

April 20, 2018

**BY ELECTRONIC DELIVERY**

Demetrios Kouzoukas  
Principal Deputy Administrator & Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Principal Deputy Administrator Kouzoukas:

The National Home Infusion Association (NHIA) and the Immune Deficiency Foundation (IDF) are writing to ask that you add ICD-10 code D83.1 – common variable immunodeficiency with predominant immunoregulatory T-cell disorder to the Medicare Policy Manual Chapter 15 section 50.6, *“Coverage of Intravenous Immune Deficiency Diseases in the Home.”*

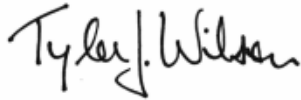
Diagnosis code D83.1 was added to the ICD-10 manual on October 1, 2017. The D83.1 code has since been added to the Durable Medical Equipment (DME) Medicare Administrative Contractors’ (MAC) *“External Infusion Pump Local Coverage Determination”* as a covered diagnosis for subcutaneous immune globulin (SCIG) therapy but has not been added to the Medicare Policy Manual for intravenous immune globulin (IVIG) coverage. The policy manual’s lack of inclusion of the D83.1 code prevents Medicare beneficiaries with the diagnosis of common variable immunodeficiency (CVID) with predominant immunoregulatory T-cell disorder from accessing coverage for IVIG in their home. This also includes coverage within the recently extended IVIG Demonstration. All individuals with the diagnosis of CVID, whether or not they have one of the frequently associated conditions such as a *“predominant immunoregulatory T-cell disorder”* (D83.1), have clinically significant antibody deficiency requiring immunoglobulin replacement therapy as the keystone of their treatment. This is true whether that immunoglobulin is delivered by either the intravenous (IVIG) or subcutaneous (SCIG) route, an individualized treatment decision best made by the treating physician.

Recently, NHIA requested the DME MACs clarify this policy. When NHIA asked the DME MACs why D83.1 had not also been added to the Intravenous Immune Globulin Local Coverage Determination, they responded that *“Code D83.1 is not included in the array of ICD-10 codes that the Centers for Medicare & Medicaid Services (CMS) has deemed covered for IVIG (see CMS Benefit Policy Manual (Internet-only Manual 100-2, Ch. 15, §50.6)). The DME MACs do not have discretion to add ICD-10 codes.”*

For this reason, ICD-10 code D83.1 – common variable immunodeficiency with predominant immunoregulatory T-cell disorder needs to be added to the Medicare Policy Manual Chapter 15 section 50.6 – Coverage of Intravenous Immune Deficiency Diseases in the Home. Additionally, we ask that CMS instruct the DME MACs that D83.1 is eligible for the IVIG demonstration project currently in effect.

NHIA and IDF appreciate continuing to work with CMS to ensure Medicare beneficiaries have access to home infusion drugs and services. Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Government Affairs, at (703) 838-2664 ([kendall.vanpool@nhia.org](mailto:kendall.vanpool@nhia.org)) or Lynn H. Albizo, IDF Senior Director of Public Policy at (443) 632-2544 ([lalbizo@primaryimmune.org](mailto:lalbizo@primaryimmune.org)) should you want to discuss the issue further.

Sincerely,

Handwritten signature of Tyler J. Wilson in black ink.

Tyler J. Wilson  
President & CEO  
National Home Infusion Association

Handwritten signature of John G. Boyle in blue ink.

John G. Boyle  
President & CEO  
Immune Deficiency Foundation