INFUSION PROVIDERS ALLIANCE

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

November 11, 2020

Ms. Gail Boudreaux,
President and Chief Executive Officer
Anthem, Inc.
220 Virginia Ave.
Indianapolis, IN 46204

Re: New Requirement to Obtain Certain Drugs from CVS Specialty Pharmacy

Dear Ms. Boudreaux,

I am writing to you to express concerns raised by the members of the Infusion Providers Alliance regarding a policy issued by Anthem Blue Cross of California that could negatively affect your members and our patients. The Infusion Providers Alliance is the leading voice for in-office and freestanding ambulatory infusion providers, representing more than 750 community-based providers across the United 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. The Infusion Providers Alliance'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. The Infusion Providers Alliance supports the delivery of low-cost, high quality care for all patients in need of provider administered medications.

Recently, Anthem of California sent a letter to a number of providers informing them of a new requirement, scheduled to be implemented on December 1, 2020, mandating them to obtain a lengthy list of provider-administered medications through the CVS Specialty Pharmacy (a practice commonly known as "white-bagging"). It is unclear whether Anthem intends this policy to apply to all providers, or only a subset of providers. Provider organizations such as the California Medical Association have attempted to engage Anthem of California, but have not received a response or clear indication of Anthem's intent. Anthem has not engaged the provider community in developing or rolling out this policy, and that is why we are writing you today.

Anthem's mandate is bad for Anthem, patients, and community-providers for several reasons; it would increase Anthem's costs, increase waste of medications, cause treatment delays, and significantly increase the burden on providers. If this policy is extended to community-based providers, it may be infeasible for them to continue offering the administration of these infused and injectable medications in their offices. Many studies, which are discussed below, have shown that ambulatory community-based providers are the lowest cost setting of care for administration of these medications. They also achieve the best outcomes for patients. If Anthem extends its white-bagging policy to community providers, many of these high-quality, low-cost providers will be forced to stop offering cost-efficient administration of these medications to Anthem patients. This will restrict Anthem members' access to care and force them to sub-optimal and more costly providers, such as hospital outpatient departments. Nationwide, the cost of providing these

medications in hospital outpatient departments can be 2 to 5 times as expensive as providing these medications in a community setting.[1]

These medications treat cancer and other debilitating conditions such as Crohn's disease, ulcerative colitis, multiple sclerosis, rheumatoid arthritis, psoriatic arthritis, and other chronic, life-long diseases. These biologic medications are life-changing for patients and enable them to carry on their lives and contribute to the economy, their communities, and families.

Specialty Pharmacy Requirement Would Prevent Providers from Serving Anthem Members

If Anthem's proposed specialty pharmacy mandate is extended to community-providers, and those providers are no longer free to procure medications in the competitive marketplace, many will be unable to provide infused medications to Anthem of California members. Under Anthem's policy, these providers would be forced to use one supplier, the CVS specialty pharmacy. Moreover, the providers would not bill or be reimbursed for the medication; they would only receive the "administration charge," which is insufficient to cover the cost to providers of administering these medications.

The safe administration of these complex medications requires significant time and expertise from the providers' office staff and the skilled RNs or other practitioners administering the medications. The provider must first determine whether the medication is covered by the patient's plan, gather the documentation and lab tests required for the prior authorization, request the prior authorization, follow-up on any additional documentation requests, and coordinate the delivery of the medication from the specialty pharmacy with the patient's schedule (which often changes). On the day of administration, the provider must reconstitute the drug (many of which are powders) according to the manufacturer's precise instructions in an aseptic environment, administer any pre-medications required (such as diphenhydramine), establish venous access, begin the infusion, monitor the venous access for continued patency, monitor the patient for anaphylaxis or adverse side effect, remove the venous access device (or flush the device if it is an implanted device), and monitor the patient for the required post-infusion monitoring time to ensure no adverse reactions. This is just an illustrative, not exhaustive, list of the tasks that must be performed for the various drugs that are administered by providers.

While community-providers want to provide the best care to their patients, they cannot do so at a financial loss. The system of free-market acquisition of medications, and buy-and-bill drug reimbursement that has been the reliable distribution system for decades, is critical to the ability of community-based providers to continue to offer these services. If community-providers are taken out of the equation, patients will be forced to seek services elsewhere, likely in hospital outpatient departments, which are far more costly and are associated with less-optimal outcomes. This is a lose-lose scenario for Anthem of California and its members and customers.

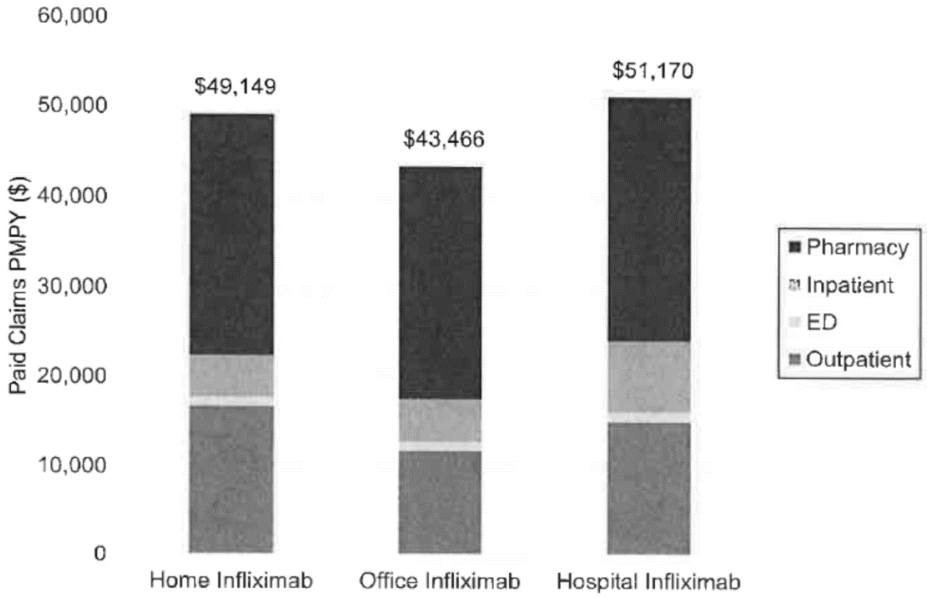
Non-Hospital, Community Based Providers are the Lowest Cost and Highest Quality Site of Care

Non-hospital, community-based care settings, including physician offices and stand-alone infusion centers, represent the lowest-cost care settings in which to receive provider-administered specialty medications. A report authored by UnitedHealth Group estimated that administering specialty drugs in the provider office or home instead of the hospital outpatient setting reduces the costs of drugs and their administration by $16,000 to $37,000 per privately-insured patient per year for the five conditions that account for nearly

[1]Administering Specialty Drugs Outside Hospitals Can Improve Care and Reduce Costs by $4 Billion Each Year. UnitedHealth Group, 2019. https://www.unitedhealthgroup.com/viewer.html?file=/content/dam/UHG/PDF/2019/UHG-Administered-Specialty-Drugs.pdf

three-quarters of overall spending.[2] The 2019 Magellan Specialty Trend report found that hospital-based administration of provider administered medications cost up to 390% more than community-settings.[3] Given Anthem's 8.3 million covered lives in California, the savings that could be achieved by moving patients out of the hospital-outpatient setting could be enormous.

A study published in the American Journal of Gastroenterology in July of 2020, authored by Stanford University physicians and pharmacists, found that patients serviced through community-based providers incurred lower total costs of care as compared to patients receiving infusions in hospital outpatient departments or through home-infusion.[4]



Giese-Kim, et al., American Journal of Gastroenterology, p.7

The Stanford study further found that patients receiving infliximab infusions in community-based settings were more adherent to their medication and discontinued therapy at lower rates than patients receiving their medication through home-infusion or hospital outpatient departments. Patients who are adherent to their medications have fewer flare ups, fewer missed days of work, fewer hospitalizations, and a lower overall cost of care. Additionally, the Stanford study found that patients treated in community settings required fewer steroid treatments.[5] Low steroid use by inflammatory bowel disease patients is often used as an indicator of well-controlled disease.

The data overwhelmingly support the conclusion that community-based infusion providers provide the best quality, and the lowest cost care. To the extent that Anthem's policy extends to those providers, it would interfere with this success, and would inevitably end up harming patients, while increasing costs to Anthem's California employers and members.

Specialty Pharmacy Mandates Only Benefit the Specialty Pharmacies and PBM-Middlemen

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[2] *Id.*
[3] Medical Pharmacy Trend Report. Magellan Rx Management, 2018. https://www1.magellanrx.com/documents/2019/03/medical-pharmacy-trend-report_2018.pdf.
[4] Giese-Kim, Nozomi; Wu, May; Dehghan, Melody; Sceats, Lindsay and Park, K.T., Home Infliximab Infusions Are Associated with Suboptimal Outcomes Without Cost Savings in Inflammatory Bowel Diseases. American Journal of Gastroenterology, July 22, 2020. https://doi.org/10.14309/ajg.0000000000000750, p.1
[5] *Giese-Kim, et al., p.3*

The only party that will benefit from this mandate is the CVS specialty pharmacy and its PBM-middlemen owners. Acquisition of products through specialty pharmacies increases waste, causes delays to initiation and maintenance of therapy for patients, and increases administrative burden on practices. Adding another middleman between treating clinicians and their patients adds complexity and delays treatment. Delays in care for patients increase the economic burden of disease. A real-world analysis found that therapy delays and disruptions for patients with Crohn's and ulcerative colitis caused a 130% increase in total cost of care.[6] Specialty pharmacies have an important role in the healthcare system and provide excellent care to many patients with many debilitating diseases. However, a non-competitive, single-source specialty pharmacy program is not appropriate for community-provider administered medications.

Conclusion

Anthem's mission statement states that Anthem is "dedicated to delivering better care to our members, providing greater value to our customers and helping improve the health of our communities." If the proposed specialty pharmacy mandate is extended to community-providers, it would harm members, erode value, and harm communities. Anthem's policy would make it infeasible for many community-based providers, the lowest-cost and highest-quality setting, to continue to offer the administration of provider administered medications to Anthem members.

Additionally, implementing such a policy during a pandemic, when many providers are already struggling to stay solvent and our healthcare system is taxed, is misguided and ill-timed. Unfortunately, as you know, our country is experiencing an increase in COVID cases. Implementing a change that will force more patients into hospital outpatient departments, utilize more hospital resources, and expose more vulnerable patients to COVID, would be particularly ill-advised. Many of these patients are immune-compromised due to their illness and medications. We should be doing all we can to ensure that this vulnerable group of patients is not exposed to COVID. Anthem should be looking to expand infusion access in safe, clinician managed, community-based clinics, not limit it.

Further, the change has not been publicized well and no clarifying communication has been provided. Right now, the provider community is confused as to whether this policy change will apply to them. We can find no mention of this policy change in Anthem's provider manual or provider updates. Instead, providers were sent letters, many of which may have been lost in the shuffle as they struggled to run their practices in an incredibly challenging time.

We understand that Anthem, like all payors, has a need to control utilization and cost of specialty medications. We urge Anthem not to extend this policy to community-based providers and to seek the feedback and input of providers before making any significant changes to the way care is delivered. We are eager to work with Anthem to develop alternative options to constrain costs, including migrating care from expensive hospital settings to the more efficient community setting offered by our providers. We are confident that working together, we can achieve better outcomes at lower overall cost for Anthem and its California employers and members.

Sincerely,

Doug Ghertner, President
Infusion Providers Alliance

[6] Rubin DT, Mody R, Davis KL, Wang CC. Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease. *Ailment Pharmacol Ther*. 2014; 29:1143-1155.

Cc:

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