August 30, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

We write to express our grave concerns with the so-called "code correction" changes made by Medicare Administrative Contractors (MACs) through Local Coverage Articles (LCAs). The changes downgrade the classification and payment codes for the administration of certain complex biologic drugs from high-level to low-level codes. Specifically, the MACs have downcoded approximately 20 complex biologics relevant to our practices (see appendix) to the less complex "Therapeutic Prophylactic, and Diagnostic Injections and Infusions codes" (CPT 96360-96379) from the correct and long-standing "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration Current Procedural Terminology (CPT) Codes" (CPT 96401-96549)[1].

We are troubled that MACs have arbitrarily reclassified drugs for complex chronic diseases (e.g., multiple sclerosis, rheumatoid arthritis and Crohn's disease) that have similar risk and administration profiles as drugs to treat patients with cancer. Yet no chemotherapy drug has been similarly reclassified. Coding classification decisions should be standardized across diseases and guided by nurse time, specialized training, patient acuity, history of infusion reactions, and physician supervision requirements. Specialized training and time working with patients are essential to ensuring patient safety and reduce the risk of adverse reactions for complex drugs, particularly those that are subject to FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) requirements.

The mere fact that a drug is an infused non-oncology biologic is not an indicator of less administration complexity or clinical risk relative to chemotherapy products. Many biologic medicines, particularly monoclonal antibodies, utilize the same mechanism of action and require the same premedication and preadministration protocols and monitoring requirements as those products used in oncology practices. Both classes of drugs carry similar clinical monitoring requirements, specialized training and competency demonstration, pre-medication routines, anaphylaxis risk, post-administration observation/monitoring periods, and lab and other workup requirements regardless of the disease or chronic condition these products are treating. These requirements are reflective of the science behind these types of medications, not the specialty in which they are indicated.

Both chemotherapy drugs and biologics used to treat other chronic and complex diseases have serious potential side effects including:

- Immediate risk of anaphylaxis or other allergic reaction, for which monitoring during and after administration is required;
- Long-term risk of serious conditions such as osteonecrosis of the jaw (jaw cell deterioration and death) with administration of densumab, and;
- Development of antibodies to drugs such as vedolizumab and ustekinumab that requires close clinical monitoring and/or intervention.

Several biologic therapies also require intense Risk Evaluation and Mitigation Strategy (REMS) programs. For example, Biogen's TOUCH program for natalizumab requires time-consuming supplemental provider documentation. Also requiring REMS certification are ravulizumab-cwvz and eculizumab to treat PNH, a devastating clonal hematologic disease that can have serious complications.

Furthermore, multiple studies have shown that infusion center administration is significantly less costly, and often with better outcomes, than the identical infusion treatment in a hospital setting. An EBRI report found that

employer plan payments to hospitals are 3x higher than payments in physician offices and infusion centers. Eventually, that is where this could end up: hospital inpatient infusions at two to three times the cost to Medicare compared to our setting of care.

In summary, biologic therapies are used not only for treatment of patients with cancer, but for treatment of patients with other serious and complex diseases including progressive neurologic diseases, erosive rheumatologic diseases, and devastating gastrointestinal diseases because other treatment modalities have proven ineffective. These biologics are comparable in risk and complexity and require the same intense level of clinical care, specialized training, and monitoring regardless of the particular disease state or chronic condition for which the biologic is being used. Disease states should not prejudice reimbursement when the risks, preparation, specialized training requirements, physician supervision requirements, and toxicity management of products are equivalent whether the biologic is being used to treat a patient with cancer or a patient with multiple sclerosis, rheumatoid arthritis, or Crohn's disease.

The MACs' decision to reclassify these products does not somehow erase the significant staff time, training and clinical diligence needed to safely administer these biologics to Medicare beneficiaries. All of those things are still required. The only changes worked through reclassifications are devastating cuts in payments for these drugs when they are administered in the most cost-effective setting: community-based infusion centers and physician offices. The consequence of this decision will be reduced patient access to cost-effective care because physician offices and infusion centers will no longer receive the reimbursement they require to continue delivering the services.

Biologic medications are the future of healthcare because they are so effective at treating conditions that were difficult or impossible to treat with conventional care. When people get the right drug at the right time in a cost-effective setting, they present to the emergency room less frequently and are hospitalized fewer times throughout the year.[2] The result is better care at a lower cost to the Medicare program.

The MACs' arbitrary decisions – operationalized through LCAs to bypass stakeholder input – are especially troubling because they may prompt commercial payers to implement similarly misguided policies. If that happens, the most cost-effective care model for provider-administered medications will cease to exist because it will no longer be viable economically.

We request that CMS reverse the MACs decisions 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 (see appendix). CMS should also allow stakeholders to provide input on the criteria for all future Medicare Part B coding and billing issues to ensure that reimbursement for these life-saving drugs takes into account the perspectives of the clinicians furnishing care and the patients receiving that care. Thank you very much for your time and we appreciate your consideration of our recommendation. Please let us know if you would like to discuss further.

Sincerely yours,

American Gastroenterological Association
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Digestive Health Physicians Association
Infusion Providers Alliance
National Infusion Center Association
National Organization of Rheumatology Management

[1] See current procedural terminology (CPT) Codebook on Chemotherapy and Other Highly Complex Drugs or Highly Complex Biological Agent Administration Code. See attached for a list of drugs that have been inappropriately reclassified by the MACs.
[2] https://avalere.com/insights/patients-with-undermanaged-ra-have-higher-medicare-costs-than-other-ra-patients

Appendix: List of relevant biosimilars miscoded by MACs

Infusion Non-Chemo Brand Name + J-code	Disease(s) Treated
Cinqair J2786	severe asthma
Entyvio J3380	Crohn's disease, ulcerative colitis
Nulojix J0485	kidney transplant rejection
Onpattro J022	hereditary amyloidosis
Orencia J0129	rheumatoid arthritis, juvenile idoepathic arthritis and psoriatic arthritis
Radicava J1301	amyotrophic lateral sclerosis (ALS)
Simponi Aria J1602	rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis
Soliris J1300	paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS) and generalized Mysathenia Gravis (gMG)
Stelara J3358	Crohn's disease, ulcerative colitis, psoriatic arthritis, plaque psoriasis
Tezspire J3590	severe asthma
Tysabri J2356	Crohn's disease, multiple sclerosis
Zinplava J0565	c-diff

Subcutaneous Non-Chemo + J-code	Disease(s) Treated
Cimzia 0717	Crohn's disease, rheumatoid arthritis, inflammatory arthritis, ankylosing spondylitis, Psoriatic arthritis, Plaque psoriasis, and Non-Radiographic axial spondyloarthritis
Fasenra 0517	severe asthma
Ilaris 0638	Periodic Fever Syndrome, Still's Disease
Ilumya 3245	plaque psoriasis
Nucala 2182	severe asthma
Prolia 0897	Osteoporosis
Xolair 2357	severe asthma, chronic hives