

Toolkit for Evaluating Complex Medication Therapies and Creating Customized Scopes of Service Based on Medication Therapy Considerations

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Purpose

This toolkit aims to provide a framework for both medication-related and scope of services-related considerations that health system specialty pharmacies (HSSPs) may apply as they evaluate specialty medications and determine if the traditional specialty scope of services applies or if alternative scopes of service could be utilized based on the unique medication considerations evaluated.

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Introduction & Purpose

As the pipeline and marketplace for specialty medications continue to grow, so too grows the need to better equip ourselves with tools and a framework for evaluating this diverse group of medications. The definition of a "specialty" medication is as complex as the medications themselves, however, it is clear that integrated health system pharmacies, including specialty pharmacies, are well-positioned to address the unique needs of each therapy and offer customized scopes of services tailored to meet the complexity of care associated with each medication.

Alternative scopes of services can be a clinically appropriate way to ensure cost-effective care while meeting unique patient and population needs for non-traditional specialty therapeutic areas such as diabetes, lipid management, anticoagulation, osteoporosis, migraine, and many others.

This toolkit aims to provide a framework for both medication-related and scope of services-related considerations that health systems pharmacies may apply as they evaluate specialty medications and determine if the traditional specialty scope of services applies or if alternative scopes of service could be utilized based on the unique medication considerations evaluated.

Considerations for Evaluating Medication Inclusion in Specialty Pharmacy Scope vs. Alternative Scopes of Services

Patient-specific Considerations

- Adherence, Pharmacogenomics, Social Determinants
 - Therapies under consideration for a traditional specialty medication scope of service likely have a strong need for monitoring adherence to maximize the quality of life and reduce disease flares. These are medications for which it is not uncommon for patients to experience interruptions in therapy due to their symptoms of disease. Medications under consideration when not adhered to can lead to increased medical utilization for disease flares up to and including hospitalization. Improving adherence to these medications can reduce the total cost of care for patients. Additionally, therapies may be affected by a patient's genomic profile which can alter how well a patient may experience the therapeutic effects of an agent. Considerations such as social determinants must be considered to ensure patients can adequately access and afford their medications.

Medication Storage and Handling

- Medication Storage
 - Medications may require enhanced storage such as refrigeration and tight temperature windows. Products that require refrigeration may also necessitate services capable of managing both how they are stored in the pharmacy, in transit, and at the patient's home. These medications quickly lose their potency and efficacy when not stored in their optimal conditions, and thus would benefit from enhanced storage conditions associated with traditional specialty medications.
- Hazardous Drug Considerations
 - Medications need to be evaluated to see if they are hazardous and potentially harmful to staff or patients. The extent to which they are hazardous can drive how or where the

medications are stored, how they are handled, and how they are shipped. Some of the references or criteria you may consider in the evaluation of hazardous drugs are the following:

- The NIOSH List or if the medication has a mechanism of action on the list
- Evidence of carcinogenicity/mutagenicity/genotoxicity in the package insert or Safety Data Sheet (SDS)
- Evidence of potential reproductive toxicity
- The manufacturer-specific handling information (MSHI)
- The Pregnancy and Lactation Risk category

Safety & Pre-requisites to Initiation

- Adverse Drug Event Risk and Black Box Warnings
 - Medications should be evaluated for potential risk for adverse drug events with improper use or administration, drug-drug and drug-food interactions, lab value fluctuations, etc. Medications that need to be closely monitored to ensure that adverse drug events are prevented may warrant a more comprehensive scope of services. Additionally, these medications require extra steps to be taken to educate or manage adverse drug events either prophylactically or in response to these events. Some of these medications may require supportive medications for managing adverse drug reactions (e.g. antiemetics for oncolytics, antidiarrheal medication for ILD, epinephrine injection for allergy).
- Monitoring Requirements
 - Evaluate if the medication requires labs, immunizations, or imaging before initiation per package insert, insurance approval, and clinical guidelines (i.e. TB testing, LFT, EKG, antibody levels, etc.). Multiple pre-requisites can be coordinated and streamlined to expedite a safe initiation of the specialty medication.
 - During the initiation of the therapy, does the patient require frequent monitoring (first dose observation, weekly, monthly, or more frequently).
 - Medications with a narrow therapeutic index include high-risk medications and those with clinically significant impact. A multitude of considerations including laboratory monitoring, care coordination, dose adjustments, and triaging & escalation of dose-limiting side effects could be facilitated by expanded services. Certain medications and/or groups could facilitate an organic bundling with other medications in specialty disease states whereas others may be disconnected.
- Risk Evaluation and Mitigation Strategies
 - Risk Evaluation and Mitigation Strategies is a drug safety program that the United States Food and Drug Administration requires for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The majority require a medication guide to be distributed with the medication and some have additional requirements like training and documentation from the patient, provider, and pharmacy. The specialty pharmacy team can help coordinate the process and ensure all criteria are met to comply with the program.

Patient Education & Dosing Complexities

- Dosage Form
 - Medications with unique or complex dosage formulations such as self-injectables, patches, etc. present opportunities for closer pharmacist management to provide education on the administration technique and assess adherence.
- Dosing Schedule
 - Medications with non-standard or complex dosing schedules such as titrated medications, medications dosed in cycles, or medications with many drug interactions can pose a risk for improper administration and potentially poor patient outcomes. Having a higher-touch patient-pharmacist relationship may improve patient understanding and outcomes with these medications.
- Importance of Adherence to Outcome
 - Adherence is important to achieving the intended therapeutic outcome(s) for all medications, however, some medications such as those used for the treatment of HIV, Hepatitis C, or transplant, can have serious and potentially irreversible consequences if patients fail to take their medications as prescribed. For medications identified as having high-risk consequences for non-adherence, increasing the scope of services provided to patients on these medications can potentially mitigate the risk of poor outcomes.
- Health-care Provider Administered Medications
 - Some medications covered under the pharmacy benefit require administration by a health care provider. In these scenarios, extra coordination is required to ensure that the medication delivery to the clinic is coordinated with the patient's appointment.

Drug Access

- Ordering Prescriber/Hospital Discharge
 - Medications prescribed inpatient and filled for the first time at discharge have inherent challenges. Variation in prior authorization service level between weekdays, weekends, and non-business hours could lead to multiple and preventable rate-limiting steps. A last-minute change in therapy utilization could require last-minute clinical assessment, education, or procurement which could be challenging for optimized outcomes with non-business hours staffing. Coordination is needed between the discharge entity or pharmacy and the patient's longitudinal pharmacy to prevent lapses in therapy.
- Limited Distribution Drugs
 - Limited distribution drugs inherently create supply chain, patient access, and care coordination complexities. Medications frequently have criteria for participation by manufacturers, may be associated with REMS or data requirements, and could have significant insurance barriers for prior authorization approval. Without sufficient investiture, gaps in care can be realized with transitions of care.
- Complex Procurement
 - Some medications will have complex procurement requirements outside of the usual wholesaler procurement channels that are typically utilized. Medications acquired through drop-ship, direct-order, or consignment may influence the complexity of the handling of the product and may warrant inclusion/exclusion from the traditional specialty scope of service.

Financials

- Revenue/Reimbursement
 - Each medication will have unique contractual reimbursement rates within payer contracts. For drugs not designated as “specialty” by the payer, health system may need to consider the individual financial impact of dispensing a product when determining inclusion or exclusion of the product from their specialty pharmacy scope of services. Financial considerations should be balanced with patient and product specific needs. Consideration of the overhead resources that can be allocated to support the product based on its reimbursement or contribution margin should be factored alongside considerations for patient experience, patient safety, quality of care, and cost-avoidance. In addition to reimbursement at the drug level, additional billable services such as Medication Therapy Management (MTM), may also help institutions assess the scope of service provided for each medication
- Acquisition Cost of the Medication
 - On the expense side of the equation, acquisition cost is an important consideration for evaluating the total financial vitality of medications serviced within the pharmacy. Some medications may be eligible for contractual or programmatic discounts, others may be subject to programmatic exclusions (ex. Orphan Drug exclusion from 340B program).

Considerations for Implementing Alternative Scopes of Service

Not all specialty medications will necessitate the same scope of services. The dimensions listed above can help each health system specialty pharmacies (HSSPs) evaluate the applicability of each of the service areas (below) based on medication assessment.

Below are common scopes of service that apply to traditional specialty medications. HSSPs may consider omitting or augmenting the traditional application of these services based on medication needs assessment.

Patient Management Program Services

- Collaborative Practice Agreements
 - Collaborative Practice Agreements (CPAs) can be utilized in a variety of care settings to improve the efficiency and efficacy of the care delivery model. The use of CPAs for refill authorization protocols, therapeutic interchanges (ex. Inhalers for payer formulary alignment), and comprehensive disease state management can all aid in improving targeted therapeutic outcomes and can be essential services for population health management or total cost of care arrangements.
- Clinical Assessments
 - Clinical assessments are traditionally a cornerstone of specialty pharmacy patient management programs and are often used to meet standards of specialty pharmacy accreditation. A specialty program may use medication-specific criteria (such as those described above) to define which medications are managed. Some non-traditional specialty medications may not require full assessments based on clinical need or pre-defined exclusion from the patient management program drug list. Decreasing the length or frequency or eliminating these assessments may increase efficiency and not sacrifice the best outcomes depending on the therapeutic needs of the medication and patient.

- Chart reviews
 - Chart reviews at certain intervals can help ensure the best outcomes. Depending on the patient and medication considerations, increasing or decreasing chart review intervals may be warranted.

Patient Access Services

- Prior Authorization
 - Prior authorizations may be needed for non-traditional specialty medications but in some cases are less likely to be required. Programs can weigh the benefits or risks of providing such a service outside of traditional specialty medications.
- Financial Assistance
 - While non-traditional specialty medications are usually less expensive than traditional specialty medications, financial barriers are still present for patients. For branded products, you will find copay cards and free medication programs for patients who meet the criteria. There are usually not many medication foundations for most non-specialty disease states but that is not true for all. Since there are fewer foundations available for non-specialty disease states and you cannot use copay cards for Medicare patients, finding assistance for patients with Medicare can be a challenge. Financial assistance may be required but difficult to access. Financial assistance is still a key area of service to help patients overcome financial barriers.
- Patient Outreach and Call Center
 - Staff can still provide proactive phone calls to coordinate refills as many do with specialty medications. Pharmacies might also utilize refill reminders via text or EMR portal communications. Pharmacies may also consider having patients manage their refills and request to have their medications filled and shipped using various platforms.

Benefits of Flexible Service Models in Specialty Pharmacy

Providing flexible or tailored services based on the assessed needs for each medication can allow specialty pharmacies to extend their unique skills in the management of complex therapies to improve outcomes among a broader network of patients while reducing overhead and labor costs for the pharmacy.



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