



Advancing Transfusion and  
Cellular Therapies Worldwide

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Tamara Syrek Jensen  
Director, Coverage and Analysis Group  
Center for Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Proposed Decision Memo for Autologous Blood-Derived Products for Chronic Non-Healing Wounds (CAG-00190R4)**

Dear Ms. Jensen:

AABB appreciates the opportunity to submit comments in response to the Proposed Decision Memo for Autologous Blood-Derived Products for Chronic Non-Healing Wounds. AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to “improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.” AABB works toward this vision by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers. AABB’s accreditation program started in 1958, and since 1995 AABB has served as a deemed accrediting organization for the Centers for Medicare & Medicaid Services (CMS) for transfusion medicine, blood donor activity, cellular therapy services, immunohematology reference laboratories and molecular testing laboratories.

AABB appreciates that CMS relied on an extensive review of clinical evidence for the coverage determination analysis. We recommend that CMS recognize in its decision memo for autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing wounds standards-setting and accreditation organizations, including AABB, to ensure the safety and quality of these treatments.

For example, AABB has an established standards and accreditation program that supports improved outcomes for patients receiving PRP. The AABB Standards for Perioperative Autologous Blood Collection and Administration (Perioperative Standards) covers all elements of collecting, manufacturing, and administering PRP. Additionally, these Standards are written by experts and include guidance on the collection, storage, transport, testing, processing, administration, and patient outcomes for these products. The Perioperative Standards also contain requirements that focus on the clinical care of the patient, including any special conditions that should be considered for optimal patient outcomes after treatment.

We encourage CMS to work with AABB to ensure product quality and patient safety for treatment options utilizing blood and blood products. Thank you for the opportunity to provide feedback. If you have any questions, please contact Susan Leppke at [sleppke@aabb.org](mailto:sleppke@aabb.org) or 301.547.3962.

Sincerely,

Debra BenAvram  
Chief Executive Officer  
AABB