NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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Mark T. Jansen, M.D.
Vice President, Chief Medical Officer
Arkansas Blue Cross Blue Shield
601 South Gaines St
Little Rock, AR 72201

Wendy See
Vice President, Pharmacy & Primary Care Programs
Arkansas Blue Cross Blue Shield
601 South Gaines St
Little Rock, AR 72201

Subject: Self-Administered Medication Policy

Dear Dr. Jansen & Ms. See,

The National Infusion Center Association (NICA) would like to express our concern regarding the self-administered medication policy for Arkansas BlueCross BlueShield members. The policy devalues member and provider choice, ultimately to the detriment of patients, and **we ask that you clarify the policy language, and reverse the decision to shift specialty medications to the pharmacy benefit.**

NICA is a nonprofit patient advocacy organization formed to ensure that our nation's sickest and most vulnerable patients can access provider-administered medications in non-hospital care settings through advocacy, education, and resource development. We represent hundreds of thousands of patients managing complex, chronic, rare, life-threatening, and/or difficult-to-manage diseases—like autoimmune diseases—with medical benefit drugs, like biologics, in over four thousand non-hospital infusion centers across the country. To improve the affordability of these drugs for patients, we work to ensure that patients can access their prescribed therapy in more affordable and accessible alternatives to hospital-based or hospital-affiliated care settings.

Specialty medications, particularly therapeutic biological products ("biologics"), are some of the most innovative and life-changing medications developed in the last decade and provide tremendous value to those that need them. Consequently, these therapies are incredibly expensive, and we understand that payers have an ongoing desire to control medication expenditure through formulary development and utilization management strategies. However, if utilization management strategies or benefit plan design are to be used to reduce cost liabilities in the growing specialty medication market, payers have a responsibility to do so judiciously and responsibly. There are many reasons we oppose this particular policy, not the least of which is a concern for the recurrent pattern of a payer deviating from its role as an insurer and encroaching on the practice of medicine. Not only is this conduct inappropriate, bordering on violating state scope of practice laws, but will increase clinical risk, produce poorer health outcomes, reduce quality of life, and increase the burdens of disease, while increasing costs.

Coverage guidelines referenced in the Self-Administration Policy are unclear. The policy states "Any applicable clinician-administered dosage form (e.g. intravenous infusion) of a drug that can also be self-administered **may** be covered under the medical benefit."[1] The policy provides no further explanation of

[1] Blue Cross Blue Shield of Arkansas. "Policy #2020005 Self-Administered Medication Policy." In *Coverage Policy Manual*, 2020.

what circumstances or medications may or may not be covered. The perplexing implication here is that if a provider-administered dosage form can also be self-administered, it *may not* be covered under the medical benefit. Drugs prepared and administered by a healthcare professional in outpatient settings are defined by the National Association of Insurance Commissioners as *medical benefit drugs*.[2] If a patient and their provider made the shared decision to use a provider-administered dosage form, and that dosage form is administered by a provider in accordance with FDA labeling, the fact that it is also available in a different dosage form should have no bearing on how the claim is processed. For example, certolizumab pegol is available in both a self-administered injectable formulation as well as a lyophilized powder for injection which, per the FDA-approved labeling, is to be reconstituted and administered by a healthcare professional.[3] Under the policy as currently worded, a patient has no way to determine if that claim will be paid. As per the professed Arkansas Blue Cross Blue Shield "Member Rights and Responsibilities", patients have the right to an explanation of their benefits.[4] We ask that Arkansas Blue Cross Blue Shield clarify this ambiguous language in order to fulfil its responsibility to its members so they may determine the proper course of treatment without concerns of coverage or reimbursement.

Providers' patient relationships and medical expertise make them the best source to decide the most appropriate plan of care with and for their patients. There is a reason that specialty medications—like biologics—require a valid prescription and cannot be obtained over the counter or dispensed from a vending machine. These complex therapies provide incredible benefits for the patients that need them, but also require thoughtful consideration of not only the clinical risks and benefits, but also analysis of those factors in the holistic context of a patient. There is a very good chance, given the proclivity of rheumatoid arthritis (RA) to attack small, peripheral joints like those in the hands and fingers, that a patient receiving biologics to treat their disease would lack the required dexterity to be physically able to self-inject. Physical limitations aside, providers may have concerns about cognitive deficits, memory loss, or complex social, emotional, or behavioral health dynamics that would render self-administration inappropriate or even dangerous for a particular patient.

We recognize that the prescriber may be able to submit an attestation that neither the patient nor the caregiver is competent to administer an injection; however, in practice this is just another access barrier. When a licensed independent practitioner prescribes a medication, that signed prescription *is their attestation* that in their clinical opinion, the ordered therapy is the most appropriate for that patient. Requiring prescribers to then submit an attestation as to why they didn't select an alternative is not a benevolent concession; it is an added administrative burden that is strategically employed to dissuade providers from proceeding with their intended treatment plan in favor of the path of least resistance—and least expense.

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[2] National Association of Insurance Commissioners, "Health Carrier Prescription Drug Benefit Management Act," (2018. https://www.naic.org/store/free/MDL-022.pdf.

[3] "Cimzia," (Smyrna, GA: UCB, Inc., 2019.

[4] "Member Rights and Responsibilities," (web page), Arkansas Blue Cross Blue Shield, n.d., accessed July 21, 2020, https://www.arkansasbluecross.com/members/individual-and-family/member-rights/members-rights-responsibilities.

This policy irresponsibly forces providers and patients into a one-size-may-fit-some approach which precludes the practice of personalized medicine. While self-administration may be appropriate for some patient populations, there are certainly patients who would benefit from the closer clinical monitoring provided by in-office administration, or who may be unable or simply unwilling to self-administer. For patients with rheumatoid arthritis, certolizumab is the only injectable provider-administered TNF-inhibitor which does not require concomitant use of methotrexate. There are a number of reasons methotrexate may be contraindicated for a particular patient including alcohol use, hepatic impairment, family planning concerns, and intolerable side effects. If certolizumab is subjected to this policy, providers and patients will be left without an in-office injectable TNF-inhibitor monotherapy option for these patients.

The ability to regularly communicate with patients during their visits for treatment is a critical touchpoint. Some patients are better equipped for self-advocacy and are more engaged in their health care than others. When patients receive their therapy in their provider's office, they are afforded the opportunity to connect with familiar healthcare providers on a regular basis. These touchpoints provide valuable insight into a patient's progress, treatment tolerance, side effects and overall perception of treatment effectiveness. These episodes of care punctuate the intervals between office visits, allowing providers to more readily identify suboptimal disease control or adverse reactions, and change the treatment plan accordingly. The all-too-common alternate scenario is that patients suffer in silence until their next scheduled office visit, at which point they may have incurred irreparable harm.

Infusion providers perform critical assessments prior to administering medications in the office to identify contraindications to therapy. Complex biologic treatments require assessment and monitoring for contraindications prior to administration. While some patients can be provided with a list of these contraindications along with instructions to hold their injection and be expected to self-monitor appropriately, many cannot. For some patients this is not only an unreasonable plan but an unsafe one, especially for those who may struggle with health literacy. Direct patient care clinicians report it is a common occurrence for patients to present for their infusion with contraindications, despite repeated education. Patients may not realize that there are a multitude of ways an infection presents itself, or that their new abdominal pain, dermatological changes, or recent live vaccinations are reasons to hold treatment.

Patients with a high degree of health literacy may still opt to proceed with self-administration despite having received and understood information about when to hold their treatment. When a patient with a chronic debilitating disease like rheumatoid arthritis finally achieves disease control, they can be very wary of missing their treatment for fear of their symptoms returning and their disease progressing. Even when provided with education as to the serious risks of proceeding with treatment in the setting of contraindications, many patients are unwilling to hold their treatment during times of illness for fear of symptom flares and the associated physical, emotional, and financial implications.[5] Provider-administered

[5] Mitchell Cole et al., "Patients with Undermanaged RA Have Higher Medicare Costs Than Other RA Patients," (Avalere Health, 2020).

medications can be held in the setting of contraindications, but this safeguard is lost when patients who may be reluctant to miss treatment are able to self-administer.

If patients are not receiving their treatment in the office, it is more difficult to determine the presence or source of treatment failure or side effects. Assessing treatment adherence is especially challenging when medications are self-administered, as providers have no reliable means of determining if a patient is taking their medication properly. Reported injection site adverse effects may be the result of improper injection technique. A perceived medication intolerance may really be caused by an overdose due to misunderstanding of the dose or dosing schedule. Lab values may reflect high levels of disease activity, causing the provider to consider escalating the dose or changing the treatment plan altogether, when, in reality, the patient has been splitting doses or stretching out dosing intervals due to financial concerns. These real examples from frontline clinicians demonstrate just a few reasons why providers may opt for in-office administration rather than self-administration in the home. Providers should not have to justify the rationale for the clinical choices they make in the best interests of their patients.

Formulary restrictions have negative consequences on treatment adherence and clinical outcomes. The practitioners prescribing specialty medications are the clinical experts best positioned to skillfully balance evidence-based guidelines with their intimate knowledge of each patient's medical history, socioeconomic situation, and lifestyle factors to design a plan of care they have determined—in concert with their patients—to be reasonable, safe and efficacious. That is why patients who are actively involved in designing their plan of care are shown to be more satisfied with their care and more likely to stick to their regimen and reduce consumption of medical services (i.e. achieve treatment adherence)[6,7]. It should come as no surprise that when patients follow their plan of care, they are able to achieve symptom control and keep their disease in a state of remission[8]. Limiting available treatment options by shifting medical benefit drugs to the pharmacy benefit for the sake of the payers' bottom line subverts the shared decision-making process. Because that shared decision-making process is a prerequisite for treatment adherence, which is required to maintain remission, it becomes abundantly clear that we must preserve the ability of healthcare providers to practice personalized medicine to effectively manage these complex, chronic diseases.

When chronic diseases—like those treated with parenteral biologics—are undermanaged, patients utilize more healthcare services and incur substantially higher costs. As formulary restrictions limit providers' ability to effectively manage their patients' conditions, patients will utilize more healthcare services and incur substantially greater costs. A recent analysis of beneficiaries with undermanaged rheumatoid arthritis showed that these patients' overall medical costs are 120% higher than other RA

[6] Jennifer H. Lofland et al., "Shared Decision-Making for Biologic Treatment of Autoimmune Disease: Influence on Adherence, Persistence, Satisfaction, and Health Care Costs," *Patient Preference and Adherence* 11 (2017).

[7] Yujin Park et al., "The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review," *Journal of Managed Care & Specialty Pharmacy* 23, no. 8 (2017).

[8] G. C. Actis and R. Pellicano, "Inflammatory Bowel Disease: Efficient Remission Maintenance Is Crucial for Cost Containment," *World Journal of Gastrointestinal Pharmacology & Therapeutics* 8, no. 2 (May 6 2017).

patients; hospital outpatient services for undermanaged patients are 240% higher.[5] Under most commercial health plans, these costs will be borne by both the patient and the insurance provider.

Mandating self-administration shifts costs to the pharmacy benefit, potentially increasing patient out-of-pocket costs. While we appreciate the concern for reducing medical benefit drug spend, shifting the burden to patients is not a viable solution as out-of-pocket (OOP) costs are one of the biggest drivers of medication non-adherence.[9] As OOP expenses increase, so does the likelihood that patients will stop their medication. One study showed that among patients prescribed a TNF-blocker, an OOP expense above $100 per month makes patients significantly more likely to stop taking their medication; every $10 increase in weekly OOP expenses made patients 8% more likely to stop therapy, and when OOP expenses exceed $500 per month, patients are 700% more likely to abandon treatment.[10] With these linear relationships in mind, it is clear that reducing OOP expenses for specialty medications is absolutely essential to promote treatment adherence, which the literature clearly demonstrates results in decreased disease activity, better clinical outcomes, better physical ability, increased quality of life and decreased hospital costs.[11]

NICA opposes any policies that aim to transition a patient from the therapy prescribed by their provider to an insurer-preferred product for reasons other than health and safety. These utilization management strategies undermine the patient-provider relationship, devalue the clinical expertise of the prescriber, and are simply inappropriate and ineffective mechanisms for payers to employ in an effort to control cost liabilities. The National Infusion Center Association is deeply concerned by the possibility that patients' health and well-being will be adversely affected by these policy changes, and strongly encourages Arkansas BCBS to reconsider its decision to supersede providers' prescribing authority and clinical expertise by dictating the course of treatment for its members. It is our hope that we can find solutions that control costs and maximize member value without compromising care.

Should you have any questions or need more information, please contact me at kaitey.morgan@infusioncenter.org. Thank you in advance for your attention and careful consideration.

Sincerely,

KAITEY MORGAN, RN, BSN, CRNI

[9] Miranda, Aimon C., Erini S. Serag-Bolos, and Julie B. Cooper. "Cost-Related Medication Underuse: Strategies to Improve Medication Adherence at Care Transitions." Article. American Journal of Health-System Pharmacy 76, no. 8 (2019): 560-65.

[10] Patrick P. Gleason et al., "Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications," *Journal of managed care pharmacy: JMCP* 15, no. 8 (2009).

[11] Parvaneh Heidari, Wendy Cross, and Kimberley Crawford, "Do out-of-Pocket Costs Affect Medication Adherence in Adults with Rheumatoid Arthritis? A Systematic Review," 48 (2018).

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DIRECTOR OF QUALITY & STANDARDS

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