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October 22<sup>nd</sup>, 2018

Lewis Sandy, MD  
Executive Vice President, Clinical Advancement  
United Health Group  
9900 Bren Road East  
Minnetonka, MN 55343

#### **Re: Changes to the Coordinated Commercial Reimbursement Policy for Injection & Infusion Services**

*Submitted electronically via email to [lewisgsandy@uhg.com](mailto:lewisgsandy@uhg.com)*

Dr. Sandy,

On behalf of the Coalition of State Rheumatology Organizations (CSRO), and the undersigned state and regional rheumatology societies, we are writing to register our vigorous opposition to United Health Group's decision to revise its reimbursement policy for injection and infusion services reported in conjunction with certain drugs utilized frequently by rheumatologists.<sup>1</sup>

The CSRO is comprised of state and regional professional rheumatology societies whose mission is to advocate for excellence in the rheumatology community, and ensure access to the highest quality care for rheumatology patients. Rheumatologists are at the forefront of innovative treatments for patients with complex rheumatologic, autoimmune, and musculoskeletal diseases that require the careful choice of therapies based on the unique clinical considerations of each patient. United Health's decision to downcode reimbursement for the administration services provided in conjunction with the aforementioned drugs greatly hinders our ability to do so.

Prior to the announced change, United Health Group reimbursed injection and infusion services for the cited drugs using codes 96413 and 96415 designated for chemotherapy. This policy was consistent with findings by medical professional societies that the administration of biologics definitively met the threshold for chemotherapy services according to CPT and CMS manuals.<sup>2,3</sup> The referenced section of the CMS *Claims Processing Manual* specifically states that "chemotherapy administration codes apply to parenteral administration of...substances such as...biologic response modifiers."<sup>4</sup>

(1) 3380 (Entyvio), J0129 (Orencia), J3262 (Actemra), J1602 (Simponi)

(2) CMS Chapter 12 30.5 CMS Chapter 12 Section 30.5 - 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions. Rev. 968. Issued: 05-26-06; Effective: 06-26-06.

[http://www.rheumatology.org/CMS\\_Chapter\\_12\\_Section\\_30\\_5.pdf](http://www.rheumatology.org/CMS_Chapter_12_Section_30_5.pdf)

[http://www.rheumatology.org/ACA\\_and\\_Medical\\_Necessity.pdf](http://www.rheumatology.org/ACA_and_Medical_Necessity.pdf)

(3) CPT Manual Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Adminsitration (96401-96549)

(4) CMS Chapter 12 30.5 CMS Chapter 12 Section 30.5 - 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions. Rev. 968. Issued: 05-26-06; Effective: 06-26-06.

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The American Medical Association's 2018 *Professional CPT Manual* specifically distinguishes biologic agents from simple injection services identified under codes 96365 – 96379.<sup>1</sup>

Downcoding for these services is incongruent with professional consensus regarding the complexity of administering biologic drugs. The injection and infusion services provided for biologic drugs far surpass those currently covered by the therapeutic infusion codes 96365 and 96366.

Specifically, relative to other therapies represented by therapeutic infusion codes 96365 and 96366:

1. Biologics require additional preparation time for reconstitution and administration due to the drugs' temperamental nature. Biologics can require protection from climactic variation, and special attention to exclude certain materials from contact with the drug during preparation.
2. Injection and infusion services provided in conjunction with biologics require additional physician supervision and short and long-term monitoring by specialized personnel. Although these drugs have significantly improved the lives of patients' living with complex illnesses in the United States, they are not without their attendant risks. Following administration patients can experience serious adverse events in both acute and delayed manners. These reactions can include life threatening conditions such as anaphylaxis, tuberculosis, and fungal infections. As a result, administration of these drugs requires additional infection screening, monitoring of comorbidities, and other supervision beyond injection and infusion services currently represented under codes 96365 and 96366.

These distinctions are confirmed by the American Medical Association's CPT Manual, which notes that biologic designated agents require advanced practice training and other special considerations in the course of their administration. Indeed, the manual holds that the highly complex nature of biologic agent administration requires "physician and other qualified health care professional work and/or clinical staff monitoring well beyond that of a therapeutic drug agent." These processes 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."<sup>2</sup> The complexity of a drug is directly related to the difficulty associated with its administration, and CSRO believes this should serve as the litmus test for how its relevant administration services are coded rather than another arbitrary measure. Although the biologic drugs referenced under the new policy are utilized to treat indications outside of the oncology space, there is very little variability amongst specialties in the manner in which they are prepared and administered.

Furthermore, this change would fail to fulfill United Health's stated goal to reduce abrasion between payers and providers and shift infusion services outside of hospital sites of care. The new reimbursement policy will exacerbate existing tensions between United Health and

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<sup>1</sup> CPT 2018 Professional Manual. American Medical Association, 2018. Pg. 679, 681.

<sup>2</sup> Professional CPT Manual, American Medical Association, 2015, 624-625

providers, and practices may opt to close practices to new United Health policyholders. This would force patients to migrate back to hospital outpatient departments, a site of care which United Health is attempting to move these procedures away from. Due to the aforementioned issues with complexity of administration, and dedication to responsibly providing quality rheumatologic care, personnel, resource, and time costs associated with administering biologic drugs for rheumatology practices are relatively inelastic. Continuing this policy would hamper patient access to services that are already under-reimbursed.

For these reasons we urge United Health Group to continue reimbursing administration of biologics at their previous level under chemotherapy codes 96413 and 96415.

Respectfully,

Madelaine Feldman, MD, FACP  
President, CSRO

Alaska Rheumatology Alliance  
Arizona United Rheumatology Alliance  
Arkansas Rheumatology Association  
Colorado Rheumatology Association  
Georgia Rheumatology Society  
Kentuckiana Rheumatology Alliance  
Metropolitan Atlanta Rheumatology  
Michigan Rheumatism Society  
Midwest Rheumatology Association  
Mississippi Arthritis and Rheumatism Society  
New York Rheumatism Society  
Rheumatology Association of Iowa  
Rheumatology Association of Minnesota and the Dakotas  
Rheumatology Association of Nevada  
South Carolina Rheumatology Alliance  
Washington State Rheumatology Alliance  
West Virginia Rheumatology Society  
Wisconsin Rheumatology Association