AMERICAN COLLEGE OF RHEUMATOLOGY
POSITION STATEMENT

SUBJECT: Infusion and Clinic-Administered Injection Therapy in Community Rheumatology Practices

PRESENTED BY: Committee on Rheumatologic Care

PRESENTED TO: Members of the American College of Rheumatology
State Insurance Commissioners
Pharmacy Benefit Management Companies
Managed Care Entities and Insurance Companies
Pharmaceutical Companies
Members of US Congress
Centers for Medicare Services

POSITIONS:

1. The American College of Rheumatology (ACR) supports patient access to safe and cost-effective intravenous infusion and clinic-administered injection therapies.

2. The ACR supports measures to preserve the long-term viability of, and patient access to, clinic or hospital-based therapies in a variety of administration settings including community and independent rheumatology practices.

3. The ACR strongly supports the traditional "buy and bill" model for ordering medications, which allows for immediate availability to medication, less waste to the system, safer handling and storage of drug, and substantially-reduced administrative burden, especially in small practices.

4. The ACR supports equality in payment at different sites of service for identical intravenous therapy.

5. The ACR opposes "white bagging", "brown bagging", and other similar attempts to limit access to infusions and other clinic-administered medications by companies attempting to vertically integrate the supply chain. These policies take control from the physician and patient and reduce access to care and treatment.

BACKGROUND:

Intravenous infusion and other clinic-administered biologic medications have long been mainstay therapies for patients with rheumatologic illness. The benefits of these medications can be life

altering, resulting in a greater quality of life for the patient; allowing them to participate fully in work and family activities; and to achieve their best potential. Administration of intravenous and other clinic-administered medications requires a higher level of planning and orchestration, and closer monitoring than other routes of administration.

Currently, rheumatology practices, including hospital-based and private practices, primarily utilize a “buy and bill” system to obtain intravenous and clinic-administered injection medications for patients. The ACR recognizes the value of the “buy and bill” model for treating a diversity of patient populations, and this process offers many advantages to the patient and the practice.

This “buy and bill” system has been in place for decades, allows for ease of patient access to the drug, and has proven to be an effective means for practices to obtain, administer and deliver medications. “Buy and bill” allows for a relatively low administrative burden to the practice due to having a single storage site with products that are interchangeable (i.e., not “earmarked” for a particular patient), whereas mandated “bagging” practices increase clinic administrative and personnel costs because of the need to track and deliver an earmarked medication to a specific patient (1). Contrasted with white bagging schemes, the buy-and-bill system reduces drug waste that can occur due to last minute changes in dosing or timing of administration. The buy-and-bill method of drug acquisition also ensures “cold chain custody” of the drug from manufacturing to administration. This supply chain is crucial to maintaining the integrity of these highly sensitive pharmaceuticals at all stages of the distribution process (2). In return, the practice clears a small profit, which can substantially stabilize the financial security of the practice, and results in personalized care for patients.

The ACR remains concerned about the trend of payers shifting location of service away from office-based infusions, for example forcing infusions in the home setting or toward stand alone infusion suites without appropriate oversight. The ACR has additional statements on biologic access and site of service that relate to this concerning development. Contrasted with home infusion, office-based infusion has been shown to have numerous benefits including upholding high safety standards of care by allowing for closer supervision by a treating provider and is associated with lower rates of ER visits after infusion compared to home infusion (3). Not only are there reduced ER admissions, but when compared to a facility-based infusion, home infusions demonstrate no overall difference in cost with a notable increase in steroid use for those infusing at home (4).

The ACR is concerned about monetary inequities and particularly the impacts to independent practices. Nationally, payers reimburse infusion differently based on location (i.e. higher reimbursement in hospital-based infusion centers and lower in stand-alone clinics). Medication can be purchased at a significantly reduced cost by large healthcare systems through the 340B

program. The 340B program is designed to help offset losses of hospital systems in underserved areas by assisting in obtaining drug at a lower cost (5). While the ACR understands the intent of this process and the complexity of healthcare finance, it creates a scenario in which independent practices obtain the drug at a higher cost and get reimbursed at a lower rate than other facilities for identical infusion of medication. In an environment where the cost of healthcare continues to rise, it is paradoxical that the infusion with the lowest cost to the system (an independent office) is being squeezed out by larger entities who are able to charge more and buy drug cheaper.

In addition, the ACR remains concerned by recent attempts by payers to provide medications directly to patients, who bring the drug to be infused to the infusion suite ("brown bagging") or to ship drug directly to the infusion suite ("white bagging"). These attempts, and other similar attempts, to bypass traditional supply processes simply to increase profitability of the company are concerning on many levels. They dramatically increase administrative burden upon a practice, lead to wasted drug when last minute changes are made, and unnecessarily change the traditional "cold chain custody", raising safety concerns. The Drug Supply Chain Security Act (DCSCA) was enacted to ensure drug product integrity during handoffs in the supply chain to protect consumers against this very practice (6). The American Hospital Association (AHA) and American Society of Health-System Pharmacists (ASHP) have criticized this practice, as it bypasses all normal checks and balances that have represented our medical system for so long and served the patient so well (7).

"White bagging" provides no clinical benefit to patients and no administrative streamlining for rheumatology practices. It will ultimately lead to an increased cost burden to the system. Rheumatologists will need to push to more expensive sites of care, ultimately leading to an increased cost burden to the system. There is a risk that smaller and independent practices will need to push infusions to more expensive sites of care and smaller practices will experience financial strain that may lead to practice closure or absorption into larger hospital systems. The ACR supports the preservation of long-term viability of community rheumatology practice-based infusion centers and is deeply concerned by threats to independent practices imposed by various forms of "bagging". Rheumatology infusion practices better operate under the buy and bill model, which over time reduces the cost of drugs, allows for immediate availability of medication, less waste to the system, safer handling and storage of drugs, and a substantially reduced administrative burden.

Similarly, the consequences of these payer policies for pediatric patients can be dramatic. Most pediatric rheumatology practices are based in tertiary pediatric hospitals that do not accept white bagging. When an insurer insists on white bagging, pediatric rheumatology providers are forced to spend administrative time to help find an alternative infusion center willing to participate in white bagging and accept a pediatric patient. In order to obtain appropriate care, the patient and

family may need to drive for hours to receive their medication. In some cases, this is not possible, and this forces providers to select another therapy that may be suboptimal.

In summary, delivering intravenous infusion and other clinic-administered medications inside a rheumatology clinic offers safer, more patient-centric care that is more cost-effective to the healthcare system. The site of infusion service should be in a rheumatology clinic supervised by a licensed physician. Once the patients are in the office, they must be able to access infusion therapy in a timely, safe, and cost-effective method. This is done through the 'buy and bill" model, which is mutually beneficial to the patient, practice, and healthcare system. The ACR firmly believes that infusions in community rheumatology practices is a vital service that must be strongly supported by appropriate legislation and regulatory provisions.

REFERENCES

1. American Hospital Association . (n.d.). *Health insurer specialty pharmacy policies threaten patient quality of care: AHA*. aha.org. Retrieved from https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care
2. Nickels, T; Kraus , T. (2021, March 31). Acting FDA commissioner Food and Drug Administration - ASHP & AHA . ashp.org. Retrieved from https://www.ashp.org/-/media/assets/advocacy-issues/docs/GRD-AHA-ASHP-White-Bagging-Letter-to-FDA.ashx?la=en&hash=8AFD90D868BB27DA94F4658DA1AE3498CA533584
3. Baker, M. C., Weng, Y., Fairchild, R., Ahuja, N., & Rohatgi, N. (2021). Comparison of adverse events among home- vs facility-administered biologic infusions, 2007-2017. JAMA Network Open, 4(6). https://doi.org/10.1001/jamanetworkopen.2021.10268
4. Giese-Kim N, Wu M, Dehghan M, Sceats LA, Park KT. Home Infliximab Infusions Are Associated With Suboptimal Outcomes Without Cost Savings in Inflammatory Bowel Diseases. *Am J Gastroenterol*. 2020;115(10):1698-1706. doi:10.14309/ajg.0000000000000750
5. Health Resources & Services Administration. (n.d.). 340B Drug Pricing Program. HRSA. Retrieved from https://www.hrsa.gov/opa
6. United States Food and Drug Administration . (2014, December 16). *Title II of the Drug Quality and Security Act* . fda.gov. Retrieved from https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act
7. Traynor, K. (2021, March 23). White bagging a growing concern for Health Systems. ASHP.org. Retrieved from https://www.ashp.org/News/2021/03/22/White-Bagging-a-Growing-Concern-for-Health-Systems

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