Defining Distribution: LDNs and Impact on the Patient Journey

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NCODA

Mission Statement

Our Mission is to empower the medically integrated oncology team to deliver positive, patient-centered outcomes by providing leadership, expertise, quality standards and best practices.

Our Guiding Values:
- Patient-centered
- Always collaborative

Vision

Our vision is to be the world leader in oncology by building a patient-centered medically integrated community whose focus is to innovate the continuity of cancer care, so every patient receives the maximum benefit from their cancer treatment.

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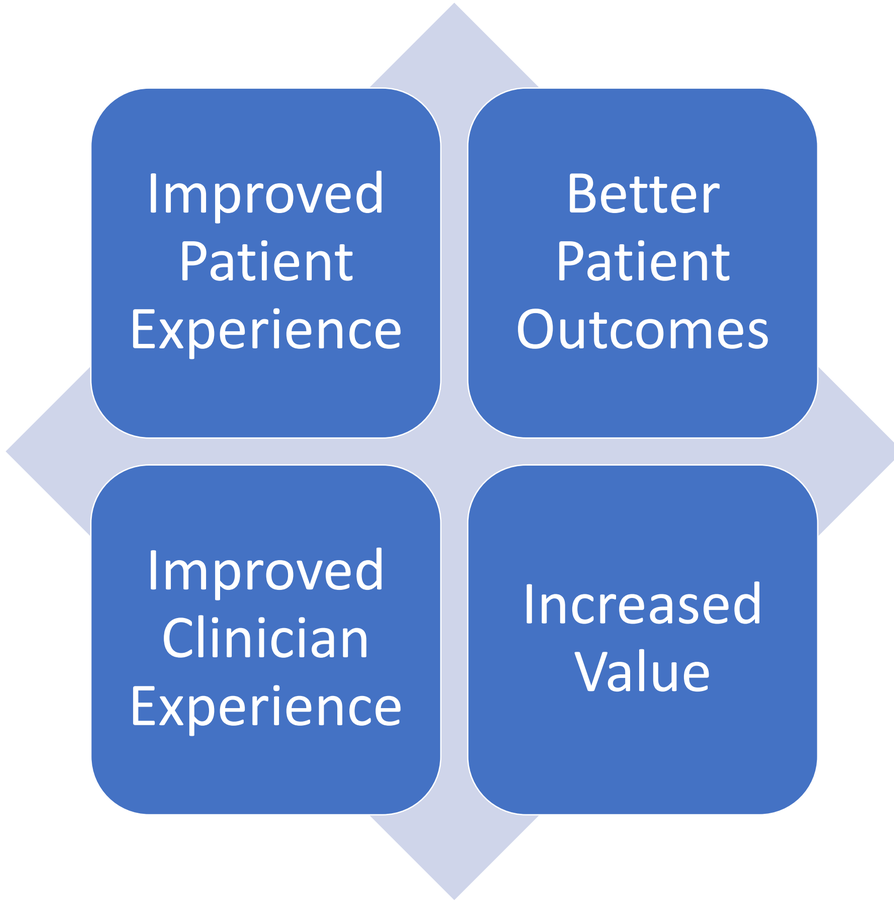
Objectives

- Understand the impact of the Medically Integrated Pharmacy on patient outcomes and cost effectiveness
- Highlight different roles on the integrated care team and the impact on the patient access journey
- Explore the limited distribution networks and the potential effect on MIP Capture Rates and impact to patients

A medically integrated oncology team represents a collaborative approach to cancer treatment and care management

Core Members

- Oncologists
- Pharmacists
- Advanced Practice Providers
- Nurses
- Nurse Navigators
- Pharmacy Technicians
- Social Workers
- Nutritionists
- Patient Advocates
- Mental Health Professionals



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The Medically Integrated Pharmacy (MIP) allows patient management directly at the clinic: enhancing patient outcomes and increasing cost effectiveness.

The medically integrated oncology team involvement in the prescription process results in:

- Quicker initiation of therapy
- Decreased fragmentation of care
- Thorough counseling and dedicated follow-up
- Better adherence and compliance

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Patient Journey Map

Phase 1

Prescription issued by prescriber / initial consultation

- **Oncologist***
- **APP***
- **Pharmacist**
- **Nurse***

MIP: Initial consult involves introduction to MID + expectations + initial medication counseling

SP: May be fragmented due to potential initial outreach hurdles

Phase 2

Insurance Verification and Financial Counseling

- **Pharmacy Technicians**
- **Financial Counselors**
- **Social/Case Workers***

MIP: Access to EMR and initial intake documents increases efficiency of PA process and Financial Navigation

SP: May be fragmented due to limited EMR access, and serving as middleman between practice and Insurance

Phase 3

Clinical Verification and Medication Preparation

- **Pharmacists in consultation with prescriber**

MIP: Clinical Pharmacists provide comprehensive chart workup due to access to EMR and patient records

SP: Clinical information may be based off pharmacy and insurance records, Limited EMR access represents a barrier to thorough clinical review

Phase 4

Patient Education and Support

- **Oncologist/ APP***
- **Pharmacist**
- **Nurse***
- **Nurse Navigator***

MIP: Education typically provided before and during treatment by different members of the integrated care team

SP: Education typically provided at initiation and as needed per patient request

Phase 5

Medication Delivery

- **Pharmacist**
- **Pharmacy Technicians**
- **Nurses***
- **Courier/Delivery Staff**

MIP: Are typically flexible regarding medication delivery, and can tailor delivery needs to the specific patient

SP: If an SP does not have local options, mail order can be a barrier for some patients

Phase 6

Ongoing Monitoring and Continuous Integrated Team Coordination

- **The entire medically integrated care team**

MIP: Multiple members of the integrated team participate in monitoring of patient on therapy often documented in the EMR

SP: Monitoring occurs; however, communication methods with integrated care team is fragmented

* May not be available in external SP model

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Improved Adherence Rates and Clinical Outcomes of an Integrated, Closed-Loop, Pharmacist-Led Oral Chemotherapy Management Program: Major Molecular Response in CML

Table 1. Improved Molecular Response Rates in Patients With CML

	Percentage (No.)			
Response	Clinical Trial	Preintervention	Postintervention	P
100% adherence	41 (36 of 87)[7]	48 (14 of 29)	60 (12 of 20)	.253* .104†
> 90% adherence	74 (64 of 87)[7]	NA	95 (24 of 26)	.029†
EMR (PCR < 10%)	66[13,14]	54.8 (17 of 31)	88.9 (16 of 18)	.0138*
MMR at 12 months (PCR < 0.1%)	60[9-12]	57.6 (19 of 33)	83.3 (15 of 18)	.0575*

NOTE. Table shows percentage of patients who achieved a goal adherence that was predetermined based on the literature; 95% of patients with CML who started therapy after the program was established achieved a goal adherence rate of > 90%.

Abbreviations: CML, chronic myeloid leukemia; EMR, early molecular response; MMR, major molecular response; NA, not applicable; PCR, polymerase chain reaction.

*Pre versus post.

†Versus clinical trial.[7]

https://ascopubs.org/doi/full/10.1200/JOP.17.00039#FA-1

The financial impact of MIP-interventions on oral oncolytics prescriptions was assessed utilizing NCODA's Cost Avoidance and Waste Tracker Tool

- Volunteers input data from their oncology practice into NCODA's Cost Avoidance and Waste Tracker tool to document any cost saving interventions or waste occurrences.
- 26 practices submitted cost avoidance data 677 cost avoidance events led to a total cost avoidance of $7,057,053.73

Net cost avoidance for the MIP's was $6,510,971.28 USD compared with $546,082.45 USD for the external mail-order pharmacies.

TABLE 2. Medications With 10 or More Interventions Leading to Cost Avoidance

Medication	No. of Interventions	Cost Avoided ($; USD)
Capecitabine	131	364,059.46
Palbociclib	80	1,074,288.85
Ibrutinib	43	464,859.34
Lenalidomide	40	565,280.41
Enzalutamide	22	264,506.60
Venetoclax	21	179,074.92
Abiraterone	28	320,865.60
Ixazomib	20	228,497.30
Temozolomide	18	125,059.70
Regorafenib	16	290,748.16
Everolimus	15	279,678.76
Cyclophosphamide	15	9,499.04
Axitinib	14	243,904.00
Pazopanib	13	163,834.90
Afatinib	11	102,569.20
Cabozantinib	11	224,047.20
Nilotinib	10	130,960.44
Dasatinib	10	115,993.30

Abbreviation: USD, US dollars.

https://ascopubs.org/doi/full/10.1200/OP.22.00022

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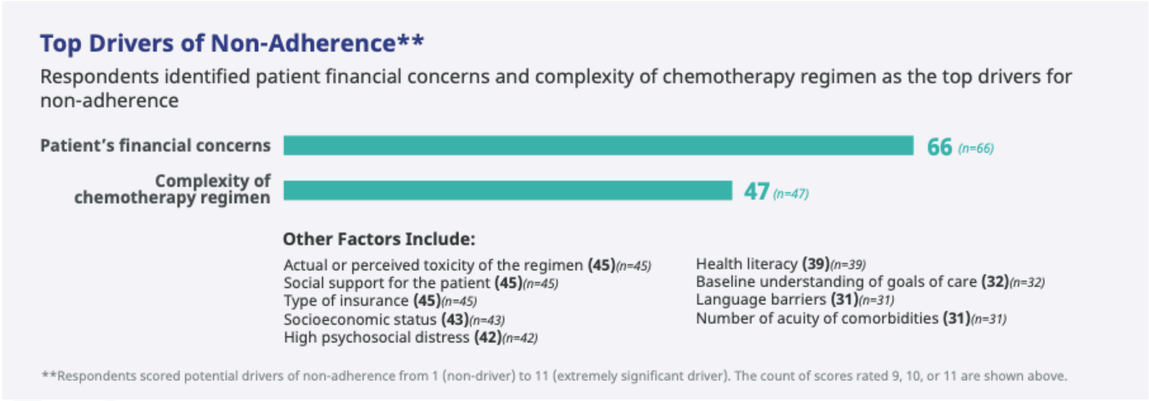
MIP practices create disease state and patient specific workflows to provide optimal and quality patient care.

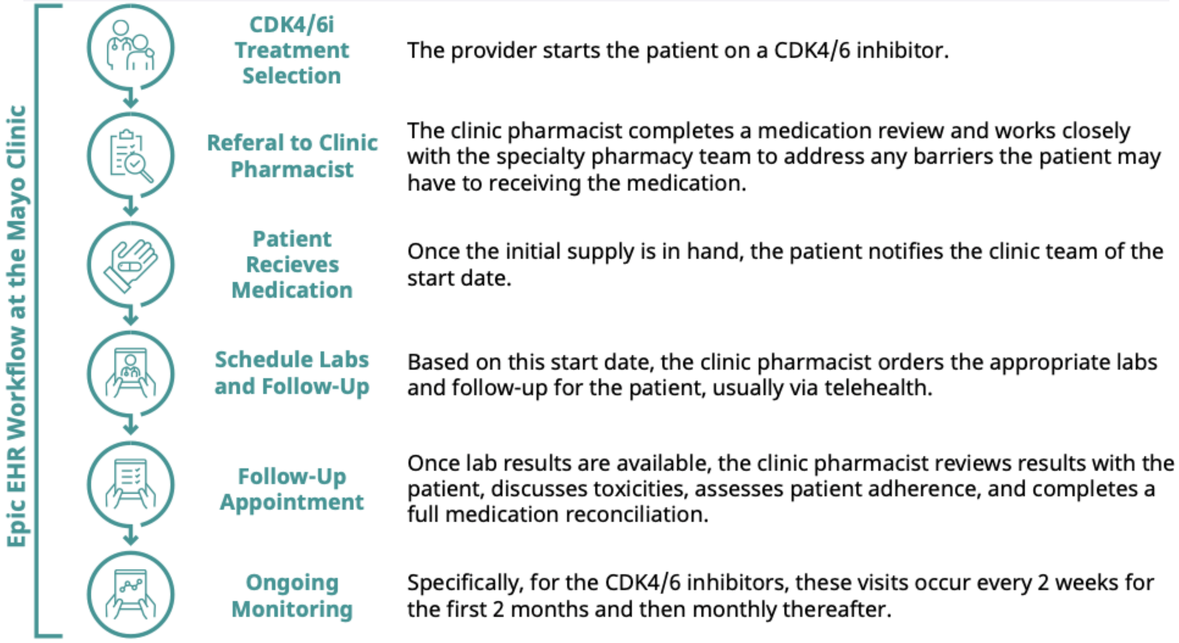
NCODA, in collaboration with Pfizer Oncology, conducted an online survey of its members in May 2021 to better understand adherence risk assessment and the management of patients receiving oral oncolytic therapy.

The results were presented in a Survey Research Paper to

- Understand current practices to identify and/or triage patients at high risk of non-adherence
- Identify the solutions that Medically Integrated Dispensing (MID) pharmacies are utilizing to optimize patients' adherence to oral oncolytic treatment

Mayo Clinic and Billings Clinic pharmacy processed were highlighted as part of the initiative, representing different models for patient management





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Limited Distribution Drugs (LDDs) are medication only available through certain pharmacies.

LDDs are specialty medications, typically requiring unique fulfillment an/or patient care support services including:

- Coordination of Care
- Maintaining cold-chain or mail order delivery logistics
- Products requiring REMS
- Benefits Investigation, PA and PAP management
- Disease State Management

Also, these medications can be high cost, part of a complex treatment regimen, for rare disease, or treat diseases marked by long-term symptoms, side effects, or increased fatality.

Manufacturers will work with a small number of pharmacies (the Limited Distribution Network – LDN) to dispense these LDDs

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Limited Distribution Networks can be challenging to navigate for clinicians and commercial patients due to definitions of what constitutes “limited distribution”

Independent Specialty Pharmacies

Onco360

Biologics by McKesson

PBM-Owned Specialty Pharmacies

FROM: THE 2024 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS

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NCODA is involved in discussions around defining an exclusive LDN Model, and identifying manufacturers with products utilizing this MIP supportive model

Script Retention Rates by Pharmacy Network

Pharmacy Network	Script Capture Rate (All Payors)	Script Capture Rate (Commercial Only)
No PBM-owned SP	98%	95%
1 PBM-owned SP	79%	40%
3+ PBM-owned SPs	58%	15%

Independent Pharmacy Network?
MIP Direct Network?
Referral Rates vs. Capture Rates
vs. Retention rates? OH MY!

Retention Rate of LDD with an exclusive distribution network

Large Practice	MIP Retained	Sent to SP	TKI Script Retention Rate
Q1'23	16	0	100%
Q2'23	17	0	100%
Q3'23	21	0	100%
Q4'23	13	0	100%

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Conclusion and Other Considerations

- Medically Integrated Pharmacy allows for the care team to be involved throughout the entire process resulting in decreased fragmentation and increase care quality.
- The current Limited Distribution Framework results in commercial patients being pulled away from filling in office.
- There is a need to standardize the LDN definition to increase transparency and to set a standard for manufacturers to utilize the model
- Keeping prescriptions in house has impact to the business of oncology as well

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