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American Red Cross

January 4, 2019

Cynthia Hake, Director, CMS' National Level II HCPCS Coding Program
Centers for Medicare and Medicaid Services
Mailstop: C5-09-14
7500 Security Blvd
Baltimore, Maryland 21244-1850

Re: **ESTABLISHMENT OF "MISCELLANEOUS/NOT OTHERWISE CLASSIFIED" HCPCS LEVEL II P-CODE FOR USE BY HOSPITALS TO BILL 3rd PARTY PAYERS FOR ANTICIPATED NEW BLOOD PRODUCTS**

Dear Ms. Hake,

AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross are submitting this letter to request that the Centers for Medicare & Medicaid Services (CMS) establish a HCPCS Level II "miscellaneous/not otherwise classified" code for blood products. Collectively, our organizations represent the nation's transfusion services, transfusion medicine professionals and blood collection establishments.

As recognized by CMS, "the importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA), even though there is no distinct code that describes the service or item."[1] The group of HCPCS codes for blood products (i.e., P-codes) does not currently have a "not otherwise classified" code. This is different from other code sets; examples of existing "not otherwise classified" codes include J3490 (unclassified drugs), J3590 (unclassified biologics) and J7599 (immunosuppressive drug, NOC). Thus, unlike drugs, biologics and immunosuppressive drugs, there is no current mechanism to immediately begin billing for a new blood product or new technology that is not captured by any of the existing P-codes.

AABB, America's Blood Centers and the American Red Cross strongly believe that the creation of a miscellaneous/not otherwise classified code for blood products is instrumental to facilitating the timely adoption of new products that may have the potential to result in improved clinical outcomes. As illustrated by the products highlighted on Table 1, a variety of new blood products are currently being evaluated in clinical trials, or are progressing toward clinical development, with the intention of seeking marketing approval from the U.S. Food and Drug

[1] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. Nov. 29, 2018. Accessed 12/6/2018 at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.

Administration (FDA). Table 1 is not intended to be comprehensive, and there may be additional investigational blood products in development that are not included on this list.

Table 1: Examples of Investigational Blood Products Currently In Development

Investigational Blood Product	Current Development Status
Freeze dried plasma (RePlas™)	Submission requesting FDA marketing approval anticipated in early 2019; clinical testing completed[2]
Psoralen-treated, pathogen reduced cryoprecipitate	Submission requesting FDA marketing approval anticipated in 2019[3]
Riboflavin-treated, pathogen reduced platelets	Currently in Phase 3 clinical testing[4]
Amustaline/glutathione-treated, pathogen reduced red blood cells	Currently in Phase 3 clinical testing[5]
Freeze dried, heat-treated platelets (Thrombosomes®)	Currently in Phase 1 clinical testing[6]
Spray dried plasma	Pre-clinical development[7]

Since no "miscellaneous/not otherwise classified" HCPCS code currently exists for use by hospitals to bill third party payers during the interim period between FDA approval and establishment of a specific HCPCS Level II code, hospitals would find themselves unable to immediately bill third party payers for any of these currently investigational blood products in the event that one or more of them – or other future new blood products not adequately described by any existing P-code – receives FDA approval. Our organizations and others have previously recommended that CMS establish a miscellaneous/not otherwise classified HCPCS code for blood products to avoid this predicament and to accommodate new technologies and products.[8]

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[2] Teleflex presentation. Accessed 12/17/2018 at: https://teleflexincorporated.gcs-web.com/static-files/96f136f9-7b4a-4d9c-9f22-fd6ff770f8dd

[3] Cerus press release. Accessed 12/17/2018 at: http://www.cerus.com/Investors/Press-Releases/Press-Release-Details/2018/Cerus-to-Provide-Update-to-Development-Programs-and-Outline-Growth-Strategy-at-2018-Institutional-Investor-Meeting/default.aspx

[4] Terumo BCT press release. Accessed 12/28/2018 at: https://www.massdevice.com/terumo-launches-mirasol-pathogen-reduction-tech-trial/

[5] ClinicalTrials.gov. Accessed 12/17/2018 at: https://clinicaltrials.gov/ct2/show/NCT03459287?term=amustaline&rank=5

[6] ClinicalTrials.gov. Accessed 12/17/2018 at: https://clinicaltrials.gov/ct2/show/NCT03394755?term=cellphire&rank=1

[7] Velico Medical press release. Accessed 12/17/2018 at: http://www.velicomedical.com/1182-2/

[8] I.e., AABB comments in response to the 2018 Medicare OPPS proposed rule, available at https://www.regulations.gov/document?D=CMS-2017-0091-1565, America's Blood Centers comments in response to the 2018 Medicare OPPS proposed rule, available at https://www.regulations.gov/document?D=CMS-2017-0091-0552; American Red Cross comments in response to the 2018 Medicare OPPS proposed rule, available at

In order to enable providers to initiate immediate billing for new human blood products that may be approved by the FDA and become available in the near future, we formally request that the CMS HCPCS Workgroup revise the HCPCS Level II code set to establish a new "miscellaneous/not otherwise specified" HCPCS "P" code, under the Pathology and Laboratory Services section of the HCPCS code set, that is specific for human blood products.

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If you have any questions, please contact Leah Stone, Director, Public Policy and Advocacy, AABB (301-215-6554, lmstone@aabb.org), Kate Fry, Chief Executive Officer, America's Blood Centers (202-654-2911, kfry@americasblood.org) or Liz Marcus, Director, Hospital Sales and Marketing, American Red Cross (202-303-7980, liz.marcus@redcross.org).

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AABB	America's Blood Centers	American Red Cross

https://www.regulations.gov/document?D=CMS-2017-0091-3102; American Hospital Association comments in response to the 2018 Medicare OPPS proposed rule, available at https://www.regulations.gov/document?D=CMS-2017-0091-2637.