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Re: Requiring acquisition of specialty drugs through specialty pharmacy

Dear Drs. Hickey and Willis:

The National Infusion Center Association (NICA) and the National Organization of Rheumatology Managers (NORM) are pleased to submit joint comments to BlueCross BlueShield of Tennessee regarding a change in policy relating to the acquisition and billing of specialty medications that would require acquisition of specialty medications through a specialty pharmacy.[1] We understand that BCBS of Tennessee recently sent letters to providers indicating a postponed implementation. We commend BCBSTN for this decision but urge you to consider permanently reversing this policy for the reasons outlined below.

NICA is a 501(c)(3) nonprofit patient advocacy organization formed to represent patients requiring provider-administered medications and the providers that treat them. NICA works to ensure that our nation's sickest and most vulnerable patients can access the outpatient infusion and injectable medications they rely upon to manage their complex, chronic condition(s) through advocacy, education, and resource development. NICA represents hundreds of thousands of patients managing complex, chronic, rare, life-threatening and/or difficult-to-manage diseases (e.g., autoimmune diseases) with medical benefit drugs (e.g., biologics) in one of several thousand outpatient infusion facilities across the country. We work to ensure that patients can access these medications in non-hospital care settings to improve affordability and access.

NORM is a 501(c)(6) nonprofit advocacy organization representing rheumatology managers, physicians, and patients. NORM promotes and supports education, expertise, and advocacy for access to care in rheumatology practices across the country. NORM represents nearly 500 rheumatology practices across the country that strive to offer a lower-cost alternative to hospital care settings for provider-administered medications.

NICA and NORM work to support patients' ability to optimize health outcomes, maximize quality of life, and minimize the physical, emotional, and economic burden of autoimmune diseases. On behalf of our stakeholders, we support payor policies that: (1) facilitate and expand access to the right medication at the right time, in the right setting; (2) support patients' ability to minimize the burdens of disease; and, (3) preserve providers' ability to choose the drug acquisition model most conducive to the successful management of their patient's condition.

When word of this policy change surfaced, NICA and NORM reached out to our collective provider networks (roughly 3,400 and 500, respectively) for feedback. The response was overwhelmingly negative,

[1] BlueCross BlueShield of Tennessee, Inc. Blue Alert. November 2019.

and many took the opportunity to cite major concerns and implications for patients, the treating clinics, and the affected insurance plans.

Our organizations write to bring the following concerns to BlueCross BlueShield of Tennessee's attention:

- The hidden costs and waste associated with sourcing infusion drugs from specialty pharmacies make this model inviable;
- Mandated specialty pharmacy acquisition will cause delays in treatment for members with significant health outcome, quality of life, and financial implications; and,
- Specialty pharmacy mandates increase the administrative burden on providers, restricting access to care and increasing costs.

Background

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—as much as 2 to 3 hours of additional labor—that offices do not receive reimbursement for and much of this time requires the non-delegable skills of a highly-trained registered nurse or clinical provider.

For example, per Medicare's Physician Fee Schedule, a 3-hour infusion procedure billed at complex codes (96413 and 96415) is reimbursed at approximately $200. However, it costs an average of $300 to $400 per infusion hour ($900 to $1,200 for a 3-hour infusion)—or even more in certain markets—to furnish this service.

Accordingly, this $200 reimbursement is expected to cover the costs associated with:

1. Pre-administration services and care coordination
    - Prior authorization, benefits investigation, coverage verification, scheduling, medical history, screening, etc.
    - Some of these services would be eliminated through a specialty pharmacy acquisition/reimbursement model, but the offices would still experience some of the administrative burden associated with care coordination.
2. The time of a highly trained Registered Nurse (RN) required to prepare the medication for administration.
    - Many specialty IV/injectable medications require 30-minutes of preparation as most of these medications arrive as lyophilized powder requiring reconstitution and pooling.
3. Time to establish venous access.
    - The complexity and time required vary patient to patient depending on many factors.
4. Administration of pre-medications and pre-treatment clinical assessments and screening as required by the FDA-approved package insert or the ordering provider.

5. Patient monitoring during the infusion.
    - Reprogramming of the IV pump, monitoring for adverse events and continued patency of the venous access, and rate-increase management per the medication protocol are all performed by a highly skilled and highly trained RN.
6. Post-administration monitoring/observation and discharge.
    - Many biologic medicines have a clinical requirement to observe the patient post-treatment for signs of reactions and adverse events.
    - There is also a requirement to remove the venous access device and/or prepare the venous access site for future access in the case of multi-day protocols.

It is this cost-reimbursement disparity that has forced infusion providers to rely on drug payments to make this business model sustainable. Losing this drug payment by forcing providers into a specialty pharmacy acquisition/reimbursement model will jeopardize the financial viability of this care setting to the detriment of both patients and payer.

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 and environment at a cost significantly lower than hospital care settings. The result will be a discontinuation of infusion services for BlueCross BlueShield of Tennessee's members in these lower-cost settings, forcing these members into the highest-cost care setting: hospital-affiliated settings—a very expensive lose-lose proposition for BCBS of TN and its members.

The hidden costs and waste associated with sourcing infusion drugs from specialty pharmacy make this model inviable.

Infusion providers maintain that, if forced to source medications from specialty pharmacy, 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 biologics, we worry that many of BCBS of Tennessee's 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 the latest 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.[2] 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 over 4 months of treatments per member with multiple sclerosis; $32,000 in per capita savings over 6 months of treatments per member with immune deficiency; $28,000 in per capita savings over 5 months of treatment per member with rheumatoid arthritis; $21,000 in per capita savings over 5 months of treatment per member with inflammatory bowel disease; and, $16,000 in per capita savings over 4 months of treatment per member with cancer chemotherapy.[3] The bottom line is that non-hospital care

[2] Magellan Rx Management. Medical Pharmacy Trend Report. 2017; 8th edition. Accessed on December 4, 2019. https://www1.magellanrx.com/documents/2019/03/medical-pharmacy-trend-report_2018.pdf/

[3] UnitedHealth Group. Administering Specialty Drugs Outside Hospitals Can Improve Care and Reduce Costs by $4 Billion Each Year. September 2019. Accessed on December 16, 2019. https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2019/UHG-Administered-Specialty-Drugs.pdf

settings are administering these medications more efficiently and more economically than hospitals when given the flexibility to acquire drug through whatever model is most conducive to supporting their patients. **Forcing providers into a specialty pharmacy acquisition model reduces this flexibility, resulting in increased waste, increased burden, increased cost, and poorer health outcomes.**

One practice manager wrote:

> "We have used [specialty pharmacy] for [rheumatoid arthritis] Rituxan infusions before. The pharmacy always wants us to order the whole treatment (day 1 dose and day 15 dose) so they can bill and ship the entire order. If the patient has an adverse event to their first Rituxan infusion, they are pulled from therapy. We are left with the second dose—which has been paid for. The patient cannot use it, we cannot return it, and the insurance company and patient have already paid for it. The drug is then managed in inventory—with overhead cost for my practice—until it expires and is disposed of. The result is wasted money that patient and payer could have avoided. Under the buy-and-bill model, that drug would not have been billed for and would instead be administered to a different patient. Each time we waste a specialty pharmacy drug, it costs the healthcare system approximately $9,000." *[Data source uncited]*

Another administrator wrote:

> "We've had to fight with [specialty pharmacy] to stop sending an entire loading dose at once (e.g., receiving 15 vials of Remicade in one shipment to cover the first 3 infusions). We asked to them to send one dose at a time and the pharmacy FOUGHT us on this. We have to explain to them every time this is a waste of insurance money if the patient has to stop treatment during that start up."

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. A study found that undermanaging patients with inflammatory bowel disease resulted in a 130 percent increase in the annual per capita economic burden of disease[4] as these patients consume exponentially more non-drug medical services to manage disease flares (e.g., PCP visits, specialist visits, ED presentation, repeat labs/diagnostics, inpatient care). To reiterate, 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 400mg." 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."

[4] 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.

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. Similarly, other providers reported that [specialty pharmacies] frequently ship medications to patients' homes instead of directly to the physician office. For quality control reasons, most infusion operators do not accept "brown-bagged" medications, since they cannot assure pedigree or appropriate handling/storage, etc., infusion providers are not comfortable putting patients at undue risk by administering a medication for which they cannot assure the safety and integrity. As such, these medications are wasted, and the specialty pharmacy ships replacement drug to the office.

Another major concern involves dose escalation. The dosage for some drugs used to treat autoimmune diseases is commonly adjusted throughout the treatment protocol to manage disease optimally. For drugs acquired through specialty pharmacy, escalations in dosage are delayed until the next treatment, meaning that patients are not getting an effective dose, increasing the chance of disease flare resulting from suboptimal therapy. One respondent expressed their frustration saying, "You cannot increase the dosage [with specialty pharmacy] at the time of the infusion/visit; the patient has to wait until the next visit, even though we know the dosage no longer works for the patient." Then the patient winds up in the hospital because their disease flared, and then we have to start over at square one *[Paraphrased for concision].*

As patients on specialty drugs often struggle with affordability, another significant concern that providers expressed involve cost-share assistance. Referring prescribers and infusion operators are heavily focused on assisting patients navigate cost-share assistance programs, a service that specialty pharmacies typically do not assist patients. One practice manager said, "Pharmacies forget to run the copay assistance card, which creates a patient balance. Pharmacies also withhold medications due to an account balance. Our office spends an exorbitant amount of time calling the specialty pharmacy to correct their own mistake." This is a major—and unnecessary—increase in administrative for offices, for which offices are not compensated.

Another model that many infusion operators offer—that specialty pharmacies do not—is a payment plan. Under buy-and-bill, offices have the flexibility to offer payment plans to spread the cost-burden over time. For biologic medicines costing thousands of dollars per treatment, this reduced barrier is critical to improving adherence rates and health outcomes by improving the affordability of accessing the only therapeutic option that effectively manages disease. Under specialty pharmacy, if the medication is not paid for up front and in full, the patient will not receive treatment.

Specialty pharmacy mandates increase the administrative burden on providers, increasing costs and restricting access to care.

Most infusion providers have neither the technology infrastructure nor the staff capacity to efficiently navigate specialty pharmacy acquisition of drug. The resulting burden increases costs, restricts access to care, and produces sub-optimal health outcomes.

One practice manager outlined the burden on their practice by saying, "We are a small office and simply don't have the manpower to arrange shipment for each patient, most of the time we are on the phone with the specialty pharmacy for at least an hour per patient."

When discussing administrative burden with our provider members, the issue of Prior Authorization frequently came up. One administrator noted, "The insurance company approves the medications, but there's a lack of communication to the pharmacy, so we have to go back and forth between departments to get them to communicate the approval and ship the drug." Infusion operators are frequently forced into a logistics management role, coordinating a drug order between the insurance company and the specialty pharmacy; detracting from patient care at increased burden and negative reimbursement.

Another common issue that was uncovered involves denials in automated claims systems. Very often, automated claims systems used to automatically adjudicate claims will deny a claim which bills an administration code without a drug code. In these situations, providers' options are forgoing payment or commit insurance fraud by billing one cent for the drug, risking an audit and loss of admin payments. Either way, offices are not getting paid for the professional services they render.

Additionally, infusion operators spend a great deal of time navigating insurer utilization management programs, whether prior authorization, step therapy, or non-medical switching. This work requires real staff time and greatly affects business sustainability. Offices typically spend one hour per patient with benefits investigation and coverage verification, working through prior authorization, counseling the patient on their cost-sharing liability and cost-share assistance programs, etc. Tying providers' hands by forcing them to acquire drug through specialty pharmacy only increases administrative burden and cost, further threatening the financial viability of the lowest-cost care settings for expensive specialty drugs.

Conclusion

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. The health outcome, quality of life, and financial implications associated with such an outcome would be significant.

We received reports from infusion providers across the country that, under the current reimbursement structure for professional services associated delivering provider-administered medications, loss of drug payments would make the non-hospital, office-based infusion/injection model financially unsustainable—irrespective of geographic market. If providers are no longer able to deliver provider-administered medications in non-hospital settings, patients will be forced into the hospital at an immediate-term increase in per patient, per treatment costs—at best—or forced to undermanage disease at a long-term increase in annual per capita costs—at worst. Either outcome will increase the cost-sharing liability for the payer and its members.

There are many complex, multi-faceted challenges threatening the sustainability of our health care system. Specialty medications, particularly therapeutic biological products, are expensive, and patients continually struggle with affordability as payers struggle to mitigate increased cost-sharing liability.

NICA and NORM understand that payers have an ongoing need to better manage utilization and costs related to the growing specialty medication market, while providing value for their members. Biologics are some of the most innovative and life-changing medications developed in the last 20 years. They bring tremendous value to those that need them. Consequently, they are incredibly expensive to research, develop, and manufacture, making them some of the most expensive medications on the market. As such, this class of medications brings unique challenges to manufacturers, providers, patients, and insurers, including escalating costs, affordability, complex administration, a volatile reimbursement environment, and an increasingly pressurized atmosphere for providers to treat more patients with higher-quality care and produce better health outcomes at reduced reimbursement without jeopardizing quality, amidst increased administrative burden and reduced autonomy.

NICA and NORM understand that some specialty medications, namely self-administered medications may be better managed through the pharmacy benefit. We disagree, however, and strongly caution against applying the same pharmacy methodology to manage provider-administered medications that require healthcare provider supervision. As insurers seek to better control medical benefit spending, we understand that diverting reimbursement of these medications from buy-and-bill to specialty pharmacy may initially

seem like a reasonable solution on a spreadsheet. However, we are concerned that the effects of tying providers' hands and forcing them to acquire drug through specialty pharmacy will severely limit your members' access to care, inadvertently shifting the delivery of high-cost medications—like biologics—into higher-cost hospital settings, at best, or force patients to undermanage disease, at worst.

What remains clear along this arduous journey toward reducing health care spending is the fact that autoimmune disease will progress in the absence of appropriate intervention. Neither patients, nor providers, set drug pricing, but they are unanimously committed to reducing the burdens of disease, remaining productive, reducing consumption of medical services, and minimizing health care spending. Any policy changes that reduce a patient's ability to access the right care at the right time will drive-up long-term costs. Any policy changes that would disrupt the viability of non-hospital care settings for provider-administered drugs will restrict, delay, or disrupt patients access to care, threatening to reroute millions of dollars in medical benefit drug spend into hospital care settings at a significant increase in per patient, per treatment cost.

NICA and NORM applaud BlueCross BlueShield of Tennessee for its commitment to reducing beneficiaries' health care costs, improving health outcomes, and minimizing the physical, emotional, and economic burdens of complex, chronic disease.

On behalf of your beneficiaries that rely on access to provider-administered medications in non-hospital care settings, we implore you to further evaluate the unanticipated ramifications associated with mandating acquisition of drug through a specific model. NICA, NORM, and our networks of infusion experts and patients look forward to the opportunity to serve as a resource in shaping responsible, effective, and patient-centered reform in the medical benefit landscape.

Should you have any questions, comments, or require additional information, please feel free to contact me directly at Brian.Nyquist@infusioncenter.org or 512-623-7705.

Sincerely,

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