610 10th Street NW, Ste 300
Washington, DC 20001

September 13th, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2022 (CMS-1751-P)

The Infusion Providers Alliance (IPA) is pleased to provide comments regarding two issues related to the physician fee schedule proposed rule:

- IPA opposes recent downcoding of reimbursement for administration of certain intravenous biologic drug administration services for complex, rare, and chronic diseases by Medicare Administrative Contractors (MACs) and asks that CMS carefully review these decisions and our clinical and policy arguments that these determinations be made consistently and appropriately.

- IPA offers comments on payment and coverage of monoclonal antibodies (MABs) used to treat COVID-19 once the public health emergency ends and the benefits of administering MABs used to treat COVID-19 at in-office and freestanding ambulatory infusion centers instead of at home.

Background on the Infusion Providers Alliance

The IPA has become the leading voice for in-office and freestanding ambulatory infusion providers, with nearly 1,000 community-based, non-hospital sites across 43 states. Our members are committed to preserving the integrity of the provider-patient relationship in a manner that delivers exceptional care to patients and value to the health care system, typically saving Medicare more than 50 cents on the dollar per infusion compared to hospital administration. Our facilities are major access points of care for patients with complex and chronic health conditions in communities, large and small. The IPA's mission is to serve as a thought leader and to educate on issues critical to safeguarding, supporting, and strengthening provider-directed, patient-focused access to infused medications. More information about IPA can be found on our website: www.infusionprovidersalliance.org.

Addressing MAC Downcoding of Certain Complex Biologic Infused Drugs

IPA has raised concerns with CGS Administrators, National Government Services (NGS), Noridian, and Wisconsin Physician Services (WPS) regarding their decisions to downcode the administration of certain complex biologic infused drugs; unfortunately, we did not receive a substantive response to the policy and clinical arguments we raised on why these downcoding decisions were inappropriate and unwarranted. Indeed, the MACs letter dated August 15 to the IPA simply stated:

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> "CMS has given MAC discretion in providing additional guidance as to which drugs may be chemotherapy drugs under Medicare in the Medicare Claims Processing Manual, Chapter 12, Section 30.5, Part D. To be clear, this Billing and Coding Article is provided to help ensure correct, accurate CPT code application. The CPT administration codes are correctly set by reviewing the detailed definitions of the CPT codes for Therapeutic/Prophylactic/Diagnostic Injections and Infusions and for Chemotherapy/Other Highly Complex Drugs and Biologic Agents in concert with analysis of the administration requirements for a given drug in its prescribing information. In conclusion, the workgroup will continue to encourage correct coding of drugs based on information in the CPT manual and the Internet Only Manual. No changes are currently planned to the Billing and Coding Article for the Correct Coding for Administration of Complex Drugs."[1]

We now ask CMS to consider our clinical and policy arguments we provided the MACs. IPA believes the decision to "downcode" the administration of certain complex biologic infused drugs from the Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration ("Chemotherapy Administration") Current Procedural Terminology (CPT) codes (CPT 96401-96549) to the less complex Therapeutic Prophylactic, and Diagnostic Injections and Infusions ("Non-Chemotherapy Infusions") CPT (CPT 963690-96379) codes was made on an arbitrary and inconsistent basis. The change in reimbursement methodology under-values the patient care resources needed to provide these complex drug administrations to beneficiaries and may endanger patient care by failing to compensate providers for the many steps that must be taken to ensure these drugs are provided in a safe manner. IPA supports a more thoughtful approach to how the Chemotherapy Administration criteria are applied. We believe the list of drugs categorized as "non-chemotherapy infusions" in CGS's latest coding change includes several drugs that meet the "highly complex" requirement, warranting their previous Chemotherapy Administration CPT coding.

Foremost is our concern regarding patient access to these important and complex biologicals. Medicare already pays freestanding infusion centers and physician offices about half the cost of its payment to hospitals for the identical services, as depicted below. Our facilities are located in the community and rural areas and are important access points of care for patients with these chronic and debilitating diseases. Unlike hospitals who can cost-shift infusion administration cuts to other lines of business (including surgery, labs and diagnostics), infusion centers have no ability to cost-shift because we do not have any other lines of business. That means patient access to our facilities for many of these complex therapies will be put in jeopardy if they are not adequately reimbursed. At best, many will be sent to hospitals where Medicare will pay double the cost for the drug administrations. We think this is shortsighted.

[1] [1] August 15, 2021 letter to the Infusion Providers Alliance from Ella M. Noel, DO FACOI, J8 Contractor Medical Director, Medicare WPS Government Health Administrators

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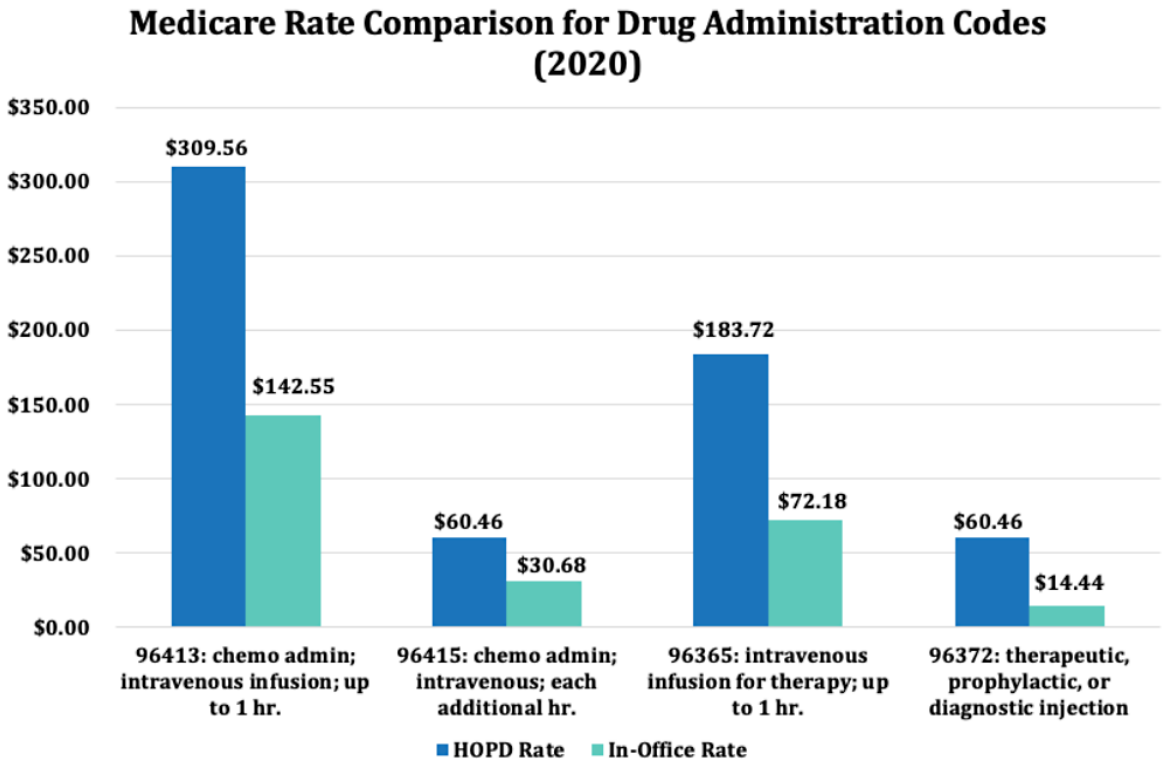

IPA concurs that intravenous drug administration services billed under the Chemotherapy Administration CPT code must exhibit certain resource-intensive characteristics (e.g. adjustments to dosage or infusion rate, post-administration monitoring, etc.). But these this criterion must be applied consistently across all drugs. A summary of our recommendations based on various criteria of complexity involved with each drug's administration is included for your reference in the appendix.

Below are our primary arguments for why the list of drugs categorized as "non-chemotherapy infusions" in the latest coding change includes several drugs that meet the "highly complex" requirement and warrants their previous Chemotherapy Administration CPT coding:

1) **Drugs that are subject to FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) requirements should not be downcoded**. This includes eculizumab (Soliris) and natalizumab (Tysabri). CPT guidance states that CPT codes 96401-96549 apply to certain monoclonal antibody agents and are of higher complexity as they "require physician or other qualified health care professional work and/or clinical staff monitoring well beyond that of therapeutic drug agents (CPT 96360-96379) because the incidence of severe adverse patients is typically greater. Typically, such chemotherapy services require advanced practice training and competence for staff who provide these services; special considerations for preparation,

dosage, or disposal; and commonly, these services entail significant patient risk and frequent monitoring."

Eculizumab (Soliris) is subject to REMS requirements that mandate prescribers and infusion professionals be specifically certified to administer the drug due to its need for immediate medical evaluation from potential meningococcal infections. Natalizumab (Tysabri) is subject to REMS requirements that mandate ongoing monitoring for progressive multifocal leukoencephalopathy (PML), an extremely dangerous brain infections that usually leads to death or severe disability. The REMS program for natalizumab is also exclusively for prescribers and infusion professionals authorized to administer natalizumab. Both drugs undoubtedly "require advanced practice training and competence for staff" who administer these drugs and require "special considerations for preparation, dosage, or disposal."

2. **Monoclonal antibodies should not be downcoded.** They have the same mechanism of action and require the same pre-medication protocols and monitoring requirements as monoclonal antibodies that are used in connection with cancer diagnoses. When used in a cancer diagnosis, the drugs are not subject to downcoding; however, when used in a non-cancer context, they are subject to downcoding. The diagnosis should not dictate the reimbursement for the administration of the drug. The drugs carry the same clinical monitoring requirements, the same pre-medication routine, the same anaphylaxis risk, the same 60-minute observation period post-administration, and the same lab and other workup requirements whether for a cancer or non-cancer diagnosis. Furthermore, these drugs are often used to treat COVID patients and require significant fixed costs such as the retrofitting of our facilities to provide a safe environment for non-COVID patients and our staff as explained below in our comments on payment for monoclonal antibodies.

3. **Drugs that require extra nurse time for preadministration or complexity should not be downcoded.** For instance, patisiran (Onpattro) requires additional nurse staff time due to required premedication and a filtration step prior to drug administration. CMS itself assumed patisiran would be paid at the category 3 level, which includes intravenous chemotherapy infusions and certain chemotherapy drugs and biologicals, in its Medicare Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) proposed rule (42 CFR 414). Edaravone (Radicava) is indicated for the treatment of amyotrophic lateral sclerosis (ALS), a progressive neurodegenerative disease that severely weakens patient motor function over time. The pre-administration preparation for this population, which commonly suffers from significant logistical and health equity challenges, often requires not only careful scheduling of dosing days but also close physician and caretaker collaboration, including multiple caretakers to assist in moving the patient in and out of the treatment facility, and documenting and managing substantial changes in patient health status.

4. **Drugs that have black box warnings also should not be downcoded**. Black box warnings are the FDA's most stringent warnings for drugs to alert patients and providers of the potential serious side effects, including injury or death. Our summary of downcoded drugs

details the black box warnings associated with 9 of the downcoded drugs. For example, reslizumab (Cinqair) requires observation after infusion and belatacept (Nulojix) may put a patient at risk for post-transplant lymphoproliferative disorder (PTLD), a type of cancer.

Addressing Payment and Coverage of Monoclonal Antibodies (MABs)

Additionally, IPA wishes to comment on issues raised by CMS regarding payment and coverage of monoclonal antibodies (MABs) used to treat COVID-19. Once the public health emergency ends and on the benefits of administering MABs used to treat COVID-19 in in-office and freestanding ambulatory infusion centers instead of at home.

Treating patients for COVID-19 with a monoclonal antibody places the healthcare worker and environment at risk. Significant investments must be made to treat these patients and others in our facilities safely. Optimally, a patient is placed in a reverse airflow room which increases the cost of delivering this potentially life-saving therapy. At a minimum, all personnel in contact with the patient must be wearing the most protective PPE to avoid acquiring the infection. Some of our Members have built suites of negative pressure rooms with a separate entry to facilitate treatment of these patients and to isolate them from the general population to prevent transmission to other patients or staff. Our facilities use the most protective equipment we can to minimize staff risk, which can be expensive.

First, it should be axiomatic that whether the PHE is declared over by the Administration, is not pertinent to the resources and intensity required to treat COVID-positive patients. We expect to be treating thousands of COVID-positive patients even after the PHE termination is declared. While the number of COVID-positive patients may diminish over time, what is most relevant is whether payments adequately cover the increased costs of administering drugs to these resource-intensive COVID patients. Additionally, we do not foresee decreasing the purchase of PPE supplies to protect our staff just because the number of COVID positive patients declines over time.

Second, CMS requests feedback on whether it should provide separate codes for drugs, such as Acterma, that are both COVID and non-COVID related. To downcode the payment for these COVID-related infusions will limit the non-hospital-based facilities available, decreasing access while increasing the overall cost of care by sending these patients back to the hospital. We must still invest the same fixed cost resources in our facilities and PPE to treat these patients. For simplicity sake, we suggest retaining a single code based on the COVID-administered complexity level.

Finally, we remind policymakers that providing MABs in infusion facilities is safer for patients than home infusions, and since the complexity of MABs warrants professional oversight to prevent potential adverse effects. This study by Baker et. al published in JAMA shows that home infusions are associated with 25% increased odds of emergency department or hospital admission on the same or next day after infusion compared with facility infusions.[2] It also shows that there are 28% increased odds of permanent discontinuation of the biologic after emergency department or hospital admission. This suggests that

[2] JAMA, Comparison of Adverse Events Among Home Vs. Facility- Administered Biological Infusions 2007-2017 June 3, 2021 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780573

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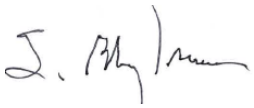
home infusions are potentially more resource intensive than facility-administered provisions (i.e. more expensive) and less safe—the study itself notes that "the safety of receiving biologic infusions for immune-mediated diseases at home remains unclear."

Conclusion

The IPA asks that CMS carefully review the suggested downcoding of change to ensure providers are appropriately reimbursed for infusions used to treat complex, rare, and chronic disease and that providers are not forced to choose between providing safe care and economically feasible care. CMS must take into account significant resources our facilities provide to administer drugs with REMS, black box warnings, MABs and drugs whose FDA labels require extra nurse time for pre-administration or complexity. CMS should take the long view on drug reimbursement policy and encourage more drugs to be provided in the freestanding infusion center and physician office setting in lieu of hospitals, because it can save more than 50 percent on drug administration costs. A straightforward and consistent approach to paying for the administration of drugs to treat COVID before and after the PHE is declared is warranted, and these drugs should be provided in safe clinics, not the home.

Sincerely,

Doug Ghertner
President
Infusion Providers Alliance



Brad Traverse
Executive Director
Infusion Provider Alliance
Brad.Traverse@infusionprovidersalliance.org

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Appendix I: Summary of Downcoded Drugs

Product Name	HCPCS Code	Downcode?	REMS	Black Box Warning	Monoclonal Antibody (MAB)	Extra Nurse Time for Pre-administration or Complexity	Reason for Complexity
Abtacept (Orencia)	J0129	Yes					
belatacept (Nulojix)	J0485	No		X			Black box warning for risk for post-transplant lymphoproliferative disorder (PTLD), a type of cancer where white blood cells grow out of control; Use in Epstein-Barr virus (EBV) seropositive patients only; Increased susceptibility to infection and development of malignancies from immunosuppression; Increased risk of graft loss and death in liver transplant patients
bezlotoxumab (Zinplava)	J0565	No		X	X		Black box warning for risk of death in dementia-related psychosis
eculizumab (Soliris)	J1300	No	X	X	X		Black box warning for causing increased risk of meningococcal disease
edaravone (Radicava)	J1301	No				X	Dosing scheduling and moving in/out of facility for ALS patients considered pre-administration workup
Filgrastim (g-csf) excludes biosimilars (Neupogen)	J1442	Yes					
Filgrastim-sndz, biosimilar (Zarxio)	Q5101	Yes					

Filgrastim-aafi (Nivestym)	Q5110	Yes					
golimumab (Simponi Aria)	J1602	No		X	X		Black box warning for serious infections that can lead to hospitalizations or death (tuberculosis, bacterial sepsis, invasive fungal, viral, and other infections); Lymphoma and other cancers, including skin cancer; some cancers have led to death
natalizumab (Tysabri)	J2323	No	X	X	X		Black box warning for risk of rare, serious brain disease called progressive multifocal leukoencephalopathy (PML); must be treated in infusion center
octreotide acetate non-depot (Sandotstatin)	J2354	Yes					
patisiran (Onpattro)	J0222	No				X	Requires additional filtration step before administration and premedication
reslizumab (Cinqair)	J2786	No		X	X		Black box warning for anaphylaxis in 0.3% of patients in placebo-controlled studies (dyspnea, decreased oxygen saturation, wheezing, vomiting, skin and mucosal involvement, including uticaria); requires observation after infusion
ustekinumab (Stelara)	J3358	No			X		MAB has same mechanism of action and requires premedication protocols and monitoring as MABs used with cancer diagnoses

vedolizumab (Entyvio)	J3380				X		MAB has same mechanism of action and requires premedication protocols and monitoring as MABs used with cancer diagnoses