Q&A:
Medicare CY 2022 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule

Comments due September 17, 2021 by 5:00 p.m. EDT

Overview

On July 19, 2021, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule, available here.[1] The CMS fact sheet for the Proposed Rule can be found here. The following "Questions and Answers" provide an overview of relevant topics covered in the Proposed Rule. Please see the end of this document for a glossary of key terms.

Q. What policies does the CY 2022 OPPS Proposed Rule address?

A. The Proposed Rule presents payment changes for Medicare hospital outpatient services effective for CY 2022. OPPS payments cover facility resources, such as equipment, supplies, certain drugs and biologics (including biosimilar products), and the cost of hospital staff, but do not include professional fees for physicians and non-physician practitioners who are paid separately under the Medicare Part B Physician Fee Schedule (PFS).

Key policies from the Proposed Rule include:

- Continuing to assign HCPCS codes G2082 and G2083—which CMS created to facilitate access to treatment for treatment-resistant depression using esketamine—to New Technology APCs 1508 and 1511, respectively;
- Using CY 2019 data, rather than CY 2020 data, to set CY 2022 payment system rates;
- Maintaining payment for 340B outpatient drugs at Average Sales Price (ASP) – 22.5%;
- Continuing to allow follow-on biosimilars to be eligible for pass-through status;
- Continuing to base reimbursement for non-pass-through biosimilar products acquired under the 340B program entirely on the ASP of the biosimilar;
- Maintaining payment for non-340B outpatient drugs at ASP + 6%;
- Increasing overall OPPS payments by 2.3%;
- Amending hospital price transparency policies to encourage compliance, including increasing penalties and reducing barriers to accessing standard charge information;

- Including COVID-19 vaccination of health care personnel as a measure of the Hospital Outpatient Quality Reporting (OQR) program, in addition to other revisions;

- Modifying the timing and design of the Radiation Oncology (RO) model, which was delayed to January 1, 2022 due to the COVID-19 pandemic;

- Modifying the Ambulatory Surgical Center Quality Reporting (ASCQR) Program by adopting the COVID–19 Vaccination Coverage Among HCP measure and resuming data collection for four measures in CY 2025, in addition to other revisions; and

- Issuing requests for information regarding interoperability, including transitioning to digital quality measurement.

I. Esketamine G Codes

Q. Does CMS propose any changes to the ambulatory payment classifications (APCs) for the G codes it established to facilitate access to treatment for treatment-resistant depression using esketamine?

A. No. CMS proposes to continue to assign HCPCS code G2082 to New Technology APC 1508 and HCPCS code G2083 to New Technology APC 1511.[2] In an interim final rule, CMS established G2082 and G2083 effective January 1, 2020 to facilitate beneficiary access to treatment for treatment-resistant depression using esketamine.[3] The agency proposes to continue to assign these codes to New Technology APCs 1508 and 1511, respectively, for CY 2021 because no OPPS claims have been reported for either code since they took effect.[4] CMS pays for services under New Technology APCs, which are defined solely by cost, such as labor, equipment, and supplies, until sufficient claims data have been submitted to allow CMS to assign the service to a clinical APC.[5]

Code	Long Descriptor	CY 2021 APC	Proposed CY 2022 APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.	1508	1508
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.	1511	1511

- **No change in policy.**

II. Payment for Drugs, Biologics, and Biosimilars

Q. Will CMS use CY 2020 data in setting rates for CY 2022?

A. No. Typically, uses the claims data from two years prior to the relevant calendar year to set rates.[6] CMS is concerned with using CY 2020 data due to the effects of the COVID–19 public health emergency (PHE).[7] As a result, the agency proposes to use CY 2019 claims data and the related data components in establishing the CY 2022 OPPS.[8]

- **Current policy:** CMS uses claims data from two years prior to the relevant calendar year in setting rates.[9]
- **2022 proposal:** CMS proposes to use claims data from CY 2019, three years prior.[10]
- **Why it matters:** CMS is proposing to use older claims data to avoid any irregularities caused by the COVID-19 PHE.[11]

Q. Does CMS propose changes to reimbursement for 340B drugs in CY 2022?

A. No. CMS proposes to maintain payments for 340B drugs at average sales price (ASP) – 22.5%.[12] CMS initially proposed a reduced payment rate of ASP – 28.7% last year based on the results of a MedPAC analysis, but ultimately maintained the ASP – 22.5% rate based on stakeholder feedback; the agency proposes to continue its current policy for CY 2022.[13]

- **No change in policy.**

Q. Are any entities exempt from the reduced payments for 340B drugs?

A. Yes. Rural sole community hospitals, PPS-exempt cancer hospitals, and children's hospitals continue to be exempt from this payment reduction.[14] These entities are currently paid ASP + 6% for 340B drugs and they would continue to be paid at that rate under this proposal.[15] CMS may revisit whether these types of hospitals should be excluded from the 340B payment policy in the future.[16]

- **No change in policy.**

Q. What is the status of the litigation regarding CMS' previous payment reduction for 340B drugs to ASP – 22.5%?

A. CMS' payment reduction for 340B drugs has been the subject of ongoing litigation since the policy took effect in 2018.

In December 2018, the U.S. District Court for the District of Columbia ruled that CMS exceeded its statutory authority by reducing the payment rate for 340B outpatient drugs from ASP + 6% to ASP – 22.5% in the 2018 OPPS Final Rule.[17] In May 2019, the same court held that CMS exceeded its statutory authority again in maintaining the payment reduction for 2019.[18] The Court declined to vacate the rule,

however, explaining that because the cuts were budget neutral, the issuance of retroactive Medicare Part B payments would require similar offsets elsewhere, and would thus be highly disruptive.

On July 31, 2020, the Court of Appeals for the D.C. Circuit reversed—it held that CMS did not exceed its statutory authority in reducing payment for 340B-acquired drugs from ASP + 6% to ASP – 22.5%.[19] Accordingly, the reduced payment rate remains in place.

On February 10, 2021, the appellees filed a petition for a writ of certiorari in the United States Supreme Court.[20] On July 2, 2021, the Supreme Court granted their petition for a writ of certiorari.[21] The court asked the parties to brief whether petitioner' suit is precluded by 42 U.S.C. § 1395l(t)(12),[22] which limits judicial review of certain rate-setting by HHS.[23]

Q. Does CMS propose to continue to base reimbursement for non-pass-through biosimilars purchased under the 340B program entirely on the ASP of the biosimilar?

A. Yes. CMS proposes to continue its policy to pay non-pass-through biosimilar products acquired under the 340B program at the ASP of the biosimilar – 22.5% of the biosimilar's ASP, instead of the ASP of the biosimilar – 22.5% of the reference product's ASP.[24]

- **No change in policy.**

Q. Does CMS continue to allow follow-on biosimilars to be eligible for pass-through status?

A. Yes. Follow-on biosimilars would continue to be eligible for pass-through status, meaning they would be eligible for payment at ASP + 6% rather than ASP – 22.5% when purchased under the 340B program (subject to sequestration).[25] CMS announced in the CY 2018 Final Rule that all biosimilar biological products would be eligible for pass-through status, not just the first biosimilar to market for a given reference product.[26]

Pass-through payments are temporary payments made under the OPPS for certain "new" drugs and biologics, including biosimilars.[27] Pass-through status generally lasts two to three years.[28]

- **No change in policy.**

Q. Is CMS continuing to pay Wholesale Acquisition Cost (WAC) + 3% for new, non-340B drugs for which ASP data are not yet available?

A. Yes. In the CY 2019 Final Rule, CMS reduced payments from WAC + 6% to WAC + 3% for non-340B drugs during the first quarter of sales when ASP is unavailable.[29] When a drug first launches, ASP may not be available for two to three quarters to allow time for manufacturers to report sales data and for CMS to calculate ASP.[30] During this time period, the new drug is reimbursed based on WAC, which does not account for discounts. In reducing WAC-based payment for new drugs to WAC + 3%, the agency sought to address concern that WAC-based payment results in higher reimbursement than ASP-based payment.[31] CMS proposes to maintain this payment reduction in CY 2022.[32]

- **No change in policy.**

Q. Does CMS propose to change the ASP payment methodology for non-340B separately payable drugs and biologics?

A. No. The Proposed Rule would maintain payment for non-340B outpatient drugs at ASP + 6%.[33] This payment rate is generally subject to sequestration, resulting in payment of ASP + 4.3%.[34] Currently, the application of sequestration is temporarily suspended through December 31, 2021 due to the COVID-19 PHE.[35] Sequestration is set to go back into effect beginning January 1, 2022, meaning that the payment rate would be ASP + 4.3%.[36]

- **No change in policy.**

Q. What is the proposed payment rate for drugs and biologics with pass-through status?

A. For CY 2022, CMS proposes to maintain reimbursement for eligible pass-through drugs and biologics at ASP + 6%, equivalent to the rate these drugs would receive in the physician office setting.[37]

Pass-through payment status will end for 25 drugs and biologics during CY 2021.[38] The agency proposes to end pass-through payment status for 26 drugs and biologics during CY 2022.[39] CMAS also proposes to continue pass-through status for 46 drugs and biologics for CY 2022.[40] Please see **Appendix 1** for complete lists of these drugs and biologics.

- **No change in policy.**

Q. Does CMS propose to change the OPPS packaging threshold for drugs and biologicals?

A. No. The Proposed Rule would maintain the packaging threshold at its current rate of $130 for CY 2022.[41] If finalized, drugs and biologicals with a per-day cost of less than or equal to $130 would be packaged with the service or procedure with which they are associated.[42]

- **No change in policy.**

III. Payments to OPPS Providers

Q. How would the Proposed Rule impact Medicare payments to hospitals overall?

A. CMS estimates that payments under OPPS would increase overall by 2.3% in 2022.[43] This estimate reflects a proposed 2.3% increase in OPPS payment rates for 2022, which is based on a hospital market basket increase of 2.5%, minus a 0.2 percentage point adjustment for multi-factor productivity.[44] In comparison, the payment rate update from CY 2020 to CY 2021 was 2.4%.[45] Note that hospitals that do not meet the reporting requirements under the Medicare Hospital Outpatient Quality Reporting program would continue to incur a 2% reduction to their annual OPPS update factor.[46] A crosswalk of proposed CY 2021 drug administration rates for relevant services under the OPPS is attached as **Appendix 2**.

IV. Price Transparency Requirements

Q. Does CMS address the implementation of the hospital price transparency requirements that took effect January 1, 2021?

A. Yes. CMS is proposing to amend several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance.[47] First, CMS is proposing to increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count.[48] Currently, the maximum daily dollar civil monetary penalty (CMP) amount, regardless of hospital size, is $300 (with an annual maximum of $109,500), subject to a standard annual adjustment.[49] Proposed CMPs range from a daily maximum of $300 to $5,500 (with an annual maximum of $109,500 - $2,007,500), regardless of the number of discrete violations.[50]

Proposed Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.[51]		
Number of Beds	**Penalty Applied Per Day**	**Total Penalty Amount for Full Calendar Year of Noncompliance**
30 or less	**$300 per hospital**	**$109,500 hospital**
31 up to 550	**$310-$5,500 per hospital (number of beds times $10)**	**$113,150-$2,007,500 per hospital**
>550	**$5,500 per hospital**	**$2,007,500 per hospital**
Note: In subsequent years, amounts adjusted according to 45 C.F.R. § 180.90(c)(3).		

Second, CMS proposes to amend the regulations to reduce barriers to access to information.[52] Hospitals would need to ensure that the standard charge information is easily accessible, including ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website.[53]

V. Radiation Oncology Model

Q. Does CMS propose to change the Radiation Oncology (RO) model?

A. Yes. CMS proposes revisions to a number of provisions in the model. In 2020, CMS announced a mandatory Radiation Oncology (RO) Model in select geographic areas, which would provide site-neutral, episode-based payments to providers and suppliers of radiation therapy services to Medicare fee-for-service beneficiaries diagnosed with certain cancer types over 90-day episodes of care.[54] For CY 2022, CMS proposes to revise the cancer inclusion criteria, as well as modifying and adding definitions, modifying and adding exclusions, clarifying low-volume opt-out, excluding certain techniques, and clarifying prices, among other changes.[55]

Notably, CMS proposes that the performance period for the RO Model will be January 1, 2022 through December 31, 2026.[56] The performance period for the RO Model was originally January 1, 2021 to December 31, 2025.[57] Due to the COVID-19 PHE, CMS announced that the performance period would be July 1, 2021 to December 31, 2025 in the CY 2021 OPPS Final Rule.[58] Section 133 of the Consolidated Appropriations Act, enacted on December 27, 2020, prohibits implementation before January 1, 2022.[59]

VI. Hospital Outpatient Quality Reporting Program

Q. Does CMS propose to change the Hospital Outpatient Quality Reporting (OQR) Program?

A. Yes. CMS proposes a number of changes to the OQR program, including adding COVID-19 vaccination of health care personnel as a measure.[60] The Hospital OQR Program is a pay-for-reporting quality program for the hospital outpatient department setting.[61] The Hospital OQR Program requires hospitals to meet quality reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update if these requirements are not met.[62] CMS proposes to adopt three new measures for CY 2022, including the COVID-19 Vaccination of Health Care Personnel (HCP) measure,[63] as well as proposing other revisions to reduce provider burden and improve processes.[64] In addition, CMS is soliciting comments on potential future measure adoptions.[65]

VII. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Q. Does CMS propose to change the Ambulatory Surgical Center Quality Reporting (ASCQR) Program?

A. Yes. CMS proposes several changes to the ASCQR program, including adopting the COVID–19 Vaccination Coverage Among HCP measure and resuming data collection for four measures in CY 2025.[66] The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting, quality data program administered by CMS.[67] The ASCQR Program requires ASCs to meet quality reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update if these requirements are not met.[68]

VIII. Interoperability

Q. Does CMS address interoperability?

A. Yes. CMS issues a request for information (RFI) regarding its intention to transition to digital quality measurement by 2025.[69] CMS also issues an RFI seeking input regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure.[70]

IX. Commenting on the Proposed Rule

Q. How can an interested individual or organization submit comments on the Proposed Rule?

A. Interested stakeholders can submit comments electronically by visiting regulations.gov. Alternatively, comments can be submitted by mail to the following addresses:

Regular Mail
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
P.O. Box 8010
Baltimore, MD 21244-1850

Express or Overnight Mail
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Commenters must refer to file code CMS-1753-P when commenting on the Proposed Rule. The deadline for submitting comments is 5:00 p.m. ET on September 17, 2021.

Glossary

Key Term	Definition
HCPCS	The Healthcare Common Procedure Coding System (HCPCS) is a set of health care procedure codes used by health care providers to describe the specific items and services provided.[71]
APC	The ambulatory payment classification (APC) is the OPPS unit of payment in most cases. CMS assigns individual services (HCPCS codes) to APCs based on similar clinical characteristics and similar costs. The ACP payment rate and calculated copayment apply to each service within the APC.[72]
340B	The 340B drug discount program allows certain health care providers to pay less for covered outpatient drugs. Under 340B, certain safety net health care providers can obtain discounted prices on covered outpatient drugs from drug manufacturers. Drug manufacturers are required to provide discounts on covered outpatient drugs as a condition of their drugs being covered by Medicaid.[73]
ASP	Average Sales Price (ASP) reflects the weighted average of sales prices to all purchasers, excluding nominal sales to certain entities and sales exempt from the calculation of Medicaid best price. ASP is calculated from sales data using a CMS formula and includes most discounts and rebates.[74]
WAC	Wholesale Acquisition Cost (WAC) is the manufacturer's published "list price" for a drug to wholesalers or direct purchasers. WAC is reported in wholesale price guides or other publications of drug pricing data. It does not include discounts or rebates.[75]
Biosimilar	A biosimilar (also known as a follow-on biologic) is a biological product that is highly similar to another biological product already licensed by FDA (known as the reference product).[76]
Sequestration	Sequestration is an automatic reduction in federal spending (generally by a uniform percentage) across all non-exempted federal programs.[77]

Appendix 1

TABLE 28: PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2022[78]

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
J0642	J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimabrwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	J0691	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

TABLE 29: PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2022[79]

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9122	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab	G	9364	07/01/2020	06/30/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		vedotin-ejfv, 0.25 mg				
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
C9060	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9062	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
C9064	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
C9065	C9065	Injection, romidepsin, nonlyophilized (e.g. liquid), 1mg	G	9379	10/01/2020	09/30/2023
C9066	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
C9068	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
C9069	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
C9070	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
C9071	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
C9072	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
C9073	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023
N/A	J0693	Injection, cefiderocol, 5 mg	G	9380	01/01/2021	12/31/2023
N/A	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
N/A	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	12/31/2023
N/A	C9074	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
N/A	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024

Appendix 2

2022 Proposed Medicare Coding & Payment for Drug Administration Services Under the Hospital Outpatient Prospective Payment System

CPT® Codes	Descriptor	2021 National Final OPPS $ Rates[1]	2022 National *Proposed* OPPS $ Rates[2]
Hydration Infusion			
96360	IV infusion, hydration; initial, 31 minutes to 1 hour	203.50	209.93
96361	IV infusion, hydration; each additional hour	40.00	41.06
Therapeutic/prophylactic/diagnostic infusion			
96365	IV infusion for therapy/prophylaxis/diagnosis, initial, up to 1 hour	203.50	209.93
96366	IV infusion for therapy/prophylaxis/diagnosis; each additional hour	40.00	41.06
96367	Additional sequential infusion of a new drug/substance, up to 1 hour	61.97	63.62
96368	Concurrent infusion	*Packaged*	
96369	Subcutaneous infusion; therapy/prophylaxis; initial, up to 1 hour	203.50	209.93
96370	Subcutaneous infusion; therapy/prophylaxis, each additional hour	40.00	41.06
96379	Unlisted therapeutic/prophylactic/diagnostic iv or ia injection or infusion*	40.00	41.06
Chemotherapy & complex biologic infusion			
96413	Chemo administration, iv infusion; up to 1 hr, single/initial substance or drug	310.75	327.19
96415	Chemo administration, intravenous infusion; each additional hour	61.97	63.62
96417	Chemo IV; each additional sequential infusion (different substance/drug) up to 1 hour	61.97	63.62
96422	Chemotherapy, intra-arterial infusion technique up to 1 hour	203.50	209.93
96423	Chemotherapy, intra-arterial infusion technique; each additional hour	40.00	41.06
IV push technique			
96374	Therapeutic/prophylactic/diagnostic iv push; single or initial substance or drug	203.50	209.93
96375	Therapeutic, prophylactic or diagnostic iv push, new substance/drug	40.00	41.06
96376	Therapeutic, prophylactic or diagnostic injection same substance/drug provided in facility	*Packaged*	
96373	Therapeutic prophylactic or diagnostic injection, intra-arterial	203.50	209.93
96409	Chemo administration, intravenous push, single or initial substance/drug	203.50	209.93
96411	IV push, each additional chemo substance/drug	61.97	63.62
96420	Chemotherapy, intra-arterial, push technique	310.75	327.19
Injection			
96372	Therapeutic, prophylactic or diagnostic injection, sc or im*	61.97	63.62
96377	Application on-body injector*	40.00	41.06
96401	Chemo administration sc or im; non-hormonal anti-neoplastic*	61.97	63.62
96402	Chemo administration, sc or im; hormonal anti-neoplastic*	61.97	63.62
Prolonged infusion and related codes			
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (>8 hrs), requiring use of portable or implantable pump	310.75	327.19

96416	Chemo, initiation of prolonged intravenous infusion (>8 hrs); portable/implantable pump	310.75	327.19
96425	Chemo, initiation of prolonged intra-arterial infusion (>8 hrs); portable/implantable pump	310.75	327.19
96521	Refill & maintenance of portable pump	203.50	209.93
96522	Refill/maintenance of implantable pump/reservoir system (e.g., iv, ia)	203.50	209.93
96523	Irrigation of implanted venous access device for drug delivery systems*	55.66	57.12
Other chemo administration codes			
96405	Chemo intralesional, up to and including 7 lesions*	61.97	63.62
96406	Chemo intralesional, more than 7 lesions	203.50	209.93
96440	Chemo, intracavitary; pleural cavity	310.75	327.19
96446	Chemo, admn peritoneal cavity	310.75	327.19
96450	Chemo, into CNS; e.g., intrathecal	310.75	327.19
96542	Chemo injection subarachnoid or intraventricular via sc reservoir	203.50	209.93
96549	Chemotherapy unspecified*	40.00	41.06

**** STV-Packaged Code: packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator "S", "T", or "V"; listed rates apply when code is separately payable.***

NOTE: All reimbursement is presented as national rates. Actual provider payment rates will vary according to the geographic location of the facility, resulting from application of the appropriate adjustment factor to the rate calculation. These rates have not been adjusted for any impact of sequestration. Furthermore, these rates do not apply to drug administration services furnished at off-campus outpatient departments that are subject to the site neutrality provision in Section 603 of the Bipartisan Budget Act of 2015 ("nonexcepted" departments). Such nonexcepted services, when provided by a nonexcepted off-campus provider-based department of a hospital, are paid under the MPFS at a rate 40% of the OPPS rate (PFS Relativity Adjuster).[3]

[1] CMS-1736-FC Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Final rule with comment period, 85 Fed. Reg. 85,866 (Dec. 29, 2020) and addenda B and D1, available at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-fc

[2] CMS-1753-P Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed rule, displayed Jul. 19, 2021, and addenda B and D1 available at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p

[3] CMS-1693-F Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Final rule, 83 Fed. Reg. 59,505-59,511 (Nov. 23, 2018), available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html

Collected in 07/21 and is subject to change. This information is not a guarantee of coverage or payment, not intended to provide reimbursement advice, and not intended to increase or maximize reimbursement by any payer.
Legal requirements and plan information can be updated frequently. We strongly recommend contacting the plan for more information about current coverage, reimbursement policies, restrictions, or prerequisites that may apply.

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[1] CMS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals, 86 Fed. Reg. 42,018 (Aug. 4, 2021), available at https://www.federalregister.gov/documents/2021/08/04/2021-15496/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment [hereinafter "OPPS Proposed Rule"].

[2] *Id.* at 42,081.

[3] *Id*.

[4] *Id*.

[5] CMS, Process and Information Required for a New Technology Ambulatory Payment Classification (APC) Assignment Under the Hospital Outpatient Prospective Payment System (OPPS) at 4, *available at*

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/newtechapc.pdf.

[6] OPPS Proposed Rule at 42,188.

[7] *Id*. at 42,188-89.

[8] *Id.*

[9] *Id.* at 42,188

[10] *Id*. at 42,188-89.

[11] *Id*. at 42,188-89.

[12] *Id.* at 42,136.

[13] *Id.*

[14] *Id.*

[15] *Id.* at 305.

[16] *Id.*

[17] *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018).

[18] *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019).

[19] *Am. Hosp. Ass'n v. Azar*, 983 F.3d 528 (D.C. Cir. 2020).

[20] Petition for Writ of Certiorari, *Am. Hosp. Ass'n v. Azar*, 983 F.3d 528 (D.C. Cir. 2020) (Feb. 10, 2021).

[21] *Am. Hosp. Assn. v. Becerra*, No. 20-1114, 2021 WL 2742784 (U.S. July 2, 2021).

[22] *Id.*

[23] 42 U.S.C. § 1395l(t)(12).

[24] OPPS Proposed Rule at 42,133.

[25] *Id.*

[26] CMS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59,216, 59,351 (Dec. 14, 2017), *available at* https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf.

[27] 42 U.S.C. § 1395*l*(t)(6).

[28] *Id.*

[29] OPPS Proposed Rule at 42,132.

[30] *See* CMS, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, Proposed Rule, 83 Fed. Reg. 35,704, 35,854–55 (July 27, 2018).

[31] *See id.*

[32] OPPS Proposed Rule at 42,132.

[33] *Id.*

[34] Office of the Assistant Secretary for Planning and Evaluation; HHS, Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017 (Nov. 20, 2020) at 3, FN 10, https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf.

[35] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136 § 3709, https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf; An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, Pub L. No. 117-7 (2021), https://www.congress.gov/117/plaws/publ7/PLAW-117publ7.pdf.

[36] Office of the Assistant Secretary for Planning and Evaluation; HHS, Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017 (Nov. 20, 2020) at 3, FN 10, https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf.

[37] OPPS Proposed Rule at 42,133.

[38] *Id*. at 42,117.

[39] *Id.* at 42,120.

[40] *Id.* at 42,122.

[41] *Id.* at 42,128.

[42] *Id*.

[43] *Id.* at 42,048.

[44] *Id.*

[45] CMS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19), 85 Fed. Reg. 85,866, 86,275 (Dec. 29, 2020), *available at* https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf [hereinafter "CY 2021 OPPS Final Rule"].

[46] OPPS Proposed Rule at 42,048-49.

[47] *See id.* at 42,314-18.

[48] *Id.* at 42,314.

[49] 45 C.F.R. § 180.90(c)(2).

[50] OPPS Proposed Rule at 42,314-15.

[51] *Id.* at 42,315.

[52] *Id.* at 42,318.

[53] *Id.* at 42,319.

[54] *Id.* at 42,289.

[55] *Id.* at 42,290-312.

[56] *Id.* at 42,290.

[57] *Id.*

[58] CY 2021 OPPS Final Rule at 86,261.

[59] Consolidated Appropriations Act, Pub. L. No. 116-260, Div. CC, Title I, Subtitle B, § 113 (2020).

[60] OPPS Proposed Rule at 42,238-46.

[61] *See* 42 C.F.R. 419.46.

[62] Social Security Act § 1833(t)(17)(A); 42 C.F.R. 419.46(a).

[63] OPPS Proposed Rule at 42,238-46.

[64] *Id.* at 42,246-51.

[65] *Id.* at 42,251-53.

[66] *Id.* at 42,267-73.

[67] *See* CMS, ASC Quality Reporting, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting (last accessed Aug. 12, 2021).

[68] *See CMS*, Ambulatory Surgical Center Quality Reporting (ASCQR) Program, QUALITYNET, https://qualitynet.cms.gov/asc/ascqr (last accessed Aug. 12, 2021).

[69] *Id.* at 42,232-37.

[70] *Id.* at 42,323-24.

[71] CMS, HCPCS – General Information, HCPCS Background Information, https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html (last accessed July 20, 2021).

[72] CMS, Medicare Payment Systems: Hospital Outpatient Prospective Payment System, MEDICARE LEARNING NETWORK, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/html/medicare-payment-systems.html#Hospital (last accessed July 20, 2021).

[73] Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Overview of the 340B Drug Pricing Program at vii (May 2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 (last accessed July 20, 2021); 42 U.S.C. §§ 256b, 1396r-8.

[74] 42 U.S.C. § 1395w–3a(b)(4)(A), (b)(6), (c)(1)–(3); *see also* MedPAC, Part B Drugs Payment Systems at 2 (Oct. 2017), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0 (last accessed July 20, 2021).

[75] 42 U.S.C. § 1395w–3a(c)(6)(B).

[76] Food and Drug Administration, Biosimilar and Interchangeable Products (Oct. 2017), https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (last accessed July 20, 2021).

[77] Congressional Research Service, Medicare and Budget Sequestration at 1 (Feb. 16, 2018), https://www.everycrsreport.com/files/20180216_R45106_fd97ee14ac3cccb6634abb9616e6f899f9d816a4.pdf (last accessed July 20, 2021).

[78] OPPS Proposed Rule at 42,121-22 tbl. 28.

[79] *Id.* at 42,124-26 tbl. 29.