INFUSION PROVIDERS ALLIANCE

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

June 25, 2021

Dear CGS Administrators, LLC ("CGS"),

The Infusion Providers Alliance ("IPA") writes to request a meeting to share our concerns regarding CGS's recent reimbursement treatment of certain intravenous drug administration services for complex, rare, and chronic diseases,[1] which went into effect on April 8, 2021.

As the leading voice for in-office and freestanding ambulatory facility providers of drug infusion services, representing more than 930 community-based non-hospital providers across 43 states and the District of Columbia, IPA understands CGS's responsibility to safeguard the best interests of the Medicare program in Jurisdiction 15 and hopes to collaborate with CGS to promote reimbursement and access policies that benefit the Medicare program and its beneficiaries.

IPA believes CGS's recent 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 96360-96379) 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.

IPA agrees with CGS that eligible intravenous drug administration services billed under the Chemotherapy Administration CPT code must exhibit certain resource-intensive characteristics. For example, eligible drugs administered may require frequent adjustments to dosage or infusion rate, prolonged presence of an administering nurse, or require close collaboration with a physician or other qualified healthcare professional.[2] Patients receiving eligible drug administration may also require substantial pre-administration preparation, monitoring, or screening that supports the complexity of the administration services.

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[1] As described in Article A58526 in the Medicare Coverage Database

[2] See Current Procedural Terminology (CPT) codebook on Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration codes.

Downcoding of some of the products on CGS's list, such as Neupogen and the filgrastim biosimilars, may be warranted. Downcoding for the other products, however, is not commensurate with the level of effort associated with their safe administration. For instance, the other drugs subject to the recent downcoding decision are subject to FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) requirements, significant prophylaxis concerns, and other clinical considerations that make their administration highly complex. Asking providers to take lower reimbursement, and coincidently provide a lower-level of monitoring and care, is irresponsible and puts Medicare beneficiary's health at risk. For instance, patisiran (Onpattro) is used to treat polyneuropathy caused by hereditary ATTR amyloidosis, a rare hereditary disease affecting 15,000 people in the United States, and 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), Prosethetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) proposed rule (42 CFR 414).[3]

Natalizumab (Tysabri) and eculizumab (Soliris) are subject to FDA-mandated REMS programs that require rigorous patient clinical and monitoring requirements for safe and effective ongoing use. Natalizumab is subject to REMS requirements mandating ongoing monitoring for progressive multifocal leukoencephalopathy (PML), an extremely dangerous brain infection that usually leads to death or severe disability. This REMS program is explicitly designed for use by prescribers as well as infusion professionals who are involved in the complex care required to appropriately administer natalizumab. Drugs that warrant REMS programs undoubtedly meet the "highly complex" criteria associated with Chemotherapy Administration codes.

In addition to the pharmacotherapeutic considerations of the affected drugs, the clinical challenges of the populations treated by the affected drugs often warrant significant pre-administration workup and screening. For example, edaravone (Radicava) is indicated for the treatment of amyotrophic lateral sclerosis (ALS), a progressive neurodegenerative disease that severely weakens patient motor function over time. Patients suffering from ALS not only gradually lose the ability to walk or operate a motor vehicle but are also often unable to effectively speak and are highly susceptible to injury or infection. 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.

Finally, we note that some of the monoclonal antibodies on the downcoding list 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

[3] See Section B. Detailed Discussion of Impacts by Major Provisions, 6. Expanded Classification of External Infusion Pumps as DME

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, and the same lab and other workup requirements whether being used for a cancer or non-cancer diagnosis.

Compared to many drugs outside of the scope of CGS's recent policy change, the affected drugs, when considered in totality, are not substantially less resource-intensive or less complex. IPA strongly recommends CGS reconsider and reverse its recent coding change and reinstate billing eligibility of the Chemotherapy Administration CPT code for the administration services associated with the affected drugs.

IPA would appreciate the opportunity to meet with CGS to discuss the implementation of this coding change 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. Please contact John McManus at jmcmanus@mcmanusgrp.com to set up a meeting.

Sincerely,

Doug Ghertner

President
Infusion Providers Alliance