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Cellular Therapies Worldwide

2016 Medicare Proposed Hospital Outpatient Payments *CMS Proposes Severe Cuts in Blood Product Payments*

The Centers for Medicare and Medicaid Services (CMS) has released the Hospital Outpatient Prospective Payment System (OPPS) [proposed rule](#) for 2016. The proposed rule includes drastic cuts in payments for many blood products. In addition, payments for many transfusion laboratory services would decrease substantially, perhaps due to changes in bundling of payments. CMS continues to move toward increased bundling of many products and services – including blood processing and transfusion and stem cell processing procedures into payments for primary procedures. Overall, CMS proposes reducing hospital outpatient payments by 0.1 percent in Calendar Year (CY) 2016.

Comments are due to CMS by August 31, 2015. Provisions of the final rule will be effective January 1, 2016, unless stated otherwise. The following summary highlights provisions of the proposed rule of interest to the transfusion medicine and cellular therapy communities.

Changes in Packaging of Services

Building on its intent of making OPPS more of a prospective payment system than a fee schedule where every procedure is paid separately, CMS proposes expanding the packaging of ancillary items and services into the payment for the primary procedure. In 2015, CMS designated about 20 APCs – including Level 1 pathology and Level 1 transfusion procedures – to be affected by its new packaging policy. In 2016, CMS proposes to include several additional transfusion and pathology procedures on the list of affected APCs.

For 2016, CMS will continue to 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) and performed on the same day. However, if a procedure with an S, T or V status is not performed on the same day, 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 is proposing to change the status indicator for approximately 14 transfusion laboratory procedures from “S” to “Q1.”

The Level 1 Transfusion Laboratory Procedures affected by this policy are assigned to APC 345 and include the following procedure codes: 86850, 86900, 86901, 86902, 86905, 86905, 86906, 86921, 86930, 86932, 86945, 86950, 86976, 86977, 86978, and 86999. If one of these codes is billed and is not accompanied by a billing for an S, T or V code, the APC will be paid.

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 is proposing 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.

Impact of Rule on Blood and Stem Cell Providers

Attached are charts comparing 2014 payments with the proposed 2015 rates for blood products (Table 1), procedural services (Table 2), and transfusion and blood processing (Table 3) 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)

Payments for most blood products would be severely cut under the proposal. For example, the payment for leukocyte-reduced red blood cells (P9016) would fall over 30% from \$189 in 2015 to \$131 in 2016. Similarly, payment for platelets pheresis, leukocyte-reduced (P9035) would decrease from \$498 to \$349 in 2016.

There is no explanation as to why blood payments are being hit so hard. Except for the decision to package blood and blood products into the comprehensive APCs discussed above, 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.

Transfusion, Apheresis and Stem Cell Procedures (Table 2)

The payment for a blood transfusion (HCPCS 36430) and other procedures, such as cryopreserving stem cells, included in APC 5241 (formerly APC 0110) is proposed to increase approximately 20 percent to \$357.20. The payment for T-cell depletion and other depletions included in APC 5271 (formerly APC 0393) would see a big jump from \$628 to \$1065. Payments for other apheresis and stem cell procedure codes would change more modestly, generally increasing by one to seven percent.

Transfusion Laboratory and Blood Processing Services (Table 3)

Proposed 2016 payments for the majority of transfusion laboratory and blood processing codes would decrease substantially, some by as much as 54 percent. Others would experience increases. Some of the changes may be due to the packaging of the costs of transfusion laboratory procedures.

Laboratory Services

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 proposing to reduce the 2016 conversion factor by 2.0 percent to account for this \$1 billion. CMS is also proposing changes to the laboratory packaging policy, including a new conditional packaging status indicator for lab tests. When a lab test is the only service rendered on a claim, it would 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 is proposing to 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.

**TABLE 1
BLOOD PRODUCTS**

HCPCS	Description	2016 SI*	2015 APC	Proposed 2016 APC	2015 Payment	Proposed 2016 Payment	% Change
P9010	Whole blood for transfusion	R	0950	9510	\$217.16	\$166.85	-23.2%
P9011	Blood split unit	R	0967	9520	\$130.40	\$71.3	-45.3%
P9012	Cryoprecipitate each unit	R	0952	9511	\$70.79	\$47.31	-33.2%
P9016	Rbc leukocytes reduced	R	0954	9512	\$189.37	\$131.12	-30.8%
P9017	Plasma 1 donor frz w/in 8 hr	R	9508	9508	\$74.82	\$50.88	-32.0%
P9019	Platelets, each unit	R	0957	9515	\$115.31	\$92.51	-19.8%
P9020	Platelet rich plasma unit	R	0958	9516	\$135.88	\$72.86	-46.4%
P9021	Red blood cells unit	R	0959	9517	\$150.51	\$99.65	-33.8%
P9022	Washed red blood cells unit	R	0960	9518	\$320.19	\$201.87	-37.0%
P9023	Frozen plasma, pooled, sd	R	0949	9509	\$69.26	\$70.91	2.4%
P9031	Platelets leukocytes reduced	R	1013	9526	\$112.08	\$87.36	-22.1%
P9032	Platelets, irradiated	R	9500	9500	\$168.57	\$91.36	-45.8%
P9033	Platelets leukoreduced irradiated	R	0968	9521	\$162.19	\$127.21	-21.6%
P9034	Platelets, pheresis	R	9507	9507	\$419.39	\$274.8	-34.5%
P9035	Platelet pheres leukoreduced	R	9501	9501	\$497.57	\$349.38	-29.8%
P9036	Platelet pheresis irradiated	R	9502	9502	\$569.29	\$310.21	-45.5%
P9037	Platelet pheres leukoreduced irradiated	R	1019	9530	\$674.16	\$486.47	-27.8%
P9038	Rbc irradiated	R	9505	9505	\$207.77	\$129.76	-37.5%
P9039	Rbc deglycerolized	R	9504	9504	\$463.79	\$275.75	-40.5%
P9040	Rbc leukoreduced irradiated	R	0969	9522	\$275.36	\$198.32	-28.0%
P9043	Plasma protein fract,5%,50ml	R	0956	9514	\$23.04	\$83.98	264.5%
P9044	Cryoprecipitate reduced plasma	R	1009	9523	\$78.53	\$43.94	-44.0%
P9048	Plasma protein fract,5%,250ml	R	0966	9519	\$33.62	\$37.9	12.7%
P9050	Granulocytes, pheresis unit	R	9506	9506	\$1836.96	\$848.65	-53.8%
P9051	Blood, l/r, cmv-neg	R	1010	9524	\$163.92	\$180.44	10.1%
P9052	Platelets, hla-m, l/r, unit	R	1011	9525	\$704.09	\$546.99	-22.3%
P9053	Plt, pher, l/r cmv-neg, irr	R	1020	9531	\$658.23	\$443.65	-32.6%
P9054	Blood, l/r, froz/degly/wash	R	1016	9527	\$244.08	\$239.96	-1.7%
P9055	Plt, aph/pher, l/r, cmv-neg	R	1017	9528	\$393.94	\$352.2	-10.6%
P9056	Blood, l/r, irradiated	R	1018	9529	\$134.47	\$110.13	-18.1%
P9057	Rbc, frz/deg/wsh, l/r, irradiated	R	1021	9532	\$448.67	\$150.97	-66.4%
P9058	Rbc, l/r, cmv-neg, irradiated	R	1022	9533	\$274.67	\$185.81	-32.4%
P9059	Plasma, frz between 8-24hour	R	0955	9513	\$71.36	\$54.42	-23.7%
P9060	Fr frz plasma donor retested	R	9503	9503	\$58.80	\$40.52	-31.1%

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

HCPCS	Description	2015 SI*	2016 SI*	2015 APC	Proposed 2016 APC	2015 Payment	Proposed 2016 Payment	% Change
36430	Blood transfusion service	S	S	0110	5241	\$297.18	\$357.20	20.2%
36440	Bl push transfuse 2 yr/<	S	S	0110	5241	\$297.18	\$357.20	20.2%
36450	Bl exchange/transfuse non-hb	S	S	0110	5241	\$297.18	\$357.20	20.2%
36455	Bl exchange/transfuse non-hb	S	S	0110	5241	\$297.18	\$357.20	20.2%
36460	Transfusion service fetal	S	S	0110	5241	\$297.18	\$357.20	20.2%
36511	Apheresis wbc	S	S	0111	5271	\$1054.99	\$1065.09	1.0%
36512	Apheresis rbc	S	S	0111	5271	\$1054.99	\$1065.09	1.0%
36513	Apheresis platelets	S	S	0111	5271	\$1054.99	\$1065.09	1.0%
36514	Apheresis plasma	S	S	0111	5271	\$1054.99	\$1065.09	1.0%
36515	Apheresis adsorp/reinfuse	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
36516	Apheresis selective	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
36522	Photopheresis	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
38206	Harvest auto stem cells	S	S	0111	5271	\$1054.99	\$1065.09	1.0%
38207	Cryopreserve stem cells	S	S	0110	5241	\$297.18	\$357.2	20.2%
38208	Thaw preserved stem cells	S	S	0110	5241	\$297.18	\$357.2	20.2%
38209	Wash harvest stem cells	S	S	0110	5241	\$297.18	\$357.2	20.2%
38210	T-cell depletion of harvest	S	S	0393	5271	\$627.95	\$1065.09	69.6%
38211	Tumor cell deplete of harvst	S	S	0393	5271	\$627.95	\$1065.09	69.6%
38212	Rbc depletion of harvest	S	S	0393	5271	\$627.95	\$1065.09	69.6%
38213	Platelet deplete of harvest	S	S	0393	5271	\$627.95	\$1065.09	69.6%
38214	Volume deplete of harvest	S	S	0393	5271	\$627.95	\$1065.09	69.6%
38215	Harvest stem cell concentrte	S	S	0393	5271	\$627.95	\$1065.09	69.6%
38220	Bone marrow aspiration	T	T	0020	5073	\$826.26	\$994.3	20.3%
38221	Bone marrow biopsy	T	T	0020	5073	\$826.26	\$994.3	20.3%
38230	Bone marrow harvest allogene	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
38232	Bone marrow harvest autolog	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
38240	Transplt allo hct/donor	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
38241	Transplt autol hct/donor	S	S	0112	5281	\$2844.69	\$3045.31	7.1%
38242	Transplt allo lymphocytes	S	S	0111	5271	\$1054.99	\$1065.09	1.0%
38243	Transplj hematopoietic boost		S		5271		\$1065.09	
88184	Flowcytometry/tc, 1 marker	Q1	Q2	0433	56733	\$183.62	\$209.49	14.1%
88185	Flowcytometry/tc, add-on	N	N	NA				
88187	Flowcytometry/read, 2-8	B	B	NA				
88188	Flowcytometry/read, 9-15	B	B	NA				
88189	Flowcytometry/read, 16 & >	B	B	NA				
G0364	Bone marrow aspirate & biopsy	N		NA		NA		

**TABLE 3
TRANSFUSION LABORATORY PROCEDURES**

HCPCS	Description	2015 SI*	2016 SI*	2015 APC	Proposed 2016 APC	2015 Payment	Proposed 2016 Payment	% Change
86850	Rbc antibody screen	Q1	Q1	0345	5671	\$76.04	\$48.63	-36.0%
86860	Rbc antibody elution	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86870	Rbc antibody identification	Q1	Q2	0433	5673	\$183.62	\$209.49	14.1%
86880	Coombs test direct	S	Q1	0346	5733	\$125.07	\$56.7	-54.7%
86885	Coombs test indirect qual	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86886	Coombs test indirect titer	Q1	Q1	0433	5672	\$183.62	\$96.56	-47.4%
86890	Autologous blood process	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86891	Autologous blood op salvage	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86900	Blood typing serologic abo	Q1	Q1	0345	5733	\$76.04	\$56.7	-25.4%
86901	Blood typing serologic rh(d)	Q1	Q1	0345	5732	\$76.04	\$31.03	-59.2%
86902	Blood type antigen donor ea	Q1	Q1	0345	5681	\$76.04	\$104.37	37.3%
86904	Blood typing patient serum	Q1	Q1	0345	5733	\$76.04	\$56.7	-25.4%
86905	Blood typing rbc antigens	Q1	Q1	0345	5681	\$76.04	\$104.37	37.3%
86906	Bld typing serologic rh phnt	Q1	Q1	0345	5732	\$76.04	\$31.03	-59.2%
86920	Compatibility test spin	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86921	Compatibility test incubate	Q1	Q1	0345	5681	\$76.04	\$104.37	37.3%
86922	Compatibility test antiglob	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86923	Compatibility test electric	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86927	Plasma fresh frozen	S	S	0438	5693	\$108.20	\$93.48	-13.6%
86930	Frozen blood prep	Q1	Q1	0345	5681	\$76.04	\$104.37	37.3%
86931	Frozen blood thaw	S	Q1	0346	5733	\$125.07	\$56.7	-54.7%
86932	Frozen blood freeze/thaw	Q1	Q1	0345	5732	\$76.04	\$31.03	-59.2%
86945	Blood product/irradiation	Q1	Q1	0345	5732	\$76.04	\$31.03	-59.2%
86950	Leukocyte transfusion	Q1	Q1	0345	5681	\$76.04	\$104.37	37.3%
86960	Vol reduction of blood/prod	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86965	Pooling blood platelets	S	Q1	0450	5681	\$125.07	\$104.37	-16.6%
86970	Rbc pretx incubatj w/chemicl	Q1	Q1	0346	5733	\$29.23	\$56.7	94.0%
86971	Rbc pretx incubatj w/enzymes	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86972	Rbc pretx incubatj w/density	S	Q1	0346	5681	\$125.07	\$104.37	-16.6%
86975	Rbc serum pretx incubj drugs	S	Q1	0346	5732	\$125.07	\$31.03	-75.2%
86976	Rbc serum pretx id dilution	Q1	Q1	0345	5732	\$76.04	\$31.03	-59.2%
86977	Rbc serum pretx incubj/inhib	Q1	Q1	0345	5681	\$76.04	\$104.37	37.3%
86978	Rbc pretreatment serum	Q1	Q1	0345	5732	\$76.04	\$31.03	-59.2%
86985	Split blood or products	S	Q1	0346	5734	\$125.07	\$93.27	-25.4%
86999	Transfusion procedure	Q1	Q1	0345	5731	\$76.04	\$12.60	-83.4%

<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.