NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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Subject: Concerns regarding specialty medical injectable drug policy changes

Dear Mr. Elhert,

The National Infusion Center Association (NICA) has received reports from concerned providers and patients regarding several recently announced changes to UnitedHealthcare plans— step-therapy directives, specialty pharmacy mandates and non-medical switching policies. 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 changes:**

- **New step therapy requirement through rituximab for members with relapsing-remitting multiple sclerosis for whom the provider has prescribed Ocrevus.**
- **Requirement for Ocrevus to be obtained through Optum Infusion Pharmacy or Optum Pharmacy**
- **Steer members toward self-administered formulations for reasons unrelated to health or safety, regardless of prescribed route of administration.**

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.

There are many complex, multi-faceted challenges threatening the sustainability of our healthcare system. Specialty medications, particularly biological products, are some of the most innovative and life-changing medications developed in the last decade and they bring tremendous value to those that need them. Consequently, these therapies are incredibly expensive, and patients continually struggle with affordability as payers struggle to mitigate increased cost-sharing liability. NICA understands that payors have an ongoing need to control formularies and costs related to the growing specialty medication market, however in the meantime, disease continues to progress in the absence of appropriate and effective intervention. The health outcome, quality of life, and financial implications associated with such increased disease activity and progression would be significant.

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Specialty Pharmacy Mandate

The hidden costs associated with sourcing infusion drugs from specialty pharmacies make this model inviable. Non-hospital settings represent the lowest cost care settings in which to receive provider-administered specialty medications. Removing an office's ability to buy-and-bill medications through the implementation of mandatory specialty pharmacy requirements will limit providers' ability to continue delivering consistent, high-quality care in a safe environment, at a cost significantly lower than hospital care settings. The result will be a discontinuation of infusion services for UnitedHealthcare's members in these lower-cost settings, forcing these members into the highest-cost site of care: hospital-affiliated settings—a very expensive lose-lose proposition for UnitedHealthcare and its members.

The current fee-for-service reimbursement model under the medical benefit covers very little of the provider's risk and total facility cost associated with coordinating the pre-administration, administration, and post-administration aspects of administering specialty medications. It is important to understand that the preparation and administration of many specialty drugs, particularly therapeutic biological products, represent much more complicated medical procedures than drawing and administering simple therapeutic infusions or injections (e.g., vaccines). The current CPT code set for reimbursement of professional services associated with preparing and administering these medications is limited to the time the infusion is started to the time it is stopped (aka drip-to-drip). However, there is much more time involved for preparation and monitoring—as much as 2 to 3 hours of additional labor—for which offices do not receive reimbursement. Much of this time requires the non-delegable skills of a highly trained registered nurse or clinical provider as patients are monitored for treatment tolerance and adverse effects. It is this cost-reimbursement disparity that has forced infusion providers to rely on drug payments to make this business model sustainable.

Infusion providers maintain that, if forced to source medications from specialty pharmacies, they could not support the lost revenue under the current professional services reimbursement model, even at complex ("chemo") codes (e.g., 96413, 96415). Instead, providers would be forced to send patients to another facility for treatment. Since home administration is not appropriate for complex and reaction-prone therapies, like Ocrevus, members will end up in hospital-affiliated care settings at a significant increase in cost-sharing liability for both patient and payer.

While many hospital facilities provide high-quality care, their increased cost has been well documented and creates significant financial barriers for most patients. In a recent Magellan Medical Pharmacy Trend report, insurers reported paying up to 390 percent more for the 96413 and 96365 administration codes in the hospital setting when looking at the per member, per month cost of commercial lives covered. Similarly, a recent flyer produced by UnitedHealth Group confirmed that administering specialty medications outside of hospital-affiliated settings creates significant per capita savings. For example, $37,000 in savings can be appreciated over 4 months of treatments per member with multiple sclerosis[1]. Non-hospital care settings are administering these medications more efficiently and more economically than hospitals when given the flexibility to acquire drugs through whatever model is most conducive to supporting

[1] UnitedHealth Group. (2019). Administering Specialty Drugs Outside Hospitals Can Improve Care and Reduce Costs by $4 Billion Each Year. Retrieved from https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2019/UHG-Administered-Specialty-Drugs.pdf

their patients. As previously stated, forcing providers into a specialty pharmacy acquisition model reduces this flexibility, jeopardizing their financial viability resulting in decreased access to non-hospital care settings.

Mandatory specialty pharmacy acquisition will cause delays in treatment for members with significant health outcome, quality of life, and financial implications. Adding another middleman between treating clinicians and their patients adds complexity and delays treatment. Delays or disruptions in care for autoimmune patients can significantly increase the economic burden of disease. The per capita cost burden more than doubles when autoimmune patients cannot access the prophylactic care they need to manage disease progression. Any changes that may prove disruptive to non-hospital administration of specialty medications carry significant implications.

Multiple infusion providers cited service issues with reputable national specialty pharmacies relating to incorrect quantity of drug and wasted drug. One respondent said, "We ordered and needed 600mg of drug, but we only received 300mg." In this instance, the patient had to be rescheduled and the delay caused the patient to flare and present to the emergency department. Another administrator said, "We've had shipping delays for various reasons with no specific explanation from the specialty pharmacy. Such as 'It seems it just didn't make it on the truck, but we don't know why' or 'I see the order was placed, but it doesn't look like the drug was released', but no further explanation was provided for either instance." Several others reported that they have had patients who missed treatment, because the drug did not arrive in time for the scheduled infusion, having to cancel appointments due to delays that would have been avoided through buy-and-bill.

Specialty pharmacy mandates increase the administrative burden on providers, increasing costs and ultimately restricting access to care. Most infusion providers have neither the technology infrastructure nor the staff capacity to efficiently navigate specialty pharmacy acquisition of drugs. Infusion operators are frequently forced into a logistics management role, coordinating a drug order between the insurance company and the specialty pharmacy. This work requires real staff time and greatly affects business sustainability, detracting from patient care at increased burden and negative reimbursement.

We are deeply concerned that this recently announced specialty pharmacy policy could threaten the financial viability of office-based case settings, crippling capacity within a low-cost delivery channel for specialty medications, and undermining patients' ability to access the outpatient infusion/injection care they desperately need to effectively manage disease progression. Again, the health outcome, quality of life, and financial implications associated with such an outcome would be significant.

Specialty pharmacy mandates result in unnecessary waste. When patient medications are acquired through specialty pharmacies, there are two possible outcomes: the medication can be administered to the intended recipient, or it can be discarded. Any number of events—a change in patient condition, presence of contraindications, or even simply poor treatment adherence— can result in a patient not receiving their scheduled treatment. When this happens, the provider cannot return the medication to the specialty pharmacy nor can it reallocate that dose to another patient. The practice has no choice but to keep the product on site, increasing the administrative burden associated with this extraneous inventory until the product expires, at which time it must be discarded. Under the buy-and-bill model, this additional work and waste is avoided entirely.

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Step Therapy Policies

Step therapy mandates have a place in the utilization management toolbox but must be employed judiciously and responsibly. Healthcare is a business; however, as we are in the business of taking care of human lives, all decisions must be guided by principles of sound ethics. For step therapy policies to be ethical—and we are confident in our assumption that UHC is aligned in this objective— they should measure favorably against several core principles[2]: 1) first-step failure must not cause long-term harm; 2) cost savings must weigh favorably against long-term outcomes; 3) first-step drugs must be clinically appropriate; 4) the policy must provide patients with the best chance to meet their clinical goals.

First-step failure must not cause long-term harm. Multiple sclerosis is a chronic, progressive, neurodegenerative disorder. 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 MS—as with many other chronic, progressive, degenerative disorders—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.

Cost savings must weigh favorably against long-term outcomes. In the case of the policy under consideration, application of this principle means that the short-term cost savings of rituximab compared to Ocrevus should be weighed against the long-term costs of a patient with undermanaged multiple sclerosis (MS). These costs are not incurred by payors alone, but also by patients. The impacts on patients is our primary concern, however it cannot be ignored that any immediate drug cost savings realized from the substitution of rituximab for Ocrevus will be quickly consumed with increased healthcare utilization down the road resulting from mandating the use of a unproven medication for an off-label indication. Multiple studies have drawn the same conclusion: while step therapy mandates may temporarily lower drug costs, they generally do not reduce—and often significantly increase—overall healthcare expenditures[3].

First-step drugs must be clinically appropriate. Generally speaking, this criterion is often the easiest to satisfy. The most prevalent disease states are often the subject of extensive research resulting in multiple effective treatments. Treatment of multiple sclerosis, however, is limited to a relatively short list of proven effective therapies—17 FDA-approved agents to be precise[4]. While the limited body of research surrounding the use of rituximab to treat MS may be promising, *much* more clinical trial evidence is needed before superiority—or even noninferiority—can be established between Ocrevus and rituximab. Without such clinical evidence, it has not been granted an FDA-indication; it is both perplexing and deeply concerning that UHC is requiring its members to try and fail a non-FDA-approved treatment when highly effective FDA-approved therapies exist. Additionally, requiring patients to fail an off-label product before an on-label product will be covered devalues the FDA and circumvents a well-established process to promote consumer safety.

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[2] Nayak, R.K. and S.D. Pearson, *The Ethics of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies.* Health Affairs, 2014. **33**(10): p. 1779-85.
[3] 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.
[4] Multiple Sclerosis Coalition. (2019). The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence.

The policy must provide patients with the best chance to meet their clinical goals. There is ample evidence to support the association between treatment adherence and improved clinical outcomes. Furthermore, patients who are actively involved in designing their plan of care through collaboration with their healthcare provider are more likely to follow that plan of care, thereby achieving better treatment adherence. The practitioners prescribing medications like Ocrevus 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. Limiting available treatment options for the sake of the payers' bottom line subverts the shared decision-making process; when we consider that shared decision-making is a prerequisite for treatment adherence, it comes abundantly clear that we must preserve the ability of healthcare providers to practice the art and science of personalized medicine in order to reach patients' clinical goals.

Non-Medical Switching

NICA opposes any policies that aim to transition a clinically stable patient from their current therapy—one they have chosen with their provider in a shared decision-making process—to an insurer-preferred product for reasons other than health and safety. These utilization management strategies undermine the patient-provider relationship, devalue the years of training and clinical expertise of the prescriber, and are simply inappropriate mechanisms for payers to employ in an effort to control cost liabilities.

We expressed these concerns last fall when UnitedHealthcare announced a decision to require patients to step through self-administered preparations of multiple biologics before allowing coverage for provider-administered preparations. We commended UnitedHealthcare for the decision to delay implementation of those policies to allow more time for thoughtful consideration of the outpouring of concern from stakeholders in the infusion delivery channel. In recent days, we were dismayed to learn UnitedHealthcare will be moving forward with this policy for Orencia effective July 1, 2020. Requiring patients to try and fail a self-administered injectable formulation before authorizing the provider-administered infusible medication is just one concerning example of non-medical switching. 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.

Providers' patient relationships and medical expertise make them the best source to decide the best 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, giving the proclivity of rheumatoid arthritis to attack small, peripheral joints like those in the hands and fingers, that a patient receiving Orencia 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 can submit an attestation that neither the patient nor the caregiver is competent to administer the injectable form, 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.

Infusion providers perform critical assessments prior to administering medications in the office to identify contraindications to therapy. Biological treatments like Orencia 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 many patients this is not only an unreasonable plan but an unsafe one, especially for patients who may struggle with health literacy. Those in direct patient care roles report that is a common occurrence for patients to present for their infusion with contraindications, despite repeated education about this. They 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 as well.

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 fearful 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 that we have heard from frontline clinicians are just a few examples of reasons why providers may opt for in-office administration rather than self-administration in the home. Providers should not have to fight to defend their decision making or justify the rationale for the clinical choices they make in the best interests of their patients.

Conclusion

Cost and value are not equivalent, especially in healthcare. Moreover, cost *avoidance* is not analogous to cost *savings*. On paper, it may appear that driving members towards the most "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.

The undersigned providers and practices, representing thousands of patients are deeply concerned by the possibility that patients' health and well-being will be adversely affected by these policy changes. NICA strongly encourages UnitedHealthcare to reconsider its decision to supersede providers' prescribing authority and clinical expertise by dictating the course of treatment and drug acquisition model 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 us using the information provided below. Thank you in advance for your attention and careful consideration.

Sincerely,

KAITEY MORGAN, RN, BSN, CRNI
DIRECTOR OF QUALITY & STANDARDS