INFUSION PROVIDERS ALLIANCE

440 1st Street NW, Suite 430
Washington, DC 20001

May 5, 2022

The Honorable Chiquita Brooks La-Sure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Brooks La-Sure:

The Infusion Providers Alliance ("IPA") writes to express our serious concerns with the latest announced changes made by two additional Medicare Administrative Contractors (MACs) -- Novitas and First Coast -- to "downcode" reimbursement for the infusion of certain complex biologic drugs used for a variety of complex and chronic diseases. As you may recall, IPA submitted formal comments to the physician fee schedule 2022 proposed rule[1] and we had a subsequent teleconference meeting with your CMS team on Feb. 19 after several other MAC's (CGS Administrators, National Government Services, Noridian and Wisconsin Physician Services) engaged in the same practice last year. We are alarmed that this arbitrary and unfounded downcoding of drugs that require significant staff resources and intensity has now migrated to every MAC, save one. Although we thought we had a productive discussion in which CMS seemed to appreciate our concerns, we are disappointed that CMS has not directed MACs to code and reimburse for complex drugs provided by our infusion centers appropriately.

The end result of this decision, unfortunately, is that many patients may not have access to their critical infusion therapies or to our lower cost infusion setting. In addition, we are gravely concerned that this decision by Medicare's MACs may metastasize into the commercial market and thereby threaten our economic viability and ability to serve any patients.

**Background on the Infusion Providers Alliance**

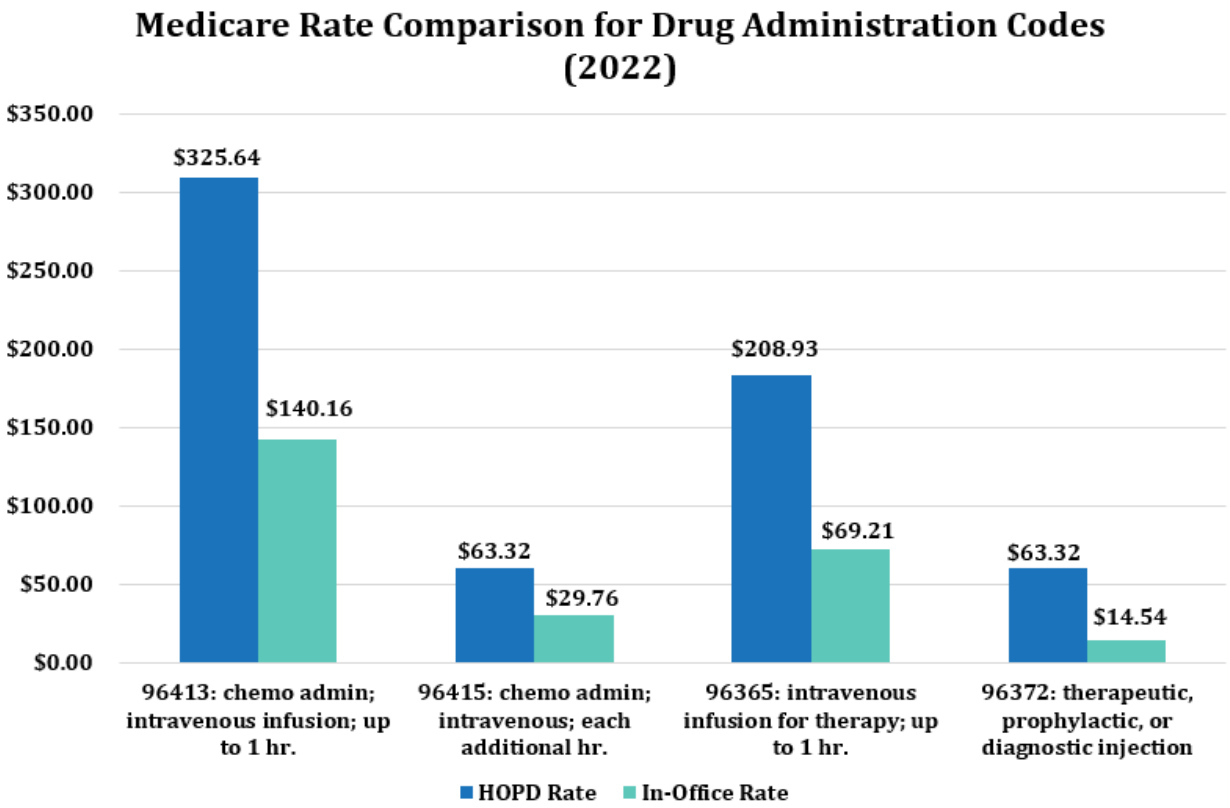
The IPA has become the leading voice for in-office and freestanding ambulatory infusion providers, with over 1,000 community-based, non-hospital sites across 43 states. Our members are committed to preserving the integrity of the provider-patient relationship in a manner that delivers exceptional care 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

[1] https://www.regulations.gov/comment/CMS-2021-0119-34331

**Addressing MAC Downcoding of Certain Complex Biologic Infused Drugs**

IPA believes the recent Novitas and First Coast decisions, which mirrors what virtually all other MACs decided last year, to "downcode" the administration of certain complex biologic infused drugs from the Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration ("C&HCB") Current Procedural Terminology (CPT) codes (CPT 96401-96549) to the less complex Therapeutic Prophylactic, and Diagnostic Injections and Infusions ("Non-Chemotherapy and Complex Infusions") CPT (CPT 96360-96379) codes was made on an arbitrary basis inconsistent with the realities of patient care. No advanced notice or communication was made with IPA member companies or any other stakeholders. 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.

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 that 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.



IPA concurs that eligible intravenous drug administration services billed under the Chemotherapy Administration CPT code and Other Highly Complex Drug or Highly Complex Biological Agent Administration must exhibit certain resource-intensive characteristics (e.g. frequent adjustments to dosage or infusion rate, prolonged presence of an administering nurse, or required close collaboration with a physician or other qualified health care professional, or significant post-administration monitoring, etc.).[2] But 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 C&HCB CPT coding:

1) **Drugs that are subject to FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) requirements should not be downcoded**. Drugs that warrant REMS programs undoubtedly meet the "highly complex" criteria associated with Chemotherapy Administration codes. 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. <u>The diagnosis should not dictate the reimbursement for the administration of the drug</u>. 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 above in our comments on payment for monoclonal antibodies.

[2] See current procedural terminology (CPT) Codebook on Chemotherapy and Other Highly Complex Drugs or Highly Complex Biological Agent Administration Codes

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.

**Conclusion**

IPA strongly recommends that CMS reverse the MACs recent coding change and reinstate billing eligibility of the Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration CPT code for the administration services associated with the affected drugs.

IPA would appreciate the opportunity to meet again with CMS senior staff to discuss the implementation of infusion service administration codes in greater detail and to ensure providers are appropriately reimbursed for infusions used to treat complex, rare, and chronic diseases and that providers are not forced to choose between providing safe care and economically feasible care. Many thanks for your kind consideration of this request.

Sincerely,

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## Appendix I: Summary of Downcoded Drugs

| Product Name | HCPCS Code | IPA Recommendation on Downcoding | 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 | | | | | |

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| **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 |

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