

August 19, 2019

Bruce Broussard  
President & CEO  
Humana, Inc.  
500 W. Main Street  
Louisville, KY 40202

**Subject: Down-coding Complex Administrative Codes for Office-Administered Intravenous Biologics**

Dear Mr. Broussard:

The National Infusion Center Association (NICA) and the National Organization of Rheumatology Managers (NORM) are pleased to submit joint comments to Humana regarding its decision to require that therapeutic infusion codes (96360-96379) be reimbursed instead of chemotherapy codes when reported for the administration of specific medications.

NICA is a 501(c)(3) nonprofit advocacy organization, established in 2010, to represent patients requiring provider-administered intravenous or injectable medications and the providers that treat them. NICA was formed to ensure that some of our nation's sickest and most vulnerable patients can access the in-office infusion therapy they rely upon to manage their complex, chronic condition(s).

NORM is a 501(c)(6) nonprofit advocacy organization representing rheumatology managers, physicians and patients. Our mission proclaims we are a forum by which we promote and support education, expertise and advocacy for access to care of our rheumatology practices and their patients.

On behalf of the stakeholders we represent, we write to share feedback on Humana's decision to reimburse the administration of complex biologic response modifiers at lower-level therapeutic codes. NICA and NORM are deeply concerned that such a position would drive inappropriate utilization of administrative coding inconsistent with medical coding guidelines directed by the American Medical Association, the Centers for Medicare & Medicaid Services, and the Government Accountability Office.

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>

The American Medical Association (AMA) categorizes the administration of biologic medications under CPT codes 96401-96549 ("Chemotherapy and Other Highly Complex Drugs or Highly Complex Biologic Agent Administration"). Additionally, **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 2018 *Professional CPT Manual*.<sup>2</sup>

Additionally, according to Centers for Medicare & Medicaid Services (CMS) *Medicare Claims Processing Manual* (Chapter 12, Section 30.5, Subsection D), "[c]hemotherapy administration codes

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<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> CPT 2018 Professional Manual. American Medical Association, 2018. pg. 679, 681. Bolded for emphasis.

**apply to parenteral administration of [...] substances such as monoclonal antibody agents, and other biologic response modifiers.** (bolded for emphasis)<sup>3</sup> This section of the manual continues with the statement: “The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes.”

According to guidance published by the Government Accountability Office (GAO), CMS’ *Medicare Claims Processing Manual*, and the American Medical Association’s *CPT 2018 Professional Manual*, reimbursement at complex administration codes is supported for complex biologic agents including, but not limited to: Actemra, Orencia, and Simponi Aria.

Furthermore, Article A54848 from CGS Administrators, LLC published in March 2016 references the Current Procedural Terminology CPT®2016 Professional Edition, supporting the use of high-level codes:

*“Chemotherapy Administration codes 96401-96549 apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses... or to substances such as certain monoclonal antibody agents, and other biologic response modifiers. The highly complex infusion of chemotherapy or other drug or biologic agents requires physician or other qualified health care professional work and/or clinical staff monitoring well beyond that of therapeutic drug agents (96360-96379) because the incidence of severe adverse patient reactions are typically greater... Chemotherapy services are typically highly complex and require direct supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intraservice supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage, or disposal; and commonly these services entail significant patient risk and frequent monitoring.”*<sup>4</sup>

Biologics are highly complex, large molecule medications used to treat complex, chronic, and difficult-to-treat conditions, like autoimmune disease. All medications carry risk. Due to the risks associated with all therapeutic biological medications and the higher frequency of adverse reactions, administration services are highly complex, requiring specialized training, handling, storage, and preparation—as well as direct supervision—to maintain product stability and minimize the risk of adverse reaction. These requirements are well beyond those associated with furnishing therapeutic drug agents. As such, CMS and AMA support high-level (chemotherapy) administration codes for complex biologic agents. Therefore, the use of high-level codes is appropriate for the professional services associated with administering outpatient infusion/injection services for therapeutic biological products.

Unlike hospital-affiliated care settings, there are currently no available admin codes or supplemental fee structure to reimburse office-based infusion providers for the cost of medical supplies or equipment utilized for the administration of intravenous biologics. In addition, the current administrative reimbursement environment does not fully cover the total practice expense associated with a patient’s care coordination, even at high-level admin codes.

Further reduction in reimbursement for the administration of intravenous biologics may result in the disruption of care for patients, driving poorer health outcomes, and unnecessary increases in the physical,

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<sup>3</sup> CMS. Medicare Claims Processing Manual, Chapter 12, Section 30.5, Subsection D. Bolded for emphasis. Retrieved from <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>

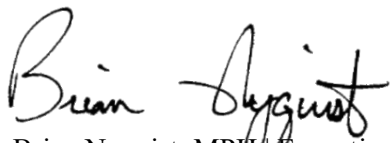
<sup>4</sup> Future Effective Article A54848: Drug Administration Coding. Version 3. CGS Administrators, LLC. March 2016. Retrieved from [https://www.cgsmedicare.com/pdf/drug\\_admin\\_coding.pdf](https://www.cgsmedicare.com/pdf/drug_admin_coding.pdf)

emotional, and economic burdens of disease. If furnishing IV/injectable medications becomes financially in-viable for office-based providers, patients will wind up in much more expensive hospital care settings—increasing Humana’s per member per month cost-liability.

NICA and NORM support Humana’s commitment to reducing overall healthcare costs and improving affordability of drugs for its members, as well as its efforts in site of care optimization for expensive specialty medications to shift these beneficiaries into lower cost office-based care settings. If Humana proceeds with down-coding the administration codes for complex biologics, we are concerned that the change will produce unintended consequences and increase the cost-sharing liability for Humana and its members. We do not believe that Humana would knowingly drive physicians to bill an inappropriate CPT code for a medical service that has a more descriptive code which clearly supports the service provided. Particularly, when inconsistent with guidance widely accepted among the medical community.

As such, we implore Humana to reconsider its decision to down-code biologics that require complex preparation and administration, as well as carry the risk of adverse reactions. NICA and NORM appreciate the opportunity to submit comments and would welcome the opportunity to work with Humana toward addressing the concerns expressed in this letter to ensure that its members continue to receive high-quality infusion/injection services in a safe, low-cost environment.

Sincerely,



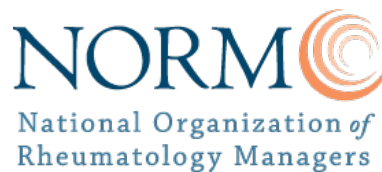
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cc: William Shrank, M.D., MSHS  
Chief Medical & Corporate Affairs Officer

William Fleming, PharmD  
Segment President, Healthcare Services

The following organizations have signed a petition in opposition of down-coding the administrative codes for complex biologics:

Advanced Arthritis and Rheumatology Care  
Advanced Rheumatology  
Advanced Rheumatology and Arthritis Center  
Advanced Rheumatology and Arthritis Research Center, PC  
Ahmed M. Fahmy, MD, LLC  
Albuquerque Center for Rheumatology, PC  
Allergy and Rheumatology Associates, LLC  
Allergy, Asthma, Arthritis, and Osteoporosis Center  
Amarillo Medical Specialists  
Americare Medical Partners, PLLC  
Arizona Arthritis and Rheumatology  
Arthritis and Osteoporosis Center  
Arthritis and Osteoporosis Center, LLC  
Arthritis and Osteoporosis Consultants of the Carolinas  
Arthritis and Osteoporosis Treatment and Research Center  
Arthritis and Osteoporosis Treatment Center, PA  
Arthritis and Rheumatic Care Center  
Arthritis and Rheumatic Disease Specialties  
Arthritis and Rheumatic Diseases, PC  
Arthritis and Rheumatism Associates  
Arthritis and Rheumatology Associates of Palm Beach  
Arthritis and Rheumatology Care Center  
Arthritis and Rheumatology Center of South Florida  
Arthritis and Rheumatology Clinic (ARC)  
Arthritis and Rheumatology Consultants, PA  
Arthritis Associates  
Arthritis Associates of South Florida  
Arthritis Associates, PLLC  
Arthritis Center of Nebraska  
Arthritis Clinic of Central Utah  
Arthritis Consultants  
Arthritis Consultants of Tidewater  
Arthritis Specialists  
Arthritis, Rheumatic and Back Disease Associates  
Articularis Healthcare  
Asheville Arthritis  
Austin Regional Clinic  
Ballantyne Rheumatology  
Baptist Rheumatology  
Bay Area Arthritis and Osteoporosis  
Cape Fear Arthritis Care  
Carlos L. Martinez, MD, PC  
Carolina Arthritis Center

Carolina Center for Rheumatology and Arthritis Care, P.A.  
Catherine N. Kowal, MD, PA  
Center for Arthritis  
Center for Arthritis and Rheumatic Diseases  
Centre for Rheumatology, Immunology and Arthritis  
Charles A. Birbara, MD, Inc  
Chester County Rheumatology PC  
Chi Arthritis and Rheumatology Associates  
Clayton Medical Associates, P.C.  
Clinic for Rheumatic Diseases  
Colorado Center for Arthritis and Osteoporosis  
Columbus Arthritis Center  
David R. Mandel, MD  
Dianne M. Cooper, MD  
East Cooper Rheumatology  
East Penn Rheumatology  
Eldersburg Arthritis  
Emerald Coast Rheumatology  
Family Arthritis Center  
Florida Arthritis and Osteoporosis Center  
Florida Rheumatology Care  
Fort Smith Rheumatology  
Franciscan Alliance d/b/a Franciscan Physician Network  
Guillermo Valenzuela, MD, PA  
Gulf Coast Medical Group Rheumatology  
Hattiesburg Clinic Arthritis Center  
Healix Infusion Management  
Heritage Valley Rheumatology  
Highlands Advanced Rheumatology and Arthritis Center  
Idaho Arthritis Center  
Infusion Center of Denver  
Infusion Center of Pennsylvania  
Integral Rheumatology and Immunology Specialists (IRIS)  
Integrative Rheumatology  
Jeffrey A. Alper, MD, PA  
Joint & Muscle Medical Care  
Klein and Associates, MD, PA  
Lake Rheumatology  
Medical Specialists of Johnson City  
Mercy Health Partners  
Metro Infusion Center  
Milwaukee Rheumatology Center  
MPP Infusion d/b/a Multispecialty Physician Partners  
Northwest Rheumatology Associates  
Orthopaedics and Rheumatology of the North Shore

Paragon Healthcare  
Philip A. Waller, MD, PA  
Physician Surgical Network D/B/A Central Florida Arthritis and Osteoporosis  
Center  
Piedmont Arthritis Clinic  
Premier HealthCare Associates, Inc.  
Premier Rheumatology of Oklahoma  
RDC of Volusia  
Regional Rheumatology Associates  
Rheumatic Disease Associates  
Rheumatology and Osteoporosis Specialists  
Rheumatology Associates  
Rheumatology Associates of Baltimore, LLC  
Rheumatology Associates of Central Florida  
Rheumatology Associates of East Tennessee  
Rheumatology Associates of North Jersey  
Rheumatology Associates of South Florida  
Rheumatology Associates, LTD  
Rheumatology Associates, PC  
Rheumatology Center, Inc.  
Rheumatology Consultants  
Rheumatology Consultants of WNY, PC  
Rheumatology Consultants, PLLC  
Rheumatology Services Medical Group  
Rheumatology Specialists of Connecticut  
Richard D. Gordon, MD  
Robert W. Levin, MD, PA  
Sandhills Rheumatology, LLC  
Sarasota Arthritis Center  
Savannah Rheumatology Associates, PC  
South Florida Rheumatology  
Southwest Florida Rheumatology  
Suncoast Rheumatology  
Sunshine Rheumatology and Arthritis Center  
Terrence Foley, MD, Inc.  
The Carolina Center for Rheumatology and Arthritis Care, P.A.  
Tristate Arthritis and Rheumatology  
Virginia Rheumatology Clinic  
Wasatch Infusion  
Wayne Heart and Internal Medicine Associates, P.A.  
West Broward Rheumatology Associates  
Woodlands Arthritis Clinic, PA