

COMMENTS BY
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ON BEHALF OF
THE AMERICAN RED CROSS
Before The Advisory Panel on Ambulatory Payment Classification Groups
August 23-25, 2006

REQUIRED INFORMATION

The Presenter/Presentation Information Checklist (Form CMS-20017) specifies the required information that must be stated on page 1 of written comments. We provide this information below.

Requested Information	Response
Financial relationship of presenter, if any, with any company whose products, services, or procedures are under consideration	Dr. Jerry Squires is a salaried employee of the American Red Cross (Red Cross). His title is Executive Medical Officer. The Red Cross is a national, not-for-profit organization that collects, processes, and distributes nearly one-half of the nation's blood supply. Additionally, the Red Cross provides on-site services at numerous hospital-based collection sites across the country. The Red Cross's national system of regional facilities supplies over 3,000 hospitals with blood and blood products.
CPT/HCPCS codes involved	Blood and blood products are reported with the HCPCS P-codes listed below. Blood component transfusions are billed with CPT codes 36430 (transfusion, blood or blood components); 36440 (push transfusion, blood, 2 years or under); 36450 (exchange transfusion, blood, newborn); 36455 (exchange transfusion, blood, other than newborn); 36460 (transfusion, intrauterine, fetal). ¹
APCs affected	Blood and blood product P-codes are assigned to the following APCs: 0949 Plasma, Pooled Multiple Donor, Solvent/Detergent Tr (P9023) 0950 Blood (Whole) for Transfusion (P9010) 0952 Cryoprecipitate (P9012) 0954 RBC Leukocytes Reduced (P9016) 0955 Plasma, Fresh Frozen (P9059) 0956 Plasma Protein Fraction (P9043) 0957Platelet Concentrate (P9019) 0958Platelet Rich Plasma (P9020) 0959Red Blood Cells (P9021) 0960Washed Red Blood Cells (P9022) 0966Plasma Protein Fract, 5%, 250ml (P9048) 0967Split Unit of Blood (P9011) 0968Platelets Leukocyte Reduced Irradiated (P9033) 0969Red Blood Cell Leukocyte Reduced Irradiated (P9040) 1009Cryoprecip Reduced Plasma (P9044) 1010Blood, L/R, CMV-Neg (P9051) 1011Platelets, HLA-M, L/R, Unit. (P9052) 1013Platelet Concentrate, L/R, Unit (P9031) 1016Blood, L/R, Froz/Deglycerol/Washed (P9054) 1017Platelets, Aph/Pher, L/R, CMV-Neg, Unit (P9055) 1018Blood, L/R, Irradiated (P9056) 1019Platelets, Aph/Pher, L/R, Irradiated, Unit (P9037) 1020Plt, Pher, L/R, CMV, Irrad (P9053) 1021RBC, Frz/Deg/Wsh, L/R, Irrad (P9057) 1022RBC, L/R, CMV Neg, Irrad (P9058) 9500Platelets, Irradiated (P9032) 9501Platelets, Pheresis, Leukocytes Reduced (P9035) 9502Platelet Pheresis Irradiated (P9036) 9503Fresh Frozen Plasma, Ea Unit (P9060) 9504RBC Deglycerolized (P9039) 9505 RBC Irradiated (P9038)

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Requested Information	Response
	9506Granulocytes, Pheresis (P9050) 9507Platelets, Pheresis (P9034) 9508Plasma, Frozen w/in 8 Hours (P9017)
Description of issues	<p>Although CMS has proposed to increase the payment rates for 19 of the 34 blood product APCs in 2007, blood product payment rates require further upward adjustments to ensure adequate reimbursement levels for hospitals. Volume-weighted Red Cross sales data indicate that, on average, the proposed APC payment rates for blood products would <u>not</u> reimburse hospitals even for the acquisition cost that they pay to the Red Cross (net of discounts and rebates). For red cells (HCPCS P9016 and P9021), the reimbursement would represent only 79% of the volume-weighted acquisition cost of these products. Although OPSS is not intended to pay 100 percent of aggregate hospital costs, the proposed rates on average will not cover the product <i>acquisition</i> costs, and in many cases, would not cover <i>any</i> of the overhead costs that hospitals incur internally once the blood has been obtained from the blood supplier. The need for increased reimbursement is driven by the fact that the costs of blood products continue to increase due to challenges with finding new donors, new testing requirements, and advances in blood safety. Appropriate reimbursement to hospitals is essential to maintaining beneficiary access to a safe and adequate blood supply.</p>
Clinical description of service under discussion (with comparison to other services within the APC)	<p>The services in question are human-collected blood components, each assigned to its own APC.</p>
Recommendations and rationale for change	<p>The Red Cross urges <i>The Panel</i> to continue its support for increased blood product reimbursement by recommending that CMS base the final 2007 APC payment rates for blood products on simulated <i>mean</i> costs instead of simulated median costs. This would more adequately capture hospitals' acquisition and overhead costs for blood products, would allow CMS to continue to use OPSS claims data as the basis of payment for blood products, and would align the OPSS rate-setting methodology for blood products with the current methodology used for most separately payable drugs and biologicals.</p>
Expected outcome of change and potential consequences of not making the change	<p>Improvements in blood product APC payment rates will help hospitals to more fully cover their acquisition and overhead costs for these products, thereby ensuring continued beneficiary access to blood and blood products. In contrast, if hospitals continue to be reimbursed at rates that do not adequately reflect the costs that they incur for blood products, beneficiary access to the blood supply could be threatened.</p>

COMMENTS

On the Need for Adequate Reimbursement for Blood and Blood Products under the Medicare Hospital Outpatient Prospective Payment System [Docket No. CMS-1295-N]

I am Dr. Jerry Squires, Executive Medical Officer with the American Red Cross, speaking on behalf of the Red Cross. I am a physician who has served as an Adjunct Assistant Professor of Pathology at Duke University Medical Center since 1988, as a Director of a Blood Bank, and as Executive Director of the Carolinas Blood Services Region of the Red Cross for over 15 years. I also have served on the Board of Directors of the North Carolina Association of Blood Banks. As a salaried employee of the Red Cross, my responsibilities include serving as the medical advisor to Red Cross medical personnel who help our hospital customers address concerns regarding the medical use, testing, efficacy, and safety of blood and blood products.

The Red Cross is a primary provider of blood products and related services to over 3,000 hospitals and other health care providers. The Red Cross, through its 35 Blood Regions, supplies almost half of the nation's blood products for patients' transfusion needs.

The Red Cross thanks you for the opportunity to speak to the Advisory Panel on Ambulatory Payment Classification (APC) Groups (*The Panel*) today, and we appreciate *The Panel's* ongoing commitment to addressing the concerns about blood product reimbursement that the Red Cross and others have raised at previous *Panel* meetings.

We also appreciate the Centers for Medicare and Medicaid Services' (CMS's) recent proposal to increase the APC payment rates for several blood products, including leukoreduced red blood cells (HCPCS code P9016), which represent the single largest volume blood product acquired by hospitals. Increases in payment for this and other key blood products are urgently needed in order to maintain adequate beneficiary access to the nation's blood supply.

However, the Red Cross is concerned that even with the proposed increases, the APC payment rates included in the calendar year (CY) 2007 Medicare hospital outpatient prospective payment system (OPPS) proposed rule still would not cover many hospitals' average acquisition costs for blood and blood products.

Therefore, the Red Cross urges *The Panel* to continue its support for increased blood product reimbursement by recommending that CMS base the final 2007 APC payment rates for blood products on simulated *mean* costs instead of simulated median costs. Below, we discuss the factors that contribute to the need for increased reimbursement and explain the rationale for our recommendation.

NEED FOR INCREASED REIMBURSEMENT

The need for increased APC payment rates is driven by the fact that the costs of blood products continue to increase. Over the past several years, the Red Cross has presented before *The Panel* on numerous occasions, highlighting the growing complexity and the resulting rise in costs of blood banking operations. An increasingly challenging aspect of blood bank operations is the recruitment of new, qualified, younger blood donors to meet hospital demand and replace aging, repeat blood donors. Donor recruitment and retention are becoming significantly more expensive, driving up the expenses associated with making blood available to patients in need.

Costly federally mandated requirements and recommendations by the U.S. Food and Drug Administration and its advisory committees also have significant impact on the increasing costs of blood products. The introduction of new technologies and tests, while improving the availability and safety of blood products, also leads to higher complexity and greater costs. Most recently, for example, the licensure of the West Nile Virus test in early 2006 resulted in significant increase in the cost of that test. New safety-enhancing tests, such as a test for Chagas, are also on the horizon. Hospitals and blood centers cannot absorb these rising costs and appropriate reimbursement is critical to hospitals' and blood centers' ability to maintain the supply chain for a safe and adequate blood supply.

RATIONALE FOR BASING PAYMENT ON SIMULATED MEAN COSTS

The Red Cross provides approximately 45 percent of the nation's blood supply. As CMS noted in the CY 2007 OPSS proposed rule, blood utilization varies significantly depending on the type of blood component. The products transfused most often are red blood cells – leukoreduced red blood cells and non-leukoreduced red blood cells (HCPCS P9016 and P9021) together account for 72% of Red Cross sales. A volume-weighted analysis of the Red Cross sales data shows that, on average, the proposed 2007 APC payment rates for these two blood products would reimburse hospitals for only 79% percent of the acquisition cost they pay the Red Cross (net of discounts and rebates).

Although OPSS is not intended to pay 100 percent of aggregate hospital costs, it is important to note that the proposed blood product APC payment rates would not cover on average hospitals' *acquisition* costs; and therefore, in many cases, these rates would not cover *any* of the overhead costs that hospitals incur internally once the blood has been obtained from the blood supplier. These blood-related overhead costs—which are intended to be captured in the blood product APC payment rates—include expenses associated with critical transfusion services activities such as retyping, handling, storage, delivery, and inventory management. When such overhead costs are taken into account, the discrepancy between costs incurred by hospitals and reimbursement becomes even more significant.

The Red Cross believes that CMS could better account for the costs incurred by hospitals by modeling its blood product rate-setting methodology (which currently is based on median costs) after the methodology that the agency used to determine the OPSS payment rate for specified covered outpatient drugs (SCODs) in 2006 and is proposing to use again for SCODs in 2007. Specifically, in the CY 2007 OPSS proposed rule, CMS concludes that using *mean*

unit costs to set the SCOD payment rate “would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in 2007.”²

We believe that using mean unit costs in conjunction with the simulated blood cost-to-charge ratio methodology would be appropriate for setting the APC payment rates for blood products in 2007. With very few exceptions, the mean unit costs for blood products are consistently higher than the median unit costs.³ Therefore, the use of simulated mean unit costs instead of simulated median unit costs would also more adequately capture hospitals’ acquisition and overhead costs for blood products.

The use of mean unit costs will still be based on OPSS claims data as the basis of payment for blood products, and would align the OPSS rate-setting methodology for blood products with the current methodology used for most separately payable drugs and biologicals. Although blood products are not recognized as SCODs by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), they are defined as “drugs” under section 201 (g) of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 321 (g), and as “biological products” under section 351 of the Public Health Service Act (PHSA), 42 U.S.C. § 262. We believe that it is also equally important to ensure that blood product payment rates are set at levels that allow hospitals to cover their acquisition and overhead costs and continue to provide beneficiaries with adequate access to the nation’s blood supply.

RECOMMENDATION

For the reasons described above, we ask *The Panel* to recommend that CMS base the final 2007 APC payment rates for blood products on simulated *mean* costs instead of simulated median costs.

Using simulated mean costs would more adequately capture hospitals’ acquisition and overhead costs for blood products, would allow CMS to continue to use OPSS claims data as the basis of payment for blood products, and would align the OPSS rate-setting methodology for blood products with the current methodology used for most separately payable drugs and biologicals.

The Red Cross believes that prompt and adequate reimbursement to hospitals is essential to maintaining the supply chain for a safe and adequate blood supply, and we appreciate CMS’s and *The Panel’s* longstanding acknowledgment of the importance of this issue. Improvements in blood product APC payment rates will help hospitals to more fully recover the costs associated with the acquisition and administration of blood products, thereby ensuring continued beneficiary access to blood and blood products.

The Red Cross would like to thank *The Panel* and CMS for their time and attention to this issue. If you have any questions, I would be glad to answer them.

² CMS-1506-P, public inspection version, p. 267.

³ Based on a comparison of mean unit costs and median unit costs as listed in the “Median Costs for Drugs, Biologicals, and Radiopharmaceuticals” file used to develop the CY 2007 OPSS proposed rule. Available at: www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/CMS1506P_Median_Costs_for_Drugs_Biologicals_and_Radiopharmaceuticals.zip