

Centers for Medicare & Medicaid Services Finalizes Medicare Hospital Outpatient Payment Policies for 2019

On November 2, the Centers for Medicare & Medicaid Services (CMS) released a <u>final</u> <u>rule</u> updating the Medicare payment rates and policies under the hospital outpatient prospective payment system (OPPS) for 2019. The final rule includes updates to several payment policies that may impact AABB members, including payment policies and rates for blood and blood products, transfusion, apheresis and stem cell procedures covered by the OPPS, as well as transfusion laboratory services. The final rule becomes effective on January 1, 2019.

Blood and Blood Products

AABB successfully advocated for CMS to reconsider the payment rate for pathogen-reduced platelets (P9073). CMS originally had proposed to use claims data to determine the payment rate for P9073 for 2019, which would have resulted in a payment rate of \$445.68. AABB, America's Blood Centers and the American Red Cross, as well as other stakeholders, highlighted that pathogen reduction of platelets is a relatively new service and the data used to calculate the proposed payment rate was flawed. In the final rule, CMS acknowledged these concerns and agreed to crosswalk P9073 to the payment rate for P9037 for 2019, resulting in a payment rate of \$624.93.

CMS finalized payment increases of more than 20% for the following blood products: blood split units (P9011); frozen plasma, pooled, solvent/detergent treated (P9023); plasma protein fraction, 5%, 50ml (P9043); plasma protein fraction, 5%, 250 ml (P9048); leukoreduced, cmv-negative, apheresis platelets (P9055); leukoreduced, irradiated whole blood (P9056); and fresh frozen plasma, donor retested (P9060). In contrast, CMS finalized payment reductions of 20% or more for the following blood products: whole blood for transfusion (P9010); apheresis platelets (P9034); deglycerolized red blood cells (P9039); frozen/deglycerolized/washed, leukoreduced, irradiated red blood cells (P9057); and pathogen-reduced pooled plasma (P9070).

See Table 1 for a summary of the final payment rates for blood and blood products.

Transfusion, Apheresis, and Stem Cell Procedures

Table 2 provides a summary of the final payment rates for transfusion, apheresis and stem cell procedures. Notably, CMS agreed with concerns raised by AABB and other stakeholders that the agency inadvertently excluded revenue code 0815 (Allogeneic Stem Cell Acquisition Services) from the packaged revenue code list for use in the OPPS rate-setting calculation. CMS added revenue code 0815 to the packaged revenue code list and finalized the proposed methodology for calculating geometric mean costs for purposes of creating relative payment weights and subsequent APC payment rates for the CY 2019 OPPS. As a result, the final payment rate for allogeneic transplantation of hematopoietic progenitor cells (C-APC 5244) is \$37,892.76, compared with the proposed payment rate of \$25,645.86.



In addition, AABB joined other stakeholders in requesting that CMS consider establishing a C-APC for autologous stem cell transplant to improve the accuracy of reimbursement. The Advisory Panel on Hospital Outpatient Payment (HOP) Panel acknowledged these concerns and recommended that CMS study the appropriateness of creating a C-APC for autologous hematopoietic stem cell transplantation. In response, CMS indicated that it may consider creating a C-APC for autologous stem cell transplants in future rulemaking.

Transfusion Laboratory Services

Table 3 provides a summary of transfusion laboratory services. Many transfusion laboratory services received payment increases of 12% or more. However, autologous blood processing (86890) and thawing of fresh frozen plasma (86927) received payment reductions of 33%.

Chimeric Antigen Receptor T-Cell (CAR-T) Therapy

CMS explained in the preamble to the final rule that since CAR T-cell therapies were approved as biologics, the provisions of the Medicare statute governing biologicals apply. Medicare does not typically pay separately for each step used to manufacture a drug or biological. Thus, CMS did not adopt the recommendation made by AABB and other stakeholders to make separate payment under the OPPS for the following steps required to collect and prepare genetically modified T-cells: (1) harvesting of blood-derived T lymphocytes for the development of genetically modified autologous CAR T-cells (CPT code 0537T); (2) preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage) (CPT code 0538T); or (3) receipt and preparation of CAR T-cells for administration (CPT code 0539T).

CMS used the same reasoning when determining not to adopt commenters' recommendations to remove leukapheresis and dose preparation procedures from the HCPCS codes approved for CAR T-cell therapy drugs – Q2040 (Tisagenlecleucel car-pos t) (effective January 1, 2019, this code will be discontinued and replaced with Q2042) and Q2041 (Axicabtagene ciloleucel car+). In response to a comment asking for clarification regarding whether the current National Coverage Decision (NCD) for apheresis applies to harvesting blood-derived T-lymphocytes for the development of genetically modified autologous CAR T-cells, CMS specified that the current National Coverage Decision (NCD) for apheresis "refers only to therapeutic treatments where blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure and is distinguished from situations where a patient is transfused at a later date."

Conversely, CMS adopted the recommendation to make a separate payment for the administration of CAR-T cells (CPT code 0540T). The Agency assigned CPT code 0540T to APC 5694 (Level IV Drug Administration) for 2019, with a proposed payment rate of



approximately \$291. CMS reasoned that the services involved in autologous CAR-T cell administration were similar to other services included in APC 5694, such as the administration of chemotherapy via intravenous infusion (CPT code 96413).

CMS finalized its proposal to continue pass-through payment status for HCPCS Q2040 (to be replaced by Q2042) and HCPCS code Q2041 for 2019, and to determine the pass-through payment rate following the standard ASP methodology. As a result, CMS finalized payment rates of \$395,380.000 for Q2041 and \$489,764.125 for Q2042. CMS updates pass-through payment rates on a quarterly basis if needed.

Payment Policies for Services Furnished at Off-Campus Provider-Based Hospital Departments

CMS finalized a change to the payment policy applicable to clinic visits furnished at off-campus provider-based hospital departments (PBDs), which will reduce payments for these services by 60% by 2020. Similarly, CMS finalized a change to the payment policy for certain outpatient drugs furnished in certain PBDs, which will reduce the payment rate for these drugs.

However, CMS did not finalize its proposal to expand a site-neutral payment policy to new "clinical families of services" furnished at PBDs, which would have applied to nineteen "clinical families of services," including blood product exchange (including transfusion, apheresis and stem cell procedures, covered by APCs 5241-5244), pathology (APCs 5671 – 5674), and diagnostic/screening test and related procedures (APCs 5721-5724; 5731-5735; 5741-5743)).

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If you have any questions or would like additional information about the final rule, please contact AABB's Department of Public Policy and Advocacy at <a href="mailto:government-governmen



		Table	1. Bloc	od and E	Blood Produ	cts			
HCPCS Code	Short Descriptor	2019 SI	2018 APC	2019 APC	Final 2018	Proposed 2019	Final 2019	\$ Change 2018-	% Change 2018-
					Payment ¹	Payment	Payment	2019**	2019**
P9010	Whole blood for transfusion	R	9510	9510	\$156.91	\$123.59	\$111.18	-\$45.73	-29%
P9011	Blood split unit	R	9520	9520	\$102.67	\$125.88	\$126.06	\$23.39	23%
P9012	Cryoprecipitate each unit	R	9511	9511	\$44.00	\$44.32	\$49.40	\$5.40	12%
P9016	Rbc leukocytes reduced	R	9512	9512	\$183.76	\$183.54	\$184.78	\$1.02	1%
P9017	Plasma 1 donor frz w/in 8 hr	R	9508	9508	\$72.41	\$73.02	\$71.53	-\$0.88	-1%
P9019	Platelets, each unit	R	9515	9515	\$114.94	\$116.43	\$107.96	-\$6.98	-6%
P9020	Plaelet rich plasma unit	R	9516	9516	\$123.50	\$131.65	\$125.23	\$1.73	1%
P9021	Red blood cells unit	R	9517	9517	\$142.78	\$144.85	\$140.12	-\$2.66	-2%
P9022	Washed red blood cells unit	R	9518	9518	\$384.25	\$343.35	\$355.93	-\$28.32	-7%
P9023	Frozen plasma, pooled, sd	R	9509	9509	\$60.57	\$81.51	\$75.96	\$15.39	25%
P9031	Platelets leukocytes reduced	R	9526	9526	\$116.70	\$125.75	\$136.61	\$19.91	17%
P9032	Platelets, irradiated	R	9500	9500	\$179.13	\$180.17	\$171.91	-\$7.22	-4%
P9033	Platelets leukoreduced irrad	R	9521	9521	\$167.64	\$165.17	\$167.14	-\$0.50	-0.3%
P9034	Platelets, pheresis	R	9507	9507	\$421.17	\$342.33	\$337.08	-\$84.09	-20%
P9035	Platelet pheres leukoreduced	R	9501	9501	\$476.96	\$482.12	\$486.30	\$9.34	2%
P9036	Platelet pheresis irradiated	R	9502	9502	\$554.42	\$547.95	\$552.91	-\$1.51	-0.3%
P9037	Plate pheres leukoredu irrad	R	9530	9530	\$624.61	\$623.47	\$624.93	\$0.32	0.05%
P9038	Rbc irradiated	R	9505	9505	\$213.77	\$226.44	\$221.36	\$7.59	4%
P9039	Rbc deglycerolized	R	9504	9504	\$420.80	\$306.89	\$331.14	-\$89.66	-21%
P9040	Rbc leukoreduced irradiated	R	9522	9522	\$260.18	\$258.41	\$255.58	-\$4.60	-2%
P9043	Plasma protein fract,5%,50ml	R	9514	9514	\$15.39	\$157.85	\$26.95	\$11.56	75%
P9044	Cryoprecipitatereducedplasma	R	9523	9523	\$105.53	\$89.30	\$88.73	-\$16.80	-16%
P9048	Plasmaprotein fract,5%,250ml	R	9519	9519	\$46.90	\$58.02	\$76.98	\$30.08	64%
P9050	Granulocytes, pheresis unit	E2	-	-	-	-	-	-	-
P9051	Blood, I/r, cmv-neg	R	9524	9524	\$192.66	\$181.44	\$175.94	-\$16.72	-9%
P9052	Platelets, hla-m, l/r, unit	R	9525	9525	\$769.26	\$827.93	\$844.83	\$75.57	10%
P9053	Plt, pher, I/r cmv-neg, irr	R	9531	9531	\$539.80	\$492.32	\$492.31	-\$47.49	-9%
P9054	Blood, I/r, froz/degly/wash	R	9527	9527	\$283.48	\$322.53	\$298.37	\$14.89	5%
P9055	Plt, aph/pher, l/r, cmv-neg	R	9528	9528	\$339.93	\$426.96	\$445.06	\$105.13	31%

 $^{^{1}}$ Payment rates are updated by CMS on a quarterly basis. These payment rates reflect the 2018 final rule, 2019 proposed rule and 2019 final rule.

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		Table	Table 1. Blood and Blood Products							
HCPCS	Short Descriptor	2019	2018	2019	Final	Proposed	Final	\$ Change	% Change	
Code		SI	APC	APC	2018	2019	2019	2018-	2018-	
					Payment ¹	Payment	Payment	2019**	2019**	
P9056	Blood, I/r, irradiated	R	9529	9529	\$155.24	\$218.48	\$225.47	\$70.23	45%	
P9057	Rbc, frz/deg/wsh, l/r, irrad	R	9532	9532	\$281.73	\$236.16	\$224.51	-\$57.22	-20%	
P9058	Rbc, I/r, cmv-neg, irrad	R	9533	9533	\$238.03	\$228.52	\$229.29	-\$8.74	-4%	
P9059	Plasma, frz between 8-24hour	R	9513	9513	\$74.23	\$76.08	\$76.66	\$2.43	3%	
P9060	Fr frz plasma donor retested	R	9503	9503	\$48.35	\$62.72	\$62.81	\$14.46	30%	
P9070	Pathogen reduced plasma	R	9534	9534	\$74.23	\$44.65	\$41.43	-\$32.80	-44%	
	pool									
P9071	Pathogen reduced plasma sing	R	9535	9535	\$72.41	\$70.68	\$78.35	\$5.94	8%	
P9073	Platelets pheresis path redu	R	9536	9536	\$624.61	\$445.68	\$624.93	\$0.32	0.05%	



	Table 2. Transfusion, Apheresis, and Stem Cell Procedures												
HCPCS Code	Short Descriptor	2019 SI	2018 APC	2019 APC	Final 2018 Payment ²	Proposed 2019 Payment	Final 2019 Payment	\$ Change 2018- 2019**	% Change 2018- 2019**				
36430	Blood transfusion service	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36440	Bl push transfuse 2 yr/<	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36450	Bl exchange/transfuse nb	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36455	Bl exchange/transfuse non-nb	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36456	Prtl exchange transfuse nb	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36460	Transfusion service fetal	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36511	Apheresis wbc	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%				
36512	Apheresis rbc	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%				
36513	Apheresis platelets	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
36514	Apheresis plasma	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%				
36516	Apheresis immunoads slctv	S	5243	5243	\$3,699.85	\$3,912.23	\$3,922.50	\$222.65	6%				
36522	Photopheresis	S	5243	5243	\$3,699.85	\$3,912.23	\$3,922.50	\$222.65	6%				
38205	Harvest allogeneic stem cell	В	-	-	-	-	-	-	-				
38206	Harvest auto stem cells	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%				
38207	Cryopreserve stem cells	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
38208	Thaw preserved stem cells	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
38209	Wash harvest stem cells	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
38210	T-cell depletion of harvest	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
38211	Tumor cell deplete of harvst	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				
38212	Rbc depletion of harvest	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%				

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38213	Platelet deplete of harvest	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%			
38214	Volume deplete of harvest	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%			
38215	Harvest stem cell concentrte	S	5241	5241	\$375.05	\$383.39	\$382.90	\$7.85	2%			
38220	Dx bone marrow aspirations	J1	5072	5072	\$1,347.94	\$1,370.32	\$1,375.50	\$27.56	2%			
38221	Dx bone marrow biopsies	J1	5072	5072	\$1,347.94	\$1,370.32	\$1,375.50	\$27.56	2%			
38222	Dx bone marrow bx & aspir	J1	5072	5072	\$1,347.94	\$1,370.32	\$1,375.50	\$27.56	2%			
38230	Bone marrow harvest allogen	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%			
38232	Bone marrow harvest autolog	S	5243	5243	\$3,699.85	\$3,912.23	\$3,922.50	\$222.65	6%			
38240	Transplt allo hct/donor	J1	5244	5244	\$30,441.31	\$25,645.86	\$37,892.76	\$7451.45	24%			
38241	Transplt autol hct/donor	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%			
38242	Transplt allo lymphocytes	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%			
38243	Transplj hematopoietic boost	S	5242	5242	\$1,221.66	\$1,222.97	\$1,247.00	\$25.34	2%			
88184	Flowcytometry/ tc 1 marker	Q2	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
88185	Flowcytometry/tc add- on	N										
88187	Flowcytometry/read 2-8	В										
88188	Flowcytometry/read 9-	В										
88189	Flowcytometry/read 16 & >	В										



	Table 3. Transfusion Laboratory Services											
HCPCS Code	Short Descriptor	2019 SI	2018 APC	2019 APC	Final 2018 Payment ³	Proposed 2019 Payment	Final 2019 Payment	\$ Change 2018- 2019**	% Change 2018- 2019**			
86850	Rbc antibody screen	Q1	5671	5671	\$44.70	\$51.41	\$50.98	\$6.28	14%			
86860	Rbc antibody elution	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86870	Rbc antibody identification	Q2	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
86880	Coombs test direct	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86885	Coombs test indirect qual	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86886	Coombs test indirect titer	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86890	Autologous blood process	Q1	5673	5672	\$215.42	\$144.65	\$144.73	-\$70.69	-33%			
86891	Autologous blood op salvage	Q1	5674	5674	\$540.92	\$532.66	\$558.12	\$17.20	3%			
86900	Blood typing serologic abo	Q1	5734	5734	\$105.03	\$106.97	\$106.48	\$1.45	1%			
86901	Blood typing serologic rh(d)	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86902	Blood type antigen donor ea	Q1	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
86904	Blood typing patient serum	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86905	Blood typing rbc antigens	Q1	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
86906	Bld typing serologic rh phnt	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86920	Compatibility test spin	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86921	Compatibility test incubate	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86922	Compatibility test antiglob	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			

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86923	Compatibility test electric	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86927	Plasma fresh frozen	S	5673	5672	\$215.42	\$144.65	\$144.73	-\$70.69	-33%			
86930	Frozen blood prep	Q1	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
86931	Frozen blood thaw	Q1	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
86932	Frozen blood freeze/thaw	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86945	Blood product/irradiation	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86950	Leukacyte transfusion	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86960	Vol reduction of blood/prod	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86965	Pooling blood platelets	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86970	Rbc pretx incubatj w/chemicl	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86971	Rbc pretx incubatj w/enzymes	Q1	5673	5673	\$215.42	\$271.73	\$274.22	\$58.80	27%			
86972	Rbc pretx incubatj w/density	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86975	Rbc serum pretx incubj drugs	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86976	Rbc serum pretx id dilution	Q1	5731	5731	\$17.47	\$17.04	\$17.17	-\$0.30	-2%			
86977	Rbc serum pretx incubj/inhib	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86978	Rbc pretreatment serum	Q1	5732	5732	\$31.80	\$32.89	\$32.12	\$0.32	1%			
86985	Split blood or products	Q1	5672	5672	\$129.17	\$144.65	\$144.73	\$15.56	12%			
86999	Transfusion procedure	Q1	5731	5731	\$17.47	\$17.04	\$17.17	-\$0.30	-2%			
P9100	Pathogen test for platelets	S	1493	1493	\$25.50	\$25.50	\$25.50	\$0.00	n/a			