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RE: CMS-1599-P: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates

### Dear Administrator Tavenner:

The American Society for Hematology (ASH) is pleased to have the opportunity to comment on the proposed changes to the hospital inpatient prospective payment system (IPPS) for FY 2014. ASH represents approximately 14,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases, including blood cancers such as leukemia, lymphoma and myeloma, and nonmalignant illnesses such as anemias, thrombosis and bleeding disorders. ASH members include hematologists and hematologists/oncologists who regularly render services to Medicare beneficiaries.

ASH would like to offer comments on the request for a new technology add-on payment for Kcentra. This issue is discussed beginning on page 27538 of the May 10, 2013, Federal Register. As noted in the proposed rule, Kcentra is a therapy for patients with an acquired coagulation factor deficiency due to warfarin who are experiencing a severe bleed. CMS is inviting comments on whether Kcentra meets the requirements for a new technology add-on and specifically on three issues: (1) whether Kcentra is a new technology, (2) whether Kcentra meets the cost criterion for a new technology add-on payment, and (3) whether Kcentra provides a substantial clinical improvement in the treatment of this patient group as compared with existing treatments.

# Is Kcentra a New Technology?

With respect to the "newness" requirement, there are three criteria that have been established by CMS for determining whether a new technology is substantially similar to an existing technology:

- Whether the product uses the same or similar mechanism of action to achieve a therapeutic outcome,
- Whether the product is assigned to the same or a different MS-DRG category, and
- Whether the use of the new technology involves the treatment of the same or similar type of disease and the same or similar patient population.

A technology meeting all three of these criteria would not be considered "new" for purposes of the new technology add-on payment. CMS is concerned that Kcentra may be substantially similar to fresh frozen plasma and/or Vitamin K therapy.

Kcentra is the first 4-factor prothrombin complex concentrate (PCC) available for clinical use in the United States. It was approved in April, 2013 for urgent reversal of acquired coagulation factor deficiency caused by the action of a Vitamin K antagonist (VKA) such as warfarin in adults with acute major bleeding. Unlike Factor VIII Inhibitor Bypassing Activity (FEIBA), which includes activated factor VII (VIIa), the Vitamin-K dependent factors in Kcentra are in the inactive form. Kcentra also contains prothrombin, factor IX, factor X, Protein C, Protein S, antithrombin III and heparin.

The combination of therapeutic compounds in Kcentra results in it having a very different mechanism of action than plasma, Vitamin K only or FEIBA. With Kcentra, the coagulation defect is corrected more quickly and effectively than extant technologies including plasma, Vitamin K only or FEIBA. Kcentra can be infused in only a few minutes while a therapeutic dose of plasma would require 2 or more hours to infuse. Similarly, Kcentra can correct the VKA-induced coagulation defect in about 30 minutes.

Kcentra is substantially different from other current technologies in other ways as well. It is manufactured from pooled plasma, it is virally inactivated and it is 25-fold more potent than plasma. Kcentra is much less likely than plasma to cause significant adverse effects associated with plasma transfusion such as transfusion-related acute lung injury (TRALI), transfusion-associated infection (e.g. HIV, HCV, etc.) or transfusion-associated cardiovascular overload (TACO).

For all of the above reasons, ASH believes that Kcentra uses a different mechanism of action than extant technologies and should be considered a new technology.

## Does Kcentra Meet the Cost Criterion?

ASH did not independently assess the costs of Kcentra. However, ASH reviewed the cost analysis submitted by CSL Behring and believes the methodology and assumptions are sound and establish that Kcentra meets the cost criterion.

# Does Kcentra Provide a Substantial Clinical Improvement?

Hospital use of Kcentra will largely occur in the emergency department, trauma center or intensive care unit. Patients who are brought to the hospital because of severe bleeding while on VKA therapy will receive Kcentra as part of their initial emergency care. Patients will likely also receive Vitamin K either parenterally or orally. Patients whose bleeding is intracerebral (traumatic or spontaneous) and who require urgent surgical intervention will receive Kcentra prior to being brought to the operating room.

In all of these circumstances, Kcentra represents a substantial improvement compared to existing therapeutic technologies (i.e. plasma therapy). The substantial improvement in the timeliness of treatment, an appropriate consideration for the labeled indication, is a major benefit of Kcentra compared to plasma. In addition, the formulation of Kcentra with all major Vitamin K-dependent clotting factors is an advantage compared to recombinant factor VIIa which shortens the prothrombin time (a test particularly sensitive to the level of factor VIIa) but may require co-administration of plasma for effective reversal of VKA coagulopathy.

It is incorrect to conclude that Kcentra is substantially similar to plasma. Plasma is a biological fluid that contains many proteins in addition to the zymogens of the coagulation cascade. Most of the proteins in plasma are irrelevant to correcting the effects of VKA treatment, and the substantial oncotic potential of plasma results from proteins other than coagulation proteins. The risk of transfusion related acute lung injury (TRALI) from plasma transfusion is 12 times the risk from red blood cell transfusion, but Kcentra therapy is unlikely to result in TRALI.

In summary, ASH thinks Kcentra meets all of the requirements for a new technology add-on.

Thank you for the opportunity to offer these comments. Please contact ASH Government Relations and Practice Manager, Stephanie Kaplan at <a href="mailto:skaplan@hematology.org">skaplan@hematology.org</a> with any questions related to these comments.

Sincerely,

Janis L. Abkowitz, MD

President