NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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Subject: Certolizumab pegol (Cimzia®) Medical Policy Revisions

Dear Drs. Willis and Tate,

The National Infusion Center Association (NICA) would like to express our concern regarding changes to the medical policy for certolizumab for BlueCross BlueShield Tennessee members. We are concerned that the proposed policy changes devalue member and provider choice, ultimately to the detriment of patients, and **we ask that you reverse the decision to implement these step therapy requirements.**

NICA is a 501(c)(3) nonprofit patient advocacy organization formed to ensure that our nation's sickest and most vulnerable patients can access outpatient infusion and injectable medications 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 one of several thousand outpatient infusion facilities across the country. To improve the affordability of these drugs for patients, we work to ensure that patients can access these drugs in low-cost, non-hospital care settings.

Specialty medications, particularly biological products, 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 payors have an ongoing desire to control medication expenditure through formulary development. However, if utilization management strategies 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, but will increase clinical risk, produce poorer health outcomes, reduce quality of life, increase the burdens of disease, and increase costs.

Formulary restrictions have negative consequences on treatment adherence, clinical outcomes, and overall costs of care. The practitioners prescribing certolizumab and other 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 (i.e. achieve treatment adherence)[1,2]. 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[3]. Limiting available treatment options for the sake of the payers' bottom line subverts the shared decision-making process, and because that shared decision-making 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 for the overall welfare of the patient.

Step therapy mandates are a shortsighted strategy for cost savings. Cost and value are not equivalent, especially in healthcare. Moreover, cost *avoidance* is not analogous to cost *savings*. While our primary concern with this policy is the negative impact on patient care, it is also worth noting that while step therapy mandates may temporarily lower drug costs, they generally do not reduce—and in fact often significantly increase—overall healthcare expenditures due to the increased costs associated with active disease[1-3]. On paper, it may appear that driving members towards a more "cost-effective" treatment option will save money and build member value. However, please understand that any cost savings realized in the immediate term are generally heavily outweighed by the long-term quality of life, health outcome, and financial implications associated with undermanaging autoimmune diseases.

First-step failure must not cause long-term harm. Certolizumab is indicated for the treatment of several chronic, progressive, degenerative disorders. If a patient is required to fail a first-step therapy before receiving approval to begin treatment with alternatives, that "failure" is evidenced by characteristics such as increased disease activity and progression of disability. In many of these disease states, such as rheumatoid arthritis and psoriatic arthritis, the damage resulting from a failed therapy is often irreversible. To force patients to bear the long-term physical, emotional, and economic burden of disease in exchange for payer's short-term cost savings, is simply unconscionable and unethical.

Aside from the fact that patients will be required to try and fail any number of payer-preferred products, this policy requires patients to step through a large number of therapies—as many as three different biologic therapies—before certolizumab will be covered. Depending on the disease state, some patients will also be required to try and fail multiple non-steroidal anti-inflammatory drugs (NSAIDs), oral disease-modifying antirheumatic drugs (DMARDs) and/or corticosteroids; Patients with plaque psoriasis will be required to try and fail ***six*** therapies before certolizumab will be approved. This equates to a minimum time period of over one year of poorly-controlled disease before the provider-preferred treatment could be initiated. While in some circumstances it may make sense to require patients to try an evidence-based, clinically appropriate first line therapy, the requirement to try and fail half a dozen treatments is more of an access barrier than a metered approach to ensure judicious use of a medication.

This policy forces a one-size fits all approach which precludes the practice of personalized medicine. Of the six indications in the certolizumab medical policy, five require prior unsuccessful treatment with at least

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[1] Lofland, J.H., et al., *Shared decision-making for biologic treatment of autoimmune disease: influence on adherence, persistence, satisfaction, and health care costs.* Patient preference and adherence, 2017. **11**: p. 947-958.

[2] Park, Y., et al., *The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review.* Journal of Managed Care & Specialty Pharmacy, 2017. **23**(8): p. 893-901.

[3] Actis, G.C. and R. Pellicano, *Inflammatory bowel disease: Efficient remission maintenance is crucial for cost containment.* World J Gastrointest Pharmacol Ther, 2017. **8**(2): p. 114-119.

one self-administered injectable therapy—most require two or as many as three self-injected products. For patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and non-radiographic spondylarthritis, this policy leaves no option for in-office injectable therapy. 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 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. By virtue of the approved first-step therapies under this policy, providers will be left without an in-office TNF-inhibitor monotherapy option for these patients.

Providers' patient relationships and medical expertise make them the best source to decide the most appropriate of plan 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 to attack small, peripheral joints like those in the hands and fingers, that a patient receiving Certolizumab 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 the path of least resistance—and least expense.

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 more engaged in their healthcare 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.

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Infusion providers perform critical assessments prior to administering medications in the office to identify contraindications to therapy. Biological treatments like Certolizumab 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. Provider-administered 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.

Conclusion

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 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 BCBS of Tennessee 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.

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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
DIRECTOR OF QUALITY & STANDARDS