

Challenges and Concerns Associated with Member Institution Access to Limited Distribution Medications

NCCN Pharmacy Directors Forum Position Paper

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Background

Limited distribution drugs are generally considered to be specialty medications. Specialty medications are noted to have complex regimens, high-associated costs and may require special handling, administration and clinical follow-up. Most of the medications that fall into the limited distribution category are within oncology, rheumatoid arthritis, multiple sclerosis and rare diseases. Specialty drug manufacturers have continued to adopt limited distribution networks, in which the manufacturers contract with a set number of specialty pharmacies to dispense these specialty drugs. Some manufacturers maintain that a limited distribution model will enable safe and effective drug delivery and allow for optimal patient outcomes through the provision of high-touch support for patients.

Specialty pharmacies included in limited distribution networks must demonstrate their ability to manage these complex medications. Criteria for the provision of limited distribution agents may include providing therapy-specific patient management services, providing 24/7 patient and prescriber support, and supply chain management to ensure safe and accurate dispensing practices. Criteria varies widely between manufacturers as do the record-keeping requirements that support them. Obtaining accreditation is one way that pharmacies can demonstrate that their processes provide quality patient care. In fact, it has become common for payers to require accreditation before contracting with specialty pharmacies. Therefore, accreditation is becoming a critical component for specialty pharmacies to gain access to limited distribution medications. The most common accreditation obtained is the Utilization Review Accreditation Commission (URAC), followed by the Accreditation Commission for Health Care (ACHC). However, hospital-based specialty pharmacies may be denied access to limited distribution medications despite maintaining URAC and/or ACHC accreditation.

The exclusion of hospital-based specialty pharmacies from limited distribution networks disrupts the existing supply chain established by health systems. Instead of utilizing a medication supply stocked in the clinic or hospital, medications must be supplied through alternative procurement methods of “brown or white bagging”. For brown bagging, medications are sent to the patient to bring to their clinic visit, and for white bagging, patient-specific medications are sent to the health system for use prior to their clinic visit or during an infusion. These processes create operational challenges and clinical concerns for patients and health systems, and are in conflict with competing Drug Supply Chain Security Act (DSCSA) requirements for hospitals/organizations. Many health systems have developed policies strictly banning “brown bagging”. Therefore, the exclusion of NCCN member institutions from limited distribution networks may jeopardize the safety and quality of patient care that the networks hope to enhance.

Recommendations and Rationale

1. *The NCCN Pharmacy Directors Forum believes that NCCN member institution exclusion from limited distribution specialty medications diminishes the coordination of care for patients due to a loss of visibility to providers.*

A hallmark quality of a limited distribution model is to ensure safe and effective patient care by providing high-touch support. Hospitals with an accredited specialty pharmacy are in a unique position to manage these patients as they have access to a patient's electronic medical record (EMR) that is shared with providers. This model allows for enhanced multidisciplinary care and allows for crucial communication between the patient and multidisciplinary care team in a timely manner. Also, with access to the EMR, pharmacists are able to better coordinate drug refill and delivery around patient appointments or labs to ensure the correct drug and dose are being sent out appropriately. Proactive drug review to ensure that patients are receiving the correct drug at the optimal dose and the right time can improve patient outcomes and limit drug waste. If patients must fill at an outside pharmacy, difficulties may arise regarding the coordination of care. For instance, providers may not be readily aware of the communications between the specialty pharmacy and patient, limiting their knowledge of medication adherence and adverse events. This lack of communication may lead to delay of care and additional drug waste if patients require dosage adjustments.

2. *The NCCN Pharmacy Directors Forum believes that exclusion from limited distribution specialty medications leads to white bagging practices that hospitals/organizations must avoid.*

Many health systems either ban or advise against "white bagging," due to the conflict with track-and-trace requirements denoted by the Drug Supply Chain and Security Act (DSCSA). These concerns arise from disruption of the supply chain for medications. In the case of white bagging, on the day of administration a patient's treatment may be altered for a variety of reasons, including but not limited to patient response, patient tolerance, or drug-drug interactions that may require dose adjustments, switching therapy and/or drug discontinuation. In this arrangement, a patient's care may be delayed while awaiting delivery of drug, and there are no assurances for timely delivery through payer-directed distribution channels. Furthermore, when patient-specific medications are delivered and therapy is discontinued, health systems are left in the possession of patient-specific medications that have been adjudicated through the insurers or paid for out of pocket. These medications cannot be used in any other setting and are therefore wasted.

3. *The NCCN Pharmacy Directors Forum believes that NCCN member institution exclusion from limited distribution specialty medications creates substantial operational obstacles and strains limited resource pools.*

There are several operational concerns that limited distribution networks impose. Within specialty pharmacy workflows, issues often arise with the coordination of transferring a prescription to a manufacturer mandated pharmacy. This coordination often requires significant time from pharmacists, providers and/or nurses. Therefore, if hospital-based specialty pharmacies are able to access limited distribution medications, treatment delays arising from transferring prescriptions could be avoided. With regard to white bagging, there are additional steps that are created in the management of these medications, which leads to a loss of efficiency. Affected workflows include drug acquisition, product

tracking and documentation, storage and handling, and dispensing. Product acquisition is limited by both the patient's insurance and the pharmacies from which limited distributions networks allow product dispensing. This additional process interrupts existing standardized order and inventory processes that hospitals have in place in accordance with the DSCSA. Furthermore, the storage and dispensation of patient-specific supplies may require additional facility requirements for storage, such as shelving, refrigerator or freezer space. These additional facility requirements may place considerable strain or may not be feasible for health systems.

4. *The NCCN Pharmacy Directors Forum recommends that payers strive to remove constraints that limited distribution networks may impose.*

Payers may unknowingly contribute to the conflict with DSCSA requirements through their arrangements with manufacturers regarding the use of preferential pharmacies and products. Arrangements of rebates or reduced prices with the manufacturers are likely helping to provide savings. However, any savings realized by payers is offset by increasing handling and carrying costs of the entity responsible for patient care and medication administration. For the use of preferential pharmacies, the same concerns denoted above with coordination of care and white bagging apply. The imposition of preferential products plays havoc with a hospital's carefully created formulary and increases drug acquisition costs for handling products that are being obtained outside of the normal supply chain and distribution processes. In these situations, it may be beneficial to allow hospitals to choose the best "similar product". Therefore, a better practice may include paying an appropriate flat or parity payment for a specific group of similar biologics or medications and recognizing that member institutions are committed to streamlining formularies in order to strengthen inventory and operational efficiencies to enhance safety for patients. The creation of a payment system structure that is equitable between legacy and biosimilar products would be welcome. This would likely need to involve mapping legacy products and appropriate biosimilars to a common Healthcare Common Procedure Coding System (HCPCS) number.

5. *The NCCN Pharmacy Directors Forum believes that NCCN member institutions have demonstrated the ability to manage complex medications through clinical trial involvement. Therefore, the NCCN Pharmacy Directors Forum recommends that member institutions with an integrated accredited specialty pharmacy should be included in limited distribution agreements upon drug approval.*

Member institutions are often actively involved in the clinical trials for these limited distribution medications which demonstrates their ability to manage specific requirements for complex medications. The presence of an accredited specialty pharmacy further establishes their ability to provide the administrative support, data aggregation, and clinical follow-up that specialty manufacturers require to provide quality patient care once a medication is FDA-approved. Therefore, it would be prudent to allow these institutions access to dispense these medications to promote the coordination of care, enhance patient safety, limit unintended clinical consequences for patients, and prevent unnecessary costs with receiving patient specific medications within the acute care environment. We recommend that research contracts for member institutions address post-FDA approval access to medications studied if so desired by the organization.

Summary

NCCN member institutions have been excluded from access to certain limited distribution medications despite having participated in the research that may have supported the medications' FDA approval and having specialty pharmacy accreditation. Through participation in clinical trials, member institutions have demonstrated the ability to manage these complex medications while maintaining patient safety. In addition, member institutions that have accredited specialty pharmacies have further demonstrated that they possess the necessary infrastructure for the continued management of these medications. The exclusion of NCCN member institutions from limited distribution networks threatens the safety and quality of patient care that the networks hope to enhance.

References

1. Schwartz RN, Eng KJ, Frieze DA, et al. NCCN Task Force Report: Specialty Pharmacy. *JNCCN*. 2010;8:S-1-S-12.
2. Barlas S. Specialty pharmacy networks for hospitals in the offing: absence of onsite access to specialty pharmaceuticals has care and financial implications. *P T*. 2014;39(2):123–143.

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