

# ONCOLOGY CARE MODEL

## SUPPORTING ORAL CHEMOTHERAPY ADHERENCE

---

*Learning System Case Study #3*

October 10, 2017

**Prepared by:**

Booz Allen Hamilton

Brandeis University

## Contents

Supporting Oral Chemotherapy Adherence.....	1
Core Considerations .....	1
Barriers to Adherence.....	2
Assessing Nonadherence Risk.....	4
Addressing Barriers to Adherence .....	5
Access Assistance .....	5
Patient Education and Self-Management Support.....	6
Monitoring and Follow-Up .....	8
Conclusion .....	9
OCM Practices Highlighted.....	10
Resources and Toolkits .....	10
General Resources .....	10
Access Assistance.....	11
Assessment, Education, and Monitoring.....	12
References .....	13
Appendix A: Practice-Provided Tools.....	18
Texas Oncology.....	18
Allegheny Health Network Cancer Institute.....	28
Cancer Care Specialists of Illinois.....	33
Appendix B: OCM Driver Diagram .....	37

# **Supporting Oral Chemotherapy Adherence**

This case study presents a variety of strategies used to assess and address patients' capacity for adherence to oral chemotherapy regimens. Strategies presented are evidence-based or promising practices supported by primary research and peer-reviewed literature, some of which are currently being used by a diverse group of Oncology Care Model (OCM) participants. In this case study, "adherence" is defined as the degree to which patients' behavior aligns with medical advice,<sup>1</sup> or more specifically, the degree to which they take oral chemotherapy medication as prescribed.<sup>2</sup>

The following sections offer a brief overview of the evidence regarding core considerations for assessing and addressing patients' capacity for oral chemotherapy adherence. This case study also highlights the practical implementation experience of OCM practices. Throughout the document, implementation resources and relevant literature are hyperlinked directly in the text to allow for immediate access while reading relevant material. The [Resources and Toolkits](#) section, at the end of the document, lists all resources and literature specific to this Case Study.

## ***Core Considerations***

Use of oral chemotherapy has grown rapidly over the past decade and is likely to continue rising,<sup>3,4</sup> with over 50 Food and Drug Administration (FDA)-approved oral anticancer medications available as of 2015<sup>5</sup> and estimates suggesting that over one quarter of anticancer drugs currently in development will be orally administered.<sup>3</sup> This increase in oral chemotherapies may bring some advantages, including greater autonomy and convenience for patients, avoidance of more invasive infusion administration, and the potential for improved quality of life.<sup>6</sup> For health systems, advantages of oral chemotherapy may include reduced burden of care due to less health care utilization by patients,<sup>7,8</sup> though these gains may be somewhat offset by education and monitoring requirements.<sup>3</sup>

Despite these advantages, however, oral chemotherapy brings its own set of challenges. Among the most significant of these is the increased self-management responsibility placed on patients receiving oral chemotherapy. These patients themselves must closely follow drug regimens that are often complex, while also monitoring side effects and reporting them as necessary.<sup>3</sup> At the same time, patients may have significant knowledge gaps<sup>6,9</sup> and less oversight from and contact with providers,<sup>1,6</sup> and they also have to balance the physical, financial, and emotional impacts of cancer diagnosis and treatment.

Given these factors, patient adherence remains a key challenge in oral chemotherapy administration. Studies have found that anywhere from one-fifth to more than 40% of patients receiving oral chemotherapy have poor adherence.<sup>2</sup> Both over- and under-adherence to prescribed oral chemotherapy—in other words, taking either more or less than prescribed—can create negative outcomes for patients and health care systems, including worse health outcomes,<sup>1,2,10,11</sup> higher mortality,<sup>1,2,11</sup> increased toxicity,<sup>1,10</sup> delays and changes in treatment,<sup>1</sup> and higher health care utilization and total cost of care.<sup>1,10</sup>

The remainder of this case study discusses key barriers that patients may face in adhering to oral chemotherapy regimens and presents strategies for addressing these barriers. These

strategies correlate with [OCM Key Drivers](#) of access and continuity, care coordination, care planning and management, and patient and caregiver engagement.

### ***Barriers to Adherence***

Though the seriousness of a cancer diagnosis means that cancer patients are often highly-motivated to receive treatment,<sup>1,3,12</sup> a number of barriers may interfere with patients' ability to adhere to oral chemotherapy regimens. The relevance of these barriers to any particular patient varies based on a variety of factors, including the type of oral chemotherapy received and the patient's insurance coverage. For example, hormonal therapy—sometimes considered a type of oral chemotherapy, though not a focus of this case study—is often less expensive<sup>13</sup> than other types of oral chemotherapy. Similarly, barriers faced by Medicare beneficiaries may differ from those faced by patients with other insurers or who lack insurance coverage, particularly as anticancer medications are a protected class of prescription drug covered by all Medicare plans.<sup>14</sup> This case study focuses on the general population of patients, not only patients with Medicare. Barriers to oral chemotherapy adherence among this general population include:

#### **Barriers to Adherence**

- ✓ Financial affordability
- ✓ Access challenges
- ✓ Cognitive and knowledge gaps
- ✓ Side effects
- ✓ Physical and psychosocial factors

- **Financial Barriers:** Cancer patients often face significant financial hardship<sup>15,16</sup> that places them at risk for worse outcomes and higher mortality.<sup>17,18,19</sup> This obstacle is especially pronounced for oral chemotherapy as the drugs involved can be expensive,<sup>3,20</sup> may not be covered by insurance or may be subject to high copayments or coinsurance,<sup>5,20</sup> and are often taken over long periods of time or even indefinitely.<sup>1,3</sup> The resulting high costs can reduce adherence to oral chemotherapy regimens.<sup>1,2,21,22</sup> While Medicare covers nearly all FDA-approved oral chemotherapies,<sup>14,20</sup> affordability may still be a concern for Medicare beneficiaries,<sup>20</sup> particularly those without secondary insurance or whose prescribed drugs require high copayments/coinsurance.
- **Access Barriers:** Access barriers are sometimes related to financial barriers, but focus more specifically on the logistics of obtaining the prescribed oral chemotherapy drug. Some of these barriers are insurance-related: oral oncolytics are often on a high formulary tier, or in some cases may be subject to quantity limits or not covered at all.<sup>23</sup> Such situations not only make the drugs more expensive, but also mean that a significant amount of work may be required in order to receive an exception from insurance requirements. Combined with more standard requirements such as prior authorization, these considerations mean that dealing with insurance can be labor-intensive<sup>24,25</sup> as well as confusing and burdensome for patients,<sup>26</sup> particularly given that relevant information about insurance policies is not always easily accessible.<sup>23</sup>

Receiving drugs from the pharmacy can also be a source of barriers and delays. Many oral chemotherapy drugs must be procured from specialty pharmacies, and while these often provide more support to patients than do traditional pharmacies<sup>27</sup>

and may be associated with greater adherence,<sup>28</sup> delays in processing new prescriptions are common.<sup>27,29</sup> Use of specialty pharmacies may also create coordination of care challenges that can result in additional logistical burden<sup>24,25</sup> and may also raise potential safety concerns.<sup>27</sup> Some oncologists also report concern that external specialty pharmacies interfere with their ability to oversee the full course of their patients' care, as many communicate only with patients and not with their health providers. In addition, those patients who do not receive their drugs by mail must have an accessible pharmacy from which to pick them up.<sup>30</sup>

Combined, insurance and pharmacy barriers can make receiving oral chemotherapy drugs challenging. For example, one practice has found that new oral chemotherapy prescriptions prescribed for on-label use took an average of two weeks and five phone calls to procure.<sup>24,31</sup>

- **Cognitive and Knowledge Barriers:** Patients often lack knowledge about important details related to oral chemotherapy, including administration schedules, safe handling, and side effect management,<sup>6,9</sup> and these knowledge gaps can negatively impact adherence.<sup>32</sup> Oral chemotherapy administration schedules are often complicated and exacting, typically requiring pills to be taken at specific times and under specific circumstances (such as with or without food),<sup>1,3</sup> and adherence declines as complexity rises.<sup>1,21</sup> Patients may not understand these schedules well enough to follow them, or may not be aware of the importance of doing so. In addition, patients may not understand that oral chemotherapy is “real” chemotherapy and plays a key role in their overall treatment<sup>3</sup>—a misconception with the potential to lower adherence, as motivation and the belief that treatment will make a difference contribute to better adherence.<sup>1,2,21,22</sup> Similarly, patients may not understand that oral chemotherapy is not like other medications and that specific safety precautions need to be followed while taking it.<sup>6</sup>

Certain patients also face circumstances that make such issues more challenging. Patients with cognitive impairments, for example, may struggle to understand and follow their oral chemotherapy regimens.<sup>12,33</sup> Lack of literacy and/or health literacy can also present an obstacle.<sup>1,12</sup>

- **Side Effect Perception Barriers:** Side effects can be an important reason that patients receiving oral chemotherapy might under-adhere to treatment.<sup>1,2,22</sup> Though patients may have an expectation that side effects from oral chemotherapy will be less severe than side effects from intravenous chemotherapy,<sup>1,3</sup> this is not necessarily the case.<sup>3</sup> As a result, patients may sometimes adjust their adherence to minimize these side effects.<sup>3</sup>
- **Physical and Psychosocial Barriers:** Some patients may face physical barriers to oral chemotherapy adherence. These can include having trouble swallowing pills, opening packaging, or reading labels or instructions.<sup>12,22</sup> Such barriers can also include unexpected side effects, symptoms, or comorbidities—such as nausea or decreased appetite—that interfere with the ability to adhere to treatment.<sup>2,21,22</sup>

In addition, patients can face psychosocial barriers to adherence. The availability of a social support system to assist with the treatment regimen is an important factor in supporting adherence,<sup>1,2</sup> and patients without this support may struggle to maintain their regimens. Presence of a mood or thought disorder such as depression or anxiety can also negatively impact adherence.<sup>1,2,21</sup>

### ***Assessing Nonadherence Risk***

The first step in providing effective adherence support for oral chemotherapy patients is to proactively assess all candidates for the presence of potential barriers to adherence.<sup>3,34</sup> Such an assessment was included as a component of the 2013 American Society of Clinical Oncology (ASCO)/Oncology Nursing Society (ONS) [Chemotherapy Administration Safety Standards](#), which specifically addressed oral chemotherapy. The standards recommended that “socioeconomic, psychosocial, financial, administrative and regulatory factors that may influence initiation and/or adherence” be documented, and that a plan to address such issues be developed.<sup>34</sup> Doing so allows potential barriers to be addressed at the start of treatment, before problems arise. It also allows an opportunity to determine whether the patient is a good candidate for oral chemotherapy, if alternate treatment options should be explored,<sup>3</sup> or if the regimen should be simplified.<sup>10</sup>

Areas that are particularly important to assess touch on the barriers described in the previous section and include issues of affordability, accessibility, treatment regime viability, and patient and family/caregiver knowledge regarding side effect management. Many tools exist to support such evaluation, including [resources from ONS](#) and the [Association of Community Cancer Centers \(ACCC\)](#). See the [Resources and Toolkits](#) section for more information.

[Texas Oncology \(Texas Oncology, P.A.\)](#) began developing its oral chemotherapy program in advance of the start of OCM, knowing that the area would be a challenge under the model. It finds that adherence is now consistently over 90% in its internal studies. Much of the initial nonadherence risk assessment at Texas Oncology is conducted by physicians as they determine whether patients are viable candidates for oral chemotherapy. Team feedback also plays into this process, as nurses have an opportunity to interact with patients and raise any issues they encounter. In addition, the first steps in the practice’s oral chemotherapy process call for the advanced practice provider (APP) or nurse conducting the education session to assess barriers to learning, ability to obtain the prescribed drugs, and presence of any symptoms that may affect physical ability to take the medication.

[Allegheny Health Network Cancer Institute \(Allegheny Clinic\)](#) (AHNCl) started building its oral chemotherapy program in early 2014, anticipating the continuing increase in patients receiving oral chemotherapy. The program is still a work in progress and has been implemented more fully at some sites than at others. AHNCl is also working to refine its staffing model for this program. Internal studies conducted as part of this effort show that nurses spend an average of 24 minutes per patient per week managing tasks related to oral chemotherapy. Like at Texas Oncology, much of the pre-assessment of patients at AHNCl is conducted by clinical staff in the process of deciding on treatment. The practice also conducts baseline toxicity screenings before treatment begins.

[Cancer Care Specialists of Illinois \(Cancer Care Specialists of Central IL, S.C.\)](#) (CCSI) is newly developing its oral chemotherapy processes, with plans to roll out the changes in fall 2017. The practice aims to create parallel processes for oral and IV chemotherapy patients and sees its planned changes as vital to keeping patients out of the hospital. Like at Texas Oncology and AHNCL, physicians at CCSI assess patients' adherence ability when making treatment decisions, and other members of the care team can raise additional concerns should they arise. However, the practice has also developed a risk assessment system that it plans to use to proactively manage high-risk oral chemotherapy patients. Patients will be designated as high-risk based on the National Comprehensive Cancer Network's (NCCN) distress thermometer scores, type of cancer, comorbidities, recent hospitalizations or falls, polypharmacy, hierarchical condition category (HCC) scores, and barriers to understanding care (see [Appendix A](#) for more information). Any staff member can assess risk using the checklist the practice has developed, though for OCM patients the assessment is often conducted by a nurse navigator. In the future, CCSI hopes to expand this nurse navigator program to all patients. While all oral chemotherapy patients will receive follow-up calls, those identified as high-risk will receive additional calls compared to lower-risk patients. CCSI hopes to eventually circulate a weekly high-risk patient list for the care team to review, facilitating effective, multidisciplinary management of patients.

### ***Addressing Barriers to Adherence***

A variety of successful strategies exist for addressing risks found during the pre-assessment and for supporting all patients, regardless of risk status, in adhering to their oral chemotherapy regimens. Providing financial and access assistance, high-quality patient education, side effect self-management support, and monitoring and follow-up are all important elements of strong oral chemotherapy support programs. Such programs are most successful when they are multidimensional,<sup>1,10,35</sup> include information specific to the individual patient and treatment plan,<sup>11,36</sup> and are systematized within the practice.<sup>37</sup>

### ***Access Assistance***

Addressing financial and other drug access concerns is a crucial step in helping patients overcome barriers to oral chemotherapy adherence.<sup>10,34,38,39</sup> Because patients cannot adhere to medications that they do not have and because financial hardship has wide-reaching negative effects,<sup>17,18,19</sup> it is important to help patients find cost assistance as necessary, assist patients in navigating the insurance process, and identify a pharmacy from which patients will reliably be able to receive their prescriptions. When alternative treatment options exist, it may also be necessary to consider changing the regime to one the patient can access and afford.<sup>10</sup>

**“Financial toxicity can be just as bad as drug toxicity.”**

Holly Books, BSN, RN, OCN  
Director of Nurses, Texas Oncology

At **Texas Oncology**, an eight-person patient assistance team consisting primarily of pharmacy technicians handles prior authorizations and financial assistance for all patients receiving oral chemotherapy. Staff view this team as a key component of the practice's oral chemotherapy program, as it has freed nurses from these responsibilities and allows them

### **Steps to Success from Texas Oncology Pharmacy Director Jim Schwartz**

- ✓ Identify one specific pharmacy to work with
- ✓ Invest in a prior authorization resource such as [CoverMyMeds](#)
- ✓ Utilize patient assistance resources such as [NCODA](#)
- ✓ Free nurses from working on prior authorizations

to provide more-timely, higher-touch care to patients. Prescriptions are filled either by Texas Oncology's internal pharmacy network or through a specialty pharmacy, and a sufficient number of sites have retail pharmacies that physical access to pick up prescriptions is not typically a concern. Though the patient assistance team is generally successful at securing financial assistance for patients as needed, staff still consider cost to be a key barrier for patients.

At AHNCl, the access process begins when a new prescription is sent to an external pharmacy to review. The pharmacy then reports if a prior authorization is needed and, if so, practice staff complete the necessary requirements. When there is a high copayment, the pharmacy often helps to identify assistance resources, but the work of applying for these opportunities typically falls on AHNCl's team members, including nurses, pharmacists, and social workers. This process can be labor-intensive, and AHNCl is exploring ways to remove these responsibilities from clinical staff. Options under consideration include using pharmacy technicians or creating a centralized prior authorization team such as is in place for IV patients. While AHNCl does have one preferred external specialty pharmacy it works with on a consistent basis, it also works with other external specialty pharmacies depending upon insurance requirements.

CSCI fills all prescriptions at its own retail pharmacy, and pharmacy staff work with the billing office to secure prior authorizations and financial assistance for oral chemotherapy patients. They also coordinate with nurse managers at each practice site to ensure that no patients slip through the cracks. Typically, the access process begins with billing insurance for the prescription. If this results in a large copayment, pharmacy staff then work to secure assistance using a list of resources kept on file. They can also bring the issue to the physician, who may work with the patient to develop an alternate treatment plan. Once filled, prescriptions are either mailed to patients or sent by courier to patients' local practice sites. The latter approach has the benefit of ensuring that patients come in for follow-up appointments before receiving the new drug, and allows patients also receiving IV chemotherapy to receive their oral prescription on the same day.

### ***Patient Education and Self-Management Support***

To minimize knowledge gaps and proactively address any cognitive barriers, it is important to have a robust patient education program for oral chemotherapy patients.<sup>11,12,39</sup> Such programs should include family members or caregivers when possible,<sup>10,34</sup> particularly if the pre-assessment indicates that the patient may be likely to require assistance in following the treatment regimen.<sup>12,38</sup> Oral chemotherapy patient education programs should be embedded into practice workflow in order to ensure that staff responsible for education know about new oral chemotherapy prescriptions and can connect with those patients in a timely manner.<sup>26,40</sup>

To be most effective, these patient education programs should be patient-centered<sup>1,11</sup> and provide personalized information that is specific to the patient and treatment regimen.<sup>11,12</sup> The [teach-back method](#)—an approach that asks patients to restate information in their own words—can be an important part of such education,<sup>37,41</sup> allowing providers to check for and reinforce patient understanding. Other successful strategies include providing information in multiple formats (e.g. written as well as verbal)<sup>34,38,42</sup> and developing a structured program.<sup>42</sup> (For more information on patient-centered education, see [Learning System Case Study #2](#).)

Information that should be part of oral chemotherapy patient education includes administration instructions; directions for storage, handling, and disposal; potential interactions; and instructions for what to do in case of a missed dose.<sup>34</sup> In addition, patient education should ensure that patients and their families and caregivers understand possible side effects of their oral chemotherapy regimens,<sup>34</sup> know how to manage symptoms, and know when and whom to call before stopping or altering drug administration.<sup>1,22</sup> It can also be helpful to address patients' possible fears about reporting side effects, such as concern that their treatment will be stopped and their cancer will progress as a result.<sup>12</sup> See the [Resources and Toolkits](#) section and the [ASCO/ONS Chemotherapy Administration Safety Standards](#) (2016 and 2013) for more detailed information.

**Texas Oncology** provides patient education to all oral chemotherapy patients, with education sessions conducted by APPs at sites that have them and by nurses at sites that do not. These sessions typically take place in person and one-on-one, with family members and caregivers included when possible. Content includes administration instructions—provided both verbally and in writing—and encouragement to record side effects and call the practice with any concerns. Understanding is evaluated and documented in the medical record. Pharmacy staff also provides counseling at the time of dispensing, reinforcing the same information covered by the nursing/APP staff. Prior to ever dispensing the oral chemotherapy agent, the pharmacist reviews the patient's medical information to identify potential drug-drug, drug-food, and drug-disease interactions, as well as verify that the correct dose has been ordered for each individual patient. Practice staff identified communication within practice sites as a potential barrier to timely education: when nurses are not informed of new oral chemotherapy prescriptions issued, they lose the opportunity to speak with patients before they leave the office and must instead follow up at a later time.

**AHNCI** continues to develop its patient education program. Ideally, AHNCI patients receive an initial overview of their treatment at the time the drug is prescribed, but then return to the practice for a full educational session once the prescription has been filled and prior to the first dose. Conducting the full session at this time allows practice staff to complete important safety checks, including reviewing prescription accuracy, baseline labs, toxicity assessment, follow-up appointment schedule, and verification that the patient understands the treatment plan. The follow-up visit also helps patients and their family members retain more information as the stress of the initial treatment decision has passed. Offices that have implemented this educational strategy are currently capturing about 70% of patients for the additional in-person teaching visit and are working to increase that rate. For patients who have extenuating circumstances and cannot come to the office for the additional visit, the practice communicates with the patient and family via phone and completes the safety

checks as described above. AHNCI is also exploring other innovative options such as the possibility of implementing home care appointments.

At CCSI, patients receive information about their treatment from the physician at the time the prescription is given, have a dedicated educational session with a nurse, and can access counseling from pharmacy staff as needed. As the practice develops its oral chemotherapy program, one of its goals is to create a standardized patient education format that can be customized for individual patients, drugs, and treatment plans. Its education guidelines also call for the use of teach-back methods to assess understanding, and patients who have poor understanding are flagged as high-risk. In addition, CCSI has identified specific cultural beliefs in its patient population that can be proactively addressed during patient education. For example, patients from the practice's agricultural communities are often reluctant to complain or to bother the doctor or nurse by reporting side effects, so may simply stop taking their pills. Patients from lower-resource areas sometimes see cancer as being always fatal and do not believe treatment can help, and therefore do not adhere to their oral treatment regimens.

### ***Monitoring and Follow-Up***

Monitoring and providing feedback to patients on oral oncolytics is another important way to support adherence.<sup>10,12,22,35</sup> One of the first steps in this process is developing a mechanism to know when patients receive the drug from the pharmacy.<sup>34</sup> This may, for example, involve calling these patients or having them call the practice when they fill their prescription. Once patients start treatment, regular phone calls to assess adherence and toxicity<sup>10,37</sup> can support adherence. While such follow-up is especially important for patients who are new to oral chemotherapy treatment, adherence may decline over time,<sup>2,21,22</sup> so it is important to follow up with longer-term patients as well. Standardized systems for monitoring toxicity<sup>36,41</sup> and for responding to incoming phone calls and urgent needs<sup>10</sup> are also helpful.

**"We're not going to keep [patients] out of the hospital if we're not calling them at the right time, if we're not bringing them in at the right time."**

LeAnn Rhinehart, MSN, APN, FNP-BC  
OCM Director, Cancer Care Specialists of Illinois

Practices can also improve adherence by providing patients with aids to help them maintain their treatment schedules and more accurately self-report their adherence. They can also help patients to put their own reminder systems in place. Examples of such aids include diaries,<sup>10,36</sup> calendars,<sup>43</sup> phone alarms,<sup>36,43</sup> reminder texts,<sup>35</sup> automated voice response systems,<sup>35</sup> pillboxes,<sup>10,43</sup> and other memory aids.<sup>10,36,43</sup> See the [Resources and Toolkits](#) section for more information.

When patients begin oral chemotherapy, **Texas Oncology** helps them make a plan for taking their medication correctly, such as setting up an alarm, calendar, or diary. A nurse calls the patient five days after the prescription was written to find out whether the prescription has been filled, check that the drug received is correct, ensure that the patient knows how to take the medication and what to do about missed doses, and verify the treatment start date. Nurses then call weekly for the first month—sometimes longer for high-risk patients—to assess side effects and adherence. Texas Oncology staff see side effects as a significant barrier to adherence, and believe that asking about them at the start of treatment not only

captures toxicities being experienced at that time, but also reinforces to patients that certain symptoms may be related to oral chemotherapy and are something they should take seriously and call the practice about. Nurses inform physicians about any delays in receiving the medication, adherence issues, or significant side effects. In addition, an appointment is scheduled for two to four weeks after the start of treatment and at least monthly for the first two months.

At AHNCl, patients are instructed to call the practice when their prescription is filled (though practice staff will call if patients do not contact the office). The first three cycles of therapy are ordered without refills; however, up to three cycles may be ordered at a time starting with cycle four, at the prescriber's discretion. A baseline teaching appointment is scheduled to complete safety checks, including toxicity assessment. After that appointment, toxicity assessment and adherence are monitored during a follow-up call scheduled for one to two weeks following the start of therapy, and a provider visit is scheduled prior to each refill. Adherence and toxicity are assessed and documented by clinical staff in a standardized format within the electronic medical record in order to track and trend data over time. AHNCl's clinical pharmacy specialists have developed tools to support these processes, including standardized drug-specific toxicity assessment sheets and calendars that are given to patients to monitor their adherence. These tools are validated by a multidisciplinary team.

CCSI has not yet implemented its oral chemotherapy follow-up program, but plans to begin having pharmacists proactively call patients who have recently started treatment. The first call will be made three to four days after treatment begins, and practice staff will respond to problems using the [ONS telephone triage guidelines](#). If there are no problems, the pharmacist will encourage the patient to call the practice if any issues arise. This component is tailored to CCSI's patient population, many of whom live in rural areas and may choose to alter or discontinue their medication rather than notify the physician, pharmacist, or nursing staff. A second call will be made 10 days later, again using the triage pathways if appropriate and encouraging patients to call the practice as needed. If no problems exist at that point, an optional third call may be made 10 to 14 days later for high-risk patients. While CCSI does not currently have a formal mechanism for assessing adherence or toxicity, this is an area practice leadership would like to develop in the future. The practice's current approach is to bring patients into the practice if any toxicity or adherence concerns arise. CCSI is also utilizing Avella Specialty Pharmacy's [Oral Chemotherapy Monitoring & Counseling Chart](#).

### **Conclusion**

This case study presents evidence-based strategies for assessing and addressing patients' capacity for adherence to oral chemotherapy regimens, a topic which relates to [OCM Key Drivers](#) of access and continuity, care coordination, care planning and management, and patient and caregiver engagement. Lessons learned from the implementation experience of OCM practices are also presented. While these experiences can serve as a guide to others considering these strategies, implementation strategies and outcomes will vary across practices in OCM. These and other strategies will be integrated into the overall OCM Key Drivers & Change Package. The strategies highlighted here are not intended to limit the span or scope of efforts to assess and address patients' capacity for adherence to oral

chemotherapy regimens. Instead, they are examples for practices to consider in their efforts to meet those goals. As additional data are collected and our collective implementation experience accumulates in OCM, new strategies for increasing patient engagement and shared decision-making will emerge and be shared through the Learning System.

## OCM Practices Highlighted

A special thank you to practices who took time out of their busy schedules to provide insight into their practice workflows and implementation to support oral chemotherapy adherence. Our goal with this case study is to continue to spread successful strategies in achieving the OCM aim. This section provides a summary of the practices included in this case study.

### *Texas Oncology (Texas Oncology, P.A.)*

[Texas Oncology](#) is a private oncology practice with over 175 locations across Texas. Founded in 1986, it provides medical, radiation, gynecologic, and surgical oncology services; a network of urology practices; and a series of specialty programs including pediatric oncology, genetics, proton therapy, and a brain tumor center. Texas Oncology is affiliated with the [US Oncology Network](#), a national organization owned by [McKesson Specialty Health](#) that provides resources and support to community oncology practices across the country.

### *Allegheny Health Network Cancer Institute (Allegheny Clinic)*

[Allegheny Health Network Cancer Institute](#) serves patients in western Pennsylvania, West Virginia, and Ohio through its seven hospitals and more than 50 clinics. AHNCL provides medical, surgical, and radiation oncology to over 3,500 patients per year and is part of [Allegheny Health Network](#), an integrated health system formed in 2013.

### *Cancer Care Specialists of Illinois (Cancer Care Specialists of Central IL, S.C.)*

[Cancer Care Specialists of Illinois](#) provides medical, hematologic, radiation, and urologic oncology services to its patients. Founded in 1984, CCSI has 20 clinics located throughout central and southern Illinois designed to take care to the population. CCSI is affiliated with several [National Cancer Institute](#)-supported research organizations, which provide advanced research and treatment options for its patients. It has also received certification in ASCO's Quality Oncology Practice Initiative (QOPI).

## Resources and Toolkits

Links provided are for educational purposes only. The Centers for Medicare & Medicaid Services do not endorse these resources or the organizations that developed them.

### *General Resources*

Resource	Description
<a href="#">ONS Oral Adherence Toolkit</a>	Oral chemotherapy adherence toolkit with resources on a variety of topics, including assessment, education, reimbursement, and medication reconciliation

<a href="#">Steps to Success: Implementing Oral Oncolytics</a>	ACCC report providing recommendations and examples for implementing oral chemotherapy programs
<a href="#">Oral Oncology Implementation Tools</a>	List of oral chemotherapy program resources compiled by ACCC
<a href="#">Oral Oncolytics Series: Archived Webinars</a>	On-demand oral chemotherapy webinars developed by ACCC (free registration required to view)
<a href="#">Oral Oncolytics Resources</a>	Michigan Oncology Quality Consortium oral chemotherapy resources, including sample new-patient documents and information sheets for a variety of drugs
<a href="#">An Interprofessional Collaborative Approach to Improve Oral Oncolytic Adherence</a>	OncoLink educational video for providers, providing an overview of oral chemotherapy adherence including barriers and successful strategies
<a href="#">Adherence Strategies and Oral Oncolytics</a>	<i>American Journal of Managed Care</i> videotaped discussion of oral chemotherapy adherence, part of a longer video series on oral chemotherapy
<a href="#">2013 Updated ASCO/ONS Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy</a>	2013 ASCO/ONS chemotherapy administration guidelines, specifically addressing oral chemotherapy management
<a href="#">2016 Updated ASCO/ONS Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology</a>	Most recent ASCO/ONS chemotherapy administration guidelines for oral and IV chemotherapy

### Access Assistance

Resource	Description
<a href="#">ACCC Patient Assistance and Reimbursement Guide</a>	ACCC guide to patient assistance and reimbursement, with general information as well as information by pharmaceutical company and drug name
<a href="#">ACCC Financial Advocacy Network Toolkit</a>	Resources for the development, implementation, and delivery of effective financial advocacy services, including position descriptions and tools for communication, understanding the insurance process, handling denials, and information for patients
<a href="#">ACCC Financial Advocacy Network Online Courses</a>	Resources and skill-based educational materials for program staff currently providing financial counseling, as well as those new to financial advocacy (includes both free and paid offerings)

<a href="#">NCCN Virtual Reimbursement Resource Room</a>	Guide to patient assistance programs organized by cancer type, drug name, and reimbursement program
<a href="#">NCODA Financial Assistance</a>	Overview of financial assistance options for a variety of drugs (free membership required)

### *Assessment, Education, and Monitoring*

Resource	Description
<a href="#">ACCC Oral Chemotherapy Assessment</a>	Pre-oral chemotherapy assessment tool from ACCC, including questions about physical and cognitive ability, safety knowledge, social support, and drug access
<a href="#">MASCC Oral Agent Teaching Tool (MOATT)</a>	Oral chemotherapy education framework including knowledge assessment and teaching instructions
<a href="#">Oral Chemotherapy Monitoring &amp; Counseling Chart</a>	Avella Specialty Pharmacy table providing monitoring parameters and key information to provide to patients for a variety of drugs (free registration required)
<a href="#">Oral Chemotherapy – What Your Patients Need to Know</a>	ACCC report providing an overview of oral chemotherapy patients' educational needs and sample educational documents
<a href="#">Patient and Family Engagement &amp; Shared Decision-Making: Learning System Case Study #2</a>	OCM Learning System case study on patient and family engagement and shared decision-making, including information and resources relating to patient education
<a href="#">Use the Teach-Back Method</a>	AHRQ guide to using the teach-back method to assess patient understanding
<a href="#">Build My Patient Treatment Binder</a>	OncoLink informational sheets on a wide variety of topics, including handling and side effects of specific drugs (scroll to the bottom of the page and click on "Rx Sheets")
<a href="#">ONS Oral Chemo Guide</a>	Extensive interactive oral chemotherapy video guide for patients
<a href="#">The Importance of Taking Your Pills on Schedule</a>	CancerCare document explaining the importance of oral chemotherapy adherence and providing adherence tips
<a href="#">Medisafe App</a>	Free smartphone medication-tracking application
<a href="#">Oral Chemotherapy Drug Diary</a>	Sample oral chemotherapy drug diaries from Dana-Farber Cancer Institute
<a href="#">Capecitabine Pill Calendar</a>	Sample oral chemotherapy calendar from McGill University Health Center

## References

1. Given, B. A., Spoelstra, S. L., & Grant, M. (2011). The challenges of oral agents as antineoplastic treatments. *Seminars in Oncology Nursing*, 27(2), 93-103. <https://doi.org/10.1016/j.soncn.2011.02.003>
2. Greer, J. A., Amoyal, N., Nisotel, L., Fishbein, J. N., MacDonald, J., Stagl, J., ... & Pirl, W. F. (2016). A systematic review of adherence to oral antineoplastic therapies. *The Oncologist*, 21(3), 354-376. <https://doi.org/10.1634/theoncologist.2015-0405>
3. Weingart, S. N., Brown, E., Bach, P. B., Eng, K., Johnson, S. A., Kuzel, T. M., ... & Walters, R. S. (2008). NCCN task force report: oral chemotherapy. *Journal of the National Comprehensive Cancer Network*, 6(Suppl. 3), S1-S14. Retrieved from [https://www.nccn.org/JNCCN/PDF/JNSU3\\_combined\\_Oral\\_Chemo\\_2008.pdf](https://www.nccn.org/JNCCN/PDF/JNSU3_combined_Oral_Chemo_2008.pdf)
4. Conti, R. M., Fein, A. J., & Bhatta, S. S. (2014). National trends in spending on and use of oral oncologics, first quarter 2006 through third quarter 2011. *Health Affairs*, 33(10), 1721-1727. <https://doi.org/10.1377/hlthaff.2014.0001>
5. Kircher, S. M., Meeker, C. R., Nimeiri, H., Geynisman, D. M., Zafar, S. Y., Shankaran V., ... & Wong, Y. N. (2016). The parity paradigm: can legislation help reduce the cost burden of oral anticancer medications? *Value in Health*, 19(1), 88-98. <https://doi.org/10.1016/j.jval.2015.10.005>
6. Simchowitz, B., Shiman, L., Spencer, J., Brouillard, D., Gross, A., Connor, M., & Weingart, S. N. (2010). Perceptions and experiences of patients receiving oral chemotherapy. *Clinical Journal of Oncology Nursing*, 14(4), 447-453. <https://doi.org/10.1188/10.CJON.447-453>
7. Camacho, F. T., Wu, J., Wei, W., Kimmick, G., Anderson, R. T., & Balkrishnan, R. (2009). Cost impact of oral capecitabine compared to intravenous taxane-based chemotherapy in first-line metastatic breast cancer. *Journal of Medical Economics*, 12(3), 238-245. <https://doi.org/10.3111/13696990903269673>
8. Rugo, H. S., Kohles, J., & Schulman, K. L. (2010). Cost comparison of capecitabine in patients with breast cancer. *American Journal of Clinical Oncology*, 33(6), 550-556. <https://doi.org/10.1097/COC.0b013e3181c06f94>
9. Arber, A., Odelius, A., Williams, P., Lemanska, A., & Faithfull, S. (2015). Do patients on oral chemotherapy have sufficient knowledge for optimal adherence? A mixed methods study. *European Journal of Cancer Care*, 26(2), e12413. <https://doi.org/10.1111/ecc.12413>

10. McCue, D. A., Lohr, L. K., & Pick, A. M. (2014). Improving adherence to oral cancer therapy in clinical practice. *Pharmacotherapy*, 34(5), 481-494.  
<https://doi.org/10.1002/phar.1399>
11. Kavookjian, J., & Wittayanukorn, S. (2015). Interventions for adherence with oral chemotherapy in hematological malignancies: a systematic review. *Research in Social and Administrative Pharmacy*, 11(3), 303-314.  
<https://doi.org/10.1016/j.sapharm.2014.08.006>
12. Wood, L. (2012). A review on adherence management in patients on oral cancer therapies. *European Journal of Oncology Nursing*, 16(4), 432-438.  
<https://doi.org/10.1016/j.ejon.2011.10.002>
13. Conti, R. M., Fein, A. J., & Bhatta, S. S. (2014). National trends in spending on and use of oral oncologics, first quarter 2006 through third quarter 2011. *Health Affairs*, 33(10), 1721-1727. <https://doi.org/10.1377/hlthaff.2014.0001>
14. The Henry J. Kaiser Family Foundation. (2016). *The Medicare Part D prescription drug benefit*. Retrieved from <http://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>
15. Zafar, S. Y. (2016). Financial toxicity of cancer care: it's time to intervene. *Journal of the National Cancer Institute*, 108(5), djv370. <https://doi.org/10.1093/jnci/djv370>
16. Ramsey, S., Blough, D., Kirchhoff, A., Kreizenbeck, K., Fedorenko, C., Snell, K., ... & Overstreet, K. (2013). Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health Affairs*, 32(6), 1143-1152. <https://doi.org/10.1377/hlthaff.2012.1263>
17. Ramsey, S. D., Bansal, A., Fedorenko, C. R., Blough, D. K., Overstreet, K. A., Shankaran, V., & Newcomb, P. (2016). Financial insolvency as a risk factor for early mortality among patients with cancer. *Journal of Clinical Oncology*, 34(9), 980-986.  
<https://doi.org/10.1200/JCO.2015.64.6620>
18. Ward, E., Halpern, M., Schrag, N., Cokkinides, V., DeSantis, C., Bandi, P., ... & Jemal, A. (2008). Association of insurance with cancer care utilization and outcomes. *CA: A Cancer Journal for Clinicians*, 58(1), 9-31. <https://doi.org/10.3322/CA.2007.0011>
19. Bona, K., Blonquist, T. M., Neuberg, D. S., Silverman, L. B., & Wolfe, J. (2016). Impact of socioeconomic status on timing of relapse and overall survival for children treated on Dana-Farber Cancer Institute ALL Consortium Protocols (2000-2010). *Pediatric Blood and Cancer*, 63(6), 1012-1018. <https://doi.org/10.1002/pbc.25928>

20. Dusetzina, S. B., & Keating, N. L. (2016). Mind the gap: why closing the doughnut hole is insufficient for increasing Medicare beneficiary access to oral chemotherapy. *Journal of clinical oncology*, 34(4), 375-380. <https://doi.org/10.1200/JCO.2015.63.7736>
21. Mathes, T., Pieper, D., Antoine, S. L., & Eikermann, M. (2014). Adherence influencing factors in patients taking oral anticancer agents: a systematic review. *Cancer Epidemiology*, 38(3), 214-226. <https://doi.org/10.1016/j.caep.2014.03.012>
22. Verbrugghe, M., Verhaeghe, S., Lauwaert, K., Beeckman, D., & Van Hecke, A. (2013). Determinants and associated factors influencing medication adherence and persistence to oral anticancer drugs: a systematic review. *Cancer Treatment Reviews*, 39(6), 610-621. <https://doi.org/10.1016/j.ctrv.2012.12.014>
23. American Cancer Society Cancer Action Network. (2017.) ACS CAN Examination of Cancer Drug Coverage and Transparency in the Health Insurance Marketplaces. Retrieved from <https://www.acscan.org/sites/default/files/National%20Documents/QHP%20Formularies%20Analysis%20-%202017%20FINAL.pdf>
24. Wong, Y. N., Meeker, C., Doyle, J., Handorf, E., Bilusic, M., Plimack, E. R., & Geynisman, D. M. (2016). Human capital costs of obtaining oral anticancer medications. *Journal of Clinical Oncology* 34(15\_suppl), 6506-6506. Retrieved from [http://ascopubs.org/doi/abs/10.1200/JCO.2016.34.15\\_suppl.6506](http://ascopubs.org/doi/abs/10.1200/JCO.2016.34.15_suppl.6506)
25. Niccolai, J. L., Roman, D. L., Julius, J. M., & Nadour, R. W. (2017). Potential obstacles in the acquisition of oral anticancer medications. *Journal of Oncology Practice*, 13(1), e29-e36. <https://doi.org/10.1200/JOP.2016.012302>
26. Roop, J. C., & Wu, H. S. (2014). Current practice patterns for oral chemotherapy: results of a national survey. *Oncology Nursing Forum*, 41(2), 185-194. <https://doi.org/10.1188/14.ONF.41-02AP>
27. Schwartz, R. N., Eng, K. J., Frieze, D. A., Gosselin, T. K., Griffith, N., Seung, A. H., ... & Wong, M. K. (2010). NCCN task force report: specialty pharmacy. *Journal of the National Comprehensive Cancer Network*, 8(Suppl 4): S1-S12. <https://doi.org/10.6004/jnccn.2010.0127>
28. Stokes, M., Reyes, C., Xia, Y., Alas, V., Goertz, H. P., & Boulanger, L. (2017). Impact of pharmacy channel on adherence to oral oncolytics. *BMC Health Services Research*, 17, 414. <https://doi.org/10.1186/s12913-017-2373-2>
29. Association of Community Cancer Centers. (2016). Steps to Success: *Implementing Oral Oncolytics*. Retrieved from <http://www.accc-cancer.org/resources/pdf/Implementing->

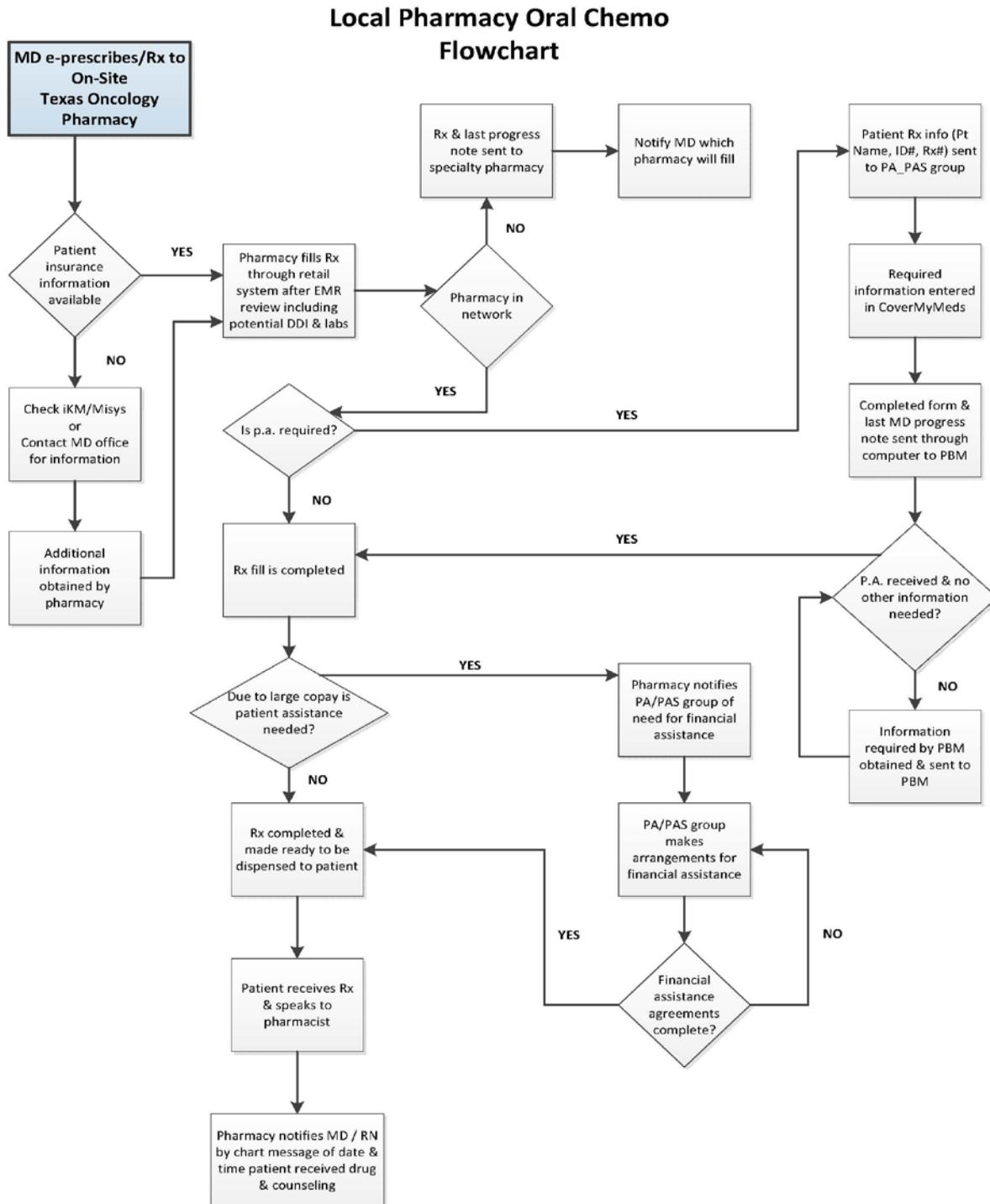
[Oral-Oncolytics-final.pdf](#)

30. Maloney, K. W., & Kagan, S. H. (2011). Adherence and oral agents with older patients. *Seminars in Oncology Nursing*, 27(2), 154-160.  
<https://doi.org/10.1016/j.soncn.2011.02.007>
31. Fox Chase Cancer Center. (2016, May 24). Patients may face barriers to starting oral chemotherapy medications, Fox Chase researchers find. *Fox Chase Cancer Center News*. Retrieved from <https://www.foxchase.org/news/2016-05-24-ASCO-Patients-Barriers-Starting-Oral-Chemotherapy-Medications>
32. Irwin, M., & Johnson, L. A. (2015). Factors influencing oral adherence: qualitative metasummary and triangulation with quantitative evidence. *Clinical Journal of Oncology Nursing*, 19(3 Suppl), 6-30. <https://doi.org/10.1188/15.S1.CJON.6-30>
33. National Comprehensive Cancer Network. (2017). *NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology* (Version 2.2017). Retrieved from [https://www.nccn.org/professionals/physician\\_gls/pdf/senior.pdf](https://www.nccn.org/professionals/physician_gls/pdf/senior.pdf)
34. Neuss, M. N., Polovich, M., McNiff, K., Esper, P., Gilmore, T. R., LeFebvre, K. B., ... & Jacobson, J. O. (2013). 2013 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards including standards for the safe administration and management of oral chemotherapy. *Journal of Oncology Practice*, 9(2 Suppl), 5s-13s. <https://doi.org/10.1200/JOP.2013.000874>
35. Spoelstra, S. L., & Sansoucie, H. (2015). Putting evidence into practice: evidence-based interventions for oral agents for cancer. *Clinical Journal of Oncology Nursing*, 19(3 Suppl), 60-72. <https://doi.org/10.1188/15.S1.CJON.60-72>
36. Schneider, S. M., Hess, K., & Gosselin, T. (2011). Interventions to promote adherence with oral agents. *Seminars in Oncology Nursing*, 27(2), 133-141.  
<https://doi.org/10.1016/j.soncn.2011.02.005>
37. Boucher, J., Lucca, J., Hooper, C., Pedulla, L., & Berry, D. L. (2015). A structured nursing intervention to address oral chemotherapy adherence in patients with non-small cell lung cancer. *Oncology Nursing Forum*, 42(4):383-389.  
<https://doi.org/10.1188/15.ONF.383-389>
38. Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvet, B. E., ... & Polovich, M. (2017). 2016 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards, including standards for pediatric oncology. *Oncology Nursing Forum*, 44(1), 31-43.  
<https://doi.org/10.1188/17.ONF.31-43>

39. Vioral, A., Leslie, M., Best, R., & Somerville, D. (2014). Patient adherence with oral oncolytic therapies. *Seminars in Oncology Nursing*, 30(3), 190-199.  
<https://doi.org/10.1016/j.soncn.2014.05.007>
40. Esper, P. (2013). Identifying strategies to optimize care with oral cancer therapy. *Clinical Journal of Oncology Nursing*, 17(6), 629-636. <https://doi.org/10.1188/13.CJON.629-636>
41. Rudnitzki, T., & McMahon, D. (2015). Oral agents for cancer: safety challenges and recommendations. *Clinical Journal of Oncology Nursing*, 19(3 Suppl), 41-46.  
<https://doi.org/10.1188/15.S1.CJON.41-46>
42. Friedman, A. J., Cosby, R., Boyko, S., Hatton-Bauer, J., & Turnbull G. (2011). Effective teaching strategies and methods of delivery for patient education: a systematic review and practice guideline recommendations. *Journal of Cancer Education*, 26(1), 12-21.  
<https://doi.org/10.1007/s13187-010-0183-x>
43. Burhenn, P. S., & Smudde, J. (2015). Using tools and technology to promote education and adherence to oral agents for cancer. *Clinical Journal of Oncology Nursing*, 19(3 Suppl), 53-95. <https://doi.org/10.1188/15.S1.CJON.53-59>

# Appendix A: Practice-Provided Tools

## Texas Oncology



Adopted By  	Document Types  <b>Network Policy</b> Responsible Party: <b>For Nursing and Pharmacy personnel</b> Policy No.: <b>NURS-6073</b>
<b>Title</b>	<b>TXO-Oral Antineoplastic Therapy Management Policy</b>
Subtopic and/or Policy Number  Issuing Department and/or Committee	<b>Oral Antineoplastic Therapy Management</b>  <b>Clinical Advisory Council</b>
	Effective Date: <b>03-21-2016</b>  Renewal Date: (if applicable) <b>MM-DD-YYYY</b>

**All employees of Texas Oncology, PA and Physician Reliance, LLC, a subsidiary of US Oncology Inc., are bound by this policy.**

## Policy

1. All patients receiving oral anticancer therapy will receive education regarding the safe use of the agents prior to starting the therapy.
2. Instructions regarding the self-administration of oral anticancer therapy will be provided to patients both verbally and in writing.
3. Patients' understanding of instructions regarding the self-administration of oral anticancer drugs will be evaluated and documented in the medical record.

## Scope

Because patients manage their own therapy at home, patient education regarding the use of oral anticancer agents is an essential element of safe administration. Physicians, nurses, and pharmacists may provide elements of the education. Family members and caregivers should be included in the education when they participate in the management of oral therapies.

## Guidelines (Procedures)

1. Identify patients who receive orders or a prescription for oral cytotoxic agents.
2. Assess the patient's barriers to learning, such as language, age, level of education, reading level, and hearing and visual problems.
3. Assess what the patient has been told about the prescribed therapy.
4. Assess the patient's ability and intent to obtain the medication.
5. Refer the patient to the social worker or financial counselor for insurance or payment issues that will affect the patient's ability to obtain the medication.
6. Assess any symptoms that may affect the patient's ability to take or swallow the medication.
7. Provide the following information, if applicable, verbally and in writing.
  - a. Drug name
  - b. Drug dose and schedule
  - c. Drug storage requirements (including to keep away from children and pets)

- d. Instructions to wash hands before and after handling the medication
  - e. Instructions for family members to wear gloves when handling the medication
  - f. Instructions not to crush or break tablets or capsules unless otherwise directed
  - g. When to start and stop the drug
  - h. What to do in case of a missed dose
  - i. What to do with any unused doses (disposal at designated locations)
  - j. Possible side effects of the drug and how to manage them
  - k. Side effects that require stopping the medication
  - l. Any foods or other drugs to avoid while taking the drug
  - m. Laboratory tests that are needed to monitor the treatment and when they are scheduled
  - n. When and whom to call about side effects or with questions
8. Include family members and caregivers in education when possible.
  9. Evaluate the patient's understanding of the instructions.
  10. It is encouraged to have an informed consent signed, copy given to patient and a copy filed in the patients medical records even with oral chemotherapeutics.
  11. Assist the patient with a plan to take the medication correctly (e.g., timer/alarm, clock, calendar or diary).
  12. Schedule follow-up calls or appointments to complete the following.
    - a. Identify any issues with the prescription or drug procurement.
    - b. Verify that the patient has started taking the prescription.
    - c. Ask how the patient is taking the medication (dose, schedule, use of gloves if applicable).
    - d. Review the prescribed dose and schedule for reinforcement.
    - e. Assess for the occurrence of side effects and the effectiveness of interventions.
    - f. Verify that laboratory and office visits for follow-up are scheduled.
  13. Notify the physician of delays in therapy due to procurement issues.
  14. Notify the physician of adherence issues or uncontrolled side effects.
  15. Document all patient teaching, follow-up, and physician notification in the medical record.

## Applicable Forms

- Oral Antineoplastic Therapy Management Checklist (see attached)

## References

American Society of Health-System Pharmacists. (2002). ASHP guidelines on preventing medication errors with antineoplastic agents. *American Journal of Health-System Pharmacy*, 59, 1648–1668. Retrieved from  
[http://www.ashp.org/s\\_ashp/docs/files/BP07/MedMis\\_Gdl\\_Antineo.pdf](http://www.ashp.org/s_ashp/docs/files/BP07/MedMis_Gdl_Antineo.pdf)

Halfdanarson, T.R., & Jatoi, A. (2010). Oral cancer chemotherapy: The critical interplay between patient education and patient safety. *Current Oncology Reports*, 12, 247–252.  
<doi:10.1007/s11912-010-0103-6>

Kav, S., Schulmeister, L., Nirenberg, A., Barber, L., Johnson, J., & Rittenberg, C. (2010). Development of the MASCC teaching tool for patients receiving oral agents for cancer. *Supportive Care in Cancer*, 18, 583–590. <doi:10.1007/s00520-009-0692-5>

Neuss, M.N., Polovich, M., McNiff, K., Esper, P., Gilmore, T.R., LeFebvre, K.B., ... Jacobson, J.O. (2013). 2013 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards including standards for the safe administration and management of oral chemotherapy. *Oncology Nursing Forum*, 40, 225–233.  
<doi:10.1188/13.ONF.40-03AP2>

Polovich, M., Olsen, M., & LeFebvre, K.B. (Eds.). (2014). *Chemotherapy and biotherapy guidelines and recommendations for practice* (4th ed.). Pittsburgh, PA: Oncology Nursing Society. Copyright © 2014 by the Oncology Nursing Society. Used with permission.



## Oral Antineoplastic or Hormone Therapy Management

Date: \_\_\_\_\_ Medication: \_\_\_\_\_

Patient Name: \_\_\_\_\_ MR #: \_\_\_\_\_

**Providers will inform the nurse when they are prescribing an oral antineoplastic or hormone therapy for a patient**

- Utilize the Rx PA\_PAS system to help with obtaining prior auths and filling the prescription**
  - Texas Oncology – Pharmacy is the preferred pharmacy for processing and will assist with the transfer to another Specialty pharmacy if the patient's insurance dictates.
  - If financial assistance is needed, the nurse will work with the Rx PA\_PAS team, Financial Counselor and pharmacy staff to identify and obtain financial assistance or help the patient obtain assistance.
- Patient education will be performed**
  - 1:1 Chemo Teach with an APP (especially for the complicated orals) or a nurse is preferred, but it can be done telephonically if needed. Document under Nursing Note > Patient Education > Resources.
  - Nurse will provide printed educational materials to the patient / caregiver along with a copy of the treatment plan. Patient education will be reinforced as needed at future visits or telephonically.
  - Encourage patient to write down side effects and to call with concerns and questions.
  - It is recommended to obtain a signed consent form.
  - TXO pharmacist will also counsel the patient upon dispensing.
- Document C1D1 start date**
  - Call the patient within 5 days after script written so the start date of the medication can be documented in iKnowMed. This can be done by entering the start date in the regimen or documenting in the Nursing Note.
  - Obtain consent from the patient for RX History to be viewed to assist with the verification of fill dates.
  - The nurse will confirm the prescription was filled correctly, verify the patient understands how to take it correctly, and confirm they know what to do if they miss a dose.
  - If the script is filled at TXO location our pharmacists will enter the C1D1 date in the regimen based on the fill date and information received from the patient at their counseling.
- Weekly call management**
  - Weekly telephone calls with the patient for the first month (depending on the patient and therapy) to assess adherence, side effects, management, and reinforce teaching.
  - If the patient is on an oral hormone therapy it is acceptable to decrease the amount of outgoing calls to 1 or 2 only if they are tolerating it well and understands to call for any issues.
  - Special consideration needs to be made for high risk patients and calls may need to continue past the first month depending on the patient's condition. This will be assessed on a case by case basis by clinical staff.



## Oral Antineoplastic or Hormone Therapy Management

---

- Nurse will enter a reminder in either iKM or Outlook after the patient starts the medication for the follow-up calls until the next scheduled visit with a provider.

**Appointment management**

- RTC with a provider is set up 2-4 weeks after the patient started the oral therapy and monthly for at least 2 months, unless the prescription is an oral hormonal agent with few side effects and the provider determines less frequent follow-up is needed.
- Refills should not be given unless appropriate follow-up with laboratory monitoring and/or provider visits is adhered to throughout treatment.
- At each clinical encounter, adherence and side effects will be assessed and addressed by clinicians.

## Xalkori™ (Crizotinib) - MTM form

Name	ID#	DOB	Physician
Rx #	Date Dispensed	Follow up date	
Contact Preference:	<input type="checkbox"/> Daytime <input type="checkbox"/> Evening	Contact Number	

**Scheduled lab work**

*Recommended: ALK positivity; CBC with differential monthly (monitor frequently if grade 3 or 4 abnormalities or with fever or infection); LFTs monthly (monitor frequently if grades 2,3, or 4 abnormalities observed); monitor electrolytes in patients with heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications known to cause QT-prolongation*

**Next scheduled physician visit** \_\_\_\_\_ :

**PATIENT COMPLIANCE:**

Any missed doses? Reasons for non-compliance ?

Taking tablet with or without food? Avoid grapefruit juice?

Severe Side Effect	None	Little	Moderate	Severe	Comments
Hepatotoxicity - Jaundice? - Unusual weakness? - Dark urine, light stools?					
Ocular toxicities? - Blurred vision? - Visual acuity decreased? - Visual brightness? - Visual field defect? - Other visual impairment?					
Pneumonitis - Shortness of breath? - Cough? - Fatigue? - Loss of appetite? - Unintentional weight loss?					
Edema - Swelling? - Rapid weight gain?					
Gastrointestinal Toxicity - Diarrhea? - Nausea? - Vomiting? - Appetite decreased?					

**Question/comments from patient:**

**Counseling notes:**

**Summary(information to be relayed to M.D.):**



**Prior Authorization Patient Assistance Referrals**  
**E-Mail the Group @ RX PA\_PAS**

**HOW TO INITIATE A PRIOR AUTHORIZATION (PA) REQUEST**

1. E-Mail the distribution group **RX PA\_PAS**
2. In the subject line enter: PA / Drug Name / iKM region
  - a. Example: **PA Xeloda CTR**
3. In the body of the E-Mail include
  - a. Rejection Error Report from Guardian or outside pharmacy
  - b. Patient name, iKM medical record number, physician name Example: **John Doe #000000 Dr. Oncology**
  - c. A clinic contact, first and last name, for clinical questions

**Important note about PA request and turn around time**

**Prior Authorizations (PA)**

1. Processes all prior authorizations for retail **drugs** written by a Texas Oncology physician.
2. The requestor must provide the patient's prescription insurance processing information
3. **We do not process quantity limits, cost overrides, days supply, drug utilization review (DUR's) or other issues not related to a clinical PA.**
  - a. If you have one of these rejections after a clinical PA is complete then call the pharmacy help desk and inform the representative that you have a clinical PA in place and offer to fax or give them the authorization number.
  - b. For quantity limits make sure you are running the RX for the approved quantity and day's supply of said approval.
4. For **non-chemo orders such as antibiotics confirm the supporting DX for the drug is in iKM**
5. The pharmacy submitting a referral should include other staff members for follow up.
6. Outcomes can take anywhere from 15 min to 72 hours.
7. Chart messages are entered in iKM on chemotherapy outcomes and necessary updates if PA is delayed 72 hrs
8. Chart messages are in iKM site name: **Pharmacy RX PA\_PAS**
  - a. Chart messages are not monitored by RX PA\_PAS, all correspondence is via E-Mail.
  - b. Chart messages are sent to the physician unless otherwise noted by referral
  - c. Hard copy of PA determination is forwarded to the clinic if received by the PA team
9. The PA team will follow up on PA's **after 48 hrs** and up to 72 hrs via E-Mail using the original E-Mail request.
10. **After 48 hours of the original request the site can ask for updates using the original E-Mail string, all requests are sent as URGENT.**
11. PA requests made for Medicare PART D after 3:00 on Friday may be submitted the following Monday morning at the discretion of the PA team.
  - a. Insurances requiring a follow up will automatically deny request after 24hrs regardless of the operating hours of the physician's office.
12. If a physician orders a drug that does not meet the full label indication then the request should include the reasoning or literature to support the PA to avoid a denial.
  - a. For instance ordering a drug that does not follow step therapy.
  - b. Ensure that the pharmacy administrative team is aware of off label requests
13. If requested an **appeal** for a PA denial will take at least 72 hours for a determination.



**Prior Authorization \_ Patient Assistance Referrals**  
**E-Mail the Group @ RX PA\_PAS**

**HOW TO INITIATE A PATIENT ASSISTANCE (PAS) REQUEST**

1. E-Mail the distribution group at **RX PA\_PAS**
  - a. In the subject line enter: PAS / Drug name / iKM region
  - b. Example: **PAS Xeloda CTR**
2. In the body of the E-Mail include
  - a. Patient name, iKM medical record number, physician name and cost to patient  
Example: **John Doe #000000 Dr. Oncology \$2500**
  - b. A clinic contact, first and last name, for application follow up

**Important note about PAS request and turnaround time**

**Patient Assistance (PAS)**

1. Patient Assistance can take 30 minutes to 10 days depending on the type of program available.
2. Notify RX PA\_PAS of any previous activity if an application or grant has been attempted.
3. For free drug programs provide a site contact to assist patient with the application, complete physician portions and to follow up with the company for refills.
4. PAS outcomes are noted in Misys under PAS notes
5. PAS outcomes are noted in iKM site **Pharmacy RX PA\_PAS** under category Prescription Assistance.
6. We will add notes under Prescription Assistance on grants, co-pay cards and drug sponsored programs (free drug). We limit patient financial information in charts and will refer to free drug programs as **PAP** programs.
7. A letter will be mailed to the patient after 48 hours if no contact is made by staff.
8. **Co-Pay Cards and Vouchers**
  - a. Drug specific co-pay cards and / or drug vouchers should always be offered and used for commercially insured patients initiated by the pharmacy.
  - b. If the pharmacy needs assistance email the RX PA\_PAS team.
  - c. Vouchers can sometimes be used for government payors and should be verified with the PAS team if needed.

**Questions?**

1. Use the original E-Mail string to the distribution group RX PA\_PAS and the appropriate team member will respond.
2. Allow at least 48 hours for follow ups, all drugs are submitted as URGENT
3. When you list a contact use first and last names
4. The site is responsible for filing all notices of outcomes sent by the RX PA\_PAS team
5. E-Mail an individual Team Member or Manager using the Outlook system by individual name
6. For process improvement concerns please contact Margaret Harville @ 512-541-5121 or Jim Schwartz @ 972-490-2926 directly.



Email referrals to **distribution group RX PA\_PAS** for prior authorization or patient assistance, *if the distribution group is not included on all correspondence the referral may not go through*. The following subject line format and email content is required for all referrals:

**PA REQUESTS**

Subject line: **PA / Drug Name / CTR**

**PA for prior authorization / Drug name is the name of the drug you need help with / iKM region is CTR**

<b>Include in the email:</b>	<ol style="list-style-type: none"><li>1. Patient name and MRN#</li><li>2. The <b>Guardian reject report</b> or the <b>faxed PA request from the outside pharmacy</b> is required</li><li>3. n</li><li>4. Ensure that diagnosis code is in iKM for all supportive and non-oncology drugs</li><li>5. Clinic contact for follow up</li><li>6. For appeal requests send all previous information and include supporting literature or documentation for the appeal</li><li>7. Unlabeled requests include verification of approval from TxO Administration to proceed and submit supporting literature or documentation</li></ol>
------------------------------	--

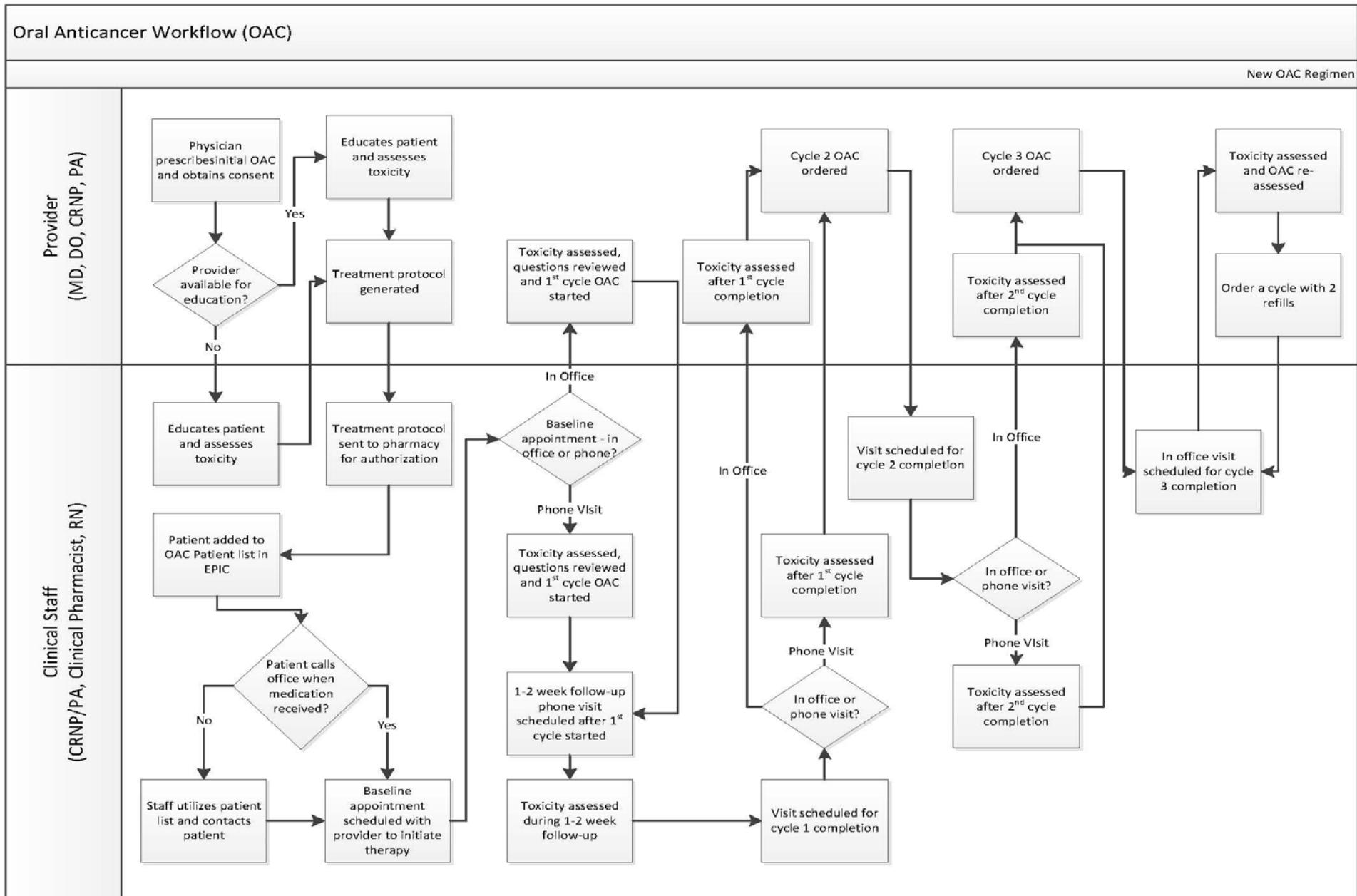
**PAS REQUESTS**

Subject line: **PAS / Drug Name / CTR**

**PAS for funding or free drug / Drug name is the name of the drug you need help with / iKM region is CTR**

<b>Include in the email:</b>	<ol style="list-style-type: none"><li>1. Patient name, MRN# and patient receipt or out of pocket amount</li><li>2. If we secured PA use same email string and change subject line to PAS, this will give us patient insurance information</li><li>3. Dispensing pharmacy if not TxO</li><li>4. If patient is uninsured</li><li>5. Include a clinic contact for applications</li><li>6. If patient was previously on a grant provide the previous grant information</li><li>7. If a voucher is used to start treatment send referral at the same time</li></ol>
------------------------------	--

# Allegheny Health Network Cancer Institute



# Revlimid (Lenalidomide) + Dexamethasone

Patient Name: \_\_\_\_\_  
 Start Date: \_\_\_\_\_

\*Check off each day after you take your Revlimid and dexamethasone dose. Circle the days you have any adverse effects and document below what you were experiencing. Please be sure to call office with any new or worsening symptoms.

	<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>	<b>Day 4</b>	<b>Day 5</b>	<b>Day 6</b>	<b>Day 7</b>
<b>Week 1</b>	Date: _____ <input type="checkbox"/> Revlimid <input type="checkbox"/> Dexamethasone	Date: _____ <input type="checkbox"/> Revlimid					
<b>Week 2</b>	Date: _____ <input type="checkbox"/> Revlimid <input type="checkbox"/> Dexamethasone	Date: _____ <input type="checkbox"/> Revlimid					
<b>Week 3</b>	Date: _____ <input type="checkbox"/> Revlimid <input type="checkbox"/> Dexamethasone	Date: _____ <input type="checkbox"/> Revlimid					
<b>Week 4</b>	Date: _____ No Revlimid <input type="checkbox"/> Dexamethasone	Date: _____ No Revlimid					

Directions: Revlimid should be taken daily at the same time with water (can be taken with or without food)  
 Dexamethasone should be taken daily in the morning with food

Office phone number: \_\_\_\_\_ Next appointment with provider: \_\_\_\_\_

# Tasigna (Nilotinib)

Patient Name: \_\_\_\_\_

Start Date: \_\_\_\_\_

\*Check off each day after you take your Tasigna dose. Circle the days you have any adverse effects and document below what you were experiencing. Please be sure to call office with any new or worsening symptoms.

	<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>	<b>Day 4</b>	<b>Day 5</b>	<b>Day 6</b>	<b>Day 7</b>
<b>Week 1</b>	Date: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM						
<b>Week 2</b>	Date: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM						
<b>Week 3</b>	Date: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM						
<b>Week 4</b>	Date: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM						

Directions: Tasigna should be taken on an empty stomach at least 1 hour before or 2 hours after eating with water twice daily (approximately 12 hours apart)

Office phone number: \_\_\_\_\_ Next appointment with provider: \_\_\_\_\_

## Oral Chemotherapy Education

Medication Name:

### GENERAL RECOMMENDATIONS



#### DO:

- Call the office when you receive your medication
- Review the package label, be sure to check medication name and dosage carefully
- Transport and store medicine as instructed and outlined in the package labeling
- Use gloves and wash hands thoroughly before and after taking medications.
  - Caregivers must wear gloves at all times while handling your medication and anything that has come into contact with your medication to minimize exposure
- Limit the number of people that come into contact with your medication
- Keep a journal of any side effects you are experiencing and record on your calendar
  - Contact the office immediately if you are having serious side effects
- If you are using a pillbox make sure you have a separate pillbox for your chemotherapy pills
- Report any overdosing or underdosing immediately
- Return wet, damaged, unused, discontinued, or expired medications to the pharmacist, hospital or doctor's office for disposal
- Report all medications including prescription, nonprescription, herbal and alternative medications and any specific dietary requirements to your healthcare provider



#### DO NOT:

- Leave your medication in open areas, near sources of water, direct sunlight, or where they can be accessed by children or pets
- Store medications where food or drinks are stored or consumed
- Crush, break or chew tablets
- Double-up on doses unless instructed to by a healthcare professional
- Share your prescriptions or medication
- Assume oral chemotherapy is safer than intravenous chemotherapy
- Skip doses unless instructed by your physician
- Discard medication down the toilet or in the garbage

## TAKE YOUR MEDICATION:

- On an empty stomach



- With a full glass of water



- With food



## REMEMBER TO CALL THE OFFICE WITH ANY OF THE FOLLOWING:

- Temperature greater than or equal to 100.4 degrees F or 38.0 degrees C or if develop shaking chills, sore throat, frequency and/or burning with urination
- Bleeding – blood in sputum, urine, or stool, bleeding from gums, nosebleeds, or excessive bruising
- Shortness of breath, dizziness, or extreme fatigue
- Nausea or vomiting persists for more than 24 hours
- Diarrhea, constipation, abdominal discomfort or pain more than 24 hours
- Experiencing 4-5 loose stool a day
- Mouth soreness, difficulty swallowing or white patches in the mouth
- Rash- new or worsening

## Cancer Care Specialists of Illinois



### PHONE INSTRUCTIONS FOR PATIENTS WHEN TO CALL

Patients who have been phoned for call backs following administration of oral oncolytics or IV chemo administration who report no side effects or problems should be given the following instructions and encouragement prior to ending the call:

- 1) Remember to take your medication, including your medication for nausea and chemo premeds, as prescribed by your doctor.
- 2) We all have off days. We all forget things from time to time. If you forget your medication, including chemo premeds or cannot remember if you took your medication, it's best to phone the clinic to ask for specific instructions regarding how to proceed in your case.
- 3) If you ever have trouble taking your medication, for example, if you cannot swallow your pills, if you cannot afford your medication, if you have difficulty picking up your medication, please call the clinic immediately. We are here to help you and there may be very simple things we can do to help assist you quickly.
- 4) You should have received a chemo alert card when you began treatment. We apologize if you did not. Please ask for one the next time you visit if you do not have one already.
- 5) On the chemo alert card it reminds you when to call for assistance.

Remember, if you have

- fever of 100.5 degrees or above
- chills (like you cannot stop shaking) or flu like symptoms
- unrelieved pain or sudden, sharp pain that is unrelieved
- unrelieved nausea (sickness to your stomach) or vomiting
- unrelieved diarrhea
- constipation accompanied by nausea or stomach pain or
- if you are considering going to an emergency room

PLEASE CALL US AT THE CLINIC

- 6) A doctor is on call 24 hours a day, 7 days a week.
- 7) The main point to remember: If it worries you, it worries us. CALL. Worry can make you lose sleep, feel anxious, feel more pain, feel depressed, and feel like giving up. We don't want that.



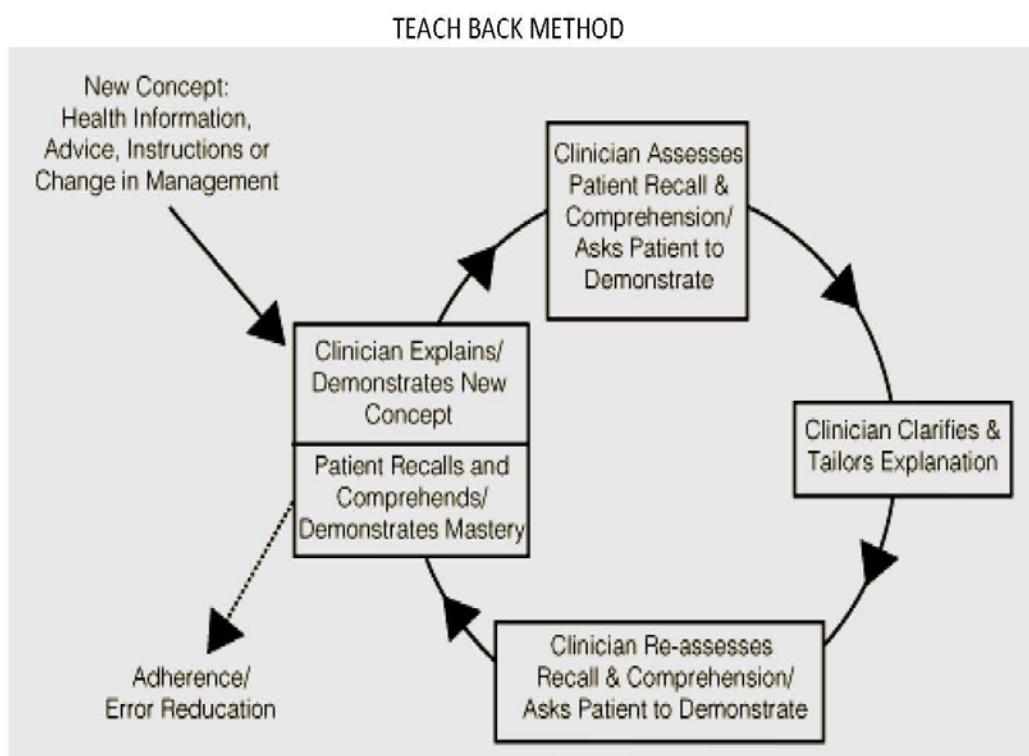
## IDENTIFICATION OF HIGH-RISK PATIENTS

**"It is more costly to not identify a high-risk patient than to falsely identify low risk patients."** ~ taken from AAMC High Risk Patient Identification Strategies for Success, 2016, pg. 24

Identifying high-risk patients has been approached by many organizations, insurers and hospitals alike. To simplify this process, taking the approach from the quote above while maintaining Cancer Care's overarching mission "to provide state of the art cancer care to patients and their families with compassion and with scientific precision, throughout central and southern Illinois", we aim to utilize the NCCN Distress Screening Tool, combined with patient diagnoses, medical history (including hospitalizations, falls and medications), HCC score where applicable and their overall ability to understand, retain and carry out information given to them.

1. The **NCCN Distress Thermometer** is currently utilized by Cancer Care Specialist Nurse Navigators, Nurses and Social Worker to determine a patient's distress level, psychosocial needs and physical needs. Should a patient flag a score of four or more or have any overt needs identified, this would place him/her in the high-risk patient category.
2. **Diagnosis:** Patients with a **Cancer Diagnosis** of: lung stage II or greater, pancreatic, colorectal (or anal) receiving chemo and/or radiation therapy, any head and neck but especially those receiving combined modality therapy, esophageal, gastric, ovarian, cervical receiving chemo and/or RT, AML, ALL, lymphoma, or any other cancer deemed high-risk by the evaluator. Additionally, patients with **Other Diagnoses** of: diabetes, chronic alcohol or drug abuse, cardiovascular disorders, stroke, CHF, ESRD, COPD, HIV/AIDS, dementia, autoimmune disorders, disabling mental health conditions, end stage liver disease, neurological disorder or any other debilitating diagnosis  
[https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation\\_Risk\\_Adj\\_Model\\_2011.pdf](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf)
3. **Hospitalization** or **Falls** within the last six months will place a patient on the high-risk list. **Polypharmacy** (taking > 10 regularly scheduled medications) should also flag a patient as high risk.
4. The **HCC** (Hierarchical Chronic Conditions) **Score** is a score specific to Medicare patients only. The patient's HCC score, potential and real time will be analyzed to determine placement on the high-risk patient list as well. Any HCC score, whether potential or real in the range of 3-5 will be considered a high-risk patient. Any HCC score over 5 will be considered seriously high risk and will be noted as such in the defined list. If both the real and potential HCC score are over 5, the patient will be placed on mandatory follow up. The assigned patient navigator would complete follow up calls and face to face visits specific to that patient's condition and in conjunction with that patient's provider to accomplish the best care possible to serve that high-risk patient.

5. Using the Teach Back Method, assess for the patient and caregiver's **Ability to Understand** and comprehend the information given to them. If person delivering education does not feel that the patient and/or the caregiver has grasped the concept(s) imparted, close follow up is warranted until the information is absorbed and effectively understood. Patient should be on the high-risk patient list until such time.



Step 1: Using simple lay language, explain the concept or demonstrate the process to the patient/caregiver.

Technical terms should generally be avoided. If the patient/caregiver has limited English proficiency, a professional translator should be utilized to reduce miscommunication.

Step 2: Ask the patient/caregiver to repeat in his or her own words how he or she understands the concept explained. If a process was demonstrated to the patient, ask the patient/caregiver to demonstrate it, independent of assistance, for the clinician.

Step 3: Identify and correct misunderstandings of or incorrect procedures by the patient/caregiver.

Step 4: Ask the patient/caregiver to demonstrate his or her understanding or procedural ability again to ensure the above-noted misunderstandings are now corrected.

Step 5: Repeat Steps 4 and 5 until the clinician is convinced the comprehension of the patient/ caregiver about

the concept or ability to perform the procedure accurately and safely is ensured.



#### HIGH-RISK PATIENT IDENTIFICATION CHECK LIST

PATIENT NAME: \_\_\_\_\_ DOB: \_\_\_\_\_ MRN: \_\_\_\_\_  
MD: \_\_\_\_\_ DIAGNOSIS: \_\_\_\_\_

Any 'yes' answer should refer the patient to the navigation team and the high-risk list for further consideration. Please refer all patients to LeAnn Rhinehart for correct navigator placement. [lrhinehart@ccsci.net](mailto:lrhinehart@ccsci.net), Epic email or via phone at 217-329-3298. Thank you.

ASSESS FOR THIS	YES OR NO	REFERRED TO HIGH-RISK PATIENT LIST
NCCN Distress Thermometer over 4?		
Psychosocial Distress Identified on NCCN screen?		
Physical Distress Identified on NCCN screen?		
High-risk cancer diagnosis?		
Other listed diagnosis?		
Hospitalization within last six months?		
Fall within last six months?		
Polypharmacy (>10 regular meds)?		
Any HCC score between 3 and 5?		
Any HCC score > 5?		
Both HCC scores > 5?		
Inability to understand?		

High-risk cancer dx: lung stage II or greater, pancreatic, colorectal/anal receiving chemo and/or RT, any head and neck, esophageal, gastric, ovarian, cervical receiving chemo and/or RT, AML, ALL, lymphoma, or any other cancer deemed high-risk by the evaluator

Other diagnoses: diabetes, chronic alcohol or drug abuse, cardiovascular disorders/disease, stroke, CHF, ESRD, COPD, HIV/AIDS, dementia, autoimmune disorders, disabling mental conditions, end stage liver disease, neurological disorders or any other debilitating diagnoses

[https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Evaluation\\_Risk\\_Adj\\_Model\\_2011.pdf](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf)

## Appendix B: OCM Driver Diagram

For driver definitions, change concepts, and related resources, see the complete [Key Drivers & Changes](#) packet.

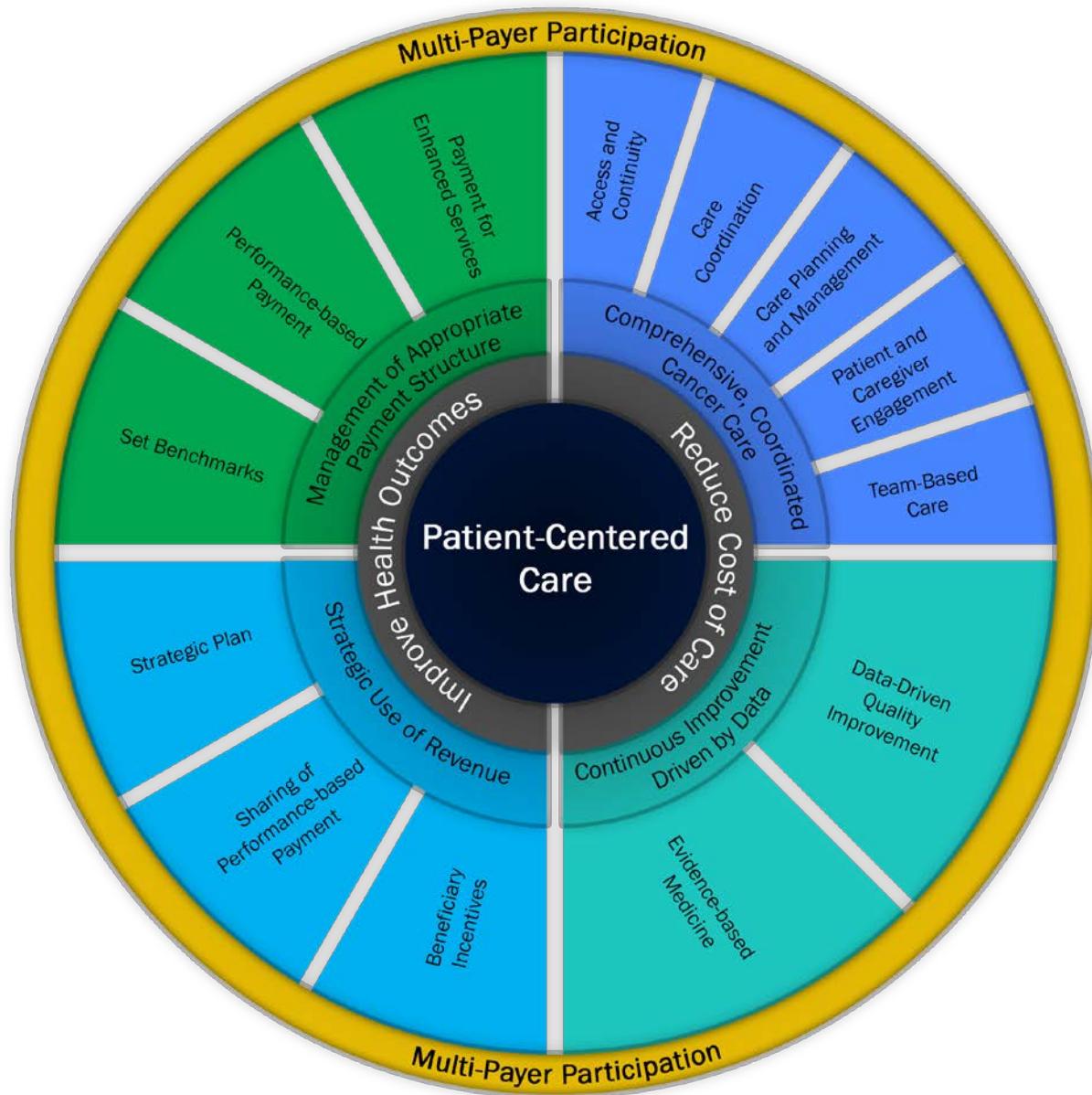


Figure 2: Oncology Care Model Driver Diagram

