

October 2, 2018

Steve Nelson
Executive Vice President, UnitedHealth Group
Chief Executive Officer, UnitedHealthcare
9900 Bren Road East
Minnetonka, MN 55343

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

Dear Mr. Nelson:

The National Infusion Center Association (NICA) and the National Organization of Rheumatology Managers (NORM) are pleased to submit joint comments to UnitedHealthcare (UHC) regarding a change in the *Injection and Infusion Services Policy* to require that therapeutic infusion codes be reimbursed instead of chemotherapy codes when reported for 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 a policy change outlined in UHC’s September Network Bulletin (Table 1). NICA and NORM are deeply concerned that such a change 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.

Table 1: UHC Coordinated Commercial Reimbursement Policy Announcement

POLICY	EFFECTIVE DATE	MEMBERSHIP PLANS IN SCOPE	SUMMARY OF CHANGE
Injection and Infusion Services	Dec. 1, 2018	Commercial	<p>The Injection and Infusion Services Policy will be updated to require that therapeutic infusion codes (96365 and 96366) be reimbursed instead of chemotherapy codes (96413 and 96415) when reported with specific medications.</p> <p>Initially, the change will apply to the following four medications:</p> <ul style="list-style-type: none"> ▪ J3380 Injection, vedolizumab, 1 mg (Entyvio) ▪ J0129 Injection, abatacept, 10 mg (Orencia) ▪ J3262 Injection, tocilizumab, 1 mg (Actemra) ▪ J1602 Injection, golimumab, 1 mg (Simponi)

Table 1 contains a summary of the change to UnitedHealthcare’s Injection and Infusion Services Policy.¹

¹ UnitedHealthcare. *Network Bulletin*. September 2018; pg.22.

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”.²

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*.³

Furthermore, according to Centers for Medicare & Medicaid Services (CMS) *Medicare Claims Processing Manual* (Chapter 12, Section 30.5, Subsection D), “[c]hemotherapy administration codes apply to parenteral administration of [...] substances such as monoclonal antibody agents, and other biologic response modifiers.”⁴ 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 Entyvio, Orencia, Actemra, and Simponi Aria, as complex biologic agents.

There are currently no available 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, administrative reimbursement does not fully cover the costs associated with patient observation/assessments before, during, and after treatment, as well as the countless hours spent on case management and care coordination.

Further reduction in reimbursement for the administration of intravenous biologics may result in the disruption of care for patients, drive poorer health outcomes and increase UnitedHealthcare’s cost-burden.

NICA and NORM support UHC’s commitment to reducing overall healthcare costs and its efforts in site of care optimization for biologics and expensive specialty medications to shift these beneficiaries into office-based care settings. If UHC proceeds with this policy change, we are concerned that the change will produce unintended consequences. We do not believe that UnitedHealth Group would ever knowingly drive physicians to bill an inappropriate CPT code for a medical service that has a more descriptive code that clearly supports the service provided. Particularly when inconsistent with guidance widely accepted among the medical community.

Biologics are highly complex, large molecule medications used to treat very complex, chronic conditions and autoimmune disease. Due to the complexity of the preparation, administration, and monitoring, the

² Medicare Administrative Contractors: CMS Should Consider Whether Alternative Approaches Could Enhance Contractor Performance. United States Government Accountability Office, 2015. GAO-15-372.

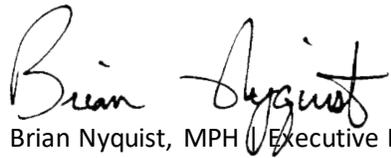
³ CPT 2018 Professional Manual. American Medical Association, 2018. pg. 679, 681. Bolded for emphasis.

⁴ 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>

high level of skill required, CMS and AMA support complex administration codes for complex biologic agents, like Entyvio, Orencia, Actemra, and Simponi Aria.

As such, we implore UHC 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 UnitedHealthcare toward addressing the concerns expressed in this letter.

Sincerely,



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