



Advancing Transfusion and
Cellular Therapies Worldwide

**2016 Medicare Hospital Outpatient Final Rule:
Key Provisions Affecting Transfusion Medicine and Cellular Therapies**
November 11, 2015

The Centers for Medicare and Medicaid Services (CMS) has released the Hospital Outpatient Prospective Payment System (OPPS) [final rule](#) for 2016. The final rule includes relatively small cuts in payments for many blood products, as CMS corrected an error in including drastic cuts in blood payments in its proposed rule. Payments for many transfusion laboratory services decrease substantially. CMS continues to move toward increased bundling of many products and services – including transfusion laboratory procedures – into payments for primary procedures. Overall, CMS will reduce hospital outpatient payments by 0.4 percent in Calendar Year (CY) 2016. Provisions of the final rule will be effective January 1, 2016, unless stated otherwise.

The following summary highlights provisions of the rule of particular interest to the transfusion medicine and cellular therapy communities. Attached are charts comparing final 2015 and 2016 payment rates for blood products (Table 1), procedural services (Table 3), and transfusion and blood processing (Table 4) codes. Unlike the physician fee schedule, it is not always obvious why payment for a particular service is increasing or decreasing under OPSS. Payment rates under OPSS are derived from hospital billed charges from 2014 converted to estimated cost and utilize a complex system of allocation of costs for packaged services.

Blood Products (Table 1)

The final 2016 payments for most blood product will decrease by small percentages. For example, the payment for leukoreduced red blood cells will fall from \$189.37 in 2015 to \$184.34 in 2016 (a much less troubling payment than the originally proposed \$131.12).

CMS acknowledged that “an error occurred in the calculation of the proposed CY 2016 payment rates for blood and blood products included in the proposed rule. . . As a result of correcting this error, payment rates for blood and blood products increased approximately 10 percent to 60 percent from the proposed CY 2016 payment rates. We have corrected this error in this final rule with comment period and the final CY 2016 payment rates reflect this correction.” This action comes in response to numerous comments from AABB and others in the transfusion medicine community voicing concern that the proposed payment rates neither accurately reflected the costs of collecting, processing and distributing blood products nor aligned with CMS’s own costs statistics data.

Except for the decision to package blood and blood products into the comprehensive APCs (see below), separate payment will continue to be paid for blood and blood products using the same methodology which has been used for a number of years.

Pathogen Reduced Products

Also responding to requests from AABB and others, CMS will now recognize three new HCPCS codes for recently approved pathogen-reduced platelet and plasma products. Because these three codes are new for 2016, there are currently no claims data on the charges and costs for the new blood products upon which to base payments. Therefore, CMS is establishing interim payment rates for the three new codes based on a crosswalk to existing blood product codes that provide the best proxy for the costs of the new blood products (see Table 2). AABB had recommended that these crosswalks be used until CMS can establish payments in 2018 based on 2016 hospital claims data.

The interim payment rates are open for public comment. In addition, CMS noted that the HCPCS P-codes for blood products “could benefit from a careful examination and review with possible revision and updating to make the HCPCS P-codes describing blood products reflect current product descriptions and utilization while minimizing redundancy and potentially outdated descriptors.” Therefore, in a future rulemaking CMS will evaluate these codes and “propose revisions that may be necessary to create a current and robust code set for blood products.”

Transfusion, Apheresis and Stem Cell Procedures (Table 3)

The payment for a blood transfusion (HCPCS 36430), which is included in APC 5241 (formerly APC 0110), will increase approximately 17 percent to \$349.14. Other procedures in APC 5241 and subject to the same payment include cryopreserving, thawing and washing stem cells. The payment for T-cell depletion and other depletions included in APC 5271 (formerly APC 0393) will increase notably from \$628 to \$1047.76. Payments for other apheresis and stem cell procedure codes would change more modestly, generally increasing by one to seven percent.

CMS will continue to pay for **stem cell transplant procedures** as it has for several years, through APCs 5271 (blood product exchange) and 5281 (apheresis and stem cell procedures). CMS rejected calls by AABB and others to enhance the payment for allogeneic stem cell transplants.

AABB and other interested parties had commented that the proposed inadequate payment for allogeneic hematopoietic progenitor cell transplant procedures (CPT 38240) failed to account for the total cost of a transplant, including substantial donor cell acquisition costs. CMS noted “the commenters’ concerns that donor acquisition cost is not appropriately captured in the current payment methodology for HCT procedures,” but again stated that because allogeneic harvesting procedures are performed on a donor, rather than the Medicare beneficiary, these services cannot be paid separately under the outpatient prospective payment system. The final 2016 payment for allogeneic transplants is \$3015.06, up six percent from 2015. CMS stated that “hospitals should report all allogeneic outpatient HCT procedure acquisition charges on the recipient’s outpatient claim as uncoded charges under revenue code 0819.”

Transfusion Laboratory and Blood Processing Services (Table 4)

Due to a CMS overestimation of the impact of laboratory packaging changes, OPSS costs rose approximately \$1 billion more than expected in 2014. Therefore, CMS is reducing the 2016 conversion factor by 2.0 percent to account for this \$1 billion.

CMS is expanding its bundling of ancillary items and services into the payment for the primary procedure offered in the outpatient setting. In 2016, several additional transfusion and pathology procedures will now be subject to bundling. One notable change in policy is that CMS will now conditionally package designated laboratory services regardless of the date of service. For 2016, CMS will conditionally package ancillary services into the rate for the primary procedure assigned a status indicator of “S” (significant procedure), “T” (usually a surgical procedure) or “V” (a clinic or ER visit). However, if a procedure with an S, T or V status is not performed, the procedure will be paid separately. CMS considers these services “conditionally packaged” as they are packaged only when a service with an S, T or V status is also performed. The conditionally packaged procedures are assigned a Q1 status indicator so that they can be identified. In 2016, CMS will change the status indicator for approximately 14 transfusion laboratory procedures from “S” to “Q1.”

Payments for the majority of transfusion laboratory and blood processing codes will decrease substantially in 2016, some by more than 50 percent. Others will increase. Changes may be due to the packaging of the costs of transfusion laboratory procedures, as well as the 2016 conversion factor reduction.

When a lab test is the only service rendered on a claim, it will be identified with a Q4 modifier and be separately paid under the clinical laboratory fee schedule without providers having to do anything from a reporting perspective.

Drugs

Consistent with current policy, drugs with per diem cost of \$90 or more will be paid separately. The payment will continue to be based on 106 percent of Average Sales Price (ASP), which is consistent with the rates paid for drugs provided in physician offices. Less costly drugs will continue to be packaged into the APC rate for the procedure.

Blood Clotting Factor

For 2016, CMS will continue to pay for blood clotting factors at ASP + 6 percent. In addition, CMS will continue to pay an additional fee for furnishing clotting factor with the amount to be announced later this year. Prothrombin complex concentrate, Kcentra, assigned to APC 9132, will no longer be paid with pass-through status.

Comprehensive APC Groupings

Comprehensive APCs (C-APCs) pay for high cost device dependent services using a single payment for the hospital stay; but unlike the existing device-dependent APCs, these payments will include room and board as well as nursing costs. There are currently 25 C-APCs, which

mostly include procedures for the implantation of costly medical devices. For 2016, CMS will add nine new C-APCs, including some surgical APCs and a new comprehensive observation service that will include all primary procedures found on the observation claim.

With some limited exceptions, a C-APC includes virtually all the hospital outpatient services received by a beneficiary. This includes payment for blood and blood products. Pass through drugs, ambulance services and preventive services are paid outside of the comprehensive APC.

**TABLE 1
BLOOD PRODUCTS**

HCPCS	Description	2016 SI	2015 APC	2016 APC	2015 Payment	2016 Payment	\$ Change	% Change
P9010	Whole blood for transfusion	R	950	9510	217.16	221.62	4.46	2%
P9011	Blood split unit	R	967	9520	130.4	102.5	-27.9	-21%
P9012	Cryoprecipitate each unit	R	952	9511	70.79	59.64	-11.15	-16%
P9016	Rbc leukocytes reduced	R	954	9512	189.37	184.34	-5.03	-3%
P9017	Plasma 1 donor frz w/in 8 hr	R	9508	9508	74.82	72.56	-2.26	-3%
P9019	Platelets, each unit	R	957	9515	115.31	118.03	2.72	2%
P9020	Platelet rich plasma unit	R	958	9516	135.88	120.16	-15.72	-12%
P9021	Red blood cells unit	R	959	9517	150.51	145.79	-4.72	-3%
P9022	Washed red blood cells unit	R	960	9518	320.19	307.46	-12.73	-4%
P9023	Frozen plasma, pooled, sd	R	949	9509	69.26	75.9	6.64	10%
P9031	Platelets leukocytes reduced	R	1013	9526	112.08	116.32	4.24	4%
P9032	Platelets, irradiated	R	9500	9500	168.57	159.09	-9.48	-6%
P9033	Platelets leukoreduced irrada	R	968	9521	162.19	162.08	-0.11	0%
P9034	Platelets, pheresis	R	9507	9507	419.39	425.15	5.76	1%
P9035	Platelet pheres leukoreduced	R	9501	9501	497.57	488.29	-9.28	-2%
P9036	Platelet pheresis irradiated	R	9502	9502	569.29	528.11	-41.18	-7%
P9037	Plate pheres leukoredu irrada	R	1019	9530	674.16	641.85	-32.31	-5%
P9038	Rbc irradiated	R	9505	9505	207.77	205.82	-1.95	-1%
P9039	Rbc deglycerolized	R	9504	9504	463.79	380.32	-83.47	-18%
P9040	Rbc leukoreduced irradiated	R	969	9522	275.36	267.63	-7.73	-3%
P9043	Plasma protein fract,5%,50ml	R	956	9514	23.04	28.28	5.24	23%
P9044	Cryoprecipitatereducedplasma	R	1009	9523	78.53	51.12	-27.41	-35%
P9048	Plasmaprotein fract,5%,250ml	R	966	9519	33.62	40.33	6.71	20%
P9050	Granulocytes, pheresis unit	R	9506	9506	1836.96	1518.48	-318.48	-17%
P9051	Blood, l/r, cmv-neg	R	1010	9524	163.92	200.46	36.54	22%
P9052	Platelets, hla-m, l/r, unit	R	1011	9525	704.09	704.98	0.89	0%
P9053	Plt, pher, l/r cmv-neg, irr	R	1020	9531	658.23	443.65	-214.58	-33%
P9054	Blood, l/r, froz/degly/wash	R	1016	9527	244.08	321.28	77.2	32%

P9055	Plt, aph/pher, l/r, cmv-neg	R	1017	9528	393.94	462.48	68.54	17%
P9056	Blood, l/r, irradiated	R	1018	9529	134.47	127.41	-7.06	-5%
P9057	Rbc, frz/deg/wsh, l/r, irradiated	R	1021	9532	448.67	203.35	-245.32	-55%
P9058	Rbc, l/r, cmv-neg, irradiated	R	1022	9533	274.67	249.23	-25.44	-9%
P9059	Plasma, frz between 8-24hour	R	955	9513	71.36	73.08	1.72	2%
P9060	Fr frz plasma donor retested	R	9503	9503	58.8	51.42	-7.38	-13%
P9070	Plasma, pooled multiple donor, pathogen reduced, frozen					\$73.08		
P9071	Plasma (single donor), pathogen reduced, frozen, each unit					\$72.56		
P9072	Platelets, pheresis, pathogen reduced, each unit					\$641.85		

TABLE 2 NEW PATHOGEN-REDUCED BLOOD PRODUCTS HCPCS P-CODES AND INTERIM 2016 PAYMENT RATES AND CROSSWALKS				
New CY 2016 HCPCS P-Code	New HCPCS P-Code Descriptor	Crosswalked HCPCS P-Code	Crosswalked HCPCS P-Code Descriptor	2016 Payment
P9070	Plasma, pooled multiple donor, pathogen reduced, frozen, each unit	P9059	Fresh frozen plasma between 8-24 hours of collection, each unit	\$73.08
P9071	Plasma (single donor), pathogen reduced, frozen, each unit	P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit	\$72.56
P9072	Platelets, pheresis, pathogen reduced, each unit	P9037	Platelets, pheresis, leukocytes reduced, irradiated, each unit	\$641.85

**TABLE 2
TRANSFUSION, APHERESIS AND STEM CELL PROCEDURES**

HCPCS	Description	SI	2015 APC	2016 APC	2015 Payment	2016 Payment	\$ Change	% Change
36430	Blood transfusion service	S	110	5241	\$297.18	349.14	51.96	17%
36440	Bl push transfuse 2 yr/<	S	110	5241	\$297.18	349.14	51.96	17%
36450	Bl exchange/transfuse non-hb	S	110	5241	\$297.18	349.14	51.96	17%
36455	Bl exchange/transfuse non-hb	S	110	5241	\$297.18	349.14	51.96	17%
36460	Transfusion service fetal	S	110	5241	\$297.18	349.14	51.96	17%
36511	Apheresis wbc	S	111	5271	1054.99	1047.76	-7.23	-1%
36512	Apheresis rbc	S	111	5271	1054.99	1047.76	-7.23	-1%
36513	Apheresis platelets	S	111	5271	1054.99	1047.76	-7.23	-1%
36514	Apheresis plasma	S	111	5271	1054.99	1047.76	-7.23	-1%
36515	Apheresis adsorp/reinfuse	S	112	5281	2844.69	3015.06	170.37	6%
36516	Apheresis selective	S	112	5281	2844.69	3015.06	170.37	6%
36522	Photopheresis	S	112	5281	2844.69	3015.06	170.37	6%
38206	Harvest auto stem cells	S	111	5271	1054.99	1047.76	-7.23	-1%
38207	Cryopreserve stem cells	S	110	5241	297.18	349.14	51.96	17%
38208	Thaw preserved stem cells	S	110	5241	297.18	349.14	51.96	17%
38209	Wash harvest stem cells	S	110	5241	297.18	349.14	51.96	17%
38210	T-cell depletion of harvest	S	393	5271	627.95	1047.76	419.81	67%
38211	Tumor cell deplete of harvst	S	393	5271	627.95	1047.76	419.81	67%
38212	Rbc depletion of harvest	S	393	5271	627.95	1047.76	419.81	67%
38213	Platelet deplete of harvest	S	393	5271	627.95	1047.76	419.81	67%
38214	Volume deplete of harvest	S	393	5271	627.95	1047.76	419.81	67%
38215	Harvest stem cell concentrte	S	393	5271	627.95	1047.76	419.81	67%
38220	Bone marrow aspiration	T	20	5073	826.26	941.98	115.72	14%
38221	Bone marrow biopsy	T	20	5073	826.26	1414.28	588.02	71%
38230	Bone marrow harvest allogene	S	112	5281	2844.69	3015.06	170.37	6%
38232	Bone marrow harvest autolog	S	112	5281	2844.69	3015.06	170.37	6%
38240	Transplt allo hct/donor	S	112	5281	2844.69	3015.06	170.37	6%
38241	Transplt autol hct/donor	S	112	5281	2844.69	3015.06	170.37	6%
38242	Transplt allo lymphocytes	S	111	5271	1054.99	1047.76	-7.23	-1%
38243	Transplj hematopoietic boost	S		5271		1047.76		
88184	Flowcytometry/tc, 1 marker	Q2	433	56733	183.62	209.42	25.80	14.1%

**TABLE 3
TRANSFUSION LABORATORY PROCEDURES**

HCPCS	Descriptor	SI	2015 APC	2016 APC	2015 Payment	Final 2016 Payment	\$ Change	% Change
86850	Rbc antibody screen	Q1	0345	5671	\$76.04	47.75	-28.29	-37%
86860	Rbc antibody elution	Q1	0346	5681	\$125.07	103.02	-22.05	-18%
86870	Rbc antibody identification	Q2	433	5673	183.62	209.42	25.8	14%
86880	Coombs test direct	Q1	346	5733	125.07	55.94	-69.13	-55%
86885	Coombs test indirect qual	Q1	346	5681	125.07	103.02	-22.05	-18%
86886	Coombs test indirect titer	Q1	433	5672	183.62	102.2	-81.42	-44%
86890	Autologous blood process	Q1	346	5681	125.07	209.42	84.35	67%
86891	Autologous blood op salvage	Q1	346	5681	125.07	440.53	315.46	252%
86900	Blood typing serologic abo	Q1	345	5733	76.04	55.94	-20.1	-26%
86901	Blood typing serologic rh(d)	Q1	345	5732	76.04	30.51	-45.53	-60%
86902	Blood type antigen donor ea	Q1	345	5681	76.04	103.02	26.98	35%
86904	Blood typing patient serum	Q1	345	5733	76.04	30.51	-45.53	-60%
86905	Blood typing rbc antigens	Q1	345	5681	76.04	103.02	26.98	35%
86906	Bld typing serologic rh phnt	Q1	345	5732	76.04	30.51	-45.53	-60%
86920	Compatibility test spin	Q1	346	5681	125.07	103.02	-22.05	-18%
86921	Compatibility test incubate	Q1	345	5681	76.04	103.02	26.98	35%
86922	Compatibility test antiglob	Q1	346	5681	125.07	103.02	-22.05	-18%
86923	Compatibility test electric	Q1	346	5681	125.07	103.02	-22.05	-18%
86927	Plasma fresh frozen	S	438	5693	108.2	209.42	101.22	94%
86930	Frozen blood prep	Q1	345	5681	76.04	103.02	26.98	35%
86931	Frozen blood thaw	Q1	346	5733	125.07	209.42	84.35	67%
86932	Frozen blood freeze/thaw	Q1	345	5732	76.04	30.51	-45.53	-60%
86945	Blood product/irradiation	Q1	345	5732	76.04	30.51	-45.53	-60%
86950	Leukocyte transfusion	Q1	345	5681	76.04	103.02	26.98	35%
86960	Vol reduction of blood/prod	Q1	346	5681	125.07	103.02	-22.05	-18%
86965	Pooling blood platelets	Q1	450	5681	125.07	103.02	-22.05	-18%
86970	Rbc pretx incubatj w/chemicl	Q1	346	5733	29.23	30.51	1.28	4%
86971	Rbc pretx incubatj w/enzymes	Q1	346	5681	125.07	103.02	-22.05	-18%
86972	Rbc pretx incubatj w/density	Q1	346	5681	125.07	103.02	-22.05	-18%
86975	Rbc serum pretx incubj drugs	Q1	346	5732	125.07	30.51	-94.56	-76%
86976	Rbc serum pretx id dilution	Q1	345	5732	76.04	30.51	-45.53	-60%
86977	Rbc serum pretx incubj/inhib	Q1	345	5681	76.04	103.02	26.98	35%
86978	Rbc pretreatment serum	Q1	345	5732	76.04	12.7	-63.34	-83%
86985	Split blood or products	Q1	346	5734	125.07	102.2	-22.87	-18%
86999	Transfusion procedure	Q1	345	5731	76.04	12.7	-63.34	-83%

<i>* Explanation of Status Indicators</i>		
	Item/Code/Service	OPPS Payment Status
B	Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x).	Not paid under OPPS.
N	Items and Services Packaged into APC Rates	Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.
Q1	STV-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator "S," "T," or "V." (2) In other circumstances, payment is made through a separate APC payment.
R	Blood and Blood Products	Paid under OPPS; separate APC payment.
S	Procedure or Service, Not Discounted When Multiple	Paid under OPPS; separate APC payment.
T	Procedure or Service, Multiple Procedure Reduction Applies	Paid under OPPS; separate APC payment.
X	Ancillary Services	Paid under OPPS in 2014. For 2015, this indicator was eliminated.