

# Making the Case for IDNs As Specialty Rx Innovators

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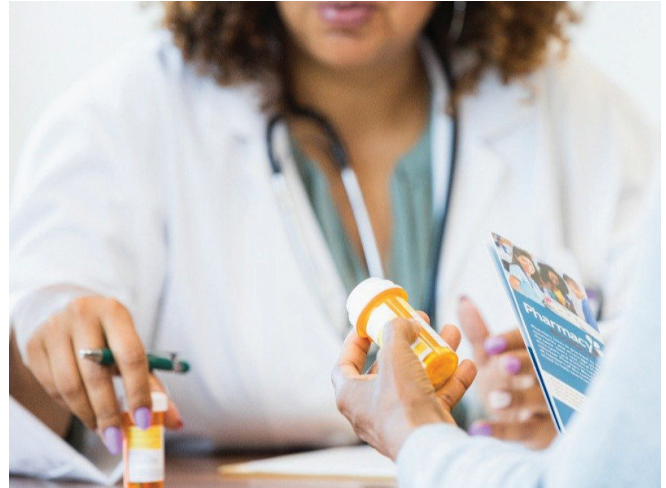
In recent years, specialty pharmacy has witnessed a shift in manufacturer distribution models as limited distribution networks (LDNs) become increasingly popular. Although LDNs are necessary in some medication launches and provide manufacturers with visibility and control of the patient journey, they can sometimes—for capable and qualified institutions—complicate the patient and provider experience.

Similar to payor limitations, restricting medication access to an LDN may cause additional administrative strain on clinical staff (providers and nurses), which can lead to delays or periods of treatment lapses.<sup>1</sup> Health systems with an integrated delivery network (IDN) are designed to help ease this burden by allocating additional resources dedicated to ensuring medication access and adherence, such as pharmacy staff assigned to assist with patient medications. Although IDNs are equipped to optimize patient experiences, the rising number of LDNs has caused changes in the industry that have restricted patients' access to specialty medications, potentially compromising their care. To address these challenges, manufacturers can develop a comprehensive "IDN strategy" to improve patient medication access and provider experience for capable and qualified institutions.

## Focusing on the Entire Patient Care Journey

Broadly defined, an IDN strategy aims to understand the difficulties both patients and providers may experience throughout the entire patient journey. This strategy bridges gaps in medication access through collaborative partnership between manufacturers and IDNs. In doing so, patients experience improved medication access, and IDNs can provide more comprehensive care by directly managing their patients' medications.

Manufacturers also benefit from working with IDNs by seeing decreases in barriers to prescribing and nonadherence to their specialty medication(s) and can also gain expanded visibility into the entire patient journey. Through an IDN, manufacturers have the opportunity to establish a better connection to providers prescribing their medication(s) and therefore gain a clearer understanding of prescriber perspectives. Manufacturers also streamline their number of communication channels as IDNs dispense and manage their patients' prescriptions, and monitor patient adherence, adverse events, and/or other interventions as needed by a pharmacist.



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As the complexity of medications brought to market increases, the need to fully understand the provider and patient perspective increases as well. For a medication to be successful and effective, the entire medication access and patient journey processes must be considered—from distribution to dispensing to ongoing monitoring. For example, despite manufacturers spending hundreds of thousands to millions of dollars building hub services for providers and patients, clinical care staff often underuse these services because of the significant effort required to handle the added complexity of contacting and working with external vendors for each product. Delays in medication fulfillment have been reported due to a lack of resources dedicated to handling these additional administrative requirements.<sup>1</sup> To optimize the investment made by manufacturers and ensure treatment success for patients, the provider experience must be considered, including whether potential partners have the resources to help mitigate this risk.

## A Valuable Partnership

IDNs are valuable partners for manufacturers due to the expansive level of prescription management they employ when directly managing their patients. For example, integrated health systems with specialty pharmacy capabilities often embed clinical pharmacists and technicians into ambulatory care settings to help patients navigate medication access and affordability challenges. They provide

**Table 1. Themes From Interviews With Healthcare Providers on Experiences With Specialty Medication And Limited Distribution Networks**

	IHSSP not included in LDN	IHSSP included in LDN
<b>Communication</b>	Access to LDDs can be affected due to delayed and fragmented communication with external parties (i.e., insurance, drug manufacturer, external pharmacy).	These barriers were reduced.
<b>Clinic workflow and workload</b>	Administrative barriers associated with LDDs can interfere with clinic workflow and other patient care responsibilities.	Participants can spend more time counseling, educating, and supporting patients and their families.
<b>Financial aspects of medication</b>	Participants felt that the high cost of specialty medications affect patient outcomes.	Participants were confident that the pharmacy team would assist the patient with financial aspects of access.
<b>Advocating for patients</b>	If the external specialty pharmacy fails to provide support for enrolling in patient assistance programs, participants do extra work advocating for their patients, which interferes with patient care.	The nursing staff can spend more time with patients.

IHSSP, integrated health-system specialty pharmacy; LDD, limited distribution drug; LDN, limited distribution network.

patient education, assist with insurance prior authorizations and appeals, and advocate for patient assistance programs when needed. Having dedicated staff familiar with clinical monitoring obligations, insurance eligibility requirements and patient assistance programs helps streamline administrative workflow and ensures patients can quickly initiate treatment.<sup>1</sup>

Beyond treatment initiation, IDNs continually monitor their patients via assessments and appointments. In accordance with accreditation guidelines and local and federal regulations, IDNs also capture, store and report applicable data about medications they dispense. In combination, this highlights how IDNs are already meeting requirements many manufacturers have for their LDN partners, while also showcasing the additional depth of information IDNs can provide due to the holistic nature of patient management they employ throughout the entire patient journey<sup>1</sup>.

When IDNs are not included in a manufacturer's network, they lose the ability to provide this same level of comprehensive care because they are unable to readily track medication access, fulfillment and initiation (Table 1). Without this data visibility, clinical care staff would be unaware of any delays or barriers to medication coverage that result in treatment lapses. Moreover, clinical staff also find routing prescriptions to be filled externally decreases transparency while increasing the time spent on administrative tasks that could instead be focused on clinical care.<sup>1</sup> As Sara Horst, MD, MPH, FACG, an associate professor in the Division of Gastroenterology, Hepatology, and Nutrition at Vanderbilt University Medical Center, in Nashville, Tenn., noted, "I take care of patients with inflammatory bowel disease, and often need to start complex medications that are subcutaneous, intravenous or in some cases a combination. These medication initiations are complicated and confusing for patients, my staff and me. Having a specialty pharmacist as a member of our team is absolutely necessary to navigate these medications. Without specialty pharmacy access to

dispense and manage these medications, the barriers to utilize these therapies are often insurmountable."

Adding pharmacies into an LDN can be challenging, which is why it is important for IDNs to demonstrate their value for future inclusion. Demonstrating the ability to meet or exceed data reporting requirements establishes a strong foundation for showing the ability to be a viable partner. IDNs have access to robust data and can deploy unique data reporting for patients seen by providers within their clinical care setting. Often, this capturing and reporting of data is already part of the IDN's day-to-day operations, which highlights how IDN capabilities are matching what manufacturers require from their LDN partners. Although these capabilities exist when patients are serviced directly by the IDN, if patients are required to fill externally, visibility into the patient journey may be either limited or nonexistent depending on the service model.

With this in mind, an IDN strategy does not suggest that only IDNs be included in a limited or exclusive distribution network, nor does it suggest all IDNs be included in a distribution network. It simply encourages decision makers to consider granting access to potential partners that are already operating in unison with their partnership criteria. Table 2 showcases how an IDN can exemplify its capabilities to match a manufacturer's inclusion requirements.

Starting with a pilot, or short-term program, can help mitigate risk for both parties by allowing for limited network access to confirm the viability of a long-term partnership. During this period, the pharmacy will confirm its ability to satisfy data and reporting requirements and present the benefits of improved medication access and clinical coordination for patients.

### Vanderbilt's Approach to Accessing LDNs

Vanderbilt Specialty Pharmacy (VSP) has used trial opportunities to obtain access to LDN specialty medications. By demonstrating comprehensive capabilities to provide care

**Table 2. Example Criteria to Evaluate Whether an IDN Can Meet a Manufacturer’s Distribution Requirements**

Potential criteria	Capability example
Data reporting	Dispense and status level
	Clinical outcomes
	Longitudinal patient tracking
	Aggregator or tokenization experience
	REMS reporting
	Ability to work with tokenization software
Special designations	Accreditation
	Center of Excellence
	Clinical trial site
Pharmacy services	REMS management
	Coordination of pretreatment requirements
	Insurance approval and financial assistance
	Primary point of contact
	Tailored interventions and therapy management protocols
Pre-/post-launch strategy	Diagnosis identification (ICD-10)
	Payor issues and resolutions post-launch
	Collaboration with physicians/specialist
	Business reviews between pharmacy and manufacturer

REMS, Risk Evaluation and Mitigation Strategies.

and data insights across the entire patient journey as an IDN, VSP was able to showcase to manufacturers the benefits of partnering with an IDN. After obtaining access to the LDN medication, both parties were able to develop and implement a structured process to ensure successful patient monitoring, outcomes and data reporting.

Within the past year, VSP has entered into contractual agreements or pilot programs for access to several limited or exclusive distribution medications. Each distribution expansion began with collaborative conversations between

VSP and a manufacturer to better understand each side’s needs and capabilities, and to establish the framework for what would be required for future inclusion. These meetings involved representatives from clinical pharmacy operations, VSP’s outcomes research team, VUMC’s healthcare team and manufacturer representatives. By outlining the entire patient and provider experience and demonstrating the capabilities and benefits of partnering with an IDN, both parties were able to better understand the entire prescription process and how therapy can be optimized for VSP’s patient population.

In these cases, VSP was ultimately added to distribution networks due to the additional value shown from current partnerships and the proven ability to provide solutions to overcome barriers to appropriate patient identification, the prescribing process and optimizing the patient journey. Since VSP has been added to the network, ongoing business reviews with the manufacturer have been conducted to assess the clinical protocols that were put in place and evaluate how the net-

work expansion impacted patient and provider satisfaction. Through collaborative partnership, IDNs can work with manufacturers to develop mutually beneficial partnerships. Doing so enables IDNs to better serve their patients, providers and communities, while providing manufacturers with visibility on the provider and patient experience.

**Reference**

1. Peter ME, Zuckerman AD, Cherry E, et al. Exploring healthcare providers’ experiences with specialty medication and limited distribution networks. *PLoS One*. 2022;17(8):e0273040.