

June 28, 2017

<u>Via E-mail</u>

Arthur Lurvey, MD, FACP, FACE Contractor Medical Director Noridian Healthcare Solutions 900 42ns Street South Fargo, North Dakota 58103

Eileen Moynihan, MD Contractor Medical Director Noridian Healthcare Solutions 900 42<sup>nd</sup> Street South Fargo, North Dakota 58103

Dear Drs. Lurvey and Moynihan:

RE: LCD Reconsideration Number AB0016, Immune Globulin Intraveneous (IVIg)

On behalf of the American Society of Transplantation (AST), representing a majority of professionals engaged in the field of solid organ transplantation, and the American Association of Kidney Patients (AAKP), an independent patient voice for kidney candidates and recipients since 1969 with over 120,000 patient members nationwide, we write to express our strong concern regarding Noridian's recent decision regarding coverage for the utilization of IVIg in organ transplantation. We recently learned from our members that Noridian will currently cover IVIg only twelve hours prior to transplantation in antibody sensitized patients with PRA >30%, and is not willing to modify this policy to pay for IVIg outside of the listed timeframe. This policy runs counter to the current standard of practice for organ transplantation and widely accepted peer reviewed publications on this topic.

IVIg use for transplant recipient desensitization is a widely accepted therapy world-wide. The benefits of desensitization have been demonstrated to exceed the increased mortality and poor quality of life experienced by patients who remain on dialysis. We are deeply troubled that Noridian has reversed its 2004 stance on this therapy, and believe that this will be an unnecessary deterrent to organ transplantation for highly sensitized patients who comprise approximately 30 % of the current OPTN wait list. Without access to transplantation, this vulnerable population of kidney candidates will remain on dialysis with only a rare opportunity at best for transplant if they cannot afford this therapy without the benefit of your coverage. Just recently, an AAKP Board member who is a sensitized patient received national attention regarding the merits of IVIg therapy as she successfully transitioned from dialysis to a transplant. The kidney patient community in particular follows developments standards of practice for IVIg therapy closely and is aware of this issue.

The AST and AAKP respectfully request that you reconsider this stance, as it impacts access to transplantation for a population of candidates who will be severely impacted due to their high sensitization. This will ultimately result in increased, and in our opinion, unnecessary, deaths. If you or your staff have questions or require any additional information, please do not hesitate to contact us directly.

Thank you in advance for your consideration of this request.

Sincerely,

Ronald G. Gill, PhD AST President

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Paul T. Conway AAKP President

CC: Charles Haley, MD, MS, FACP, Contractor Medical Director

Gary Oakes, MD, Contractor Medical Director

Richard Whitten, MD, MBA, FACP, Contractor Medical Director

Mr. Richard Knight, VP and Chair of Public Policy, AAKP