

lesser extent than blood and blood products. The commenter requested that CMS discontinue the differential dampening and apply the dampening rule equally.

Response: The commenter's concerns about rules governing payment for autologous blood and the costs associated with procuring blood for patients with special needs fall outside the scope of our proposed rule. These questions require further analysis and study, which we cannot undertake in time for implementation of the 2004 update of the OPPS. However, as we examine the current policies that affect payment for blood and blood products under the OPPS, we will consider both of the commenter's concerns.

As for the comment regarding adoption of a uniform dampening policy for both separately payable drugs as well as blood and blood products, this concern is no longer an issue because of our decision to freeze payment rates for blood and blood products at their 2003 levels for 2004.

Comment: Several commenters requested that CMS provide and promote guidance on correct coding and billing for blood and blood products to hospitals and other providers.

Response: We acknowledge the need for comprehensive billing and coding guidelines for hospitals and other providers. This is an area we expect to address in the near future.

9. Intravenous Immune Globulin

In the proposed rule, we discussed public comments suggesting that we reclassify intravenous immune globulin (IVIG) as a blood and blood product. We stated that after a review of claims data, we believe that payment for these products is appropriate using the methodology we proposed to implement for other drugs and biologicals. Therefore, we proposed to continue to classify IVIG as a biologic. We solicited comments on this proposal.

We received several comments on this proposal, which are summarized below along with our responses.

Comment: Several trade associations, manufacturers, patient organizations and individual commenters urged CMS to classify intravenous immune globulin (IVIG) under the "blood and blood product category." They indicated that IVIG is derived from plasma fractionation similar to other products categorized as a blood and blood product by CMS; and, furthermore, IVIG falls within the FDA's definition of "blood and blood product." Some of the commenters expressed concern about the potential negative impact on patient access as a result of our proposed

payment policy. Another commenter requested that we consider all plasma-derived products and their recombinant analogs as blood products.

Response: We appreciate these comments. However, we continue to believe that IVIG and other plasma-derived therapies and their recombinant analogs are comparable to other drugs and biologicals, and they do not have the same access concerns as other blood and blood products. Our policy regarding IVIG and plasma therapies were described in the November 1, 2002 final rule (67 FR 66774). For 2004, IVIG will be a separately payable item, and its payment rate will be based on approximately 26,500 claims for approximately 1.5 million services. As mentioned in the August 12, 2003 proposed rule (68 FR 48005), analysis of the claims data indicated that hospital costs and billing practices for IVIG have been consistent over the past two years. Therefore, we believe that the 2002 claims data contain a sufficiently robust set of claims for IVIG on which to base the payment rate for this item using the methodology that will be used for other separately payable non-pass-through drugs, biologicals, and radiopharmaceuticals.

10. Payment for Split Unit of Blood

Since implementation of the OPPS, we have assigned status indicator "E" to HCPCS code P9011, blood (split unit). Status indicator "E" designates services for which payment is not allowed under the OPPS or services that are not covered by Medicare. P9011 was created to identify situations where one unit of red blood cells or whole blood, for example, is split and half of the unit is transfused to one patient and the other half to another patient. Because use of split units is not uncommon, we proposed to change the status indicator for P9011 from "E" to "K" and assign it to a blood and blood product APC that pays approximately 50 percent of the payment for the whole unit of blood. We proposed to assign P9011 to APC 0957 (Platelet concentrate) with a payment rate of \$37.30. We invited comments on this proposed change in the status indicator and payment amount for P9011.

We received a few comments on this proposal, which are summarized below along with our responses.

Comment: Commenters pointed out that there was a typographical error in the proposed rule in which we referred to the split unit of blood as P9010 rather than P9011.

Response: We agree this was an error and have corrected it in this preamble and are making final our proposal to

assign P9011 to APC 0957 (platelet concentrate).

11. Other Issues

We proposed to continue our payment policy for Procrit and Aranesp for calendar year 2004. As explained in detail in the November 1, 2002 final rule (67 FR 66758), Aranesp and Procrit are in separate APCs, and are paid at equivalent rates with the application of a ratio to convert the dosage units of Aranesp into units of Procrit. We indicated that we might refine the conversion ratio as soon as feasible based on information not available at the time we established the current conversion ratio.

We have continued to gather information regarding an appropriate conversion ratio by reviewing recent published studies and data from alternative sources. In the proposed rule, we stated that we remain open to establishing a different conversion ratio in the final rule if we conclude that a change is warranted based on public comments and information submitted during the public comment period and/or any other information we consider in developing the final rule. Therefore, we proposed to continue with the current policy regarding payment for Procrit and Aranesp, including the current conversion ratio. We solicited comments on this issue and we stated that we would base any changes to our current payment policy for these two drugs only on data that we could make available to the public.

We received several comments on this proposal, which are summarized below along with our responses.

Comment: We received several comments concerning payment under the OPPS for erythropoietin and an erythropoietin-like product. Specifically, the comments pertained to payment for Aranesp™ (marketed by Amgen) and Procrit™ (marketed by Ortho Biotech) under the OPPS and the decision we made for 2003 with respect to an appropriate conversion ratio to ensure that these products, which use the same biological mechanism to produce the same results, are paid at the same rate.

Response: Erythropoietin, a protein produced by the kidney, stimulates the bone marrow to produce red blood cells. In severe kidney disease, the kidney is not able to produce normal amounts of erythropoietin and this leads to the anemia. Additionally, certain chemotherapeutic agents used in the treatment of some cancers suppress the bone marrow and cause anemia. Treatment with exogenous erythropoietin can increase red blood