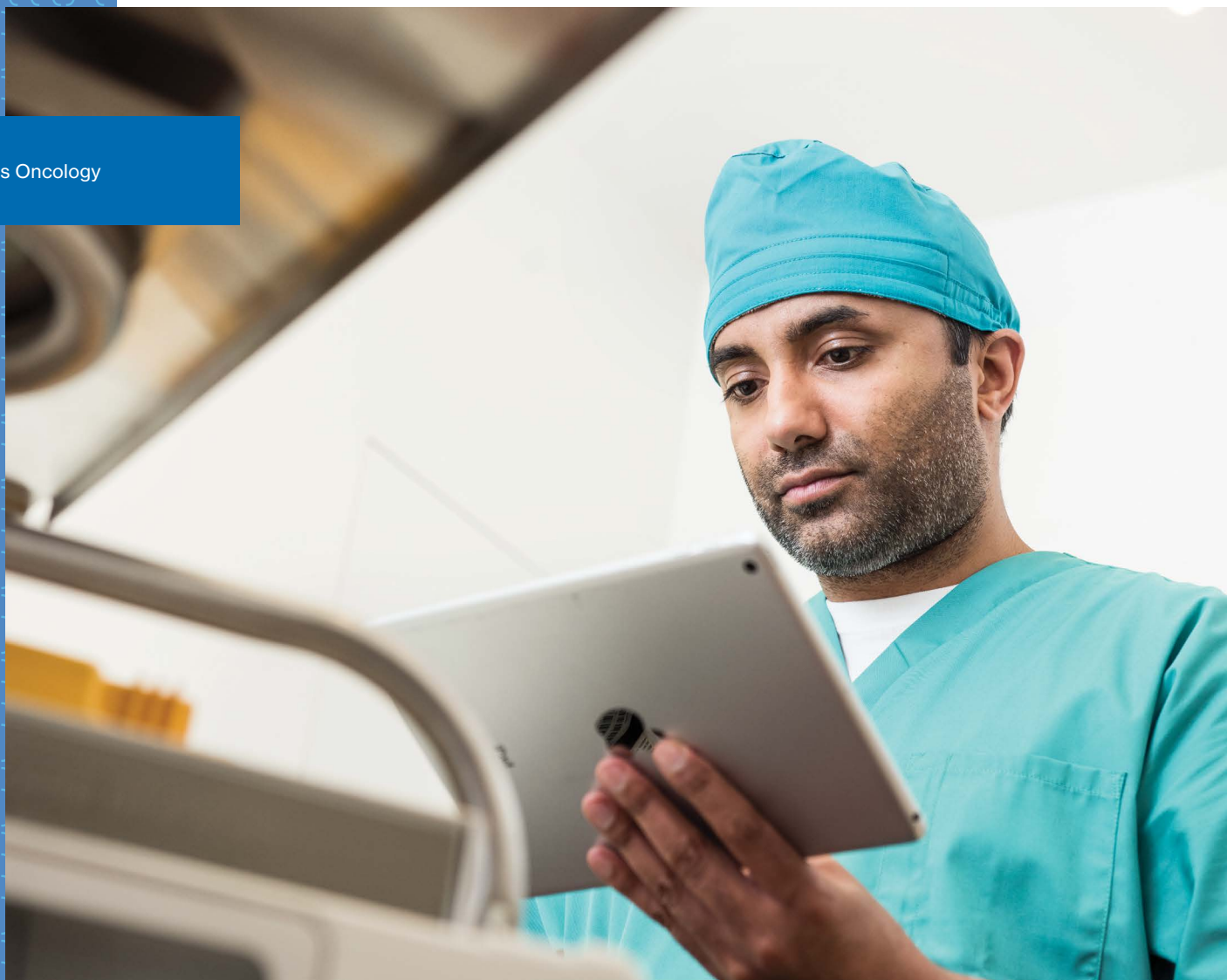


Novartis Oncology



Oral Oncology Tools for Health Care Providers

Oral Oncology Medication Tools

For Health Care Providers

When prescribing oral oncology medications, the framework and continuum of patient care may be considerably different from other forms of oncology treatment. In this toolkit, various educational pieces and support resources are available to you, as listed below. Specifically, the types of support resources provided throughout the toolkit include fact sheets, checklists, question guides, and a flowsheet. Some of the resources are interactive, such as the checklists and notes pages. These interactive tools allow you to type into the fields, and either save the item digitally or print select pages for future reference. Because each organization’s setup and patient populations may be different, this toolkit is only intended to provide general considerations in navigating patient care with oral oncology medications. The individual pieces in this toolkit are also available for download at HCP.Novartis.com/care-management.

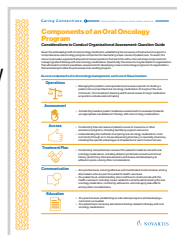
List of Tools

Health Care Provider Tools

Question Guide

Components of an Oral Oncology Program: Considerations to Conduct Organizational Assessment

This resource provides general questions that can assist the organization in developing an oral oncology framework that is in line with a core set of components. It may be helpful either to organizations that will need to conduct a readiness assessment toward developing a new oral oncology program or to organizations that are looking to refine the processes of an existing oral oncology program.



Process Flowsheet

Care Plan

Oral Oncology Medication Therapy Management

This resource provides sample considerations for navigating and managing patient therapy with oral oncology medications.



Know the Facts

Medication Acquisition: In-House Dispensing Pharmacy and Specialty Pharmacy

This resource provides an overview of the benefits and challenges of in-house dispensing pharmacies and specialty pharmacies, as well as considerations for each method of distribution.



Navigation



Click on the image of each tool shown above to navigate directly to the first page of the tool



Click on the back arrow to return to this “List of Tools” page



You can click on the checklist boxes



You can type in the note lines

Components of an Oral Oncology Program

Considerations to Conduct Organizational Assessment: Question Guide

Given the estimated growth of oral oncology treatments, establishing the necessary infrastructure to support a comprehensive oral oncology program is important to maintaining a clear course of patient care. To assist, this resource provides a general framework of review questions that are in line with a core set of key components for managing patient therapy with oral oncology medications. Specifically, this resource may be helpful to organizations that will need to conduct a readiness assessment for developing a new oral oncology program, as well as to organizations that are looking to refine the processes of an existing program.

As core components of oral oncology management, each one of these involves:

Operations



- Managing flow patterns and operational processes specific to treating a patient who is prescribed oral oncology medications throughout the care continuum, from treatment planning and financial review through medication acquisition and educational training

Assessment



- Conducting baseline patient readiness assessments to evaluate if patients are appropriate candidates for therapy with oral oncology medications

Access



- Conducting financial review of patient access to insurance or other assistance programs, including identifying support resources
- Understanding the methods of acquiring oral oncology medications, most commonly through an in-house dispensing pharmacy or specialty pharmacy, including the specific advantages or drawbacks for each route of access

Treatment Plan



- Conducting comprehensive review of the patient's medical care with oral oncology medications, including obtaining informed consent and clinical history, performing clinical evaluations and review, and developing an adherence plan, among other considerations

Communication



- At a practice level, ensuring effective and coordinated communication among all providers who are part of a patient's health care team
- At a patient level, understanding when and how to communicate with the health care team, including issues related to correctly administering the oral oncology medication, monitoring adherence, and managing side effects, among other considerations

Education



- At a practice level, establishing an educational program and developing a curriculum as needed
- At a patient level, receiving educational training related to therapy with oral oncology medications

Operations

1. What are your organization's collective beliefs about oral oncology medications?
2. What are your current patterns of patient flow with intravenous oncology treatments and how do you think the integration of oral oncology medications will affect these patterns?
3. Where and when along the patient flow of care do you suppose issues may arise with patients taking oral oncology medications? Specifically, what do you anticipate these issues will be and how will you plan to address them?
4. Who within the organization will be responsible for leading the overall effort to develop or refine the processes related to the oral oncology program?
5. How do you anticipate staff roles changing with the implementation of an oral oncology program?

Access

1. Who within the organization will be responsible for leading financial assessments and counseling for patients who are prescribed oral oncology medications?
2. How will patients be able to obtain their oral oncology medications (for example, through a specialty pharmacy or in-house dispensing pharmacy)?
3. If considering dispensing through an in-house pharmacy, what will your organization need to review in terms of requirements (for example, stocking specialized items, credentialing with insurers, assessing if payers allow refills, complying with state regulations) and who will be responsible for leading this effort?
4. If considering routing through a specialty pharmacy, what coordination of care and communication processes will your organization and the specialty pharmacy establish (for example, monitoring and communicating patient adherence, tracking patient refills, notifying about dose changes) and who will be responsible for leading this effort?

Treatment Plan

1. Who within the organization will be responsible for developing the treatment plan specific to oral oncology medications?
2. What type of information will be included in a patient's oral oncology treatment plan and how may this be different from an intravenous oncology treatment plan?
3. When will the treatment plan be reviewed with the patient and by whom?



Communication

1. How will your organization update current policies and procedures to integrate oral oncology medications? Who will be responsible for leading this effort and how will this be communicated within your practice?
2. How will patients communicate with your organization and report issues with taking their oral oncology medications should they arise (for example, adherence, side effects, toxicity/safety concerns)?
3. How does your organization anticipate that physician communication with the patients who are prescribed oral oncology medications will change and what type of training can your practice offer to address these communication changes?
4. How will your organization communicate with other providers who are part of your patient's health care team (for example, primary care physicians, specialists, specialty pharmacy)?
5. How will your organization verify that a patient's prescription has been filled? What will be your follow-up and tracking procedures?
6. How will your organization support caregivers during a patient's course of treatment with oral oncology medications? What types of resources does your organization have access to or need to develop?
7. How will your organization manage patient adherence with oral oncology medications and monitoring and what level of support will be offered?



Education

1. In general, what is the current level of staff education and knowledge on treatment with oral oncology medications?
2. What competency training will be provided to your organization's staff to review the integration of oral oncology medications (for example, documentation processes, patient education support)?
3. How will your practice develop a patient education plan for those who are prescribed treatment with oral oncology medications and who will be responsible for leading this effort?
 - Who provides the education and when will it take place (individual/collective)?
 - What will be included in the educational curriculum?
 - What educational handouts and resources are provided?
 - How is the educational process evaluated and when?
 - How is the educational process documented?
 - How is the educational process reinforced, how often, and by whom?
 - Have those educating the patient and caregivers been trained on teaching about adherence and issues related to oral oncology medications?
4. Will your practice be able to attend off-site presentations related to oral oncology management?

Organizational Assessment Outcome Summary

1. What are your organization's main areas of strength and how can these strengths be leveraged?
2. What are your organization's main areas of weakness and how can these weaknesses be addressed?



Oral Oncology Medication Therapy Management

Flowsheet

When prescribing an oral oncology medication, the processes and flow of patient care are different compared with prescribing therapy with intravenous oncology medications. While the structure and dynamics of each organization are different, this resource reviews simple considerations related to navigating key components for managing patient therapy with oral oncology medications.

Each of these core components of oral oncology management involves:

Operations



- Managing flow patterns and operational processes specific to treating a patient who is prescribed oral oncology medication throughout the care continuum, from treatment planning and financial review through medication acquisition and educational training

Assessment



- Conducting baseline patient readiness assessments to evaluate if patients are appropriate candidates for therapy with oral oncology medication

Access



- Conducting financial review of patient access to insurance or other assistance programs, including identifying support resources
- Understanding the methods of acquiring oral oncology medication, most commonly through an in-house dispensing pharmacy or specialty pharmacy, including the specific considerations for each route of access

Treatment Plan



- Conducting comprehensive review of the patient's medical care with oral oncology medication, including obtaining informed consent and clinical history, performing clinical evaluations and review, and developing an adherence plan, among other considerations

Communication



- At a practice level, ensuring effective and coordinated communication among all providers who are part of a patient's health care team
- At a patient level, understanding when and how to communicate with the health care team, including issues related to correctly administering the oral oncology medication, monitoring adherence, and managing side effects, among other considerations

Education



- At a practice level, establishing an educational program and developing a curriculum as needed
- At a patient level, receiving educational training related to therapy with oral oncology medication

Operations

1. Who in the organization will conduct the assessment with the patient?
2. Who in the organization will discuss access considerations with the patient, including financial review and medication acquisition?
3. Who in the organization will develop the treatment plan and review it as needed?
4. Who in the organization will manage communication with other providers on the health care team, as needed, and communicate with the patient and caregiver?
5. Who in the organization will provide educational training to the patient and caregiver?

Assessment

Physical Ability

1. Have you previously taken any other pills to treat your cancer diagnosis?
2. Do you have difficulty opening your medication bottle or blister packs?
3. Are you able to read the label of your medication?
4. Do you feel you may have difficulty keeping pills down?
5. Are you taking any other medications or supplements?

Cognitive Ability

1. Do you know what type of cancer and what stage have been diagnosed?
2. Can you tell me the goal of your therapy?
3. Would you be able to tell me the name of your medication and what it looks like?
4. Do you feel you may have any difficulty understanding how and when to take your medication and keeping track of any side effects?
5. Do you feel anxious, upset, tired, or do you experience sleepiness that may prevent you from taking your medication as prescribed?
6. Do you know what would happen if you don't take your medication as prescribed?

Safety

1. Where will you be storing your medications?
2. Do you have any school-aged children?
3. How do you typically dispose of medications?

Communication Skills and Social Support

1. Is anyone assisting and providing support during your treatment, such as family members, friends, partners, caregivers, or any other contacts?
2. Do you feel that you will be able to take your medication on a regular schedule, as prescribed?
3. Are you willing to follow physician and nurse instructions for taking or administering your medication?
4. What do you think your role is during your treatment and what do you expect of me?

Drug Acquisition and Access

1. Will you be able to come here regularly to fill your prescription (if dispensed through our in-house pharmacy)?
2. Do you have a mailing address where your medication can be safely sent?
3. Can you drive or arrange for transportation to come here regularly for routine follow-up appointments?
4. Would you have any difficulty paying for your medication?
5. Has your insurance ever prevented you from being able to obtain or fill your prescriptions?

Other Considerations

Do you have any other concerns I should be aware of that may affect your ability to take oral medication?
What can I do to help you?

Access



Considerations for the health care team to review and involve the

Patient Financial Review

1. Does the patient have insurance?
2. If yes, what is the name of the insurance company, name of the health plan, and if applicable, name of the pharmacy benefit manager?
3. Is the prescribed oral oncology medication covered under the patient's health plan medical benefit or pharmacy benefit?
4. Does the patient's health plan require prior authorization for an oral oncology medication before therapy initiation?
 - What information is required and how long will the prior authorization process take?
 - Once submitted, for how long will the prior authorization be valid?
5. What are the patient's cost-sharing responsibilities?
 - What is the patient's annual deductible? If the deductible has not yet been met in full, how much is remaining?
 - What is the patient's maximum out-of-pocket requirement? If the maximum out-of-pocket requirement has not yet been met in full, how much is remaining?
 - What is the patient's required coinsurance or co-payment amount for the prescribed oral oncology medication?
6. Does the patient have any other secondary or supplemental insurance benefits that would require coordination?
7. Does the patient's health plan have any specific coding or claims submission guidelines for reporting the prescribed oral oncology medication?
8. What assistance programs and/or foundations may be available to support the patient's therapy?
9. What is the reimbursement amount provided for the prescribed oral oncology medication?
10. Would the patient be able to access medication samples, if available?

Medication Acquisition Review

1. Does the patient's insurance mandate specific acquisition requirements for the prescribed oral oncology medication?
2. How will the patient acquire the prescribed oral oncology medication?

Treatment Plan



Considerations for the health care team to review and involve the patient

Informed Consent

- Yes, my patient has provided signed, informed consent to receive treatment with oral oncology medication
- No, my patient has not provided signed, informed consent to receive treatment with oral oncology medication

Medical and Treatment History

1. Prior or current medical conditions, including length of therapy
2. Prior operations and hospitalizations
3. Concurrent therapies
4. Known allergies
5. Social considerations, such as drugs/alcohol/tobacco use, religion, sexual history, and employment status

Clinical Evaluations

Imaging studies/laboratory work/scans/tests

Clinical Review

- | | | |
|---|---------------------------|-------------------------------------|
| 1. Diagnosis | 5. Dose reductions | 9. Oral administration instructions |
| 2. Stage of cancer | 6. Side effect profile | 10. Follow-up tests |
| 3. Medication schedule/cycle of therapy | 7. Toxicity profile | 11. Prognosis |
| 4. Dosing | 8. Medication interaction | |

Monitoring Plan

1. Compliance tracking, including details on date/method/percentage of adherence
2. Schedule for routine, follow-up visits

Progress Notes



Communication



Considerations for the health care team to review and involve the patient

Health Care Team Communication: Coordinating Therapy Management

1. Communication to primary care physician advising him or her of patient's current therapy, including details on date and method of communication
2. Communication to other specialists advising them of patient's current therapy, including details on date and method of communication
3. Communication to specialty pharmacy advising of patient's current therapy, including details on date and method of communication

Patient and Caregiver Communication: Topics to Consider

Which of the following topics have been discussed with the patient?

- | | |
|--|--|
| <input type="checkbox"/> Treatment plan and medication instructions | <input type="checkbox"/> Emotional counseling |
| <input type="checkbox"/> Side effect management and support | <input type="checkbox"/> Caregiver support and education |
| <input type="checkbox"/> Adherence management and support | <input type="checkbox"/> Clinical trial participation |
| <input type="checkbox"/> Dietary considerations | <input type="checkbox"/> Palliative/hospice care |
| <input type="checkbox"/> Drug access (in-house and specialty pharmacy) | <input type="checkbox"/> Cancer survivorship |
| <input type="checkbox"/> Medication storage | <input type="checkbox"/> Risks and benefits of treatment options |
| <input type="checkbox"/> Patient financial counseling | <input type="checkbox"/> Sexual activity |
| <input type="checkbox"/> Patient assistance considerations | |

Education



Considerations for the health care team to review with the patient

Support Resources

- Know the Facts – Getting Your Specialty Medication From a Specialty Pharmacy
- Know the Facts – Medicare Part D: The Prescription Drug Program
- Question Guide – Understanding the Treatment Plan: Questions for the Health Care Team
- Checklist – Considerations to Help You Adhere to Treatment
- Checklist – Considerations for Giving Care to Patients With Cancer
- Other: _____

Educational Session

Date/time of appointment, including details on method of delivery (for example, in-clinic/practice, telephone, other site of care)

Notes:



Medication Acquisition: In-House Dispensing Pharmacy and Specialty Pharmacy

Know the Facts

When prescribing oral oncology medications, acquisition methods for patients typically involve obtaining the treatment either through an in-house dispensing pharmacy or specialty pharmacy. In this fact sheet, an overview of the benefits, challenges, and considerations for each method are reviewed.

In-House Dispensing Pharmacy

Considerations for Health Care Providers and Staff

1. Support point-of-care dispensing and be willing to discuss with each patient the opportunity to obtain his or her prescribed medications
2. Plan for point-of-care dispensing and devote the necessary time to successfully train all personnel
3. Dispense oral oncology medications in an area of the office that is mindful of patient flow and individual state requirements
4. Stock all medications generally required by patients and be mindful of volumes and averages
5. Collect prescription drug benefit information on all patients as a routine part of patient check-in

Benefits

Challenges

- | | |
|--|--|
| <ul style="list-style-type: none"> • Is convenient and housed inside oncology offices • Physicians and nurses available for questions • All personnel available so that double-checking of prescriptions can be performed for safety • Patient medical records readily available for questions | <ul style="list-style-type: none"> • Varying levels of physician supervision may be required, depending on regulations • Drug safety rules mandated by Healthcare Facilities Accreditation Program, Joint Commission, Occupational Safety and Health Administration, and public health rules require additional documentation and record keeping |
|--|--|

Specialty Pharmacy

Considerations for Health Care Providers and Staff

1. Case managers know when patients receive their medications and can educate them at the outset about their particular course of therapy, side effects, and dosing schedule
2. Medication therapy management service informs case managers when to be on the lookout for specific toxicities and other issues that clinical trials and other patient experiences have made apparent
3. Physicians receive regular emails and phone calls from case managers regarding their patients taking oral oncology medications

Benefits

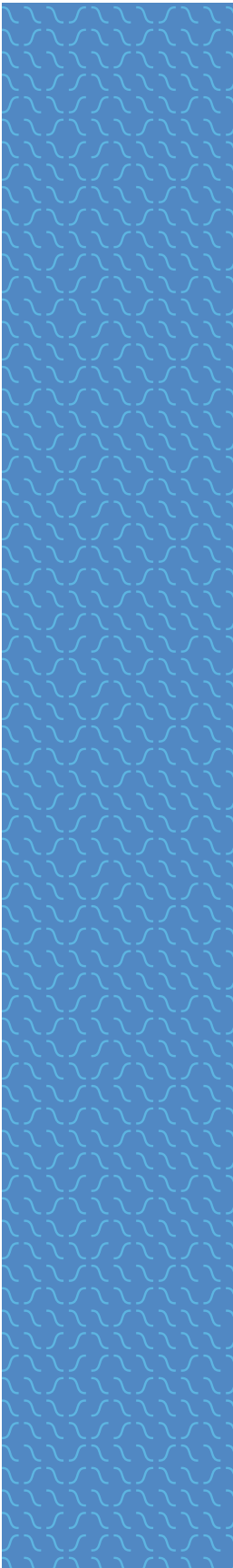
- Provides additional patient education by telephone or email
- Delivers medication to patient at no additional costs
- Likely able to custom-pack doses to avoid multiple copayments
- Works closely with various insurance plans

Challenges

- Potential challenge with differing communication about patient care between the specialty pharmacy and oncology practice
- Patients may have concerns about working with a pharmacy by telephone
- Patients may have prescriptions filled at different locations, potentially causing confusion with drug-drug or food-drug interactions

Reference: Oncology Nursing Society. Oral adherence toolkit. 2016. https://www.ons.org/sites/default/files/ONS_Toolkit_ONLINE.pdf. Accessed November 12, 2020.





**To access more resources, go to
HCP.Novartis.com/care-management**

