NCODA

NCODA Resource Guide

Integrated Oncology

MEDICALLY INTEGRATED DISPENSING PHARMACY (MIP): ASCO-NCODA STANDARDS UPDATE	
Topic	**Standard**
Domain 1. Patient-Centered Quality Standards	
1.1. Health equity and social determinants of health	**1.1.1.** Patients should be evaluated for social risks, health literacy, diagnosis and/or disease perceptions, and medication beliefs before prescribing oral anticancer medications. Refer to community and practice resources, such as NCODA's process, as appropriate.
	1.1.2. Patient care should be tailored to address cultural, linguistic, and socioeconomic factors.
1.2. Patient communication and documentation	**1.2.1.** Patient onboarding activities should include an explanation of the specialty pharmacy process, including the affiliation and close working relationship with the prescribing physician and healthcare team.
	1.2.2. Activities focused on securing drug access by coordination and submission of prior authorization, evaluating patients' ability to afford copays, and seeking financial assistance or support programs to ensure therapy initiation should be a seamless transition by accessing and providing documentation in the patient record. Point of contact, if someone other than the patient, including confirmation of authorization under HIPAA, should also be included.
	1.2.3. A direct phone line must be available during normal business hours for immediate assistance. Messages left on this line should aim to be returned within the same business day, but no later than 24 hours. Patients should have access to 24/7 support. If an answering service or other technology is utilized, the pharmacist or staff members should be available for callback within a reasonable timeframe. A phone tree must be in place appointing alternate points of contact for escalation if needed. Patients should be provided with clear instructions on how and when to contact the pharmacy, including, but not limited to, questions about medication use, side effects, potential adverse events, reporting missing or damaged medications, and requesting refills or updates on prescription orders. All information should be provided to the patient verbally and in writing with their prescription medication.
	1.2.4. Pharmacies may utilize technologies that facilitate remote communication, which may include telehealth, apps, and electronic portals.
	1.2.5. Every patient encounter should be documented in the patient record. In most cases, this would be an electronic medical record, and the Expert Panel for these standards endorses the use of electronic documentation. All questions posed by the patient or guardian and/or caregiver, related to process or clinical matters regarding therapy, should be documented in the patient's record. In cases where the patient cannot be reached, attempts should be documented, and follow-up should be coordinated with the extended medical team during the next scheduled clinic visit, as appropriate.
	1.2.6. All tools used to communicate with patients must be compliant with the Health Insurance Portability and Accountability Act and sanctioned by the MIP's affiliated institution or practice.
1.3. Benefits investigation and access coordination	**1.3.1.** Staff members within the MIP with specialized expertise should be assigned to each respective step of the patient journey to ensure coordinated and comprehensive access to care.
	1.3.2. All aspects of benefit investigations will be coordinated by the MIP, including primary and secondary insurance coverage, determination of formulary coverage including preferred drug or step edit requirements, prior authorization requirements and completed submission including biomarker testing, patient out-of-pocket cost inclusive of deductibles and copay amounts, evaluation for financial assistance eligibility, and comprehensive support for program enrollment including but not limited to charitable foundation, patient assistance programs, low-income subsidy programs, manufacturer copay cards or assistance programs, or the Medicare Prescription Payment Plan as applicable. A non-pharmacist MIP team member (e.g., pharmacy technician) may assist in managing the patient medication acquisition process, discussions with the patient, and completing applications on the patient's behalf.[1]
	1.3.3. Prescription benefits should be documented in the patient's record.
	1.3.4. The MIP will implement strategies and standard operating procedures to address prescription abandonment due to financial toxicity or situations where a filled prescription is not picked up.

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1.4. Education and medication dispense	**1.4.1.** Before initiation of therapy with an oral anticancer medication, a formal patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician's assistant. The discussion should include drug name (generic and brand), dose and schedule, potential adverse effects and how to properly manage them, potential drug-drug interactions, fertility (if applicable), treatment goal, duration of therapy, storage and handling, and financial and affordability considerations.[2-4]
	1.4.2. An informed consent form (or assent if applicable) outlining the intent of therapy should be reviewed with the patient (and their caregiver, if applicable) by a patient educator. The patient consent may be provided verbally or by signing a consent form. The patient should provide consent only after all questions have been addressed. For written consent, the patient will receive a copy for their records, and the original document will be included in the patient's record. Verbal consent should be documented as determined by institutional policy.
	1.4.3. Members of the MIP team should identify whether a patient has a caregiver, and if so, emphasize the importance of educating the caregiver in addition to the patient.
	1.4.4. Patient education should include diagnosis and the medication being dispensed. The patient's ability to understand the treatment plan and self-administer medication should be assessed. Additionally, a thorough review of current medications, allergies, and baseline lab results should be conducted to ensure safety and efficacy.
	1.4.5. At the time of any new therapy initiation, written patient education should be provided. This information should be provided in plain language with translation options wherever possible. The clinician should use techniques such as a teach-back to confirm that the patient understands the information contained in the written materials.
	1.4.6. Patient education must comply with federal, state, and Risk Evaluation and Mitigation Strategy requirements when applicable.
	1.4.7. Educational materials should be provided in multiple formats and may include medication kits with supportive care resources, self-care management strategies, as well as assistance in procuring devices or tools for self-monitoring when applicable.[5]
	1.4.8. The MIP will confirm medication dispense, confirm logistics for delivery or pick-up, maintain clear communication on any delays, and/or address any issues that may arise in this process.
	1.4.9. The MIP should document the exact date the patient begins therapy, in both the medical and pharmacy records, serving as the baseline for monitoring therapy effectiveness, adherence, and potential adverse events and aligned to the MIP care plan for patient follow-up on first dose experience, immediate concerns, and adherence review and reinforcement.
1.5. Adherence	**1.5.1.** A baseline adherence assessment should be conducted prior to dispensing the medication to evaluate potential barriers and risk of nonadherence. A specific nonadherence risk assessment tool, such as the one jointly developed by NCODA and Oncology Nursing Society, may be utilized for this purpose. This assessment should be completed prior to providing formal education and initiating therapy. Identified barriers to adherence should be addressed, and appropriate interventions implemented, to mitigate barriers and provide patient support before treatment begins.
	1.5.2. A multidisciplinary collaborative approach to monitoring adherence is recommended.[6-10]
	1.5.3. The MIP may provide calendars or other scheduling communications. If a patient calendar is provided, the calendar should include refill dates and medication schedules, clearly outlining specific dates to take medication, as well as laboratory and other monitoring parameters (e.g., electrocardiogram and/or echocardiogram) and clinician visits. A visual calendar may be helpful to illustrate combined oral and intravenous regimens. Include documentation of calendar information in the patient record.
	1.5.4. Use of an electronic portal, app, or written tool to obtain patient-reported outcome measures is encouraged.[11-15]
	1.5.5. Communication with patients and educational follow-up is essential to determine comprehension and retention of initial instructions, adherence, and toxicities.[16-18] Communications should be tailored to specific medications and patient comorbidities; re-education may be required. Subsequent follow-up calls to the patient should have a drug-specific cadence based on the anticipated time to onset of potential adverse events and be tailored to individual patient characteristics and risk factors, such as education, comprehension, performance status, tolerance to previous therapies, etc.
	1.5.6. The physician must be directly notified by the MIP team of any issues related to patient compliance, including delayed therapy initiation, tolerability, missed doses, in-home inventory, or missed lab appointments.

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1.5. Adherence	**1.5.7.** Oral anticancer medication should be dispensed in the original container as directed by the label. If medication is not dispensed in the original container or blister pack, pill caddies may be appropriate and helpful for patient adherence.
	1.5.8. The MIP should continually evaluate electronic and manual tools that may be helpful in advancing patient adherence. Smart pill bottles and mobile apps may be utilized to increase adherence.[6,19-24]
	1.5.9. The MIP should assess patient adherence and monitor toxicity at each clinical encounter. Metrics such as medication possession ratio or proportion of days covered can help evaluate adherence but have limitations when applied to oral anticancer medications. Therapy interruptions, such as those for toxicity management or disease response evaluation, require direct patient engagement and clinical context to provide a complete picture of adherence. Any variances, such as drug holidays or dose holds, should be documented within the patient record.
	1.5.10. Adherence assessment and documentation should include (1) confirmation the patient received the prescription, (2) the start date for the medication, and (3) verification that the patient fully understands how to take the medication, including the number of pills to take, specific days the medication should be taken, the dosing frequency per day, particularly for intermittent dosing, whether the medication should be taken with or without food, and instructions on safe handling.
	1.5.11. Ongoing drug utilization reviews should be conducted to verify the patient's active medication list, including all prescription and over-the-counter and herbal medications. These reviews should identify potential interactions or other concerns that may impact safety or efficacy.
	1.5.12. It is recommended to routinely inquire about any life changes, such as updates to insurance or financial status, that may affect the patient's ability to afford their medications.
	1.5.13. For prescriptions that will be dispensed outside the MIP, roles of the external specialty or mail-order pharmacy and the MIP should be determined and communicated to the patient. MIP teams are encouraged to apply the same rigorous clinical evaluation, counseling and documentation as they would for an internally dispensed prescription.
1.6. Safety	**1.6.1.** The MIP should implement a dual-check system for patient identity verification at the point of dispensing, using at least two patient identifiers (e.g., name, date of birth, and address) at both prescription entry and dispensing.
	1.6.2. The most recent physician note should be reviewed to validate the treatment plan, ensuring an appropriate diagnosis for newly prescribed oral anticancer medications or confirmation of therapy continuation. The stated dose must align with the prescribed dose and directions.
	1.6.3. Prescriptions for an oral anticancer medication, either processed internally at the MIP or transferred to an external pharmacy for fulfillment, should undergo the same rigorous review by the MIP personnel, including checks for duplicate therapies, potential drug interactions, toxicity risks, and an assessment of social determinants of health that may impact the patient's ability to access or adhere to the prescribed treatment.
	1.6.4. Drug utilization review should be conducted at each patient encounter to confirm recent medication changes, including over-the-counter medications, alternative medicines, and/or herbal therapies.
	1.6.5. Patient follow-up visits for toxicity evaluation and management should be scheduled throughout the course of therapy, with confirmation documented in the patient chart. This includes an initial tolerability and assessment visit shortly after the start of a new oral anticancer medication. Additional visits may be necessary for oral anticancer medications with potential side effects presenting later in therapy to ensure ongoing monitoring and management.
	1.6.6. Safety management and monitoring programs may be beneficial in improving patient comorbidities and managing side effects.[25-28]
	1.6.7. Labeling of prescriptions should follow legal labeling requirements.
1.7. Refilling of prescriptions	**1.7.1.** Scheduled outreach via phone, text, or email should be conducted to confirm that the patient is taking the oral anticancer medication as directed, assess for side effects or toxicities, address medication-related concerns, and determine the number of pills on hand. Findings related to adherence and persistence should be documented within the EMR.
	1.7.2. The date of the patient's most recent clinic visit, the date of the next scheduled visit, and any scheduled labs, imaging, or relevant appointments should be verified. Additionally, the most recent progress note should be reviewed to confirm the prescribing physician's intent to continue therapy.
	1.7.3. Any patient concerns or indications in the patient's record suggesting therapy modifications or discontinuation or upcoming clinic visits should be discussed with the physician to determine whether the refill should be processed.
	1.7.4. Refill requests will be submitted electronically to the prescribing physician for approval, or an existing authorized refill on file may be utilized.
	1.7.5. Secured financial assistance should be applied during medication refill processing. Patients should be informed of their copay amount, and any changes in copay compared to previous fills should be communicated to the patient and investigated for additional financial assistance if necessary.

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1.7. Refilling of prescriptions	**1.7.6.** The date and method by which the patient secures the medication refill should be confirmed. The next pharmacy outreach should be scheduled and confirmed. The patient should be reminded of the refill process, the availability of the pharmacy, and how to reach the pharmacy with any questions or concerns.
	1.7.7. All interventions related to the patient's refill (e.g., coordination with injectable chemotherapy or newly prescribed medications) should be documented in the patient record. The intervention may need to be clarified with the patient, and staff should be prepared to address any questions the patient may have.
1.8. Medication disposal	**1.8.1.** Resources should be developed to establish a consistent and compliant framework for directing patients to authorized drug take-back locations and mail-back programs for proper medication disposal.
	1.8.2. MIP staff should be trained in effective patient communication regarding proper medication disposal, emphasizing protocols and general principles, such as avoiding flushing or disposing of oral anticancer medications in regular household trash.
1.9. Patient satisfaction	**1.9.1.** A consistent, patient-centered process should be established to collect, analyze, and act on patient satisfaction feedback. Key areas should include staff communication, navigation of the fulfillment process, education provided, timeliness, and overall satisfaction. Insights from this feedback should be systematically incorporated into pharmacy operations to drive continuous improvements in service quality and patient outcomes.
	1.9.2. Feedback should be solicited from patients through surveys to identify and address continuous improvement opportunities at MIP practices.
	1.9.3. Participation should be voluntary, offering patients multiple feedback options including in-person or phone surveys (direct or automated), paper forms, digital surveys, or patient portals.
	1.9.4. Patient satisfaction data results should be analyzed and trended as part of continuous quality improvement efforts to inform, evaluate, and enhance pharmacy practices.
1.10. Patient navigation	**1.10.1.** To ensure optimal treatment outcomes, MIPs should establish a structured patient navigation program aligned with Principal Illness Navigation principles. Certified professionals (e.g., pharmacists, nurses, social workers) should conduct patient-centered assessments addressing medical, emotional, cultural, and linguistic needs, providing individualized guidance through treatment plans, medication regimens, and transitions in care while offering emotional support and connecting patients with relevant community, financial, and social resources. All interactions and care interventions should be documented and maintained within the EMR to ensure transparency and continuity of care.
	1.10.2. Patient-reported outcomes should be integrated into the MIP workflows to capture real-time feedback, evaluate treatment effectiveness and refine navigation strategies as needed.
1.11. Quality management	**1.11.1.** MIPs are encouraged to seek specialty pharmacy accreditation through recognized organizations. Accreditation standards support effective quality management (continuous quality improvement, quality assurance, and performance improvement) within clinical oversight, operational excellence, and patient-centered care requirements.
	1.11.2. A quality management plan should be developed to monitor, evaluate, and improve all aspects of pharmacy services.
	1.11.3. The MIP should establish a quality management committee to report and analyze performance metrics and trends at regularly scheduled meetings.
	1.11.4. All staff members should complete regular training and competency assessment on pharmacy operations, patient communication, and clinical updates.
	1.11.5. Performance metrics and audits of quality management activities should be transparently shared with leadership, the MIP, and medically integrated teams to promote continuous quality improvements and measurable success in patient outcomes.
	1.11.6. Key performance indicators should be tracked, including medication dispensing accuracy and operational efficiency. Root cause analysis can be helpful in identifying underlying factors of errors or suboptimal outcomes.
	1.11.7. Data analysis and staff feedback should continually refine process improvement initiatives, including refinement of operational workflows.
Domain 2. Operational Quality Standards	
2.1. Dispensing	**2.1.1.** Workflow and process flow diagrams are recommended for interdisciplinary teams operating within both embedded and decentralized MIP settings. These diagrams should outline interdepartmental workflows, communication protocols, and documentation process to promote consistent collaboration and minimize redundancies. All relevant updates, including patient encounters, workflow progress or delays should be documented within the EMR, ensuring that all team members have access to up-to-date information for care coordination.
	2.1.2. A decision tree or flow map should be established to standardize the prescription dispensing process. This framework should encompass all steps, from prescription generation by the physician to medication delivery, receipt confirmation, and the patient's initiation of therapy.

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2.1. Dispensing	**2.1.3.** Routine staff training and scheduled meetings are recommended to enhance MIP team awareness of policy updates and flow changes. These sessions should also address updates to workflow as necessary. Regular audits of documented processes are encouraged to ensure accuracy and adherence to established procedures.
	2.1.4. Consider establishing pre-built, standardized instructions, including details for special instructions, to promote consistency and accuracy in labeling. Ensure all auxiliary labels are consistent with prescribing instructions and clearly communicate critical information.
	2.1.5. A final review process should be established to ensure that labeled instructions align with the patient's treatment plan and that any potential inconsistencies in dosing schedules or drug interactions are flagged, investigated, and resolved prior to dispense.
	2.1.6. Implement a dispensing audit process to detect and prevent mislabeled prescriptions, incorrect fills (e.g., wrong drug, strength, or quantity), and incorrect patient-to-medication matching. Real-time quality control checks should be conducted during the dispense workflow, and incidents of near misses should be recorded in a quality improvement log to track trends, identify systemic issues, and determine the need for corrective action plans.
	2.1.7. Standardized packing and shipping protocols should be established. These protocols should include processes for tracking shipments, addressing delays or lost shipments requiring re-shipment, and verifying that appropriate conditions (e.g., temperature, humidity) are maintained throughout the shipping process. Periodic reviews of these procedures are recommended to ensure compliance with quality standards.
	2.1.8. In the event of a lost or damaged medication, or any other issue in the patient receiving their prescription, the circumstances of the issue should be documented, the patient made aware, and the incident documented within the EMR. Determine if re-shipment will be covered by the plan provider, submit a new claim if required, and escalate to the appeals process as needed, or evaluate options for patient assistance programs or internal financial support to allow re-dispensing and avoid any delays in therapy.
	2.1.9. A structured approach to effectively manage drug shortages should be developed. This includes maintaining strong communication channels with wholesalers, exploring alternative suppliers, and regularly monitoring inventory levels to identify potential issues as early as possible. When shortages occur, the MIP should assess available allocation from wholesalers, evaluate alternative sourcing options, and determine the expected duration of the shortage. Plans for managing the shortage, including identifying suitable alternative therapies, incorporating national guidelines such as those from ASCO when available, or developing internal guidance if no publicly available recommendations exist, should be shared promptly with the healthcare team. Proactive communication with patients is essential during drug shortages. The MIP should inform patients about any potential delays or changes to their medication regimen, providing timely updates on the status of the shortage and any adjustments, including alternative therapy options, to minimize disruption to treatment. Ensuring alignment with evidence-based practices and maintaining continuity of care are critical.
2.2. Care coordination	**2.2.1.** Assigning a dedicated care coordinator can help oversee patient treatment plans, ensure timely execution of therapy milestones, and maintain accurate documentation within the EMR. Real-time communication to the care team reduces deviations from the treatment plan and enhances coordination of care across disciplines.
	2.2.2. Clear protocols should be established to facilitate seamless coordination for a variety of therapies, including multiple oral anticancer medications, oral anticancer medication and retail medications, oral anticancer medication and injectable medications, and oral anticancer medication with other treatment modalities, such as radiation or surgery. These protocols should include detailed instructions tailored to the patient's regimen, a process for medication fill synchronization, comprehensive therapy calendars to manage overlapping treatment schedules, procedures to identify and address potential interactions between therapies, and communication plans to align all members of the care team, including external clinicians.
	2.2.3. A collaborative practice agreement between pharmacists and physicians may be considered to shorten the turnaround time for processing prescriptions. Clinical activities of the pharmacist under the collaborative practice agreement may include dose rounding, dose adjustments, prescription refill renewals, and ordering laboratory tests.[29]
	2.2.4. Proactive measures should be taken to address any potential logistical challenges, e.g., insurance authorizations, delivery delays, back orders or impending inclement weather, to avoid treatment interruptions.
	2.2.5. Ensure patients receive consistent education about their treatment plan and how different therapies interact.
	2.2.6. Develop mechanisms to capture, track, trend, report, and respond to patient-reported outcomes or concerns related to therapies.
	2.2.7. A multidisciplinary team, including clinical, operations and administrative staff with relevant expertise, should evaluate newly approved drugs reviewing prescribing information, clinical data, approved indications, and determination of ordering access. Staff training should be developed and conducted to ensure proficiency in dispensing and managing the new medication, and workflows and documentation protocols should be established and integrated into EMR and pharmacy system. A mechanism for addressing barriers to access, reimbursement challenges, and distribution limitations should be developed. Information about new medications, including overview and education and confirmation that the medication has been reviewed and loaded into all systems and is available for physician prescribing and dispensing from the MIP, should be disseminated to all pharmacy and practice staff.

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2.3. Cost and avoidance waste	**2.3.1.** Implementing strategies to mitigate financial toxicity and reduce waste is highly encouraged. Approaches such as split-fill programs and drug repositories for dispensing unused medications can result in significant cost savings.[30-32] Additional strategies include comprehensive clinical evaluation and coordination, such as: assessing imaging for signs of disease progression that may necessitate therapy discontinuation or adjustment prior to next dispense; monitoring laboratory values for abnormalities that could require dose reduction, hold, or discontinuation; identifying intolerable side effects that would prompt a change in dose or discontinuation; and drug utilization review.
	2.3.2. Waste mitigation strategies should be integrated into patient management practices and tracked for their impact. Monitoring and documenting pharmacy-led interventions and estimated healthcare cost savings can demonstrate the value of these efforts. Tools such as NCODA's Cost Avoidance and Waste Tracker or other similar tools, are recommended to quantify those savings and highlight their significance to stakeholders.
2.4. Health disparities	**2.4.1.** Operational processes that incorporate social determinants of health assessments into MIP workflows to streamline access and reduce barriers to treatment may be aligned to principles of the Community Health Integration. The MIP should consider developing partnerships with local and national organizations to provide patient access to resources, such as transportation, housing, nutrition, and financial aid, to enhance patient-centered care and promote patient self-advocacy and quality of life.
Domain 3. Foundational Standards	
3.1. Mission statement	**3.1.1.** A mission statement should include three elements: 1. Our Cause: Define the who, what, and where the MIP serves. 2. Our Actions: Highlight the services and actions provided to support patients. 3. Our Impact: Describe the positive impact for the integrated care team and the patients throughout the patient journey and in outcomes delivered.
3.2. Organizational chart	**3.2.1.** The MIP should establish and maintain an up-to-date organizational chart detailing roles and responsibilities.
3.3. Business plan	**3.3.1.** Scope of Business: Specify closed-door status, ensuring exclusivity of services for patients within a specific practice.
	3.3.2. Licensing Requirements: Specify operations type as a licensed pharmacy or a physician dispensing program, adhering to state regulations.
	3.3.3. Pro Forma Analysis: Evaluate prescription coverage and identify payer or pharmacy benefits manager limitations, including a review of regional payer relationships.
	3.3.4. Limited Distribution: Identify any LDD networks that may impact patient access. Engage with pharma and biotech companies during the development of phase to understand and provide input on distribution models selected for emerging therapies. Keep an up-to-date list of all LDD and respective networks to ensure transparency and streamline operations including direct shipments. Develop and implement SOPs to assist patients in navigating options when the MIP is unable to access or dispense a medication. This should include proactive and clear explanation to patients for any LDD restrictions, coordinating with outside specialty pharmacies to minimize delays in treatment and continuing patient engagement, where possible, with education and care management.
	3.3.5. Medication Scope: Determine the type of prescriptions to be dispensed, including: oral anticancer medication, generic medications utilized in combination with an oral anticancer medication, supportive medications for symptom management (e.g., antiemetics), and controlled substances for pain control.
	3.3.6. Staffing Model: Provide a detailed staffing plan, with the preference for oncology-trained pharmacists and certified pharmacy technicians, navigators, and oncology-certified nurses.
	3.3.7. Facility Requirements
	3.3.7.1. Ensure compliance with State Board of Pharmacy requirements, as applicable, including state specific design or infrastructure standards such as the presence of a sink near the dispensing area for handwashing and sanitation.
	3.3.7.2. For any planned renovations or relocations to meet operational and compliance needs, ensure timely notification to any relevant credentialing or accrediting bodies as required by regulatory guidelines.
	3.3.7.3. Conduct a post-renovation or relocation assessment to verify compliance with applicable regulations priorto resuming dispensing operations.

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3.4. Implementation timeline	**3.4.1.** Ensure all state Board of Pharmacy requirements, payer contracts, and physical space designs are finalized well before dispensing begins. Checkpoints to validate operational readiness must be completed in advance of the first prescription being processed.
	3.4.2. Develop a comprehensive, clear, actionable timeline for launching MIP services, including milestones for facility readiness, licensing approval, payer onboarding and staff training.
	3.4.3. Establish an internal communication plan to ensure all members of the medically integrated team and administrative teams are fully informed about the scope of services to be provided by the MIP. Communication, timelines, and training plans should be developed for operationalizing any workflow changes associated with the MIP integration.
	3.4.4. Outreach strategy to inform patient of MIP services should highlight the benefits of the MIP, such as improved coordination of care, timely access to medications, and a dedicated support team. Clear instructions should be provided to patients regarding the option to transition care, how prescriptions will be managed, and next steps should they desire to receive or transfer care to the MIP. A plan for coordination and standardization of patient messaging and interactions should be developed and executed.
3.5. Business elements	**3.5.1.** The central business office and MIP leadership should collaboratively oversee establishment and management of business operations to ensure compliance, efficiency, and sustainability. Dedicated staff, distinct from buy-and-bill, are recommended to ensure clear role delineation and continuity.
	3.5.2. Pharmacy Service Administrative Organization selection and activation to support pharmacy operational, administrative and regulatory requirements. • Payer contracts including negotiated reimbursement rates, terms and conditions, network participation and credentialing support services such as monthly Office of Inspector General exclusion • Central pay services from respective pharmacy benefits managers and payers, reconciliation, aged accounts receivable • Patient billing and statements • Fulfilment of state, federal, and pharmacy benefit manager regulation and reporting requirements, such as monthly OIG exclusion and annual fraud waste and abuse training
	3.5.3. Pharmacy processing system selection with workflow design developed to support the specialty prescription fulfillment process. **3.5.3.1.** Ensure system integration capabilities with the EMR and/or practice management systems supporting patient demographic feed at a minimum. **3.5.3.2.** Workflow design set up within the system to support documentation and work queues throughout the prescription fulfillment process and refill management including patient communication and documentation. Comprehensive staff training should be provided with staff sign-off acknowledging receipt, understanding and proficiency in completing assigned responsibilities. Training materials should be developed, including step-by-step procedures and screenshots for all new hire training. An audit plan, including frequency of conducting, should be established, with recommendation that audits be conducted no less than annually, for determination of any root-cause analysis and following onboarding of new staff members.
	3.5.4. Identify and contract with a switch company to facilitate the electronic transmission of claims.
	3.5.5. Establish affiliation with a primary wholesaler and group purchasing organization. Develop infrastructure and workflow for online catalog access, ordering, and price file updates. Collaborate with wholesaler on drug delivery and timing as a component of inventory management.
	3.5.6. Obtain liability insurance coverage as required by payer contracts, considering facility coverage and individual professional coverage.
	3.5.7. Contract with a credit card processing company to facilitate secure and efficient payment processing.
	3.5.8. Develop and maintain workflow for claims submission, editing, adjudication, and reconciliation including SOP for obtaining patient insurance, application of secondary insurance or available assistance, evaluation of received adjudication amount and audit preparation and readiness for payer and regulatory requirements.
3.6. Dispensing space requirements	**3.6.1.** Establish a patient counseling area that ensures privacy and confidentiality for patient interactions.
	3.6.2. The need for the following infrastructure items should be considered: secure storage areas and shelving for medications, adequate workstations for pharmacy staff tailored to specific functions and sufficient space to promote productivity and safety, counting trays and bins for efficient workflow, a sink for handwashing (as required by state regulation), a refrigerator for temperature sensitive medications, and software and hardware to support dispensing operations.

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3.7. Communication plan	**3.7.1.** Develop a central communication mechanism to ensure timely and consistent communication with: • Physicians, staff, and patients • Practice leadership • Practice business office and/or contracting department
	3.7.2. Ensure that marketing materials (e.g., brochures, flyers, or website) are reviewed and approved by the MIP team and leadership before dissemination to maintain accuracy and compliance.
3.8. Policies and procedures	**3.8.1.** Establish and maintain policies and procedures (P&P) to ensure clarity, consistency, and operational excellence. Policies should define overarching principles and goals of the MIP, while SOPs provide a detailed step-by-step process to implement and operationalize policies.
	3.8.2. Integrate continuous quality improvement, quality assurance, root cause analysis and corrective action/preventative action processes into both P&P and SOPs. These processes should cover the following areas: • Daily dispensing operations and workflow management, defining workflows and establishing monitoring protocols to ensure accuracy and adherence to SOPs. Quality assurance measures should include routine checks and documentation audits to identify and address discrepancies proactively. • Comprehensive staff training with a quality assurance process to evaluate training effectiveness and staff proficiency. Use root cause analysis to investigate knowledge gaps or recurring errors and refine training programs accordingly, for both onboarding new staff and annual competency of existing staff. • Detail processes for internal and external audits, including a checklist of documentation and regulatory requirements. • Include procedures for secure shipping, tracking, and confirmation of medication deliveries independent of patient confirmation to document timely and accurate patient receipt. • Ensure uniform processes across all satellite locations, with defined documentation and tracking for medication receipt, storage and patient pick-up. • Establish clear guidelines for returning medications to stock in compliance with regulatory requirements and standards. • Define and document staff responsibilities and duties, ensuring accountability of individual roles and seamless workflows across functions. An ongoing education and training program should be implemented to ensure staff remain proficient and up to date on clinical guidelines, regulatory requirements, operational procedures, and technologies. Job descriptions should be provided and regularly reviewed and updated to reflect evolving organizational needs and advancements in patient care. Performance evaluations should be provided no less than annually and professional growth opportunities promoted across all functional areas. • Detailed procedures for recalled, discontinued, expired, damaged, adulterated, misbranded, and/or medications determined to be counterfeit in compliance with federal and state regulations. • Disaster plans and emergency preparedness to address potential disruptions, including loss of power, severe weather, and other emergency situations should include a robust data backup and systems recovery plan to protect patient information and maintain continuity of operations through remote access to critical systems. Recovery systems, data backup, and remote access should be tested regularly. Protocols should be established for maintaining telephone support, communication plans, coordinating with external pharmacies to facilitate seamless prescription transfer if operations are temporarily interrupted. Periodic emergency preparedness drills should be performed, and an emergency plan should be developed and distributed to staff. • Compliance with HIPAA requirements regarding personal health information.
3.9. EMR and pharmacy dispensing system infrastructure	**3.9.1.** Integrate the practice's EMR, pharmacy dispensing system, and practice management or other applicable systems to enable seamless bidirectional, real-time data exchange where possible. Integrate capabilities with external systems, such as transport vendors and specialty pharmacies to facilitate care coordination and prescription tracking.
	3.9.2. Equip workstations with dual or ultrawide screens to optimize workflow efficiency, allowing simultaneous access to EMR and pharmacy dispensing programs. Utilize cloud-based or hybrid system architectures to enhance accessibility, scalability, and disaster recovery readiness.
	3.9.3. Ensure access to multifunctional devices such as secure network-connected printer, copier, fax, and/or scanner machines for documentation, communication and prescription processing.
	3.9.4. Provide barcode scanners for inventory management and electronic verification of prescriptions.
	3.9.5. Implement secure mobile devices or tables for patient counseling, inventory review or EMR updates, particularly in telehealth scenarios.
	3.9.6. Ensure compliance with the latest HIPAA requirements and cybersecurity best practices, including multifactor authentication, encryption, and regular penetration testing. User access level controls should be established based on roles and responsibilities to reduce the risk of unauthorized data exposure.

MEDICALLY INTEGRATED DISPENSING PHARMACY (MIP): ASCO-NCODA STANDARDS UPDATE	
Topic	**Standard**
3.10. Processes and guidance for handling of medication	**3.10.1.** Establish and maintain robust safety protocols consistent with USP <800> Standards, ASCO Standards for Safe Handling, and other relevant occupational health guidelines and provide regular competency training to ensure staff understanding of proper handling, storage, and disposal procedures. Implement personal protective equipment requirements tailored to each task, including gloves, gowns, and masks or respirators, to minimize exposure risk. Establish protocols for handling spills, exposure incidents or emergencies, including easy access to spill kits and immediate reporting procedures.
	3.10.2. Develop protocols for receiving medication orders aligned with USP standards, the NIOSH guidelines, and OSHA regulations to mitigate occupational hazards. Ensure dedicated space and process for unpacking and inspecting hazardous drugs and secure medications chain of custody from receipt to patient delivery.
	3.10.3. Provide patients with education on safe handling and disposal of sharps, including the use of FDA-cleared sharps containers, ensuring emphasize on risks of improper disposal. Maintain a resource guide of authorized sharps disposal sites or mail back programs.

ABBREVIATIONS: **EMR:** electronic medical record; **FDA:** U.S. Food and Drug Administration; **HIPAA:** Health Insurance Portability and Accountability Act; **LDD:** Limited Distribution Drug; **MIP:** medically integrated dispensing pharmacy; **NIOSH:** National Institute for Occupational Safety and Health; **OSHA:** Occupational Safety and Health Administration; **P&P:** policies and procedures; **SOP:** standard operating procedures; **USP:** US Pharmacopeia

REFERENCES

1. Lau G, Alwan L, Chi M, et al: Expanding pharmacy practice through the use of pharmacy technicians as process navigators to facilitate patient access of oral anticancer agents. Journal of the American Pharmacists Association 59:586-592, 2019

2. Zerbit J, Chevret S, Bernard S, et al: Improved time to treatment failure and survival in ibrutinib-treated malignancies with a pharmaceutical care program: an observational cohort study. Annals of Hematology 99:1615-1625, 2020

3. Feral A, Boone M, Lucas V, et al: Influence of the implementation of a multidisciplinary consultation program on adherence to the first ever course of oral antineoplastic treatment in patients with cancer. Journal of Oncology Pharmacy Practice 28:1543-1551, 2022

4. Lin M, Hackenyos D, Savidge N, et al: Enhancing patients' understanding of and adherence to oral anticancer medication: Results of a longitudinal pilot intervention. Journal of Oncology Pharmacy Practice 27:1409-1421, 2021

5. Sikorskii A, Given CW, Given BA, et al: Patient Engagement With an Automated Telephone Symptom Management Intervention: Predictors and Outcomes. Annals of Behavioral Medicine 54:484-494, 2020

6. Mir O, Ferrua M, Fourcade A, et al: Digital remote monitoring plus usual care versus usual care in patients treated with oral anticancer agents: the randomized phase 3 CAPRI trial. Nature Medicine 28:1224-1231, 2022

7. Sargent W, Whalley A: Implementation and outcomes of a pharmacist-led oral chemotherapy clinic at VA Maine Healthcare System. Journal of Oncology Pharmacy Practice 28:1704-1708, 2022

8. Megeed A, Magas H, Accursi M, et al: The impact of a pharmacist-led oral anticancer clinic on medication adherence and laboratory monitoring. Journal of Oncology Pharmacy Practice 29:1921-1927, 2023

9. Curry MA, Chineke I, Redelico T, et al: Adherence to Oral Anticancer Medications After Implementation of an Ambulatory Adherence Program at a Large Urban Academic Hospital. JCO Oncology Practice 16:e350-e356, 2020

10. Krikorian S, Pories S, Tataronis G, et al: Adherence to oral chemotherapy: challenges and opportunities. Journal of Oncology Pharmacy Practice 25:1590-1598, 2019

11. Nachar VR, Farris K, Beekman K, et al: Clinician report of oral oncolytic symptoms and adherence obtained via a patient-reported outcome measure (PROM). JCO Clinical Cancer Informatics 3:1-6, 2019

12. Collomb B, Dubromel A, Caffin AG, et al: Assessment of patient reported outcomes (PROs) in outpatients taking oral anticancer drugs included in the real-life oncoral program. Cancers 14:660, 2022.

13. Doolin JW, Berry JL, Forbath NS, et al: Implementing Electronic Patient-Reported Outcomes for Patients With New Oral Chemotherapy Prescriptions at an Academic Site and a Community Site. JCO Clinical Cancer Informatics:631-640, 2021.

14. Harbeck N, Kates R, Schinkothe T, et al: Favorable impact of therapy management by an interactive eHealth system on severe adverse events in patients with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer treated by palbociclib and endocrine therapy. Cancer Treat Rev 121:102631, 2023.

15. Saadeh C, Hill M, Snowaert S: Patient-reported outcomes for oral oncolytic therapy: A pilot study utilizing an electronic patient portal in a community cancer center. Journal of Oncology Pharmacy Practice:10781552231162013, 2023.

16. Cakmak HSG, Kapucu S: The effect of educational follow-up with the motivational interview technique on self-efficacy and drug adherence in cancer patients using oral chemotherapy treatment: a randomized controlled trial. Seminars in Oncology Nursing 37:151140, 2021.

17. Bandiera C, Cardoso E, Locatelli I, et al: A pharmacist-led interprofessional medication adherence program improved adherence to oral anticancer therapies: The OpTAT randomized controlled trial. Plos one 19:e0304573, 2024.

18. Başoğlu S, Ü. P: The Effect of Education and Monitoring via Tele-Nursing to Elderly Cancer Patients Using Oral Anticancer Agents on Self-efficacy and Medication Adherence: A Randomized Controlled Trial. Seminars in Oncology Nursing:151692, 2024.

19. Collado-Borrell R, Escudero-Vilaplana V, Ribed A, et al: Effect of a Mobile App for the Pharmacotherapeutic Follow-Up of Patients With Cancer on Their Health Outcomes: Quasi-Experimental Study. JMIR mHealth and uHealth 8:e20480, 2020.

20. Mauro J, Mathews KB, Sredzinski ES: Effect of a smart pill bottle and pharmacist intervention on medication adherence in patients with multiple myeloma new to lenalidomide therapy. Journal of Managed Care & Specialty Pharmacy 25:1244-1254, 2019.

CONTINUED ON NEXT PAGE

REFERENCES

CONTINUED FROM PREVIOUS PAGE

21. Park HR, Kang HS, Kim SH, et al: Effect of a Smart Pill Bottle Reminder Intervention on Medication Adherence, Self-efficacy, and Depression in Breast Cancer Survivors. Cancer Nursing 45:E874-E882, 2022.

22. Greer JA, Jacobs JM, Pensak N, et al: Randomized Trial of a Smartphone Mobile App to Improve Symptoms and Adherence to Oral Therapy for Cancer. J Natl Compr Canc Netw 18:133-141, 2020

23. Karaaslan-Eser A, Ayaz-Alkaya S,The effect of a mobile application on treatment adherence and symptom management in patients using oral anticancer agents: A randomized controlled trial. European Journal of Oncology Nursing 52:101969, 2021.

24. Krok-Schoen JL, Naughton MJ, Young GS, et al: Increasing Adherence to Adjuvant Hormone Therapy Among Patients With Breast Cancer: A Smart Phone App-Based Pilot Study. Cancer Control 26:107327481988328, 2019.

25. Wang G, Truong H, Dang R: Impact of a pharmacist-led hypertension management program for oral chemotherapy in a specialty pharmacy setting. Journal of Oncology Pharmacy Practice 29:52-59, 2023

This summary table is derived from recommendations in *Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update*. This is a tool based on ASCO Standards and is not intended to substitute for the independent professional judgment of the treating physician. Standards do not account for individual variation among patients. This tool does not purport to suggest any particular course of medical treatment. Use of the standards and this tool are voluntary.

26. Bouleftour W, Muron T, Guillot A, et al: Effectiveness of a nurse-led telephone follow-up in the therapeutic management of patients receiving oral antineoplastic agents: A randomized, multicenter controlled trial (ETICCO study). Supportive Care in Cancer 29:4257-4267, 2021.

27. Chow S, Tan B: Effectiveness of mHealth apps on adherence and symptoms related to oral anticancer medications: a systematic review and meta-analysis. Supportive Care in Cancer 32:426, 2024

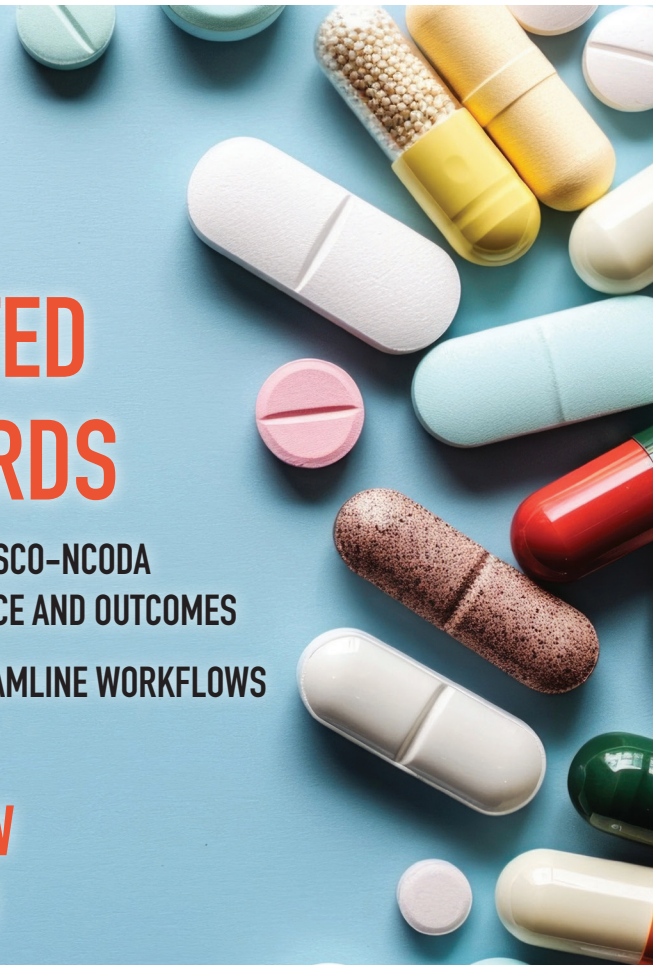
28. De Raya J, Modlin J: Evaluation of Pharmacist-Driven Approach Related to Monitoring for Neutropenia Related to CDK4/6 Inhibitors in Women With Advanced Breast Cancer. Journal of Hematology Oncology Pharmacy 14, 2024.

29. Wright AL, Matta SF, Kerr JR: Expansion of pharmacist practice in oral oncolytic therapy with a collaborative practice agreement. Journal of Oncology Pharmacy Practice 26:1886-1893, 2020.

30. Smale EM, Van Den Bemt BJF, Heerdink ER, et al: Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs. JAMA Oncology 10:87, 2024.

31. Smale EM, van Vlijmen B, Colen HB, et al: Feasibility of an Individualized Dispensing Program for Patients Prescribed Oral Anticancer Drugs to Prevent Waste. JCO Oncology Practice 19:e618-e629, 2023.

32. Staskon FC, Kirkham HS, Pfeifer A, et al: Estimated cost and savings in a patient management program for oral oncology medications: Impact of a split-fill component. Journal of Oncology Practice 15:e856-e862, 2019.



Oncology Optimized Limited Distribution (OOLD)

NCODA developed the Oncology Optimized Limited Distribution (OOLD) model to bring transparency, coordination and patient-centered care to the distribution of anticancer medications.

LEARN MORE:

OOLD is designed first and foremost to support medically integrated pharmacies (MIPs), ensuring that patients benefit from timely access, coordinated care, and improved outcomes. As part of this model, PBM-affiliated mail-order specialty pharmacies are excluded, while non-PBM pharmacies may dispense to provide access for practices without an MIP.

The **OOLD Search Tool** delivers essential therapy details-brand and generic names, indications, manufacturers, and distribution models. By classifying medications as Open Oncology Optimized Limited Distribution, or PBM-Influenced Limited Distribution, it supports informed decisions that enhance patient care and streamline access.

The **MIP Search Tool** quickly identifies Medically Integrated Pharmacies (MIPs) within oncology practices and highlights alternative ordering options. It supports integrated dispensing models that enhance care coordination, improve adherence, and optimize oncology outcomes.

These searchable NCODA resource are designed to assist oncology teams in navigating the complexities of oral anticancer medication distribution.
- Access these resources through the QR code above.

OOLD is an NCODA initiative dedicated to directly supporting the MIP and enhancing patient care.
For questions about OOLD or to connect with NCODA to learn more, please email contact@ncoda.org.

ONCOLOGY OPTIMIZED LIMITED DISTRIBUTION

REDEFINING ONCOLOGY DISTRIBUTION

By Jonas Congelli, RPh

The number of available oral anticancer medications has steadily increased over the past two decades, with oral medications playing a major role in the treatment of multiple tumor types.[1] Alongside this evolution, the medically integrated dispensing pharmacy (MIP) has become a best-in-class model for dispensing anticancer therapies while preserving a high standard of coordinated, patient-centered care.

Jonas Congelli

NCODA defines an MIP as a dispensing pharmacy within an oncology center of excellence that supports a patient-centered, multidisciplinary team approach.[2] This model enables real-time communication across the care team, improves access to anticancer therapies, and enhances outcomes by keeping treatment within the clinic's workflow. By integrating medication distribution directly into the oncology practice, MIPs streamline therapy initiation and monitoring, reduce treatment delays, and create a seamless experience for both patients and providers.[3,4,5]

ADVANCING MEDICALLY INTEGRATED, PATIENT-CENTERED CARE THROUGH ONCOLOGY OPTIMIZED LIMITED DISTRIBUTION

While MIPs are well-positioned to provide timely, coordinated care, their ability to dispense oral anticancer medications is often limited by how manufacturers choose to distribute their therapies.[6,7] In some cases, manufacturers may include Pharmacy Benefit Manager- (PBM) affiliated mail-order specialty pharmacies (PBM-SPs, those vertically integrated with large PBMs and payers, as part of their distribution network. This can prevent MIPs from filling prescriptions in-house, forcing patients to receive medications from external pharmacies that are disconnected from their care team.[7]

Limited distribution networks (LDNs) were originally intended to ensure clinical expertise and oversight of specialty medications,[8] but when PBM-SPs dominate these networks, it can disrupt continuity of care and delay therapy initiation. As more oral therapies come to market, the structure of these distribution networks plays an increasingly important role in the quality and coordination of cancer care.

This paper explores the interdependent relationships between the MIP and LDNs, highlighting how thoughtful distribution design can strengthen patient care and support optimal treatment outcomes. It also provides historical context for how these models have evolved and introduces updated terminology to bring clarity to the varying structures of LDNs across oncology.

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MEDICALLY INTEGRATED PHARMACY: A CLOSER LOOK

As stated, the MIP promotes a patient-centered multidisciplinary team approach into a clinic's workflow.[3] Direct dispensing enables enable faster therapy initiation, streamlined communication, and more effective management of oral anticancer therapies.[2]

While MIPs may vary in structure — some operating as formal pharmacies and others through alternative dispensing models — the defining feature is their integration with the clinical care team. This model allows oncology practices to manage medication access directly, aligning pharmacy services with clinical decision-making to support better patient outcomes.

Unlike traditional specialty pharmacies — which often operate independently from the oncology care team — MIPs are embedded directly within the clinic. This integration allows for real-time collaboration across the care team, enabling streamlined access to medications, timely clinical interventions, and a more seamless experience for patients.

The differences between traditional mail-order specialty pharmacies and MIPs are especially clear when looking at the patient journey. In the MIP setting, patients are introduced to the care process early, often receiving medication counseling and insurance navigation at the time of their initial consultation.

With full access to the electronic medical record (EMR), the MIP team can efficiently complete prior authorizations, verify clinical appropriateness, and offer personalized financial support. Throughout treatment, multiple care team members remain actively involved, monitoring and adjusting therapy based on real-time patient data.

External mail-order specialty pharmacies also provide important services but face limitations in accessing clinical information and coordinating with providers. This can result in delays in communication or therapy initiation, especially when mail-order delivery is the only fulfillment option.[9]

Also, due to the operational flow of the prescription-filling process, including time for delivery via mail, errant fills are increased, leading to waste and increase in cost to the overall healthcare system. In contrast, MIPs can offer more tailored delivery and education options that align with each patient's unique needs, streamlining the fulfillment process leading to increased cost avoidance and less waste.

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MIP/SP PATIENT JOURNEY MAP

PHASE 1	PHASE 2	PHASE 3	PHASE 4	PHASE 5	PHASE 6
Prescription issued by Prescriber/initial Consultation	Insurance Verification and Financial Counseling	Clinical Verification and Medication	Patient Education and Support	Medication Delivery	Ongoing Monitoring and Continuous Integrated Team Coordination
• Oncologist • APP • Pharmacist Nurse	• Pharmacy Technicians • Financial Counselors • Social Case Workers	• Pharmacists in consultation with prescriber	• Oncologist/APP • Pharmacist • Nurse • Nurse Navigator	• Pharmacist • Pharmacy Technicians • Nurses • Courier/Delivery Staff	• The entire medically integrated care team
MIP: Initial consult involves introduction to MID + expectations + initial medication counseling	MIP: Access to EMR and initial intake documents increases efficiency of PA process and Financial Navigation	MIP: Clinical Pharmacists provide comprehensive chart workup due to access to EMR and patient records	MIP: Education typically provided before and during treatment by different members of the integrated care team	MIP: Are typically flexible regarding medication delivery, and can tailor delivery needs to the specific patient	MIP: Multiple members of the integrated team participate in monitoring of patient on therapy often documented in the EMR
SP: May be fragmented due to potential initial outreach hurdles	SP: May be fragmented due to limited EMR access, and serving as middleman between practice and Insurance	SP: Clinical information may be based off pharmacy and insurance records, limited EMR access represents a barrier to thorough clinical review	SP: Education typically provided at initiation and as needed per patient request	SP: If an SP does not have local options, mail order can be a barrier for some patients	SP: Monitoring occurs; however, communication methods with integrated care team is fragmented

MAIL-ORDER SPECIALTY PHARMACY MODELS AND THEIR RELATIONSHIPS TO THE MIP

Mail-order specialty pharmacies play a vital role in supporting access to oncology therapies. However, the structure and alignment of these pharmacies can significantly influence how well they integrate with the clinical care team — and ultimately, how effectively they support the patient experience.

Some mail-order specialty pharmacies, such as Onco360 and Biologics by McKesson, operate independently of PBMs and maintain collaborative relationships with oncology practices. These organizations often work closely with MIPs, supporting seamless communication, efficient medication access, and continuity of care. Similarly, Prime Specialty Pharmacy — while affiliated with a PBM — has developed platforms like IntegratedRx that enable MIPs to remain closely involved in the dispensing process. In these models, patient choice is preserved, and care coordination remains strong.[10]

Other mail-order specialty pharmacies are part of large vertically integrated healthcare systems, where the pharmacy operates under the same ownership as a PBM or health plan (**Figure 1**). In these arrangements, prescriptions are frequently routed through the PBM-affiliated pharmacy by default, regardless of provider recommendation or patient preference.

This process, often referred to as prescription steerage, can limit the involvement of the oncology care team, delay therapy initiation, and contribute to fragmented care.[11, 12]

The distinction lies not in PBM affiliation alone, but in whether the mail-order specialty pharmacy model allows for clinical collaboration, patient-centered flexibility, and alignment with the oncology care team. When MIPs are enabled to work alongside specialty pharmacy partners, the result is more coordinated care, more informed decision-making, and better support for patients throughout their treatment journey.

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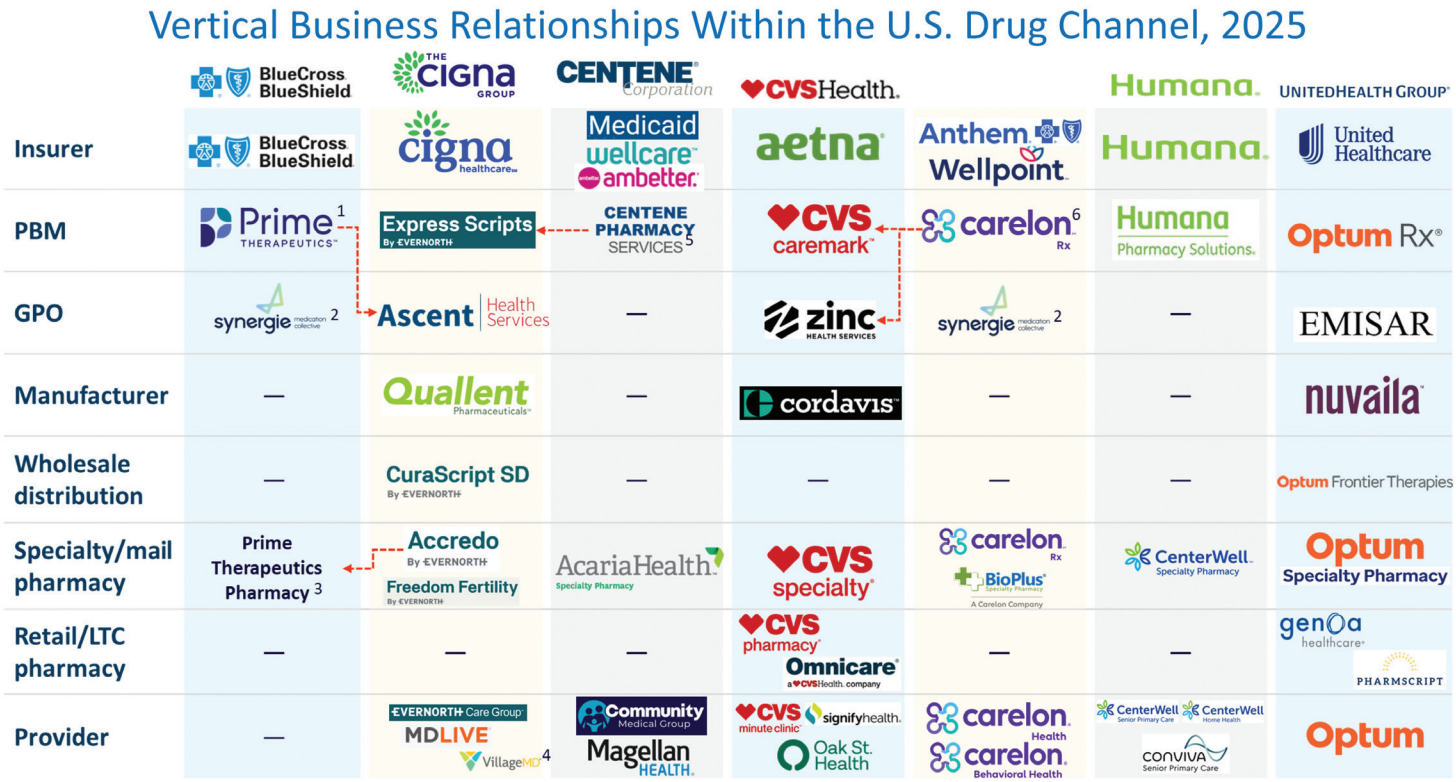
FIGURE 1: VERTICAL INTEGRATION OF MAJOR U.S. HEALTHCARE COMPANIES

ADAPTED FROM FEIN AJ. DRUG CHANNELS | APRIL 9, 2025[13]



PBM = pharmacy benefit manager; GPO = group purchasing organization; LTC = long-term care

1. Prime Therapeutics sources formulary rebates from—and has a minority ownership interest in—Ascent Health Solutions, which is part of Cigna's Evernorth segment.
2. Synergie is a buying group focused on medical benefit drugs. Its ownership includes the Blue Cross Blue Shield (BCBS) Association, Prime Therapeutics, Elevance Health, and other independent BCBS health plans.
3. Prime Therapeutics Pharmacy was previously known as Magellan Rx Pharmacy. Prime's clients have the option to use Express Scripts for mail/specialty pharmacy services.
4. In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. In 2024, it wrote down the full value of this investment. Walgreens Boots Alliance owns a majority of VillageMD.
5. Centene began outsourcing its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its Envolve Pharmacy Solutions pharmacy benefit subsidiary as Centene Pharmacy Services.
6. CVS Caremark provides certain PBM services to CarelonRx business. CarelonRx also sources formulary rebates from—and has a minority interest in—Zinc Health Services, which is a subsidiary of CVS Health.

Source: *The 2025 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 261. Exhibit does not illustrate every subsidiary business operated by each company.

DRUG CHANNELS INSTITUTE
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LIMITED DISTRIBUTION NETWORKS: BACKGROUND AND IMPACT

Limited Distribution Networks (LDNs) were originally developed to ensure safe and effective delivery of high-touch specialty medications. By partnering with a select group of pharmacies, manufacturers aimed to streamline handling, provide specialized clinical oversight, and improve patient support — particularly for therapies with complex storage, administration, or monitoring requirements.[8]

In recent years, increased consolidation across the healthcare landscape has led to increased vertical integration of mail-order specialty pharmacies with large PBMs and payers. While these changes may support operational alignment for some stakeholders, they have also contributed to a disruption of the original model benefit, leading to pharmacy steerage regardless of patient or provider choice.[11,12]

The way a distribution network is structured has a measurable impact on whether prescriptions are filled within the oncology clinic or diverted elsewhere. For patients treated within integrated oncology practices, the ability to fill prescriptions through their MIP supports stronger relationships, faster therapy starts, better adherence, reduced costs, and reduced fragmentation. In contrast, when prescriptions are routed through PBM-SPs, care coordination can be disrupted — slowing down access and limiting the oncology team's involvement in managing the patient's therapy.[3,4,5,14]

Data shows that the fewer PBM-SPs included in a network, the higher the prescription capture rate within the MIP. In networks that exclude these entities entirely, MIPs retain 98% of prescriptions across all payers (95% in commercial plans).

Data shows that the fewer PBM-SPs included in a network, the higher the prescription capture rate within the MIP. In networks that exclude these entities entirely, MIPs retain 98% of prescriptions across all payers (95% in commercial plans). That retention drops sharply as vertically integrated pharmacies are added. With one included, MIP capture falls to 79% (40% in commercial); with three or more, retention drops to just 58% (15% in commercial plans).[14]

The structure of the pharmacy network not only influences patient experience and access. It also has a direct impact on clinical and financial outcomes. When prescriptions are filled within the oncology practice, care teams can intervene more quickly, monitor adherence in real time, and make timely adjustments to therapy that leads to increased cost avoidance and less waste. This coordination leads to improved treatment continuity and greater patient satisfaction.[15]

Recent data further supports the value of integrated dispensing. A 2024 analysis by Prime Therapeutics found that patients who received oral oncolytics through integrated physician dispensing had significantly lower total costs of care compared to those using nonintegrated dispensing channels. After adjusting for patient characteristics, integrated models demonstrated a reduction of $5,379 in total healthcare spending and $6,069 in medical benefit costs per patient. These findings highlight how integrated dispensing supports not only high-quality care, but also meaningful value across the healthcare system.[16]

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TABLE 1: PRESCRIPTION CAPTURE RATE BY NETWORK AND INSURANCE TYPE [14]

PHARMACY NETWORK	PRESCRIPTION CAPTURE RATE (ALL PAYORS)	PRESCRIPTION CAPTURE RATE (COMMERCIAL ONLY)
No PBM-SP	98%	95%
1 PBM-SP	79%	40%
3+ PBM-SPs	58%	15%

INTRODUCING CLEAR TERMINOLOGY FOR LIMITED DISTRIBUTION NETWORKS

While LDNs have become a common part of oncology drug delivery, there is currently no standardized language to describe the various structures that exist. This lack of clarity can create confusion for providers, patients, and manufacturers alike — particularly as the number of oral anticancer therapies continues to grow.

To support greater clarity in distribution strategy and its impact on patient care, NCODA has introduced new terminology for describing LDNs.

NCODA's updated model includes three distribution categories with four definitions based on the level of integration and the type of specialty pharmacies included in the network.

These definitions are intended to standardize language across the oncology ecosystem, help providers assess their ability to retain prescriptions within the care team, and support meaningful dialogue with manufacturers about access and outcomes.

NCODA's updated model includes three distribution categories with four definitions based on the level of integration and the type of specialty pharmacies included in the network.

This revised terminology allows stakeholders to clearly distinguish between network designs and their clinical implications — ensuring that distribution decisions are better aligned with patient-first oncology care.

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LDN TERMINOLOGY TABLE

DISTRIBUTION MODEL	DEFINITION	PATIENT & MIP IMPACT	EXAMPLES
Closed Distribution	Medications available only through a highly restricted, manufacturer-designated network of specialty pharmacies, often due to Risk Evaluation and Mitigation Strategies or special handling requirements.	Tightly controlled access; may exclude MIPs entirely. Can delay therapy initiation and fragment care; influence is limited due to regulatory safeguards.	Revlimid, Pomalyst, Thalomid
Oncology Optimized Limited Distribution	Networks that exclude vertically integrated PBM specialty pharmacies (PBM-SPs), supporting dispensing through MIPs and independent mail-order specialty pharmacies.	Enables high care coordination; 98% retention overall (95% commercial). Improves adherence, patient satisfaction, reduces waste and cost, and supports integrated care.	Onco360, Biologics by McKesson, Prime Specialty Pharmacy (via IntegratedRx)
PBM-Influenced Limited Distribution	Networks that include one or two vertically integrated PBM specialty pharmacies, often shaped by payer or PBM pressure.	Reduces MIP retention (LDD1: 79%/40% commercial; LDD3+: 58%/15% commercial); increases care fragmentation and therapy delays.	Accredo (Express Scripts), CVS Specialty (Caremark) and Optum Rx (UHC)
Open Distribution Network	Medications are widely available through retail, hospital and mail-order pharmacies without restrictions. Includes Optum, CVS Caremark, and Express Scripts PBM-affiliated mail-order pharmacies.	Drastically reduces MIP retention (LDD3+: 58%/15% commercial); increases care fragmentation and therapy delays due to substantial decrease in MIP capture rate.	

ADVANCING A PATIENT-CENTERED APPROACH TO ONCOLOGY DISTRIBUTION

NCODA strongly supports the Oncology Optimized Limited Distribution model as the preferred standard for oral anticancer therapy access. By keeping prescriptions within the integrated oncology team setting and eliminating the influence of vertically integrated specialty pharmacies, this model enables the most coordinated, efficient, and patient-focused care. It reflects the core values of medically integrated dispensing and offers the clearest path to improving outcomes while preserving choices for both patients and providers.

NCODA recognizes that implementing a fully independent distribution model may not be feasible for all manufacturers. Market dynamics — including formulary restrictions, payer negotiations, and therapeutic area complexity — can introduce significant challenges. However, these realities do not diminish the importance of working toward a more transparent, patient-centered approach to drug distribution.

The Oncology Optimized Limited Distribution model represents a tangible step forward — one that prioritizes in-practice dispensing, fosters stronger patient-provider relationships, and supports high-quality, integrated care. Even incremental progress toward this model has a meaningful impact. As data has shown, limiting the number of vertically integrated specialty pharmacies in a distribution network improves prescription retention within the oncology clinic and leads to better adherence, improved patient satisfaction, lower costs, and improved outcomes.

We also recognize that healthcare is constantly evolving. In an ideal future, patient steerage would no longer be a barrier, and comprehensive policy solutions — such as pending PBM legislation — may fundamentally shift how access and distribution are managed. Should that landscape change, the need for terminology like this may diminish. Today, patients and providers need clarity. These definitions serve as a practical tool to evaluate access, communicate impact, and advocate for models that align with the best interests of those receiving care.

As an organization grounded in patient-centered and collaborative values, NCODA will continue to advocate for distribution models that reduce barriers to access and empower oncology teams to deliver the best possible care. We encourage pharmaceutical manufacturers, specialty pharmacy partners, and payers to join us in adopting terminology, tools, and practices that bring clarity to the distribution landscape — and ultimately, improve the cancer care journey for every patient.

Together, we can advance a more ethical, transparent, and outcomes-driven future in oncology care.

REFERENCES

1. Lv X, Ren W, Ran S, et al. Trends and prescribing patterns of oral anti-neoplastic drugs: a retrospective longitudinal study. Front Public Health. 2023;11:1294126. Published November 23, 2023. doi:10.3389/fpubh.2023.1294126.

2. NCODA. Medically Integrated Pharmacy. Accessed April 9, 2025. https://www.ncoda.org/medically-integrated-pharmacy/.

3. Zuckerman AD, Carver A, Cooper K, et al. An integrated health-system specialty pharmacy model for coordinating transitions of care: specialty medication challenges and specialty pharmacist opportunities. Pharmacy (Basel). 2019;7(4):163. Published December 3, 2019. doi:10.3390/pharmacy7040163.

4. Russell M, McCoy H, Platt T, Zeltner M, Rhudy C. Comparison of time to treatment initiation of specialty medications between an integrated health system specialty pharmacy and external specialty pharmacies. J Manag Care Spec Pharm. 2024;30(4):352-362. doi:10.18553/jmcp.2024.30.4.352.

5. Time to First Palbociclib Prescription Dispense at Mayo Clinic: Comparing a Health-System Specialty Pharmacy With External Specialty Pharmacies. J Hematol Oncol Pharm. October 2022;12(5). Accessed April 9, 2025. https://jhoponline.com/issue-archive/2022-issues/october-2022-vol-12-no-5/19381-time-to-first-palbociclib-prescription-dispense-at-mayo-clinic-comparing-a-health-system-specialty-pharmacy-with-external-specialty-pharmacies.

6. Assessing the Impact of Limited Distribution Drug Networks Based on Time to Accessing Oral Oncolytic Agents at an Integrated Specialty Pharmacy. J Hematol Oncol Pharm. August 2020;10(4). Accessed April 9, 2025. https:// jhoponline.com/issue-archive/2020-issues/august-2020-vol-10-no-4/18301.

7. Abstract 66: [Title missing]. JCO Oncol Pract. 2023;19(11_suppl):66. doi:10.1200/OP.2023.19.11_suppl.66.

8. Avella. What Are Limited Distribution Drug Networks Anyway? Accessed April 9, 2025. https://blog.avella.com/ what-are-limited-distribution-drug-networks-anyway.

9. 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. Published August 15, 2022. doi:10.1371/journal. pone.0273040.

10. Prime Therapeutics. Prime Reimagines Patient Care: Unites Care Team for a Better Experience and Smarter Treatment Plan. Accessed April 9, 2025. https://www.primetherapeutics.com/w/prime-reimagines-patient-care-unites-care-team-for-a-better-experience-and-smarter-treatment-plan.

11. U.S. House Committee on Oversight and Accountability. Pharmacy Benefit Managers and the Prescription Drug Market. Published July 2024. Accessed April 9, 2025. https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

12. Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. J Oncol Pract. 2009;5(6):363–370. doi:10.1200/JOP.19.00606.

13. Fein AJ. Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: DCI's 2025 Update and Competitive Outlook. Drug Channels. April 9, 2025. Accessed April 11, 2025. https://www.drugchannels. net/2025/04/mapping-vertical-integration-of.html.

14. Cencora, Inc. Data on oral oncolytic distribution patterns. Proprietary data. Accessed January 2025.

15. Prime Therapeutics. IntegratedRx Earns 95% Satisfaction Rating. Accessed April 9, 2025. https://www. primetherapeutics.com/w/integratedrx-earns-95-satisfaction-rating.

16. Prime Therapeutics. Integrated Dispensing of Oral Oncolytics. AMCP 2024 Poster. Accessed April 9, 2025. https:// www.primetherapeutics.com/documents/d/primetherapeutics/4085-e_amcp_sp24_integrateddispensing_ oraloncolytics.

CENTER OF EXCELLENCE MEDICALLY INTEGRATED PHARMACY ACCREDITATION

MEDICALLY INTEGRATED PHARMACY ACCREDITATION

As the leading nonprofit association for the patient-centered medically integrated oncology community, NCODA's Center of Excellence Medically Integrated Pharmacy (MIP) Accreditation Program is committed to empowering pharmacies to deliver positive, patient-centered care by providing leadership, expertise, quality standards and best practices.

The NCODA Accreditation Program is based on compliance with the ASCO/NCODA Patient-Centered Standards for Medically Integrated Dispensing.

The ASCO/NCODA Quality Standards, published in the *Journal of Clinical Oncology*, were created to elevate oncology practices' performance by focusing on dispensing oral medications in an outpatient setting. These Quality Standards help optimize patient compliance while allowing practices to be more cost-effective.

We recognize the importance of developing, endorsing, and continually improving these Quality Standards. That's why NCODA works with experts within oncology practices to make sure we're serving both patients and practices to the fullest extent.

NCODA COE MIP PROGRAM HIGHLIGHTS

▲ First and only accreditation program designed specifically for medically integrated pharmacies;

▲ Innovative patient-centered standards;

▲ Without the presence of administrative burdens;

▲ Designed to improve patient outcomes, enhance quality of services, and decrease costs;

▲ Provides a framework to foster improvement in medication adherence, reduce waste due to cost avoidance, shorten medication fill times, and improve patient and clinician satisfaction;

▲ Benefits MIPs through adoption of quality standards and best practices and tracking valuable patient outcomes; and

▲ Eliminates clinical fragmentation through seamless coordination with the patient's Care Plan Protocol.

PHARMACY ACCREDITATIONS

NCODA offers tailored MIP Accreditation programs to meet the unique needs of oncology, multispecialty, and oncology-focused multispecialty practices — recognizing excellence in patient-centered care across diverse healthcare settings: the MIP accreditation program that is designed to meet the unique needs of oncology practices — recognizing excellence in patient-centered care across diverse healthcare settings.

▲ **NCODA Center of Excellence (CoE) Accreditation:** Designed specifically for Oncology MIPs, the NCODA CoE Accreditation recognizes practices that demonstrate the highest standards of quality, safety, and clinical excellence. Built on the MIP model, the CoE framework elevates the patient experience by fostering seamless collaboration across the entire care team — including providers, pharmacists, nurses, financial advocates and support staff. This team-based approach ensures coordinated treatment planning, optimized medication management, proactive patient engagement and measurable outcomes that improve both clinical results and the overall care journey.

▲ **Canadian Pharmacy Accreditation Services (CPAS):** An NCODA company, CPAS reflects NCODA's expanding commitment to advancing patient-centered pharmacy care across Canada. Built on NCODA's proven MIP model, CPAS offers a rigorous yet accessible accreditation pathway for pharmacies of all sizes and specialties. Through a collaborative, patient-first approach, CPAS supports Canadian pharmacies in achieving the highest standards of clinical excellence, quality and safety.

For more information about **NCODA's Center of Excellence Medically Integrated Pharmacy Accreditation Program**, scan the QR code above.

NCODA QUALITY STANDARDS

NCODA's comprehensive framework for Medically Integrated Dispensing (MID) services is designed to advance patient-centered care, efficient and coordinated workflows, and data-driven clinical decision-making. This structured approach ensures that medically integrated teams deliver consistent, high-quality care while continuously improving outcomes and the overall patient experience.

▲ **Patient-Focused:** When establishing MID services, organizations must prioritize maximizing patient convenience and support throughout the treatment journey. This includes providing timely access to therapy, reducing barriers to medication initiation, ensuring financial navigation and assistance, and delivering individualized education and proactive clinical monitoring.

MID programs also enhance the patient experience through the use of treatment support kits, which provide patients with clear medication instructions, symptom management tools, and practical resources to help them confidently begin therapy. Combined with ongoing engagement and follow-up, these efforts drive improved adherence, empower patients in their care

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NCODA CoE MEDICALLY INTEGRATED PHARMACY ACCREDITATION: FREQUENTLY ASKED QUESTIONS

HOW WILL NCODA COE MIP ACCREDITATION HELP MY ORGANIZATION?

The accreditation standards provide a framework to foster improvement in medication adherence, reduce waste due to cost avoidance, shorten medication fill times and improve patient and clinician satisfaction. Our accreditation program benefits Medically Integrated Pharmacies (MIPs) through the adoption of quality standards and best practices and tracking valuable patient outcomes. The NCODA CoE MIP accreditation is preferred for the Prime Therapeutics IntegratedRx Oncology program.

WHAT IS THE COST OF THE ACCREDITATIONS?

NCODA CoE MIP Accreditation Programs are sustainable, meaningful and budget-friendly. Our focus is on the patient, not the bottom line. Initial accreditation and subsequent reaccreditations cost $10,000 to $13,500.

DOES THE PROGRAM OFFER RESOURCES AND SUPPORT?

NCODA provides comprehensive resources and hands-on support throughout the accreditation process — all designed not only to help practices achieve compliance, but to strengthen and enhance patient care.

Practices have the option to purchase accreditation templates developed to support alignment with NCODA accreditation standards. These templates include, but are not limited to, clinical evaluation forms, error logs, new patient packets, staff training checklists, and MIP standard operating procedures (SOPs). These structured tools guide practices step-by-step through the accreditation process while promoting standardized workflows, improved care coordination, and a consistent, high-quality patient experience.

Each practice is assigned a dedicated reviewer with expertise in pharmacy accreditation and pharmacy operations. This reviewer serves as a trusted resource throughout the entire process and is available by phone or email to answer questions, provide clarification, and assist with ensuring compliance. Their operational insight helps practices build efficient systems that support both regulatory standards and optimal patient outcomes.

During the four-month self-study period, pharmacies work closely with the NCODA Accreditation Team to strengthen policies and procedures, bring documentation up to current standards, and determine an appropriate readiness date for the on-site review.

The NCODA team provides ongoing, real-time feedback, allowing MIPs to confirm compliance before implementing new processes. This proactive guidance not only minimizes noncompliant findings in the final self-study review report, but also helps practices establish sustainable processes that enhance patient safety, improve medication management, and elevate the overall quality of care.

WHAT IS THE ACCREDITATION PROCESS?

The accreditation process consists of five stages: agreement, self-study, onsite review, accreditation review committee evaluation and final decision. The full process typically takes between 8 and 12 months to complete.

ACCREDITATION

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and elevate overall patient satisfaction.

▲ **Foundational Elements:** Successful implementation of an MID service requires intentional design, operational discipline and strong clinical infrastructure. NCODA developed foundational standards and systems specifically to help MID organizations achieve and sustain the highest level of quality care.

This section outlines the essential processes, operational structures, and optimized workflows that support thriving and sustainable MID services — ensuring consistency, scalability, compliance and continuous quality improvement.

▲ **Health Information Technology:** NCODA practices are data-driven organizations that leverage integrated technology systems to accurately manage each patient's condition and treatment across the entire care continuum. Through real-time documentation, shared clinical visibility, and coordinated communication, pharmacists, providers, nurses and support staff collaborate seamlessly to deliver aligned, high-quality care.

This integrated infrastructure supports proactive treatment management by maximizing duration of therapy and dose intensity, increasing medication adherence, reducing adverse drug reactions, minimizing medication waste and improving overall quality of care.

The collaborative, technology-enabled environment within medically integrated organizations empowers both patients and physicians to make informed decisions in real time — strengthening clinical outcomes while enhancing the overall patient experience.

MEDICALLY INTEGRATED PHARMACY: CORE CLAIMS

As defined by NCODA, MIPs are dispensing pharmacies within oncology centers of excellence that promote a patient-centered, multidisciplinary team approach. These outcome-based collaborative and comprehensive models involve oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated quality care and therapies for cancer patients. The pillars of MIPs that lead to excellence in patient care are based on core activities related to abandonment, time to fill, adherence, patient satisfaction, patient education, financial, and cost avoidance and waste. Evidence to support the value of these claims is summarized in this document.

ABANDONMENT: SUPPORTING EVIDENCE

1. Medication prescription abandonment is defined as a patient making the decision to not fill or to fill and never pick up a prescription.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	National abandonment rates are reported to be at 18%.	Doshi GK, et al. JCO Oncol Pract. 2023;19(11suppl):66.
1.2	Factors related to pharmacy plan, cost-sharing amount and concurrent prescription activity are significant drivers of oral oncolytic abandonment.	Streeter SB, et al. Am J Manag Care. 2011;17(Suppl 5): SP38-44.
1.2.1	Higher OOP costs are associated with higher rates of abandonment.	Doshi GK, et al. JCO Oncol Pract. 2023;19(11suppl):66.
1.2.2	Higher out-of-pocket (OOP) costs are associated with higher rates of delayed initiation and abandonment of insurer-approved new prescriptions for novel oral oncolytics.	Doshi JA, et al. JCO. 2018;36(5):476-482. https://doi.org/10.1200/JCO.2017.74.5091.
1.2.3	The likelihood of abandonment increases fourfold when OOP costs exceed $500.	From https://communityoncology.org/pdfs/ fact-sheet-oral-oncolytics.pdf.
1.2.4	Abandonment rates reached as high as 49% in patients with an OOP >$2,000 for a new oral oncolytic prescription.	Doshi JA, et al. JCO. 2018;36(5):476-482. https://doi.org/10.1200/JCO.2017.74.5091
1.2.5	Issues related to the prior authorization process lead to abandonment (in a 2020 survey of physicians, 78% report that PA can at least sometimes led to abandonment).	2020 AMA Prior Authorization Physician Survey. https://www.ama-assn.org/system/files/2021-04/ prior-authorization-survey.pdf.
1.2.6	Patients with ≥5 prescription claims processed within in the previous month had 50% higher likelihood of abandonment than patients with no other prescription activity	Streeter SB, et al. Am J Manag Care. 2011;17(Suppl 5): SP38-44.

2. MIPs lower the rate of oral oncolytic prescription abandonment.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	Prescription abandonment rates can be lowered to <1% with MIP.	Doshi GK, et al. JCO Oncol Pract. 2023;19(11suppl):66.
2.2	In a study of Medicare beneficiaries, MIP dispensing resulted in an increase in percent of men filling a prescription for abiraterone and/or enzalutamide.	Hill D, et al. JNCI Cancer Spectrum. 2023;7(5): pkad062.
2.3	The MIP team lowers the rate of abandonment through coordinated activities by the pharmacy and clinical teams in integrated patient assistance activities (e.g., copay assistance programs, charitable grant funding, manufacturer-provided free drug programs).	Doshi GK, et al. JCO Oncol Pract. 2023;19(11suppl):66. Mullangi S, et al. JCO Oncol Pract. 2024;20(5): https://doi.org/10.1200/OP.23.00691.

TIME TO FILL: SUPPORTIVE EVIDENCE

1. Time to fill is the time between when a prescription is written to when the patient takes their first dose.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	The median number of days from oral oncolytic prescription to patient receipt of the drug has been reported as 7 to12 days, showing that obtaining these medications is complex and prone to unwanted delays.	Marineau A, et al. J Oncol Pharm Pract. 2023; 29:1144-153.
1.2	Time to first fill within an MIP is impacted by many factors including benefits verification, prior authorization, patient financial assistance, initial shipment, and contact with the patient.	Khrystolubova N, et al. Am J Manag Care. 2022; 28(6 Spec No.): SP316-SP323.
1.3	Patient-identified barriers to time to fill include communication issues, prior authorization, and cost.	Gabriel MH, et al. J Manag Care Spec Pharm. 2022 Nov; 28(11): 10.18553/jmcp.2022.28.11.1244.
1.4	An ACCC membership survey on management of oral oncolytics revealed use of mail-order specialty pharmacies leads to delays for reasons including taking a long time to process the order (68%).	https://www.accc-cancer.org/docs/projects/pdf/implementing-oral-oncolytics-final.pdf?sfvrsn=274a112_0.

2. Use of a MIP reduces the time to fill oral oncolytic prescriptions.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	Time to fill is lower with MIPs vs external pharmacies	Russell M, et al. J Manag Care Spec Pharm. 2024;30:352-362. Goldbach AP, et al. J Hematol Oncol Pharm. 2022;12:241-247. Academia EC, et al. J Manag Care Spec Pharm. 2021; 27:1438-1446.
2.1.1	Average time to treatment initiation was six days shorter for patients whose specialty medications were filled at MIPs vs an external pharmacy.	Russell M, et al. J Manag Care Spec Pharm. 2024;30:352-362.
2.1.2	One study demonstrated a doubling in the total time to first fill of palbociclib (12 days vs six days) when patients used an external specialty pharmacy compared with an MIP.	Goldbach AP, et al. J Hematol Oncol Pharm. 2022;12:241-247.
2.1.3	Time to fill oral oncolytics was significantly lower (median, 22 days) using internal MIP vs external pharmacies.	Academia EC, et al. J Manag Care Spec Pharm. 2021;27:1438-1446.
2.1.4	The average time to first fill of dasatinib, palbociclib and ibrutinib was three, four and 4.2 days, respectively in one community MIP.	Khrystolubova N, et al. Am J Manag Care. 2022; 28(6 Spec No.): SP316-SP323.
2.2	Frequent communication and follow-up with payers are needed for the first few cycles.	Marineau A, et al. J Oncol Pharm Pract. 2023; 29:1144-153.
2.3	Patients who fill their oral oncolytic prescriptions using an MIP (vs an external specialty pharmacy) have significantly shorter 4.21-day time to fill.	McCabe CC, et al. Am J Health Syst Pharm. 2020;77:1118-1127.

ADHERENCE: SUPPORTIVE EVIDENCE

1. Adherence refers to the extent to which a patient takes a medication as prescribed, focusing on frequency, time ingested and dose.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	Persistence relates to the time over which a patient continues treatment.	Menditto E, et al. Int J Environ Res Public Health. 2021; 18:4872.
1.2	Primary nonadherence is the rate of a new prescription being issued but not filled within an acceptable time.	Zuckerman A, et al. J Manag Care Spec Pharm. 2023 Jul; 29(7): 10.18553/jmcp.2023.29.7.740.
1.3	Secondary nonadherence refers to medication not being taken as prescribed once the prescription is filled.	Lam WY and Fresco P. Biomed Res Int. 2015; 2015:217047.
1.4	Nonadherence to oral oncolytics includes over-adherence (intentionally or unintentionally taking too much medication in a prescribed period, which can lead to increased toxicity) or under-adherence (taking an inadequate amount of prescribed medication).	Akerley A and Karl C. J Oncol Nav Survivorship. 2021;12:6. https://www.jons-online.com/ issues/2021/june-2021-vol-12-no-6/3808-call-back-using-the-phone-to-promote-adherence-to-oral-antineoplastic-agents.
1.5	A substantial proportion of patients struggle to adhere to oral oncolytics as prescribed	Greer JA, et al. Oncologist. 2016; 21:354-76.
1.5.1	Reasons for nonadherence in one study included patient decision (25%), medication not approved by insurance (13%), intentional delays based on provider/patient request (13%), medication changed (12%), clinical decline (12%), death (12%), no longer appropriate (7%) or unaffordable copay (7%).	Zuckerman A, et al. J Manag Care Spec Pharm. 2023 Jul; 29(7): 10.18553/jmcp.2023.29.7.740.
1.5.2	Impactful factors identified as affecting compliance to oral oncolytics are patient's confidence, health literacy, perception of treatment, quality of life, social support and complexity of chemotherapy regimen.	Signorelli J, et al. J Oncol Pharm Pract. 2023. https://doi.org/10.1177/10781552231208442.

2. MIPs improve patient adherence to oral oncolytics.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	Patients who fill their oral oncolytic prescriptions using an MIP (vs an external specialty pharmacy) have significantly higher adherence (in one study as measured by MPR and PDC).	McCabe CC, et al. Am J Health Syst Pharm. 2020;77:1118-1127.
2.2	The rate of nonadherence with newly prescribed oral oncolytics from MIPs is low (11% in one study).	Zuckerman A, et al. J Manag Care Spec Pharm. 2023 Jul; 29(7): 10.18553/jmcp.2023.29.7.740.
2.3	Adherence rates with MIPs are higher than with specialty pharmacies.	Leach JW, et al. J Clin Oncol. 2022;40(16 suppl): e18645.

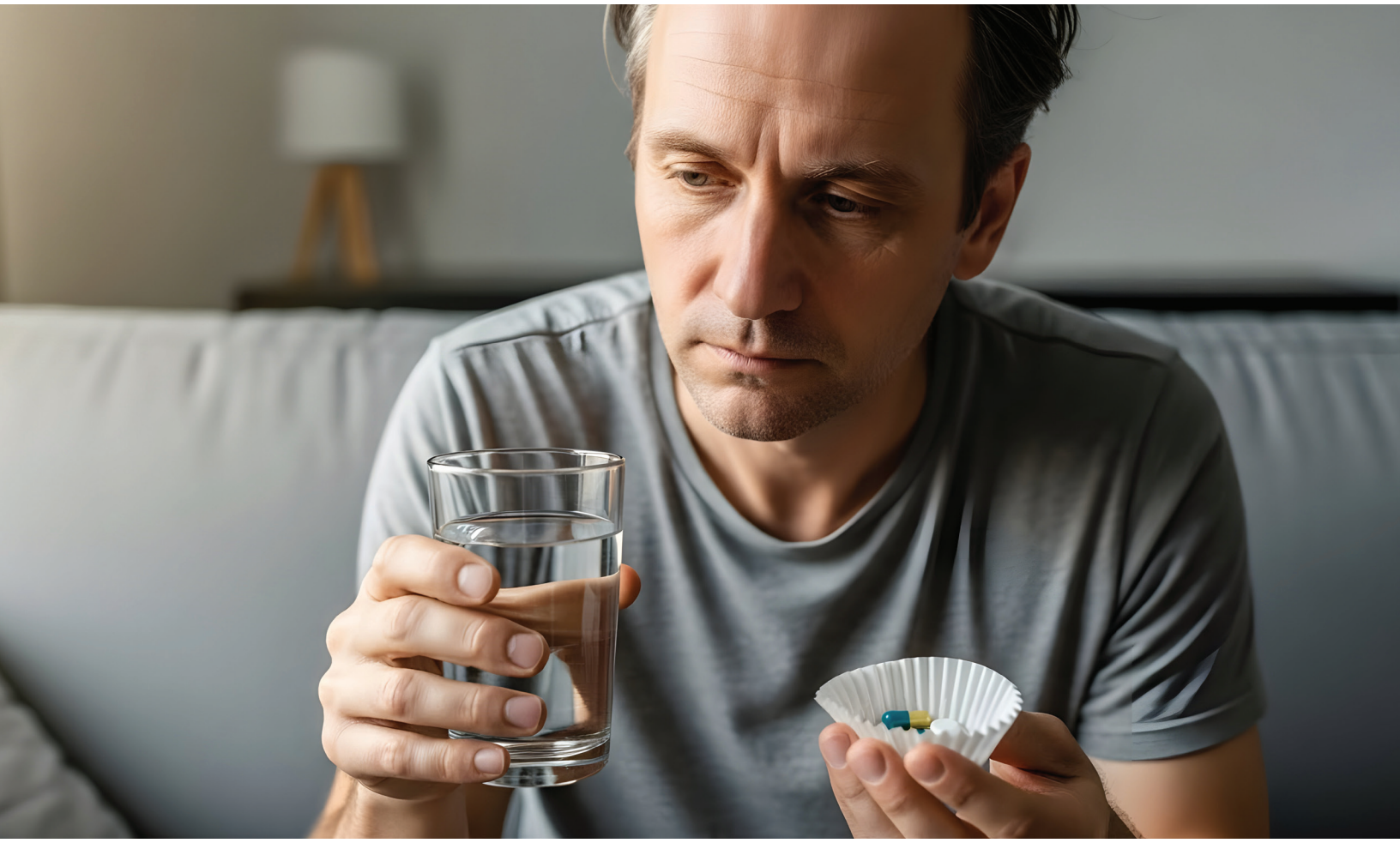
3. Adherence leads to better outcomes.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
3.1	Poor adherence to oral oncolytics can impede treatment efficacy and decrease response rates.	Marineau A, et al. J Oncol Pharm Pract. 2023; 29: 1144-153.
3.2	Nonadherence is associated with myriad adverse consequences, increase in physician visits, increased hospitalization rates, longer hospital stays, decreased patient satisfaction, poor patient-provider relationships and compromised disease outcomes (e.g., decreased time to relapse, decreased survival).	D'Amato. Oncology Issues. 2008. https://www.accc-cancer.org/docs/Documents/ oncology-issues/articles/2003-2016/2008/JA08/ ja08-improving-patient-adherence-with-oral-chemotherapy.

ADHERENCE: SUPPORTIVE EVIDENCE (CONTINUED)

4. Interventions from members of the MIP multidisciplinary team improve adherence to oral oncolytics.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
4.1	Interventions to improve adherence include use of reminder systems, management of side effects, discussions of misconceptions on disease or medication efficacy, dosing and administration instructions, strategies for accessing the medication and referral for cognitive behavioral therapy if needed.	Greer JA, et al. Oncologist. 2016; 21:354-76.
4.2	A multi-institution study of patients with chronic myelogenous leukemia found that an initial education session and follow-up as needed (related to adverse effects, drug interactions and adherence) significantly increased MPR.	Lam MS, et al. J Oncol Pharm Pract. 2016; 22:741-748.
4.3	In a multiple-institution case-control study that provided an initial education session with a pharmacist and ongoing counseling, daily adherence was significantly improved.	Simons S, et al. Support Care Cancer. 2011; 19:1009-1018.
4.4	In a case-control study, pharmacist education regarding adverse events and ongoing adherence counseling resulted in increased detection of drug-related errors, and adherence (MPR > 90%).	Ribed A, et al. Int J Clin Pharm. 2016;38:280-288.
4.5	Nurse-led weekly telephone interventions positively impacted oral adherence (100% in seven patients).	Akerley A and Karl C. J Oncol Nav Survivorship. 2021;12:6. https://www.jons-online.com/ issues/2021/june-2021-vol-12-no-6/3808-call-back-using-the-phone-to-promote-adherence-to-oral-antineoplastic-agents.



PATIENT SATISFACTION: SUPPORTIVE EVIDENCE

1. MIP activities lead to better patient satisfaction.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	Patients prefer to receive their medications through MIPs.	Hanna K. AJMC. 2019;25(6): SP193-SP194.
1.2	High satisfaction ratings can be attributed to personalized experience patients receive through MIPs.	Bagwell A, et al. J Manag Care Spec Pharm. 2017 Aug; 23(8): 10.18553/jmcp.2017.23.8.815.
1.2.1	In terms of pure satisfaction, MIP services rank high among patients looking for well-managed and vigilant care with their provider and pharmacy staff.	From https://www.ncoda.org/wp-content/uploads/2020/03/NCODA-Patient-Satisfaction-Surveys-within-Medically-Integrated-Practice.pdf.
1.2.2	Patient-centered programs, such as centralizing prior authorizations, integrating therapy management into specialty clinics, and creating health coaching options, increase patient satisfaction.	Donovan and Cha. Pharmacy Times. 2023. https://www.pharmacytimes.com/view/key-metrics-that-support-the-integrated-specialty-pharmacy-model.
1.3	Satisfaction survey data indicate high patient satisfaction with MIPs.	https://www.primetherapeutics.com/news/integratedrx-earns-95-satisfaction-rating/. Doshi G, et al. J Clin Oncol. 2018; 36 (30 suppl):140. Khrystolubova et al. AJMC.2022; 28 (6 Spec No.): SP405-SP406.
1.3.1	NCODA's Patient Satisfaction Survey results demonstrate an average 86.2 Net Promoter Score for MIPs, and 97% of patients would prefer to fill their oral oncology and/or supportive care medications at the MIP vs an external mail-order specialty pharmacy.	https://www.primetherapeutics.com/news/integratedrx-earns-95-satisfaction-rating/.
1.3.2	Patient satisfaction surveys at Texas Oncology and Florida Cancer Specialists reveal 94% to 96% satisfaction with MIPs.	Doshi G, et al. J Clin Oncol. 2018;36(30 suppl):140. Khrystolubova et al. AJMC. 2022; 28(6 Spec No.): SP405-SP406.
1.3.3	Patients enrolled in a pharmacist-led oral chemotherapy program who received their oral TKIs from MIPs were more likely to be satisfied with the care they received than patients not in the program.	Dennison T, et al. J Adv Pract Oncol. 2021; 12:148-157.

2. Patient satisfaction can lead to better patient adherence.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	Patients with high satisfaction rates have higher adherence rates to oral oncolytics.	
2.1.1	CML patients with high satisfaction rates after interactions with their treating doctor about disease information have higher adherence rates to their oral chemotherapy.	Geissler J, et al. J Cancer Res Clin Oncol. 2017;143:1167–1176.

3. Patient satisfaction surveys are critical tools in identifying and addressing opportunities for improvement.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
3.1	Patient satisfaction surveys provide critical feedback to the MIP providers.	Khrystolubova et al. AJMC. 2022; 28(6 Spec No.): SP405-SP406.

PATIENT EDUCATION: SUPPORTIVE EVIDENCE

1. A multidisciplinary approach to patient education is a critical step in the MIP dispensing process.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	A comprehensive and multifaceted approach to education is essential in helping patients better understand how to take and manage their oral oncolytic agents.	Lin M, et al. J Oncol Pharm Pract. 2021; 27:1409–1421.
1.2	In an AUA and NCODA survey of MIPs in urologic oncology care, 68% of respondents within an MIP gave printed patient education at the time of any new therapy initiation vs 35% not affiliated with a MIP (using a mail-order pharmacy) and 91% educated patients on oral oncolytics prior to initiation (vs. 49%).	https://www.auanet.org/documents/practices-resources/quality/quality-improvement-library/Integration-in-Action-Medically-Integrated-Dispensing.pdf.

2. Patient education enhances understanding of and adherence to oral oncolytics.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	A multi-institution study of patients with chronic myelogenous leukemia found that an initial education session and follow-up as needed related to adverse effects, drug interactions and adherence significantly increased MPR.	Lam MS, et al. J Oncol Pharm Pract. 2016; 22:741-748.
2.2	In a multi-institution case-control study that provided an initial education session with a pharmacist and ongoing counseling, daily adherence was significantly improved.	Simons S, et al. Support Care Cancer. 2011; 19:1009-1018.
2.3	In a case-control study, pharmacist education regarding adverse events and ongoing adherence counseling resulted in increased detection of drug-related errors and adherence (MPR > 90%).	Ribed A, et al. Int J Clin Pharm. 2016;38:280-288.
2.4	In pilot study of integrated multidisciplinary follow-up with supplemental informational tools for patients on oral oncolytics, 100% of patients (n=80) reported adequate understanding of their medication.	Lin M, et al. J Oncol Pharm Pract. 2021;27(6):1409-1421.
2.5	A comparative study assessing the effect of an app (vs traditional follow-up) on drug safety, adherence and quality of life in patients receiving oral oncolytics demonstrated significant improvements in adherence to treatment (p=0.02), QoL (p<0.001), and drug safety (p=0.01) in patients who used the app.	Collado-Borrell R, et al. MIR mHealth and uHealth 2020;8(10):e20480.

3. Patient education improves safety and toxicity of oral oncolytics.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
3.1	Patient education and phone calls by nurses using toxicity algorithms within the first week of treatment and ongoing thereafter reduced toxic effects, improved quality of life and reduced inpatient hospitalization.	Molassiotis A, et al. J Clin Oncol. 2009; 27:6191-6198.
3.2	Results of a prospective cohort study demonstrated the benefit of a clinical pharmacist education program on safety of ibrutinib. Patients in the intervention group had fewer grade 3 or higher adverse events than patients in the usual care group (8% vs 15%).	Zerbit J, et al. Ann Hematol. 2020; 99:1615-1625.
3.3	Results of a retrospective study demonstrated positive benefits of a multidisciplinary consultation program on safety of oral oncolytics. Patients in the consultation program (vs control group) had fewer adverse events in general (41 vs 109, p=0.048 and fewer digestive AEs (6 vs 29, p=0.007)	Feral A, et al. J Oncol Pharm Pract. 2022; 28(7):1543-1551.
3.4	In a randomized, controlled trial of nurse-led telephone follow-up vs standard of care in 183 patients receiving oral oncolytics, grade 3 adverse events were significantly lower (p=0.03) in patients who received adverse event advice in follow-up calls.	Bouleftour W, et al. Support Care Cancer. 2021; 29:4257-4267.
3.5	A phase 3 trial evaluating the addition of a nurse navigator-led follow-up and a mobile app to usual care in 559 patients treated with oral oncolytics demonstrated significant improvements in relative dose intensity (93% vs 89%, p=0.04) and grade ≥3 toxicities (28% vs 37%, p=0.02) with remote monitoring vs usual care alone.	Mir O, et al. Nature Medicine 2022;28(6):1224-31.

FINANCIAL: SUPPORTIVE EVIDENCE

1. Financial burden and high out-of-pocket expenses for prescriptions are functional barriers to care.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	Cost, prior authorizations and financial assistance are barriers to oral oncolytic initiation.	Gabriel MH, et al. J Manag Care Spec Pharm. 2022 Nov; 28(11): 10.18553/jmcp.2022.28.11.1244.
1.1.1	In an AUA and NCODA survey of MIPs in urologic oncology care, 73% of respondents associated with MIPs reported challenges with prior authorization and benefit verification, 55% reported challenges with payer constraints on ability to fill in-house, and 49% reported challenges with PBMs directing patient care to their preferred pharmacies.	https://www.auanet.org/documents/practices-resources/quality/quality-improvement-library/Integration-in-Action-Medically-Integrated-Dispensing.pdf.
1.2	Financial assistance programs, including copay cards, foundation grants and manufacturer patient assistance programs, can decrease financial burden.	Hung A, et al. J Manag Care Spec Pharm. 2021;27:10.18553/jmcp.2021.27.7.924.

2. MIPs seamlessly coordinate financial assistance for patients.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	Pharmacists and pharmacy technicians within an MIP can perform benefits investigations, assess patient out-of-pocket responsibility and enroll patients in assistance programs to alleviate the high cost burden of oral oncolytic agents and prevent therapy abandonment.	Farano JL, et al. J Manag Care Spec Pharm. 2019; 25:10.18553/jmcp.2019.25.7.765.
2.1.1	In one study, 18.6% of patients filling their oral oncolytics within an MIP received a patient assistance program. One in three patients was enrolled in a financial assistance program, with cost savings ranging from $5 to over $13,000 per prescription claim.	Farano JL, et al. J Manag Care Spec Pharm. 2019; 25:10.18553/jmcp.2019.25.7.765.
2.2	MIPs offer patients and insurance providers a single point of contact, reducing the paperwork and correspondence among multiple parties.	Wyatt H, et al. J Hematol Oncol Pharm. 2020;10(4):198-205.
2.3	Employers and insurers should consider investment in MIPs for clinical management of cancer patients to improve outcomes and reduce costs.	Tschida SJ, et al. Pharm Benefits. 2012;4(4):165-74.
2.4	An ACCC membership survey on management of oral oncolytics revealed use of mail-order specialty pharmacies led to delays for reasons including denials from health insurance (58%) or lack of documented prior authorization (35%).	https://www.accc-cancer.org/docs/projects/pdf/implementing-oral-oncolytics-final.pdf?sfvrsn=274a112_0.

WANT MORE INFORMATION?

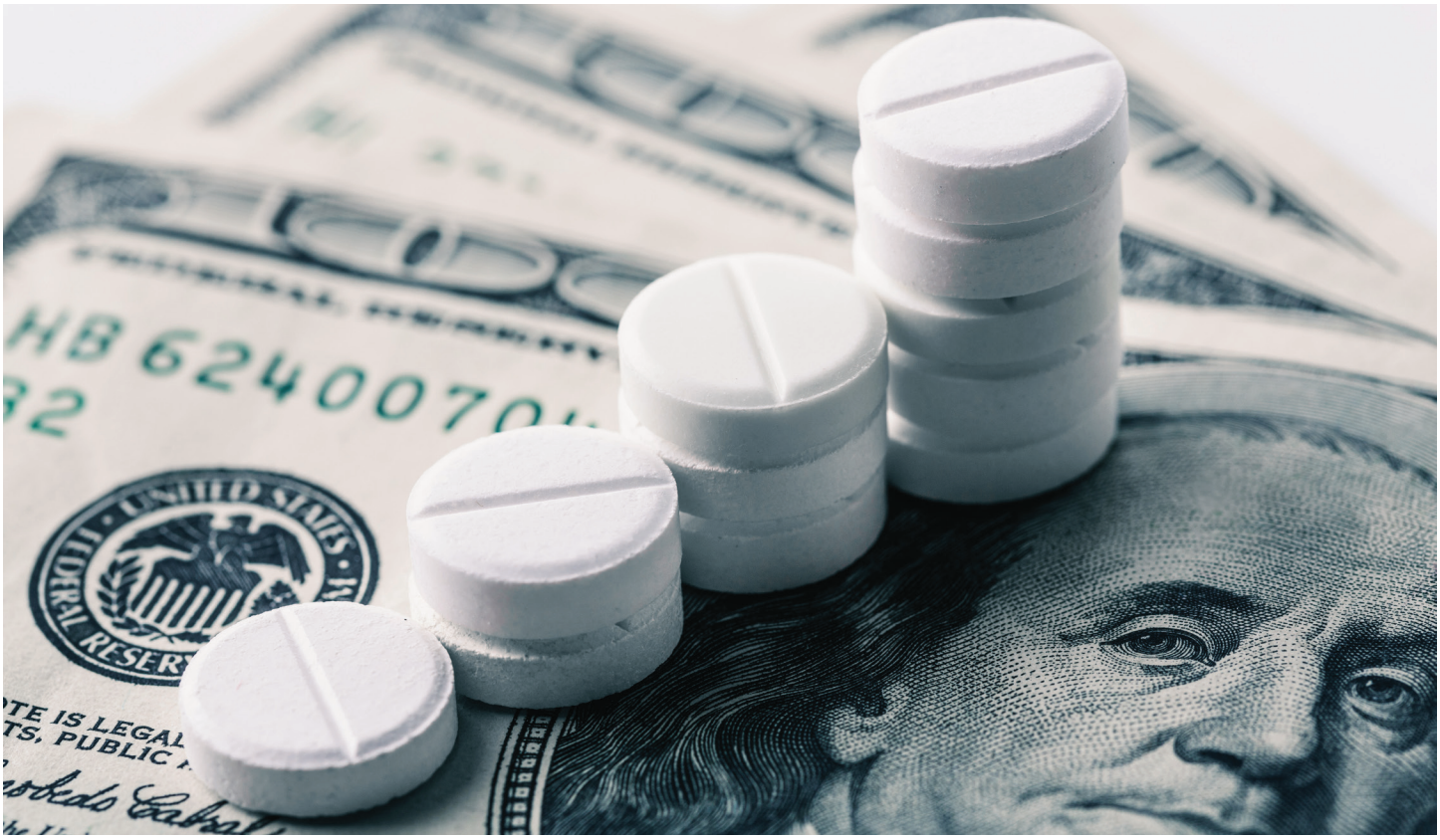
TO VIEW THE FULL CORE CLAIMS ARTICLE, SCAN THE QR CODE:

TO LEARN MORE ABOUT NCODA'S COMMITMENT TO MEDICALLY INTEGRATED PHARMACY, SCAN THE QR CODE:

FINANCIAL: SUPPORTIVE EVIDENCE (CONTINUED)

3. MIPs lead to cost savings for patients.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
3.1	MIPs allow for increased pharmacy oversight, which leads to increased cost avoidance and reduced waste for patients.	Darling JO, et al. JCO Oncol Pract. 2022 Jul; 18(7): e1225–e1230.
3.1.1	The net cost avoidance of oral oncolytics from ~50 MIPs nationwide was $6,510,971.28 vs $546,082.45 for external mail-order pharmacies,	Darling JO, et al. JCO Oncol Pract. 2022 Jul; 18(7): e1225–e1230.
3.2	Pharmacist intervention within an MIP leads to substantial cost savings.	
3.2.1	An estimated annualized cost avoidance associated with one MIP would be greater than $3.5 million in hematologic/oncologic medications.	Langkford C, et al. J Manag Care Spec Pharm. 2021 Mar; 27(3): 10.18553/jmcp.2021.27.3.379.
3.2.2	In one study, MIP pharmacist clinical review and postponement of refill renewal requests until after a scheduled follow-up resulted in an estimated cost avoidance of up to $750,000 (AWP-20%) in 12 months.	Looney B, et al. J Manag Care Spec Pharm. 2024;30:465-474.
3.3	In-office dispensing of oral chemotherapy provides significant cost savings to third-party payers compared to mail-order pharmacy dispensing as evidenced by a net cost avoidance annually of $1,730,416 in one study.	Howard A, et al. J Oncol Pharm Pract. 2018;25(7): https://doi.org/10.1177/1078155218799853.
3.4	A real-world study of MIP (vs specialty pharmacies) demonstrated the potential of MIP to save ~$1.1 million from wasted medications through dose change.	Jackson SK, et al. Presented at Academy of Managed Care Pharmacy (AMCP) Annual Meeting, March 21–24, 2023, San Antonio, Texas.
3.5	MIP dispensing of oral oncolytics was associated with a $5,672 reduction per patient in medical spending vs non-MIP.	Urick B, et al. J Clin Oncol. 2024;42(16 suppl): e23098.
3.6	Point-of-sale prices paid for oral oncolytics were 1.12% lower at MIPs vs. other pharmacies.	Kakani P, et al. JAMA Network Open.2024;7(2):e2356592.



COST AVOIDANCE & WASTE: SUPPORTIVE EVIDENCE

1. MIPs provide waste mitigation strategies that lead to cost savings and cost avoidance.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
1.1	MIPs allow for increased pharmacy oversight, which leads to increased cost avoidance and reduced waste for third-party payers.	Darling JO, et al. JCO Oncol Pract. 2022 Jul; 18(7): e1225–e1230.
1.1.1	Using NCODA's Cost Avoidance & Waste Tracker tool, net cost avoidance of oral oncolytics from ~50 MIPs nationwide was determined to be $6,510,971.28 vs $546,082.45 for external mail-order pharmacies.	Darling JO, et al. JCO Oncol Pract. 2022 Jul; 18(7): e1225–e1230.
1.2	Drug repository programs that collect drug donations and redispense medications are associated with decreased healthcare costs and cost savings to poor, uninsured and underinsured patients.	Stanz L, et al. JCO Oncol Pract. 2021; 17:e426-e432.
1.3	Real-world pharmacy claims data demonstrate that MID (vs specialty pharmacy dispensing) was associated with significantly lower waste (29% vs 50%) and expense (specialty pharmacy associated with additional dose change cost of $1,796).	Leach JW, et al. J Clin Oncol. 2022;40(suppl 16):e18645.
1.4	A 68% waste reduction and net annual cost savings was seen in an interventional study by redispensing unused medications originally provided in sealed packaging and returned to the pharmacy if unused.	Smale EM, et al. JAMA Oncol. 2024; 10:87.
1.5	Individualized dispensing of oral oncolytics reduced unused unit doses by 34%, leading to cost savings and waste reduction.	Smale EM, et al. JCO Oncol Pract. 2023; 19:e618-e629.
1.6	Payers for patients who received their oral oncolytics via a split fill program had significant medication savings per covered month ($2,147.60 at one month) and less waste.	Staskon FC, et al. JCO Oncol Pract. 2019; 15:e856-e862.

2. Interventions by the MIP team lead to cost savings and cost avoidance.

CLAIM #	KEY EVIDENCE-BASED CLAIM	REFERENCE
2.1	MIP pharmacist clinical review and postponement of refill renewal requests until after a scheduled follow-up led to an estimated cost avoidance of up to $750,000 (average wholesale price minus 20%) in 12 months.	Looney B, et al. J Manag Care Spec Pharm. 2024;30(5):465-474.
2.2	Pharmacist interventions in an oral chemotherapy clinic led to total cost savings and cost avoidance of $2,245,856 in a nine-month period.	Nguyen A. J Clin Oncol. 2022; 40 (16 suppl): e18839.
2.3	Clinical pharmacist interventions within an MIP were associated with significant cost avoidance of $1,508,131 during a five-month study period.	Lankford C, et al. J Manag Care Spec Pharm. 2021;27:379-384.
2.4	Pharmacist interventions in an outpatient cancer center were associated with a net benefit of $753,150 per year.	Trinidad DM, Patel PR. J Adv Pract Oncol. 2022; 13:673-682.
2.5	Interventions made by a pharmacist for patients on an oral oncolytic at a community oncology center were associated with an average cost savings of $12,058 per intervention.	Rees M, et al. AMCP 2024 Annual Meeting.
2.6	Oncology nurse interventions before a refill of an oral oncolytic at an MIP were associated with $1,994,629.88 saved in waste and cost avoidance in 2023.	Weinberg T. J Clin Oncol. 2024;42(suppl 16): e23207.

ACROSS THE ONCOLOGY LANDSCAPE, ADVOCACY PLAYS A CENTRAL ROLE IN NCODA'S MISSION

As a clinically grounded voice in national oncology policy discussions, NCODA works to ensure that regulations and coverage decisions reflect the realities of cancer care rather than administrative convenience. Through formal perspectives, policy statements, engagement with payers and policymakers, and collaboration with manufacturers and patient advocates, NCODA elevates medically integrated oncology practices and the patients they serve.

Cancer care is complex, highly individualized and increasingly dependent on timely access to targeted and biomarker-driven therapies. Administrative barriers that delay appropriate treatment can carry serious clinical consequences. NCODA's advocacy prioritizes timely access to evidence-based therapies, preservation of clinical autonomy and advancement of value-based care models focused on measurable outcomes rather than short-term cost shifting.

At the center of every advocacy effort is a clear standard: the right therapy, at the right time, for the right patient — selected by the physician. Policy should support that standard, not obstruct it.

MOVING FROM PRINCIPLE TO ACTION

NCODA's advocacy spans the oncology spectrum — from utilization management and reimbursement reform to access pathways for emerging therapies, medically integrated dispensing, quality reporting and value-based payment design. The organization translates frontline oncology experience into policy dialogue, sharing real-world data and operational insight to ensure regulatory and payer frameworks align with clinical complexity.

NCODA's advocacy prioritizes timely access to evidence-based therapies, preservation of clinical autonomy and advancement of value-based care models focused on measurable outcomes rather than short-term cost shifting.

Whether addressing prior authorization, coverage criteria, specialty pharmacy restrictions or care model innovation, NCODA promotes safeguards that protect timely access to evidence-based treatment while supporting responsible stewardship of healthcare resources. Policies developed for other therapeutic areas cannot be applied to oncology without thoughtful adaptation. Transparent, clinically grounded criteria, practical exception processes and meaningful collaboration with oncology stakeholders are essential components of sound policy.

A recent example can be found in NCODA's Perspective on step therapy, which examines the growing use of step edits in oncology and outlines oncology-specific safeguards. **(See the Step Therapy Perspective on the next page.)**

NCODA also advances policy frameworks that recognize medically integrated oncology practices as partners in value-based care. By embedding pharmacy services within the clinical setting and aligning quality measurement with patient outcomes, integrated models demonstrate how access, coordination and accountability can coexist. Through its advocacy, NCODA reinforces that sustainable oncology policy must be built around patient outcomes and clinical expertise.

ELEVATING THE ONCOLOGY PRACTICE VOICE

Through our Positive Quality Interventions (PQIs), educational programming and policy perspectives, NCODA equips oncology practices with structured tools to document outcomes, demonstrate quality and engage in meaningful policy dialogue. Advocacy is informed by the day-to-day experience of clinicians, pharmacists, nurses and administrators working directly with patients.

NCODA collaborates across the oncology ecosystem — partnering with patient advocates, health plans, manufacturers and professional organizations to ensure evolving policy frameworks reflect clinical nuance. As regulatory complexity increases, advocacy helps ensure innovation in cancer treatment is matched by thoughtful, clinically informed policy. When policy is shaped by those closest to care delivery, the system works better for patients.

NCODA's advocacy reinforces a simple principle: cancer policy must be built around patient outcomes and clinical expertise. By grounding its positions in real-world data and the experience of medically integrated oncology practices, NCODA works to ensure administrative processes support — rather than hinder — high-quality cancer care.

PERSPECTIVE: PROTECTING PATIENT-CENTERED ONCOLOGY CARE FROM HARMFUL STEP EDITS

The right therapy, the right time, the right patient — selected by the physician

NCODA's mission is to advance patient-centered, medically integrated oncology care. At our core is a simple principle: people with cancer deserve timely access to the most appropriate, evidence-based therapies, guided by the clinical expertise of their oncology care team and informed by each patient's unique disease characteristics and personal circumstances.

NCODA strongly opposes step therapy policies in oncology, as they delay appropriate treatment, increase the risk of avoidable complications and drug waste, and undermine the cost-avoidance benefits achieved through medically integrated oncology care. While we recognize the need for responsible healthcare spending and collaboration among payers, oncologists, manufacturers, and policymakers, cancer care requires flexibility, nuance, and trust in clinical expertise.

Patient-centered care is not achieved through rigid algorithms, but through thoughtful collaboration and respect for

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WHAT NCODA CALLS FOR ON THE STEP THERAPY ISSUE

- Meaningful oncology-specific exemptions from step therapy requirements.
- Transparent, clinically grounded criteria when utilization management is applied.
- Timely, streamlined exception and appeals processes that prioritize patient safety (including rapid review pathways when delay risks harm).
- Collaboration with oncology clinicians and patient advocates in policy design.
- Recognition of medically integrated oncology practices as partners in value-based care.

ADVOCACY

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the complexity of cancer treatment.

In 2025, NCODA published a Perspective addressing growing concerns around step therapy and its implications for oncology care. Since that time, the use of step edits has continued to expand across payers and care settings. While step therapy is often positioned as a cost-management tool by insurers, its routine application in oncology raises serious concerns about safety, equity, clinical autonomy, and outcomes.

NCODA recognizes the complexity of healthcare economics and the importance of stewardship of limited resources. However, policies that delay or restrict access to the right cancer therapy at the right time undermine both patient outcomes and the long-term value of care.

Our goal is to elevate the conversation around step therapy in oncology by increasing visibility to its real-world impact and encouraging thoughtful, patient-centered policies grounded in clinical evidence, patient needs and shared accountability.

THE UNIQUE NATURE OF ONCOLOGY CARE

Cancer care presents unique clinical and timing considerations that distinguish it from many other areas of medicine. Oncology treatment decisions are rarely interchangeable, rarely straightforward, and rarely forgiving of delay. Advances in precision medicine have transformed cancer treatment from a one-size-fits-all approach to one that is increasingly driven by tumor biology, biomarkers, genetic mutations, disease stage, prior treatment response and patient-specific factors.

In this context, step therapy, which requires patients to try and fail one or more insurer-preferred therapies before accessing the therapy selected by their oncologist, is particularly problematic. Unlike many chronic disease medications, cancer therapies are often not therapeutically equivalent substitutes. A "fail-first" or "intolerance" requirement can mean knowingly exposing patients to treatments that are less likely to work, and more likely to cause harm, or both.

Patient-centered care is not achieved through rigid algorithms, but through thoughtful collaboration and respect for the complexity of cancer treatment.

Timing matters in cancer. Delays in initiating the most appropriate therapy, and interruptions in treatment sequencing, can allow disease progression, reduce the likelihood of response, and narrow future treatment options. Even short interruptions or detours in care can have lifelong consequences.

DISRUPTION OF CONTINUITY AND PERSONALIZED MEDICINE

One of the most significant harms of step edits in oncology is the disruption of continuity of care. Patients begin their cancer journey at a moment of profound vulnerability, relying on their care team for clarity, trust, and guidance. When a payer-mandated step edit overrides a carefully constructed treatment plan by a healthcare provider, that trust is strained.

Step therapy policies also ignore the reality of personalized medicine and undermine clinical judgment. Treatment decisions are complex, based on clinical trial data tied to specific patient populations. Step edits often apply blunt rules to nuanced clinical situations, forcing patients into standardized pathways that do not reflect their individual disease and can have serious consequences on health outcomes.

By treating patients as members of a generalized group rather than as individuals, step edits undermine the very progress oncology has made over the past two decades.

RISK OF DISEASE PROGRESSION AND INCREASED TOXICITY

Requiring patients to try suboptimal therapies first is not a benign exercise. For many patients, progression during an ineffective line of therapy can mean loss of performance status, increased symptom burden and reduced eligibility for future treatments or clinical trials.

Step edits may force patients into older therapies or regimens with higher toxicity profiles. Increased adverse effects can lead to emergency department visits, hospitalizations, treatment interruptions, and diminished quality of life. These downstream consequences are not only harmful to patients — they also increase the total cost of care.

EMOTIONAL AND PSYCHOLOGICAL IMPACT ON PATIENTS

A cancer diagnosis already carries immense emotional weight. Patients face fear, uncertainty, and loss of control. Being told that the treatment recommended by their oncologist is delayed or denied — not due to medical reasoning, but because of an administrative requirement — adds another layer of distress.

The message patients often hear is not "This is the best care for you," but rather "You must wait" or "you must try something else first." This uncertainty erodes confidence in the healthcare system and exacerbates anxiety at a time when emotional support is critical.

ADMINISTRATIVE BURDEN AND CLINICIAN BURNOUT

Step therapy policies place a significant administrative burden on oncology practices. Prior authorizations, appeals, peer-to-peer reviews, and repeated documentation requirements divert time and resources away from direct patient care.

Over time, this burden contributes to staff burnout and practice strain. In some cases, the complexity and time required to appeal a step edit may discourage pursuit of the optimal therapy altogether — resulting in patients receiving treatments that neither the physician nor the patient believes are best.

This shift of decision-making authority away from oncologists undermines shared decision-making and

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ADVOCACY

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devalues clinical expertise.

QUESTIONING THE COST NARRATIVE

While step therapy is often justified as a cost-containment strategy, the financial reality in oncology is far more complex. Delays in accessing the most appropriate therapy can result in disease progression, additional lines of treatment, increased toxicity, and hospitalizations, all of which drive higher total costs of care.

Step edits can increase drug waste. When patients are required to initiate therapies that are unlikely to be effective, partially administered regimens, unused medications, and treatment changes due to progression or toxicity contribute to avoidable financial waste. These inefficiencies stand in contrast to the cost-avoidance benefits achieved through medically integrated oncology practices, where close coordination of care, real-time clinical oversight, and adherence help optimize therapy selection and minimize unnecessary utilization.

Short-term cost shifting should not be mistaken for sustainable, long-term value. True value in oncology is achieved by ensuring the right therapy is delivered at the right time, reducing avoidable complications, minimizing waste, and supporting sustainable, patient-centered care delivery.

As step edit policies continue to evolve, NCODA will remain actively engaged in leading education and advocacy efforts that prioritize clinical integrity and patient outcomes.

ADVANCING A BETTER PATH FORWARD

As the oncology landscape continues to evolve, policies must evolve with it. Cancer care demands precision, timeliness, and trust in clinical expertise. Administrative mechanisms that delay or redirect evidence-based treatment decisions do not reflect the complexity of modern oncology or the shared goal of improving outcomes while stewarding resources responsibly.

Patients with cancer deserve more than administrative complexity. They deserve care that is timely, individualized, and grounded in clinical evidence. Step therapy, as currently applied in oncology, too often falls short of that standard.

NCODA remains committed to being a leading, constructive voice in this conversation. By shining a light on the real-world impact of step edits and advocating for policies aligned with patient needs, we can move toward a healthcare system that balances cost considerations with compassion, precision, and outcomes.

Delivering the right cancer therapy, at the right time, for the right patient, is not only good medicine, it is sound health policy.

As step edit policies continue to evolve, NCODA will remain actively engaged in leading education and advocacy efforts that prioritize clinical integrity and patient outcomes. Our commitment to addressing these challenges alongside our members and partners is ongoing.

Please reach out to **contact@ncoda.org** for further information or to discuss this important issue.