

Centers for Medicare & Medicaid Services CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) Final Rule Summary

On November 2, the Centers for Medicare & Medicaid Services (CMS) released a <u>final rule</u> updating Medicare payment rates and policies under the hospital outpatient prospective payment system (OPPS) and the ambulatory surgical center payment system for calendar year 2022. The final rule (1) updates payment policies and rates for CY 2022; (2) establishes the payment rate for the blood not otherwise classified (NOC) HCPCS code P9099; (3) finalizes the payment for pathogen(s) tests for platelets HCPCS Code P9100; and (4) clarifies the payment for CAR-T cell therapy Current Procedural Terminology (CPT) codes. The final rule is effective on January 1, 2022.

Payment Policies and Rates for Transfusion Medicine and Cellular Therapies

Consistent with the longstanding methodology used since 2005, CMS finalized the <u>proposal</u> to continue establishing separate payment rates for blood and blood products using their blood-specific cost-to-charge ratio (CCR) methodology, which uses actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs.

For CY 2022, CMS finalized the proposal to use the CY 2019 claims data to establish the OPPS rates for CY 2022 as a result of the COVID-19 public health emergency (PHE). As detailed in the Tables below, CMS finalized 2022 payment rates and policies for all items and services furnished under OPPS, including blood products, transfusion, apheresis, stem cell procedures, and transfusion laboratory services and increased the payment rate for nearly all blood products and services by 2.1 percent.

Payment Policy for Blood Not Otherwise Classified (NOC) HCPCS Code P9099

On January 1, 2020, CMS established a new HCPCS code P9099 to enable providers to report unclassified blood products. In CY 2020, CMS originally assigned P9099 to status indicator "E2" (Not payable by Medicare when submitted on an outpatient claim) in order to identify an individual blood product HCPCS code and crosswalk the payment rate from an established blood product HCPCS code to HCPCS code P9099. CMS recognized concerns from the blood community that assigning HCPCS code P9099 to a non-payable status in the OPPS meant that hospitals would not receive payment when they used unclassified blood products and claim lines billed with P9099 would be rejected by Medicare, which prevents providers from tracking the utilization of unclassified blood products.

Additionally, AABB, America's Blood Centers and the American Red Cross submitted comments requesting that CMS not set a payment rate for P9099 at the rate of the lowest cost blood product (P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), as this rate could have the unintended effect of discouraging the adoption and implementation of new items and services, which would be contrary to the intent of establishing a miscellaneous code. Unfortunately, CMS finalized a proposal to make P9099 separately payable, assigning it a status indicator of "R" and the payment rate equal to the lowest paid separately payable blood product in the OPPS, which is P9043 (Infusion, plasma protein fraction [human], 5 percent, 50 ml), with a payment rate of \$7.79 per unit for CY 2021 and proposed this same policy for CY 2022.

On August 23, 2021, the CMS Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that CMS authorize the Medicare administrative contractors to compensate hospitals on the basis of reasonable cost for new blood products billed with HCPCS code P9099. The blood community



urged CMS to adopt the recommendation of the HOP Panel and assign HCPCS code P9099 the "F" status indicator (paid at reasonable cost) and that regardless of the status indicator assigned to P9099, the code continues to be identified and processed as a blood product HCPCS P-code in all of its systems. However, CMS did not support reasonable cost payment for HCPCS code P9099 and explained that since the OPPS is a prospective payment system, it is important to limit rather than expand the types of services within the system that do not receive a prospective payment.

Therefore, CMS finalized the proposal to make P9099 separately payable, assigning it a status indicator of "R" and the payment rate equal to the lowest paid separately payable blood product in the OPPS, which is P9043 (Infusion, plasma protein fraction [human], 5 percent, 50 ml), with a payment rate of \$7.79 per unit. CMS further indicated that this policy aligns with OPPS policy to pay not otherwise classified codes at the lowest available ambulatory payment classification (APC) rate (APC 9537 - blood component/product noc) for a service category, while providing a payment when a service is reported. Finally, the agency stated that they understand the challenge in creating payment methodology for HCPCS code P9099 and will explore other ideas for payment policy in the future.

Payment Policy for Pathogen(s) Tests for Platelets HCPCS Code P9100

In CY 2018, CMS established new HCPCS code P9100 to identify pathogen test for platelets. This code was assigned to the New Technology APC 1494 through CY 2020 with payment rates ranging from \$25.50 to \$35.50. During this time, only rapid bacterial testing was described by HCPCS code P9100 with an estimated cost of \$33.00. Therefore, in CY 2021, CMS assigned P9100 to APC 5732 (Level 2 Minor Procedures) with a payment rate of \$33.84.

For CY 2022, CMS proposed to keep the HCPCS code P9100 assignment to APC to 5732; however, large volume delayed sampling (LVDS) was identified as a new type of pathogen test for platelets. AABB, America's Blood Centers and the American Red Cross submitted comments requesting that CMS reassign HCPCS code P9100 from APC 5732 to APC 5733 (Level 3 Minor Procedures) with a payment rate of \$54.24 in 2022. The agency agreed and finalized the policy indicating that the payment rate for P9100 reflects the resource cost of the mixture of rapid bacterial platelet and LVDS tests.

Chimeric Antigen Receptor T-cell (CAR-T) Therapy CPT Codes

CMS reaffirmed the agency's understanding that all steps to manufacturing a CAR T-cell product from collection to administration are included in the HCPCS codes. In 2019, CMS finalized payment policy for CAR-T cell therapy and assigned the various steps required to harvest, collect, and prepare the genetically modified T-cells for administration to the CPT codes 0537T, 0538T, and 0539T with the status indicator "B" (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type) to indicate that the services are not paid under the OPPS and are for tracking purposes only. CMS believes that payment for all of these steps are included in the current HCPCS codes for the approved CAR T-cell therapies and does not pay separately for each step used to manufacture a drug or biological.

CMS stated that the current HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures, as these services are included in the manufacturing of these biologicals and therefore, payment for these services is incorporated into the drug codes. Additionally, the agency indicated the following:

We note that although there is no payment associated with CPT codes 0537T, 0538T, and 0539T for reasons stated previously, these codes can still be reported to CMS for tracking purposes. We thank commenters for their feedback related to our guidance contained in MLN



Matters Article SE19009. We are not revising this document at this time as we believe these instructions are consistent with our longstanding policies, but we appreciate the feedback from stakeholders. We believe that the comments in reference to payment for services in settings not payable under the OPPS are outside the scope of the CY 2022 OPPS/ASC proposed rule. Accordingly, we are not revising the existing codes for CAR T-cell therapies to remove leukapheresis and dose preparation procedures, and we are not accepting the recommendations at this time to revise the status indicators for procedures described by CPT codes 0537T, 0538T, and 0539T. We will continue to evaluate and monitor payment for CAR T-cell therapies.

Therefore, CMS will continue to assign procedures described by CPT codes 0537T, 0538T, and 0539T to status indicator "B" (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type). Please see the table below for description and status indicators for the CPT codes.

Table 1. CAR T-cell Therapy Preparation and Administration Final Status Indicator (SI) and APC Assignments for CY 2022

CPT Code	Long Descriptors	Proposed CY 2022 SI	Final CY 2022 SI	Final CY 2022 APC
0537T	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	В	В	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg., cryopreservation, storage)	В	В	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	В	В	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	S	5694

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If you have any feedback that you would like for AABB to consider or if you have any questions on the final rule, please email advocacy@aabb.org.



Table 2. Blood and Blood Products											
HCPCS Code	Short Descriptor	2022 SI	2021 APC	2022 APC	Final 2021 Payment Rate	Final 2022 Payment Rate	\$ Change 2021-2022	% Change 2021-2022			
P9010	Whole blood for transfusion	R	9510	9510	\$150.14	\$153.17	\$3.03	2.0%			
P9011	Blood split unit	R	9520	9520	\$147.58	\$150.69	\$3.11	2.1%			
P9012	Cryoprecipitate each unit	R	9511	9511	\$79.85	\$81.53	\$1.68	2.1%			
P9016	Rbc leukocytes reduced	R	9512	9512	\$188.51	\$192.39	\$3.88	2.1%			
P9017	Plasma 1 donor frz w/in 8 hr	R	9508	9508	\$82.66	\$84.40	\$1.74	2.1%			
P9019	Platelets, each unit	R	9515	9515	\$71.29	\$72.79	\$1.50	2.1%			
P9020	Plaelet rich plasma unit	R	9516	9516	\$200.00	\$204.20	\$4.20	2.1%			
P9021	Red blood cells unit	R	9517	9517	\$137.63	\$140.53	\$2.90	2.1%			
P9022	Washed red blood cells unit	R	9518	9518	\$379.86	\$387.85	\$7.99	2.1%			
P9023	Frozen plasma, pooled, sd	R	9509	9509	\$89.15	\$91.01	\$1.86	2.1%			
P9025*	Plasma cryo redu path each	R	9538	9538	\$65.70	\$67.08	\$1.38	2.1%			
P9026*	Cryo fib comp path redu each	R	9539	9539	\$79.85	\$81.53	\$1.68	2.1%			
P9031	Platelets leukocytes reduced	R	9526	9526	\$149.92	\$153.07	\$3.15	2.1%			
P9032	Platelets, irradiated	R	9500	9500	\$141.69	\$144.68	\$2.99	2.1%			
P9033	Platelets leukoreduced irrad	R	9521	9521	\$213.19	\$217.66	\$4.47	2.1%			
P9034	Platelets, pheresis	R	9507	9507	\$323.99	\$330.80	\$6.81	2.1%			
P9035	Platelet pheres leukoreduced	R	9501	9501	\$486.80	\$496.91	\$10.11	2.1%			
P9036	Platelet pheresis irradiated	R	9502	9502	\$604.89	\$617.61	\$12.72	2.1%			
P9037	Plate pheres leukoredu irrad	R	9530	9530	\$617.33	\$630.32	\$12.99	2.1%			
P9038	Rbc irradiated	R	9505	9505	\$169.31	\$172.87	\$3.56	2.1%			
P9039	Rbc deglycerolized	R	9504	9504	\$436.65	\$445.83	\$9.18	2.1%			
P9040	Rbc leukoreduced irradiated	R	9522	9522	\$260.55	\$266.03	\$5.48	2.1%			
P9043	Plasma protein fract,5%,50ml	R	9514	9514	\$7.99	\$8.17	\$0.18	2.3%			
P9044	Cryoprecipitatereducedplasma	R	9523	9523	\$65.70	\$67.08	\$1.38	2.1%			
P9048	Plasmaprotein fract,5%,250ml	R	9519	9519	\$160.34	\$163.72	\$3.38	2.1%			
P9050	Granulocytes, pheresis unit	E2	Not	t paid by M	ledicare when outpat	submitted on itent bill type).		ims (any			
P9051	Blood, l/r, cmv-neg	R	9524	0965	\$212.23	\$216.68	\$4.45	2.1%			
P9052	Platelets, hla-m, l/r, unit	R	9525	9519	\$805.18	\$822.11	\$16.93	2.1%			
P9053	Plt, pher, l/r cmv-neg, irr	R	9531	0964	\$447.31	\$456.71	\$9.40	2.1%			
P9054	Blood, l/r, froz/degly/wash	R	9527	0965	\$310.70	\$317.22	\$6.52	2.1%			
P9055	Plt, aph/pher, l/r, cmv-neg	R	9528	9519	\$480.04	\$490.13	\$10.09	2.1%			
P9056	Blood, l/r, irradiated	R	9529	9529	\$154.16	\$157.39	\$3.23	2.1%			
P9057	Rbc, frz/deg/wsh, l/r, irrad	R	9532	9532	\$260.59	\$266.06	\$5.47	2.1%			
P9058	Rbc, l/r, cmv-neg, irrad	R	9533	9533	\$243.87	\$248.99	\$5.12	2.1%			
P9059	Plasma, frz between 8-24hour	R	9513	9513	\$71.15	\$72.64	\$1.49	2.1%			
P9060	Fr frz plasma donor retested	R	9503	9503	\$65.08	\$66.45	\$1.37	2.1%			



Table 2 (continued). Blood and Blood Products										
P9070	Pathogen reduced plasma pool	R	9534	9534	\$53.10	\$54.22	\$1.12	2.1%		
P9071	Pathogen reduced plasma sing	R	9535	9535	\$122.82	\$125.40	\$2.58	2.1%		
P9073	Platelets pheresis path redu	R	9536	9536	\$583.87	\$596.13	\$12.26	2.1%		
P9099	Blood component/product noc	R	9537	9537	\$7.99	\$8.17	\$0.18	2.3%		

^{*}HCPCS codes P9025 and P9026 are new codes effective for dates of service on or after October 1, 2021.



	Table 3. Transfusion, Apheresis, and Stem Cell Procedures										
HCPCS Code	Short Descriptor	2022 SI	2021 APC	2022 APC	Final 2021 Payment Rate	Final 2022 Payment Rate	\$ Change 2020- 2021	% Change 2020-2021			
36430	Blood transfusion service	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36440	Bl push transfuse 2 yr/<	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36450	Bl exchange/transfuse nb	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36455	Bl exchange/transfuse non-nb	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36456	Prtl exchange transfuse nb	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36460	Transfusion service fetal	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36511	Apheresis wbc	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
36512	Apheresis rbc	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
36513	Apheresis platelets	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
36514	Apheresis plasma	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
36516	Apheresis immunoads slctv	S	5243	5243	\$4,037.71	\$4,130.46	\$92.75	2.3%			
36522	Photopheresis	S	5243	5243	\$4,037.71	\$4,130.46	\$92.75	2.3%			
38205	Harvest allogeneic stem cell	В			Not paid	under OPPS					
38206	Harvest auto stem cells	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
38207	Cryopreserve stem cells	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38208	Thaw preserved stem cells	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38209	Wash harvest stem cells	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38210	T-cell depletion of harvest	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38211	Tumor cell deplete of harvest	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38212	Rbc depletion of harvest	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38213	Platelet deplete of harvest	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38214	Volume deplete of harvest	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38215	Harvest stem cell concentrate	S	5241	5241	\$397.06	\$405.37	\$8.31	2.1%			
38220	Dx bone marrow aspirations	J1	5072	5072	\$1,407.00	\$1,436.99	\$29.99	2.1%			
38221	Dx bone marrow biopsies	J1	5072	5072	\$1,407.00	\$1,436.99	\$29.99	2.1%			
38222	Dx bone marrow bx & aspir	J1	5072	5073	\$2,370.01	\$2,421.55	\$51.54	2.2%			
38230	Bone marrow harvest allogen	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
38232	Bone marrow harvest autolog	S	5243	5243	\$4,037.71	\$4,130.46	\$92.75	2.3%			
38240	Transplt allo hct/donor	J1	5244	5244	\$31,838.13	\$41,026.98	\$9,188.85	28.9%			
38241	Transplt autol hct/donor	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
38242	Transplt allo lymphocytes	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
38243	Transplj hematopoietic boost	S	5242	5242	\$1,363.16	\$1,393.02	\$29.86	2.2%			
88184	Flowcytometry/ tc 1 marker	Q2	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
88185	Flowcytometry/tc add-on	N		der OPPS; p	payment is pack fore, there is no	aged into payı	ment for other				
88187	Flowcytometry/read 2-8	В	Not paid under OPPS.								
88188	Flowcytometry/read 9-15	В				inder OPPS.					
88189	Flowcytometry/read 16 & >	В	Not paid under OPPS.								



	Table 4. Transfusion Laboratory Services										
HCPCS Code	Short Descriptor	2022 SI	2021 APC	2022 APC	Final CY 2021 Payment	Final CY 2022 Payment Rate	\$ Change 2021-2022	% Change 2021-2022			
86850	Rbc antibody screen	Q1	5671	5671	\$49.76	\$50.75	\$0.99	2.0%			
86860	Rbc antibody elution	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86870	Rbc antibody identification	Q2	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
86880	Coombs test direct	Q1	5733	5733	\$55.66	\$56.85	\$1.19	2.1%			
86885	Coombs test indirect qual	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86886	Coombs test indirect titer	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86890	Autologous blood process	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86891	Autologous blood op salvage	Q1	5674	5674	\$656.15	\$669.29	\$13.14	2.0%			
86900	Blood typing serologic abo	Q1	5734	5734	\$111.95	\$115.16	\$3.21	2.9%			
86901	Blood typing serologic rh(d)	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86902	Blood type antigen donor ea	Q1	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
86904	Blood typing patient serum	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86905	Blood typing rbc antigens	Q1	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
86906	Bld typing serologic rh phnt	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86920	Compatibility test spin	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86921	Compatibility test incubate	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86922	Compatibility test antiglob	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86923	Compatibility test electric	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86927	Plasma fresh frozen	S	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86930	Frozen blood prep	Q1	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
86931	Frozen blood thaw	Q1	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
86932	Frozen blood freeze/thaw	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86945	Blood product/irradiation	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86950	Leukocyte transfusion	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86960	Vol reduction of blood/prod	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86965	Pooling blood platelets	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86970	Rbc pretx incubatj w/chemical	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86971	Rbc pretx incubatj w/enzymes	Q1	5673	5673	\$291.26	\$297.45	\$6.19	2.1%			
86972	Rbc pretx incubatj w/density	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86975	Rbc serum pretx incubj drugs	Q1	5735	5735	\$270.22	\$277.18	\$6.96	2.6%			
86976	Rbc serum pretx id dilution	Q1	5731	5731	\$24.67	\$25.23	\$0.56	2.3%			
86977	Rbc serum pretx incubj/inhib	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86978	Rbc pretreatment serum	Q1	5732	5732	\$33.84	\$34.57	\$0.73	2.2%			
86985	Split blood or products	Q1	5672	5672	\$149.16	\$152.32	\$3.16	2.1%			
86999	Transfusion procedure	Q1	5731	5731	\$24.67	\$25.23	\$0.56	2.3%			
P9100	Pathogen test for platelets	S	1494	5732	\$33.84	\$56.85	\$23.01	68.0%			



Table 5. CAR T-Cell Therapies											
HCPCS Code	Short Descriptor	2022 SI	2022 APC	Final CY 2021 Payment	Final CY 2022 Payment	\$ Change 2021-2022	% Change 2021- 2022				
Q2041	Axicabtagene ciloleucel car+	K	9035	\$395,380.00	\$395,380.00	\$0.00	0.0%				
Q2042	Tisagenlecleucel car pos t	K	9194	\$429,813.31	\$434,337.60	\$4,524.29	1.1%				
Q2053	Brexucabtagene car pos t	G	9391	NA	\$395,380.00	NA	NA				
Q2054	Lisocabtagene maraleucel, car pos t	G	9413	NA	\$422,609.00	NA	NA				
Q2055	Idecabtagene vicleucel car	G	9422	NA	\$432,085.00	NA	NA				