \$2,000 cap on beneficiary spending in 2025.
- The law also limits annual increases in Part D premiums for 2024 to 2030 and makes other changes to the Part D benefit design.
- Expands eligibility for full Part D Low-Income Subsidies (LIS) in 2024 to low-income beneficiaries with incomes up to 150% of poverty and modest assets.

Inflation Reduction Act

- Cost sharing for insulin limited to \$35 per month for people with Medicare, beginning 1/1/2023, including covered insulin products in Medicare Part D plans, and for insulin furnished through durable medical equipment under Medicare Part B, beginning July 1, 2023.
- Eliminates cost sharing for adult vaccines covered under Medicare Part D, as of 2023, and improves access to adult vaccines under Medicaid and CHIP.

Inflation Reduction Act

- Drug manufacturers must pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries.
- Requires the federal government to negotiate prices for some high-cost drugs covered under Medicare.
- Brand-name and biologic drugs without generic or biosimilar equivalents that are among the highest-spending Medicare-covered drugs and are seven or more years (small-molecule drugs) or eleven or more years (biologicals) from FDA approval are eligible for negotiation. (Prices would be effective two years after selection.)
- The number of negotiated drugs is limited to 10 Part D drugs in 2026, 15 Part D drugs in 2027, 15 Part B and Part D drugs in 2028, and 20 Part B and Part D drugs in 2029 and later years.

Sources: Cubanski, J., Neuman, T., Freed, M. How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries? Kaiser Family Foundation. January 24, 2023. Accessed August 7, 2023. <https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/#:~:text=On%20August%2016%2C%202022%2C%20President,spending%20by%20the%20federal%20government>; Newman, C. CMS Lays Out Plans for Negotiating Drug Prices. BIOPHARMADIVE. March 16, 2023. Accessed August 7, 2023. <https://www.biopharmadive.com/news/cms-medicare-drug-price-negotiations-initial-guidance/645182/>

Inflation Reduction Act

- Cost-sharing protections will help beneficiaries
- Reimbursement impact may pose challenges for providers
- Manufacturers are challenging the IRA in court and have expressed concerns about its impact on research and development, among other areas

Drug Shortages

- The Association of Community Cancer Centers (ACCC) is highly concerned about the ongoing shortages of platinum-based chemotherapy agents (e.g., cisplatin and carboplatin), two medications that (individually or in combination) treat and cure a wide range of cancers, including but not limited to gastric, pancreatic, colorectal, esophageal, cervical, and ovarian.
- These shortages are occurring across treatment settings and geographies, including community cancer centers, hospital-based programs, and private practices.
- The widespread and critical nature of the shortage has already forced clinicians to choose between and among patients eligible for curative and supportive therapies.
- ACCC is pleased that the FDA has worked with Qilu Pharmaceutical Co. Ltd. (Qilu) and its distributor Apotex Corp. to allow for the temporary importation of cisplatin during the shortage.
- ACCC stands behind its members as they work with stakeholders across the health care system to find solutions to the current shortages.
- The Association also supports its members' efforts to develop longer term solutions to avoid recurrences of these and other anti-cancer drug shortages.

Medicare Multi-Cancer Early Detection (MCED) Screening Coverage Act

- Multi-cancer early detection screening harnesses the latest technology to catch cancer earlier, giving patients a greater chance at survival.
- Seventy percent of all cancer diagnoses occur among Medicare beneficiaries. Therefore, it is imperative that Congress pass the Medicare Multi-Cancer Early Detection Screening Act this year so all patients – especially older Americans -- have access to these game-changing tools.
- For years, health care professionals have relied on early detection screenings for just five types of cancer. MCED tests give clinicians the ability to screen for dozens of types of cancers at once – many of which currently have no early detection methods.
- Because they require only a single draw of blood, the tests can be administered in a wide variety of health care settings.

Cancer Care Planning and Communications Act, H.R. 4414

- The bill provides for Medicare coverage and payment of cancer care planning and coordination services for individuals who are diagnosed with or treated for cancer, including the development of treatment plans and follow-up care.
- The treatment plan must include each component of the Institute of Medicine's Care Management Plan as described in the article "Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis."
- Such services may be provided at the time of diagnosis, if there is a change in the individual's treatment or their treatment preferences, at the end of active treatment and the beginning of survivorship care, if there is a recurrence of such cancer, and as otherwise provided by the Secretary of HHS.
- The treatment rate shall be the same as provided for transitional care management services, unless the Secretary of HHS provides otherwise.

QUESTIONS



Thank you!
Please Reach Out With Questions or Concerns:

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