



October 2, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically Via <http://www.regulations.gov>

RE: Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1734-P)

Dear Administrator Verma:

Our organizations appreciate the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) payment policies under the Physician Fee Schedule and other changes to Part B payment policies for calendar year 2021. Our comments focus on ensuring that patients have access to medically necessary services, and focus on CMS' proposals related to the removal of selected national coverage determinations (NCDs), including NCD 110.14, Apheresis (Therapeutic Pheresis) (07/30/1992), NCD 20.5, Extracorporeal Immunoabsorption (ECI) using Protein A Columns (01/01/2001), and NCD 190.1, Histocompatibility Testing (8/1/1978).

- **NCD 110.14, Apheresis (Therapeutic Pheresis) (07/30/1992):** We support CMS' proposal to remove NCD 110.14, Apheresis since it is outdated and does not currently reflect advances in apheresis medicine and patient care applications. We agree with CMS that, "the apheresis NCD predates the current NCD public notice standards," and that the NCD, "is vague and open to interpretation and may not be applied uniformly." In 2015, AABB, the American Society for Apheresis (ASFA) and the American Society of Hematology (ASH) submitted comments supporting CMS' proposal to retire the current NCD. Consistent with this position, the undersigned organizations urge CMS to remove the NCD. Despite our understanding that contractors do not use the existing NCD for coverage or denial determinations, we are concerned that "contractor discretion" could be used to deny treatments. We plan to work together with other professional societies to educate the Medicare Administrative Contractors on the intricacies of apheresis and the need for patients to have access to this important treatment option.
- **NCD 20.5, Extracorporeal Immunoabsorption (ECI) using Protein A Columns (01/01/2001):** Similarly, we support CMS' proposal to move coverage decisions to contractor discretion for ECI using Protein A columns since it is outdated and results in problematic coverage determinations. The Staphylococcal Protein A columns are no longer available in the United States and the specific column covered by this NCD, the ProSORBA column, is no longer manufactured anywhere in the world. Additionally, the existing NCD interferes with patients' access to medically necessary care. For example, as a result of the American Medical Association (AMA) adding the term "immunoabsorption" to the description of CPT 36516, a directive was released instructing the MACs that the NCD on immunoabsorption applied to CPT 36516. As a result, claims have been denied for patients receiving medically necessary LDL apheresis for conditions such as familial hypercholesterolemia.

- **NCD 190.1 Histocompatibility Testing (08/01/1978):** We encourage CMS to ensure that coverage and payment policies will support patients' access to all forms of histocompatibility testing. The importance of histocompatibility testing (antibody detection and identification, crossmatching and high-resolution HLA typing) is indisputable science and there is strong evidence supporting its use. Advances in transfusion therapy, hematopoietic stem cell transplantation (HSCT), and solid organ transplantation have created opportunities for more sophisticated histocompatibility tests to be performed, which are critical to improving clinical outcomes for patients. For example, molecular Human Leukocyte Antigen (HLA) allele typing and next generation sequencing techniques are performed to provide additional HLA class information in unrelated donor HSCT, where results of these tests can provide insight to avoid acute graft rejection. Also, testing for HLA alloimmunization before transfusion therapy can prevent adverse clinical outcomes for patients. We urge CMS to ensure that its coverage and payment policies do not restrict patients access to these critical services.

We encourage CMS to ensure that any changes to NCDs support flexibility, innovation, and patient care. Additionally, we urge CMS to work with the contractors to ensure that the removal of any outdated NCD does not result in denied coverage for important treatments and services. We look forward to continuing to work with CMS to ensure that coverage decisions reflect current evidence and medical practices.

If you have any questions, please contact Leah Stone (301-215-6554, lmstone@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Liz Marcus (202-303-7980, liz.marcus@redcross.org).

Sincerely,
Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

J. Chris Hrouda
President, Biomedical Services
American Red Cross