CODINGSTRATEGIES

CY 2019 Final Rule Summary Medical Oncology Hospital Outpatient Prospective Payment System (HOPPS)

Introductory Summary

On November 2, 2018, the Centers for Medicare and Medicaid Services (CMS) issued the final rule for the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2019.

HOPPS Final Rule

The CY 2019 final rule may be located in its entirety by following the link below:
https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24243.pdf

This document in PDF form is 1182 pages in length. The format of the information is intended to serve as a highlight to the finalized changes and readers are encouraged to view the document in its entirety for further details.

Payment Rates

CMS finalized an increase of payment rates under the Outpatient Department (OPD) fee schedule with a 1.35% increase. The CY 2019 conversion factor was finalized at $79.490; however, for hospitals that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements, CMS will decrease the conversion factor by an additional 2% for the hospital. To determine this payment rate, CMS utilized data released in the inpatient prospective payment system (IPPS) finalized ruling for FY 2019 which reflected a 2.9% increase for inpatient services.

Taking the IPPS finalized increase into account, CMS then applies a few other factors as mandated when calculating payment rates for hospitals. CMS finalized a decrease of 0.8% for the multifactor productivity (MFP) adjustment. The MFP takes into consideration economy-wide productivity typically on a 10-year moving average. CMS also applied the required decrease of 0.75% due to the Affordable Care Act for years 2010 through 2019. Based on the finalized payment rates, CMS estimated the CY 2019 HOPPS expenditures would be approximately $74.1 billion, an increase of approximately $5.8 billion compared to CY 2018 HOPPS payments.

CMS is again applying a rural adjustment factor of 7.1% to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs) for CY 2019 and subsequent years. This payment adjustment will continue to exclude separately payable drugs, biologicals and devices paid under the pass-through payment policy. Ambulatory Surgical Center (ASC) payments were finalized to increase by 2.1% for those meeting quality reporting under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

Wage Index

CMS finalized to continue applying a wage index of 1.000 for frontier state hospitals that would otherwise have values of less than 1.000. This is a continuation of the policy that has been in place since CY 2011. CMS finalized, as proposed, not to extend the imputed floor for CY 2019 and subsequent years. The imputed floor is an adjustment where the wage index for hospitals in metropolitan areas cannot be less than hospitals in rural areas of the state. There are three states which currently are considered all-urban, meaning states without hospitals in rural areas: Delaware, New Jersey and Rhode Island.

The imputed floor is calculated determining the average of the highest and lowest wage indexes in each all-urban state. The average can never be greater than 1.000, and if the core-based statistical area (CBSA) has a wage index already set, and it is higher than the imputed floor, there is no gained advantage. If the wage index for a particular urban hospital was lower than the calculated imputed floor, there would be a gain as the hospital could use the higher value. CMS will not extend this adjustment and is allowing it to expire as planned after December 31, 2018.

The Office of Management and Budget (OMB) released a bulletin in which it announced that one Micropolitan Statistical Area now qualified as a Metropolitan Statistical Area, the new urban CBSA is Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The significance of this relates to reimbursement. Under HOPPS, the payment rates for a particular hospital are listed by county and each county is assigned to a particular payment CBSA locale or name. If the assignment is left blank, then the county where the hospital resides is paid per the rural designation and not one of the urban specified locations. In CY 2018, Twin Falls, ID is considered rural, but will be changing for CY 2019 to urban.

Reimbursement

Using the finalized payment information, the following services are provided and payment amounts are based upon the published Medicare allowable for the CPT®/HCPCS Level II codes in an on-campus hospital outpatient department. Even though HOPPS rates are increasing overall, several of the APCs specific to medical oncology did decrease. The following table provides the final CY 2019 payment rates compared to CY 2018 for services commonly performed in outpatient medical oncology departments.

CY 2018 – CY 2019 HOPPS On-Campus Medicare National Average Rates

HCPCS Code	Short Descriptor	SI	National Payment Rate		Variance
			2018 Final	2019 Final	
20939	Bone marrow aspir bone grfg	N	$0.00	$0.00	$0.00
36415	Routine venipuncture	Q4	$0.00	$0.00	$0.00
36430	Blood transfusion service	S	$375.07	$382.90	$7.83
36591	Draw blood off venous device	Q1	$105.04	$106.48	$1.44
36593	Declot vascular device	T	$297.57	$288.38	($9.19)

38220	Dx bone marrow aspirations	J1	$1,348.03	$1,375.50	$27.47
38221	Dx bone marrow biopsies	J1	$1,348.03	$1,375.50	$27.47
38222	Dx bone marrow bx & aspir	J1	$1,348.03	$1,375.50	$27.47
51720	Treatment of bladder lesion	T	$229.53	$231.42	$1.89
96360	Hydration iv infusion init	S	$191.09	$187.18	($3.91)
96361	Hydrate iv infusion add-on	S	$37.03	$37.88	$0.85
96365	Ther/proph/diag iv inf init	S	$191.09	$187.18	($3.91)
96366	Ther/proph/diag iv inf addon	S	$37.03	$37.88	$0.85
96367	Tx/proph/dg addl seq iv inf	S	$58.20	$59.75	$1.55
96368	Ther/diag concurrent inf	N	$0.00	$0.00	$0.00
96369	Sc ther infusion up to 1 hr	S	$191.09	$187.18	($3.91)
96370	Sc ther infusion addl hr	S	$37.03	$37.88	$0.85
96371	Sc ther infusion reset pump	Q1	$58.20	$59.75	$1.55
96372	Ther/proph/diag inj sc/im	Q1	$58.20	$59.75	$1.55
96373	Ther/proph/diag inj ia	S	$191.09	$187.18	($3.91)
96374	Ther/proph/diag inj iv push	S	$191.09	$187.18	($3.91)
96375	Tx/pro/dx inj new drug addon	S	$37.03	$37.88	$0.85
96376	Tx/pro/dx inj same drug adon	N	$0.00	$0.00	$0.00
96377	Applicaton on-body injector	Q1	$37.03	$37.88	$0.85
96379	Ther/prop/diag inj/inf proc	Q1	$37.03	$37.88	$0.85
96401	Chemo anti-neopl sq/im	Q1	$58.20	$59.75	$1.55
96402	Chemo hormon antineopl sq/im	Q1	$58.20	$59.75	$1.55
96405	Chemo intralesional up to 7	Q1	$58.20	$59.75	$1.55
96406	Chemo intralesional over 7	S	$191.09	$187.18	($3.91)
96409	Chemo iv push sngl drug	S	$191.09	$187.18	($3.91)
96411	Chemo iv push addl drug	S	$58.20	$59.75	$1.55
96413	Chemo iv infusion 1 hr	S	$297.57	$288.38	($9.19)
96415	Chemo iv infusion addl hr	S	$58.20	$59.75	$1.55
96416	Chemo prolong infuse w/pump	S	$297.57	$288.38	($9.19)
96417	Chemo iv infus each addl seq	S	$58.20	$59.75	$1.55
96420	Chemo ia push tecnique	S	$297.57	$288.38	($9.19)
96422	Chemo ia infusion up to 1 hr	S	$191.09	$187.18	($3.91)
96423	Chemo ia infuse each addl hr	S	$37.03	$37.88	$0.85
96425	Chemotherapy infusion method	S	$297.57	$288.38	($9.19)
96440	Chemotherapy intracavitary	S	$297.57	$288.38	($9.19)
96446	Chemotx admn prtl cavity	S	$297.57	$288.38	($9.19)
96450	Chemotherapy into cns	S	$297.57	$288.38	($9.19)
96521	Refill/maint portable pump	S	$191.09	$187.18	($3.91)
96522	Refill/maint pump/resvr syst	S	$191.09	$187.18	($3.91)

96523	Irrig drug delivery device	Q1	$55.96	$55.90	($0.06)
96542	Chemotherapy injection	S	$191.09	$187.18	($3.91)
96549	Chemotherapy unspecified	Q1	$37.03	$37.88	$0.85
99195	Phlebotomy	Q1	$105.04	$106.48	$1.44
G0463	Hospital outpt clinic visit	J2	$113.69	$115.85	$2.16
G0498	Chemo extend iv infus w/pump	S	$297.57	$288.38	($9.19)

Cancer Hospital Payment Adjustment

CMS finalized, as proposed, in CY 2019 to continue additional payments to cancer hospitals. The payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data.

Beginning CY 2018, the 21st Century Cures Act required the weighted average PCR be reduced by 1.0 percentage point. CMS will use the target PCR of 0.88 to determine the CY 2019 cancer hospital payment adjustment to be paid at the cost report settlement. The following Table reflects the 11 designated cancer hospitals and the estimated increase in payments for CY 2019.

TABLE 10.— ESTIMATED CY 2019 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 2019 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	37.1%
050660	USC Norris Cancer Hospital	13.4%
100079	Sylvester Comprehensive Cancer Center	21.0%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3%
220162	Dana-Farber Cancer Institute	43.7%
330154	Memorial Sloan-Kettering Cancer Center	46.4%
330354	Roswell Park Cancer Institute	16.2%
360242	James Cancer Hospital & Solove Research Institute	22.6%
390196	Fox Chase Cancer Center	8.4%
450076	M.D. Anderson Cancer Center	53.6%
500138	Seattle Cancer Care Alliance	54.3%

Standardizing APC Payment Weights

Ambulatory payment classifications (APCs) group services which are considered clinically comparable to each other with respect to the resources utilized and the associated cost. Ancillary services or items which are necessary components of the primary service are packaged into the APC rates and not separately reimbursed. CMS instructs providers to apply current procedure-to-procedure edits and then report all remaining services on the claim form. CMS will only pay for those services which are considered not packaged into another service.

CMS will continue using code G0463, hospital outpatient clinic visit, for assessment and management of a patient, in APC 5012 (Level 2 Examinations and Related Services) as the standardized code for the relative payment weights. A relative payment weight of 1.00 was finalized to be assigned to APC 5012 (code G0463). CMS finalized the use of factor of 1.00 and then dividing the geometric mean cost of each APC by the geometric mean cost of APC 5012 to derive the unscaled relative payment weight for each APC.

APC 2 Times Rule Exceptions for CY 2019

CY 2019 final rule, CMS identified 17 APCs in violation of the 2 times rule. Two of these were new since the proposed rules were released, one was resolved without intervention, which left 15 for CMS to address. The 2 times rule does not allow the codes to be assigned to an APC where the highest costing code is more than 2 times that of the lowest costing code. When a 2 times rule violation is identified, CMS and the HOP Panel will reassign codes or create a new APC. CMS only considers HCPCS codes that are significant based on the number of claims when determining if there is a 2 times rule violation.

For CY 2019, CMS made exceptions to all of the 2 times rule violation APCs, this meant no adjustments or movement of codes to other APCs to balance the highest and lowest costing codes. This exception included the two APCs 5691, Level 1 Drug Administration and 5692, Level 2 Drug Administration.

Table 16 lists the APCs identified as in violation of the 2 times rule but will not be adjusted in CY 2019.

TABLE 16.— APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2019

CY 2019 APC	CY 2019 APC Title
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5193	Level 3 Endovascular Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5822	5822 Level 2 Health and Behavior Services
5823	5823 Level 3 Health and Behavior Services

Payments of Drugs, Biologicals and Radiopharmaceuticals

Each year CMS assesses the drug packaging threshold in accordance with section 1833(t)(16)(B) of the Act. For CY 2019, CMS finalized the packaging of drugs and biologicals estimated at a per day administration cost less than or equal to $125. CMS will only pay separately for items with an estimated per day cost greater than $125 with the exception of 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.

Payment rates for HCPCS codes for separately payable drugs and biologicals are published in Addenda A and B for the final rule with comment period and based on Average Sales Price (ASP) data from the third quarter of CY 2018. This published data is used for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2018. These payment rates will also be updated in the January 2019 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2019. For items that do not currently have an ASP-based payment rate, CMS recalculates their mean unit cost from all of the CY 2017 claims data and updated cost report information available for the CY 2019 final rule with comment period to determine the final per day cost.

CMS also finalized the proposal to continue the 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. For all other drugs and biologicals that have HCPCS codes describing different doses, Medicare aggregated the CY 2017 claims data and pricing information at ASP+ 6 percent for all HCPCS codes that describe each distinct drug or biological. This provided the mean units per day in terms of the HCPCS code with the lowest dosage descriptor. For other drugs and biologicals that have HCPCS codes describing different doses, CMS multiplied the proposed weighted average ASP+6 percent per unit across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2019 drug packaging threshold of $125.

CMS did not receive any public comments related to this proposal; therefore, will be finalizing the proposal without modification. The drugs and biologicals for which this final packaging status applies for CY 2019 are displayed in Table 42 below.

Table 42– HCPCS Codes To Which The CY 2019 Drug-Specific Packaging Determination Methodology Applies

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25mg	K

J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

For CY 2019, CMS will continue the current payment policy in effect since CY 2013. This payment policy pays for separately payable drugs and biologicals at ASP+6 percent. These separately payable drugs and biologicals are listed in Addenda A and B to the final rule. CMS also finalized to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at ASP minus 22.5 percent.

For drugs or biologicals without sufficient data on sales price during the initial sales period, section 1847A(c)(4) of the Act allows for payments based on Wholesale Acquisition Cost (WAC). The Act defines certain payments must be made with a 6 percent add-on; however, the Act does not require the same add-on amount when utilizing WAC-based pricing. To be consistent with proposals outlined within the CY 2019 PFS proposed rule, CMS also proposed to utilize a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs in the hospital outpatient setting. For drugs and biologicals acquired under the 340B Program, the 340B Program rate (WAC minus 22.5 percent) would apply.

CMS received numerous comments regarding this proposal and CMS indicated they feel the proposal will improve Medicare payment rates by aligning payments with acquisition costs, as the WAC does not account for discounts and rebates associated with the ASP. Some commenters requested for biosimilar biological products to be excluded from this proposal; however, CMS did not accept this request as this policy was not intended to provide preferential treatment to any particular drugs or biologicals.

After consideration of the comments received, CMS finalized their proposal without modification. Starting January 1, 2019, a 3 percent add-on will be utilized instead of a 6 percent add-on for drugs paid based on WAC.

CMS previously finalized the payment policy for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act in CY 2016 and CY 2017. For CY 2019, CMS proposed to continue the policy from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. CMS also proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

Many commenters agreed with the proposal and indicated the proposal would ensure fair access to biosimilar treatments and would continue to lower costs and improve patient access. Some commenters recommended to eliminate the proposal to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar product as it could result in inappropriate treatment changes from a reference product without pass-through status to one with pass-through payment. CMS did not agree with this concern and indicated that biosimilar products should become established within the market as with other new drugs and biologicals.

Upon review of the public comments, CMS has finalized their proposal without modification to continue to make all biosimilar biologicals products eligible for pass-through payment and not just the first product for a reference. CMS has also finalized to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent rather than that of the reference product's ASP.

CMS also finalized as proposed to expire pass-through status of twenty-three (23) drugs and biologicals on December 31, 2018. These drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2018. A section of Table 37 is provided below detailing the drugs and biologicals to be removed from the pass-through list utilized within oncology or hematology.

Table 37. – Drugs and Biologicals For Which Pass-Through Payment Status Expires December 31, 2018

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 Status Indicator	Final CY 2019 APC	Pass-Through Payment Effective Date
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	K	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	K	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	K	1846	04/01/2016

J9022	Injection, atezolizumab, 10 mg	K	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	K	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	K	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	K	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	K	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	K	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	k	1822	07/01/2015

Medicare also proposed to continue pass through status for 45 drugs and biologicals for CY 2019. These drugs and biologicals were approved for pass-through status between January 1, 2017 and July 1, 2018. In addition, an additional four drugs and biologicals that have already had 3 years of pass-through payment status but the pass-through status is required to be extended for an additional 2 years under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141) were also included bringing the total to 49 drugs. CMS finalized these 49 drugs and biologicals that will continue pass-through payment status for CY 2019, which are referenced within Table 38.

For CY 2019, CMS will continue to pay for pass-through drugs and biologicals at the ASP+6 percent and continue to update pass-through payment rates on a quarterly basis through the CMS website. A section of Table 38 is provided below detailing the drugs and biologicals commonly utilized within oncology or hematology to be maintained on the pass-through list for CY 2019.

Table 38 – Drugs and Biologicals With Pass-Through Payment Status In CY 2019

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass Through Payment Effective Date
C9016	J3316	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
C9024	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018
C9028	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9030	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9033	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018
C9463	J0185	Injection, aprepitant, 1mg	G	9463	04/01/2018
C9464	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
C9467	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018
C9468	J7203	Injection, factor ix (antihemophilic factor,	G	9468	04/01/2018

		recombinant), glycopegylated, Rebinyn, 1 i.u.			
C9492	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
N/A	Q2042*	Tisagenlecleucel, up to 600 million car - positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q2041	Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion	G	9035	04/01/2018
N/A	Q2042*	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q9993	J3304	Injection, triamcinolone acetonide, preservative - free, extended -release, Microsphere formulation, 1 mg	G	9469	04/01/2018
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018
N/A	C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019

*HCPCS code Q2040 (Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion) will be deleted on December 31, 2018 and will be replaced by Q2042 (Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose) on January 1, 2019.

340B Drug Discount Program

The 340B Drug Discount Program was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992 and is administered by the Health Resources and Services Administration (HRSA) within HHS. This program allows participating hospitals and other health care providers to purchase certain “covered outpatient drugs” at discounted prices from drug manufacturers.

HRSA calculates the ceiling price for each covered outpatient drug, which is the average manufacturer price (AMP) minus the unit rebate amount (URA). This ceiling price represents the maximum price a drug manufacturer can charge a covered entity for the drug. It is noted, covered entities have the option to participate in HRSA's Prime Vendor Program (PVP), which may allow for negotiation of additional discounts (known as "subceiling prices").

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (does not include drugs on pass-through payment status or vaccines) to be reimbursed the rate of ASP minus 22.5 percent. This was significantly different than the previous rate of ASP+6 percent. CMS stated the goal is to make Medicare payments for separately payable drugs more in alignment with resources expended by hospitals to acquire the drugs, while also recognizing the intention of the 340B Program was to allow hospitals to stretch resources and provide access to care for Medicare beneficiaries and other patients.

For CY 2019, CMS proposed to continue the policies as finalized in CY 2018 with a few exceptions. As previously addressed, CMS proposed to pay biosimilar biological products at minus 22.5 percent of the biosimilar's ASP, not the reference drug's ASP. Drugs not purchased under the 340B Program will continue to be paid at ASP+6 percent. Hospitals will continue to report drugs purchased through the 340B Drug Discount Program with modifier JG on the same claim line items as the drug HCPCS code. Additionally, rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment and report TB modifier for 340B-acquired drugs on claim forms and paid at ASP+6 percent.

Comments were received which opposed the proposal to continue to pay for separately payable drugs and biologicals obtained through the 340B Program at ASP minus 22.5 percent. Many indicated this has hurt hospitals financially and concerns were raised that the same service costing more in a non-340B hospital than at 340B hospitals. One commenter stated their cancer care options are limited versus those at non-340B hospitals and others indicated that CMS does not have the legal authority to implement payment reductions of this nature.

In response to these comments, CMS indicated the payment rate of ASP+6 significantly exceeded the discounts for covered outpatient drugs by 340B hospitals. Furthermore, these discounts were as low as 50 percent below ASP; therefore, the 22.5 percent represents as average minimum discount. Regarding the differences costs between different hospitals, CMS indicated the objective of this policy was to lower costs for Medicare beneficiaries and the cost savings of the 340B Program should be passed to their beneficiaries.

For CY 2019, CMS has finalized the proposal without modification and will continue to apply policies implemented in CY 2018 with the exception of the methodology in calculating payment for 340B-acquired biosimilars.

Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

New for CY 2019, CMS proposed to apply the 340B Drug Payment Policy to nonexcepted off-campus provider-based departments (PBDs). Due to provisions in the Bipartisan Budget Act of 2015, nonexcepted off-campus PBDs as of November 2, 2015 had not billed for services to CMS and were outside of 250 yards from the main building of the hospital. Since these departments are not considered outpatient departments of the hospital, they are paid under a different payment system; currently that is MPFS. For this reason CMS did not apply the 340B payment policy to nonexcepted off-campus PBDs in CY 2018; however, because hospitals can acquire drugs and biologicals under the 340B Program for use in a nonexcepted off-campus PBD, CMS felt this could result in incongruity between payment amounts depending on where they were provided.

Due to the potential for hospitals to move services from excepted off-campus PBDs to nonexcepted off-campus PBDs and be paid at a higher rate of ASP+6 percent versus ASP minus 22.5 percent, thereby creating a non-neutral payment structure. CMS proposed to pay under the MPFS an amount equal to ASP minus 22.5 percent, for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program and furnished and billed by nonexcepted off-campus PBDs of a hospital.

CMS received comments from organizations representing oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices and health insurers supporting the proposal. A pharmaceutical company commented, *"…the 340B Program has grown beyond its original intent and needs to be refocused to better meet the needs of vulnerable patients."* This commenter indicated there is an incentive to shift administration of drugs from excepted to nonexcepted off-campus PBDs to secure higher payment.

Some commenters including organizations representing community oncology practices indicated, "*…the opportunity for 340B-participating hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through the acquisition of independent community oncology practices",* which results in "*further fueling the program's staggering growth*". Commenters also cited a report that states, "…*over the last decade, 658 community oncology practices have been acquired by hospitals, and 3 out of 4 of these acquisitions were by hospitals already eligible for the 340B Program."* The commenters believe this growth of Part B drug spending has been driven by higher payments in the hospital outpatient setting.

One commenter indicated this creates two undesirable incentives. *"First, it creates an incentive for physicians to join a hospital to furnish the same types of services that could have been furnished in the physician office setting, thereby increasing costs to the Medicare program, Medicare beneficiaries, and taxpayers without any associated increase in access to care for Medicare beneficiaries, particularly low-income beneficiaries. Second, it encourages hospitals to*

move services off the hospital campus for financial incentives." Another commenter suggested a higher reduction in future years, as the current 22.5 percent was seen to be "conservative".

Upon review of the comments received related to this proposal, CMS finalized their proposal, without modification, to make payment for separately payable 340B-acquired drugs furnished by nonexcepted off-campus departments of a hospital under the PFS, and to establish the payment rate for those drugs at ASP minus 22.5 percent. In addition, starting January 1, 2019, nonexcepted off-campus PBDs of a hospital paid under PFS will be required to report the "JG" modifier on the claim line identifying drugs purchased under the 340B Program.

Site-Neutral Payments for Hospital Outpatient Clinic Visits

In response to the Bipartisan Budget Act of 2015, CMS established new guidelines to address the difference in reimbursement payments for the exact same procedure between varying places of service, primarily hospital vs. ambulatory surgical center (ASC) vs. physician office. The Act established a hard and fast deadline (November 2, 2015) for establishment of any new provider-based departments and the distance (250 yards) the new department could be from the main buildings of the hospital and still receive payment rates established under HOPPS.

CMS stated the provider may treat an off-campus as provider-based if it meets certain requirements. A "campus" is defined as *"the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus".* Due to what was considered an alarming rate of hospitals acquiring physician practices and the tendency for provider-based departments of a hospital to be paid more than a traditional office setting, changes were made.

As explained in previous ruling summaries, excepted off-campus provider-based departments (PBDs) are settings which were established and billing for services prior to November 2, 2015 and within the previously set distance of 35 miles. Excepted off-campus PBDs are paid at the HOPPS full established rate for each service and considered grandfathered into the payments under HOPPS even if the new distance threshold is not met.

The practice of CMS neutralizing payments for services based on utilization is not new. This occurred in the CY 2008 OPPS/ASC final rule. At that time, CMS had concerns about expenditures for some hospital outpatient services which showed significant growth. As a result, CMS established a set of packaging policies intended to encourage efficiency and potentially control future growth in the number of HOPPS services. Effective CY 2008, CMS packaged seven categories of services and items specific to primary diagnostic or therapeutic modalities believed to be ancillary or supportive.

In CY 2014, and made effective in CY 2015, CMS also introduced another method of controlling spending with the introduction of comprehensive APCs (C-APCs). CMS expanded the packaging

of services to include items involved in many same day or surgical procedures. The idea was to make HOPPS more like a prospective payment system and less like a per service fee schedule.

HOPPS is the fastest growth sector of Medicare payments out of all of the payment systems under Part A and B. The rate of growth, approximately 8% a year, is concerning to CMS. Total spending for HOPPS is projected to increase by more than $5 billion from approximately $70 billion in CY 2018 through CY 2019 to nearly $75 billion. This is approximately twice the estimated spending of a decade ago in CY 2008.

For CY 2019, CMS proposed a site-neutral method for controlling *"unnecessary increases in the volume of covered outpatient department services."* As of October 2018 (due to timely filing hospitals still have 2 months to submit charges for CY 2017), code G0463 was billed 10.8 million times with modifier PO as required for excepted off-campus provider-based departments (PBDs) out of a total 30.5 million lines in CY 2017. CMS believes the increase in reporting code G0463 is related to the payment incentive in the higher cost setting and could effectively be provided safely in a lower cost setting. By reducing the rate to one equivalent of the Physician Fee Schedule (PFS) rate, the incentive and decision about where to perform the service, so it has the most favorable financial impact, would be removed.

Several commenters questioned Medicare's authority to make a change to the reimbursement for services provided in an excepted off-campus PBDs, as these settings are paid as facilities under the full HOPPS rate. Within the final ruling, CMS indicated the adjustments to the reimbursement of the clinic visit (G0463) are for volume control reasons and would therefore fall within the authority of the Secretary per the Bipartisan Budget Act of 2015 to make the necessary changes.

For CY 2019, CMS proposed to utilize a Medicare Physician Fee Schedule (MPFS) payment rate for code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed in excepted off-campus provider-based departments. This would mean the reimbursement for code G0463 would be 40% of the HOPPS set rate, the same for nonexcepted off-campus PBDs.

CMS is moving forward with the payment adjustment for code G0463 in excepted off-campus PBDs but will implement this change over 2 years. When a reduction is greater than 20 percent for a given year, the reduction is phased in over time. CMS will apply a 50 percent reduction of the total amount to be decreased, this equates to 30 percent in CY 2019 (the total amount of the reduction is 60 percent to meet the PFS rate) and the remaining amount in CY 2020. In CY 2019, the reimbursement rate for G0463 in an excepted off-campus PBD will be 70 percent of the HOPPS full rate. In CY 2020, the reimbursement rate for G0463 will be the PFS rate for the service, this would equate to 40 percent of the full HOPPS rate, unless the PFS rate is changed.

Only on-campus hospital outpatient departments would be reimbursed at the full HOPPS value for code G0463 in CY 2019. Excepted off-campus PBDs would continue to report G0463 with modifier PO.

Expansion of Clinical Families Services in Excepted Off-Campus Departments

In response to the CY 2017 HOPPS proposed rule, CMS received questions regarding whether excepted off-campus PBDs could expand the number or type of services offered and still maintain the excepted status, meaning still be paid as an HOPPS outpatient department of the hospital. This raised concerns for CMS as there was no limit to hospitals continuing to acquire physician practices, adding new services to already established and excepted departments, and receiving potentially higher reimbursement due to the combined technical and professional amounts. CMS believes the services furnished at the time of the Act are those services which are covered or fall under the grandfathered pricing and any new services would be considered nonexcepted.

In the CY 2017 proposed rule, CMS outlined a clinical family of services. In the original proposal, if an excepted off-campus PBD provided or billed for services in one of the clinical families for the first time on or after November 2, 2015, those services were not considered expected and would not be paid under HOPPS. The services instead would be paid under MPFS in alignment with nonexcepted off-campus PBDs. The proposal was not finalized as there were considerable comments and concerns on whether or not CMS had the authority to make the changes based on interpretations of the law, the complexity of reporting and no accounting for the negative impact for emerging technologies, among other things. In CY 2018, CMS did not address the clinical families other than state claims data would continue to be monitored.

CY 2019 provided the first year in which the claims data from CY 2017 could be analyzed and review reporting of the PN and PO modifiers. The PN modifier is billed on all services in a nonexcepted off-campus PBD and modifier PO is reported for all services in an excepted off-campus PBD. CMS continues to maintain concerns that previous rulings may incentivize hospitals to continue to acquire physician practices and add those practices to nonexcepted off-campus PBDs or transition services from nonexcepted off-campus PBDs; thereby driving up expenses and decreasing competition to hospitals that own the provider-based departments.

CMS provided additional expenditure and volume data to support the growing increases in HOPPS services since CY 2010. Tables 50 and 51 reflect the updated data as of the final ruling and the increases in expenditures and volumes and intensity of services in the outpatient hospital setting.

TABLE 50. —GROWTH IN EXPENDITURES UNDER OPPS FROM CY 2010 THROUGH CY 2019* (in millions)

Calendar Year (CY)	Incurred Cost	Percent Increase
CY 2010	$36,774	-
CY 2011	$39,781	8.2%

TABLE 51. —PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES*

Calendar Year (CY)	Percentage Increase
CY 2011	3.7%
CY 2012	5.1%

CY 2012	$43,154	8.5%
CY 2013	$46,462	7.7%
CY 2014	$52,429	12.8%
CY 2015	$56,275	7.3%
CY 2016	$59,869	6.4%
CY 2017	$64,050	7.0%
CY 2018	$68,264	6.6%
CY 2019 (Estimated)	$74,468	9.1%

*Includes Medicare Part B Drug Expenditures.

CY 2013	5.5%
CY 2014	8.1%
CY 2015	3.4%
CY 2016	6.4%
CY 2017	5.4%
CY 2018	6.4%
CY 2019 (Estimated)	5.4%

*Includes Medicare Part B Drug Expenditures.

For CY 2019 and subsequent years, CMS proposed if any items or services from any of the selected clinical families were not furnished during the baseline of November 1, 2014 through November 1, 2015, the services would not be considered covered under the excepted status and would instead be nonexcepted and paid under MPFS. However, if an excepted off-campus PBD furnished new services or items from a clinical family for which other services were already provided as part of that family, these services would have been considered excepted and paid under HOPPS, as it would not have been considered a "service expansion."

CMS did not finalize the expansion of services in excepted off-campus PBDs to be paid at the PFS rates for services provided in the 19 clinical families outside the designated timeframe. CMS indicated they will continue to monitor expansion of services and may adopt a limitation on the expansion of excepted services in future rulemaking. Excepted off-campus PBDs will continue to be reimbursed under HOPPS CY 2019 rates for all services billed and items paid under HOPPS (except for the clinic visit, G0463) as long as the excepted off-campus PBD status remains.