



November 2, 2016

Joe Johnson  
President & COO  
Palmetto GBA  
17 Technology Circle  
Columbia, SC 29203

Antonietta Sculimbrene, MD, MHA  
Lead Contractor Medical Director, J11 Part A & B  
PO Box 100238  
Columbia, SC 29202-3238

*BY ELECTRONIC DELIVERY*

RE: Down-coding Complex Administration Codes for Office-Administered IV/Injectable Biologics

Dear Mr. Johnson and Dr. Sculimbrene:

The National Infusion Center Association (NICA) is pleased to submit its comments to Palmetto GBA regarding the decision to down-code the administrative coding for provider-administered biologics from complex to simple.

NICA is a nonprofit advocacy organization, established in 2010, to provide a national voice to patients relying upon office-based Infusion Centers to access high-quality, cost-effective care. Our efforts are focused on improving patient access to non-chemotherapeutic provider-administered intravenous and injectable medications in non-hospital, office-based Infusion Centers. NICA and its infusion provider partners are committed to maintaining the viability of office-based Infusion Centers as a more accessible, more patient-friendly, and more economical alternative to the hospital care setting.

NICA supports Medicare patients and their healthcare providers having access to a wide range of therapies so that they can find the right medication. This is particularly important in the case of biologic therapies for patients with immune-mediated inflammatory conditions, like rheumatoid arthritis, Crohn's disease, and ulcerative colitis. We are concerned that this down-coding decision may restrict patient access to the high-quality care they need.

NICA offers its comments on down-coding complex administration codes for biologics to direct Palmetto GBA's attention to the following concern:

- Down-coding the administrative coding for provider-administered IV/injectable biologics will geographically discriminate against 4.5 million patients by reducing patient access to these medications in North Carolina, South Carolina, Virginia, and West Virginia.



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***Down-coding will geographically discriminate against 4.5 million patients by reducing patient access to biologics in North Carolina, South Carolina, Virginia, and West Virginia.***

NICA is concerned that Palmetto GBA’s decision to down-code the administration coding for provider-administered intravenous and injectable biologics will create a negative reimbursement environment for these medications. This decision will result in geographic discrimination against some of the 4.5 million patients in Palmetto’s covered states by restricting their access to the care they need.

Biologics are highly complex medications that typically require “[a]dvanced practice training and competency for staff who provide these services [and] special considerations for preparation, dosage, or disposal”.<sup>1</sup> Due to the complexity of the preparation and administration involved, many biologics do not receive FDA approval for self-administration by the patient.

The American Medical Association categorizes the administration of biologic medications under CPT codes 96401-96549 (“Chemotherapy and Other Highly Complex Drugs or Highly Complex Biologic Agent Administration”). Furthermore, biologic agents are specifically and clearly excluded from the category of simple injections under CPT codes 96365-96379 (i.e. “Therapeutic, Prophylactic, and Diagnostic Injections and Infusions”) in the 2016 Professional CPT Manual.<sup>2</sup>

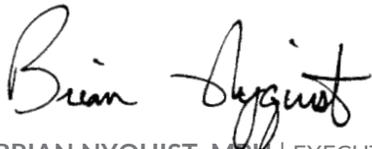
***Conclusion***

Provider-administered intravenous and injectable biologics require complex preparation, administration, and close monitoring of the patient to detect and address adverse reactions. Therefore, these medications should be reimbursed under complex administration codes accordingly.

We implore Palmetto GBA to reconsider its decision to down-code biologics, like Cimzia, that require complex preparation and administration, as well as carry the risk of adverse reactions. NICA welcomes the opportunity to work with Palmetto GBA toward developing a consistent set of biologic-specific administration coding guidelines to support patient access to the entire array of safe and effective therapy options that are currently available.

NICA appreciates the opportunity to submit its comments on behalf of office-based Infusion Centers serving some of our nation’s most vulnerable Medicare patients. We are eager to work with Palmetto GBA toward addressing the concerns expressed in this letter.

Respectfully,



**BRIAN NYQUIST, MPH | EXECUTIVE DIRECTOR  
NATIONAL INFUSION CENTER ASSOCIATION**

<sup>1</sup> Medicare Administrative Contractors: CMS Should Consider Whether Alternative Approaches Could Enhance Contractor Performance. United States Government Accountability Office, 2015. GAO-15-372.

<sup>2</sup> Professional CPT Manual. American Medical Association, 2016. 650-652.



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United States Senate, North Carolina

Shelley Moore Capito  
United States Senate, West Virginia

Lindsey Graham  
United States Senate, South Carolina

Tim Kaine  
United States Senate, Virginia

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