Oral Adherence Toolkit

Tool 1. Patient Assessment Checklist
Tool 2. Patient Education
Tool 3. Oral Chemotherapy Ordering Standards
Tool 4. Pharmacy Descriptions, Benefits, and Concerns
Tool 5. Reimbursement and Patient Assistance Resources
Tool 6. Food, Drug and Pathway Interactions and Effects
Tool 7. Sample Treatment Calendars
Tool 8. Factors Influencing Adherence
Tool 9. Methods Used to Encourage Patient Adherence
Tool 10. Traditional Counseling Versus Motivational Interviewing
Tool 11. Medication Reconciliation
Tool 12. Developing a Process of Medication Tracking
Tool 13. Readiness to Change Scale

Patient and Provider Resource List
Before beginning an oral chemotherapy regimen, the patient should be assessed for the ability to obtain and administer the regimen according to the treatment plan based on some of the following merits:

### Socioeconomic issues
- *How will the patient fill the prescription?*
- *Does the patient have insurance?*
- *What copays and out-of-pocket costs are associated with the patient’s insurance?*

### Psychosocial issues
- *What is the patient’s mental status?*
- *Does the patient have social support?*

### Regulatory or administrative needs
- *Is the drug on formulary?*
- *Is the drug approved by the FDA?*

### Health and medication beliefs and preferences
- *Is the patient ready to accept the necessity of treatment?*
- *Is the patient prepared for safety and adherence concerns?*
- *Have the patient’s expectations about treatment been managed?*

### Lifestyle
- *Where does the patient live in proximity to the clinic/pharmacy?*
- *Is the treatment regimen a good fit for the patient’s lifestyle (i.e., does the patient work, drive, etc)?*
- *Will a family member or caregiver be available to help with treatment and patient care?*

### Personal factors
- *How does the patient learn best?*
- *Does the patient have any cognitive impairment?*
- *Does the patient have the ability to take medications as prescribed (i.e., swallow pills or open packaging)?*
- *Does the patient have comorbidities that could impact or affect the treatment regimen or adherence?*
- *Does the patient use alcohol or drugs?*

### Treatment factors
- *How complex is the patient’s treatment regimen?*
- *Is there pill burden associated with the treatment regimen?*
- *What is the treatment duration?*

**SOURCES:**
Patient Education

Once a comprehensive patient assessment is completed and the treatment plan developed, patients should be provided with verbal and written or electronic information that highlights important drug and safety information. The following should be included in the educational materials:

1. Diagnosis, goal and duration of treatment
2. Drug name
3. Drug information, such as appearance and packaging
4. How the drug will be obtained
5. Potential side effects and the management of short- and long-term side effects, including reproductive and fertility risks
6. Safe storage and handling
7. Disposal of unused medication
8. Safe handling of body secretions and waste in the home
9. Dose schedule for the oral chemotherapy, as well as schedule of supplemental medications needed for the therapy
10. Food and/or drug interactions
11. Missed dose plan (i.e., what to do if the patient omits a dose)
12. Monitoring appointments (i.e., physician visits and any laboratory work needed)
13. Information on how, when, who and why to contact to report side effects and ask questions
14. The refill process, including how much time is needed to obtain refills and how to obtain them
15. A calendar with the patient’s treatment cycle clearly written out, which should be given to the patient at the initial teaching session and reviewed at each follow-up session

SOURCES:


Oral Chemotherapy Ordering Standards

A standardized process of verification is recommended with all chemotherapy orders. Include the following in oral chemotherapy prescriptions:

- Patient name and second identifier
- Date of order
- Name of drug (complete generic name)
- Allergies
- Method of dose calculation
- Dosage
- Route of administration
- Schedule and frequency of administration
- Treatment duration and time limitation
- Dispensing quantity
- Duration of therapy and number of days of treatment, if medication is not to be taken continuously
- Number of refills, including if there are no further refills
- Time limitation to ensure appropriate evaluation at predetermined intervals

SOURCES:
Filling prescriptions for oral cancer therapies can be challenging, as pharmacies must have designated areas to store and compound drugs and separate tools to count and dispense the drugs. In addition, insurance companies may require the use of other pharmacies, including mail-order pharmacies, which often provide a 30-day supply of the drugs at a lower cost but delay delivery. Some centers have begun on-site dispensing as a solution to this issue.

An overview of different types of pharmacies is provided below.

<table>
<thead>
<tr>
<th>Dispensing Site</th>
<th>Benefits</th>
<th>Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community retail pharmacy</td>
<td>• Often located near patient’s residence</td>
<td>• Community pharmacist may not have adequate experience to provide counseling for specialized medications</td>
</tr>
<tr>
<td></td>
<td>• May be better positioned to monitor for drug–drug interactions if all prescriptions are filled at this pharmacy chain</td>
<td>• May not stock less frequently used or high-cost medications, thus resulting in delay in starting cycle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Billing concerns – may not bill correctly when medication is covered under Medicare Part B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Limited resources for patients without insurance or with high copays</td>
</tr>
<tr>
<td>Specialty pharmacy</td>
<td>• Has highly experienced and knowledgeable oncology pharmacy staff</td>
<td>• May not be local – patient may have concerns about working with pharmacy by phone</td>
</tr>
<tr>
<td></td>
<td>• Provides additional patient education by phone or mail</td>
<td>• Education and instructions received may differ from information received from provider, creating patient confusion</td>
</tr>
<tr>
<td></td>
<td>• Delivers medication to patient at no additional cost</td>
<td>• Non-chemotherapy prescriptions may be filled at other locations, creating confusion with drug–drug or food–drug interactions</td>
</tr>
<tr>
<td></td>
<td>• Able to custom pack multi-strength doses to avoid multiple copays</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Works closely with insurance plans and Medicare</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Access to patient assistance programs</td>
<td></td>
</tr>
<tr>
<td>Mail-order pharmacy</td>
<td>• Usually decreased patient copay when medication is ordered in 90-day amounts</td>
<td>• Unlikely that patient will speak directly with an oncology pharmacist</td>
</tr>
<tr>
<td></td>
<td>• May have nurse case managers on staff to assist patients on medications for “catastrophic diseases”</td>
<td>• Nurse case manager may not be an oncology nurse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Most require minimum 90-day supply</td>
</tr>
<tr>
<td>Practice or physician</td>
<td>• Conveniently located inside oncology office</td>
<td>• Varying levels of physician supervision may be required, depending on regulations</td>
</tr>
<tr>
<td>dispensing pharmacy</td>
<td>• Has physician or nurse available for questions</td>
<td>• Drug safety rules mandated by HFAP, Joint Commission, OSHA and public health rules require additional documentation and record keeping</td>
</tr>
<tr>
<td></td>
<td>• Has all personnel available so that double check of prescription can be performed for safety</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Has patient medical record readily available for questions</td>
<td></td>
</tr>
<tr>
<td>Hospital Pharmacy</td>
<td>• May give patient access to an oncology pharmacist</td>
<td>• Travel burden – hospital pharmacy may not be located on same campus as office</td>
</tr>
<tr>
<td></td>
<td>• Allows close communication with practice physician or nurse</td>
<td>• May not have access to patient assistance program information</td>
</tr>
<tr>
<td></td>
<td>• Generally follows double check of prescription if given patient data</td>
<td>• May limit to 30-day supply</td>
</tr>
<tr>
<td></td>
<td>• May be connected to practice through electronic ordering system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Dispenses investigational drugs</td>
<td></td>
</tr>
</tbody>
</table>

HFAP: Healthcare Facilities Accreditation Program [American Osteopathic Association]; OSHA: Occupational Safety and Health Administration.

Based on information from

Medication cost can be a barrier to adherence. Prior to starting an oral chemotherapy regimen, determine the cost to the patient. Most manufacturers offer financial assistance or reimbursement programs. To locate these programs online, do an internet search of the drug manufacturer with the words “financial assistance” or “patient assistance” to learn about that company’s program. In addition, many foundations, including those listed here, provide patient assistance.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Website/Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>CancerCare® Co-Payment Assistance Foundation</td>
<td><a href="http://cancercarecopay.org">http://cancercarecopay.org</a></td>
</tr>
<tr>
<td>Cancer Supportive Care Programs National and International Listing of Pharmaceutical Programs</td>
<td><a href="http://www.cancersupportivecare.com/drug_assistance.html">http://www.cancersupportivecare.com/drug_assistance.html</a></td>
</tr>
<tr>
<td>Good Days from Chronic Disease Fund</td>
<td><a href="https://patientsandpros.cdfund.org">https://patientsandpros.cdfund.org</a></td>
</tr>
<tr>
<td>HealthWell Foundation</td>
<td><a href="http://www.healthwellfoundation.org">www.healthwellfoundation.org</a></td>
</tr>
<tr>
<td>The Leukemia &amp; Lymphoma Society’s® Co-Pay Assistance Program</td>
<td><a href="http://www.lls.org/copay">www.lls.org/copay</a></td>
</tr>
<tr>
<td>National Cancer Institute support and resources</td>
<td><a href="http://www.cancer.gov/cancertopics/support">www.cancer.gov/cancertopics/support</a></td>
</tr>
<tr>
<td>National Organization of Rare Disorders</td>
<td><a href="http://www.rarediseases.org">www.rarediseases.org</a></td>
</tr>
<tr>
<td>NeedyMeds</td>
<td><a href="http://www.needymeds.com">www.needymeds.com</a></td>
</tr>
<tr>
<td>Partnership for Prescription Assistance</td>
<td><a href="http://www.pparx.org">www.pparx.org</a></td>
</tr>
<tr>
<td>Patient Access Network Foundation</td>
<td><a href="http://www.panfoundation.org">www.panfoundation.org</a></td>
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<tr>
<td>Patient Advocate Foundation</td>
<td><a href="http://www.patientadvocate.org">www.patientadvocate.org</a></td>
</tr>
<tr>
<td>Patient Advocate Foundation’s Co-Pay Relief program</td>
<td><a href="http://www.copays.org">www.copays.org</a></td>
</tr>
<tr>
<td>PSI®—Patient Services Inc.</td>
<td><a href="http://www.patientservicesinc.org">www.patientservicesinc.org</a></td>
</tr>
<tr>
<td></td>
<td>1-800-366-7741</td>
</tr>
</tbody>
</table>
It is important to review your patient’s regimen prior to the start of treatment. Understanding specific administration concerns, food and drug interactions and treatment side effects will help you guide patients and manage expectations. Consult the drug manufacturer’s product information, as well as print and online drug resources for guidance on the administration of each drug. Below are general interactions that are important to know and share with your patient depending on the treatment regimen, followed by websites that provide drug information for both patients and healthcare professionals.

Food−Drug Interactions

- It is generally recommended that oral agents be taken whole (i.e., do not crush or chew), though several drugs may be dispersed in water or juice until dissolved completely.
- Foods and activities that may impact absorption of chemotherapy can include:
  - High-fat meals
  - Lack of adequate fluid intake
  - Smoking
  - Alcohol
  - Caffeine
  - Grapefruit juice
  - Calcium or dairy products
  - Seville oranges
  - Tyramine-rich foods (e.g., wine, yogurt, bananas, aged cheeses)
- Providers should consider whether the administration schedule can help to minimize adverse effects of the drug. For example, recommending that agents causing drowsiness or nausea are taken at night.

Drug−Drug Interactions

- The potential for drug interactions increases as the number of medications a patient takes increases.
- Oral chemotherapy agents often have a narrow therapeutic index, and all patients on oral chemotherapy agents should be screened for potential drug−drug or drug−herbal interactions.
- The most common interactions with oral drugs involve pharmacokinetic interactions, where one drug affects the absorption, distribution, metabolism or elimination of the other drug.
- Most of the drug interactions that nurses will see in clinical practice involve the cytochrome P450 (CYP450) enzyme system.

Pathway Interactions

- Research has identified about 50 different enzymes that metabolize drugs, though most medications are metabolized by six specific enzymes that may cause serious drug interactions: CYP3A4, CYP2D6, CYP1A2, CYP2C9, CYP2C19 and CYP2E1.
- A drug may be a substrate, inducer or inhibitor of the CYP450 system. The information about whether a drug is a substrate, an inducer or an inhibitor is very important for the nurse to know. In particular, because oral chemotherapy drugs that are substrates of the CYP450 system may have their effectiveness or tolerability affected, nurses should assess whether an oral chemotherapy drug is a substrate prior to sending the patient home with a prescription. The nurse can then provide information for the patient instructing him or her to avoid particular drugs that induce or inhibit the oral chemotherapy drug.
  - Substrates are drugs that are metabolized by the CYP450 system. Inducers and inhibitors of the CYP450 system affect the metabolism of substrates.
  - Inducers are drugs that increase the metabolism of CYP450 substrates. Most often, this results in decreased levels of the drug and potentially decreased effectiveness.
  - Inhibitors are drugs that decrease the metabolism of CYP450 substrates. Most often, this results in increased levels of the drug and potentially increased adverse effects and toxicities.

RESOURCES FOR DRUG-SPECIFIC INFORMATION:

- U.S. Food and Drug Administration: [http://www.fda.gov/Drugs/ResourcesForYou/Consumersucm45064.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumersucm45064.htm)
- Provider Resources: [http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/default.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/default.htm)
- Lexi-Comp, Inc.: [www.lexi.com](http://www.lexi.com)
- UpToDate® Information resource: [www.uptodate.com](http://www.uptodate.com)

SOURCES:


Sample Treatment Calendars

Written information on treatment regimens is vital for patients to have a thorough understanding of their therapies, and providing a patient with a folder or binder that is specific to his or her therapy will often help the patient to keep organized. These sample patient calendars are examples of tools that can be created to serve as part of patient education and treatment adherence.

**SAMPLE CALENDAR 1: Trametinib + Dabrafenib for Metastatic Melanoma**

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trametinib AM + Dabrafenib PM</td>
<td>Trametinib AM + Dabrafenib PM</td>
<td>Trametinib AM + Dabrafenib PM</td>
<td>Trametinib AM + Dabrafenib PM</td>
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<td>Trametinib AM + Dabrafenib PM</td>
<td>Trametinib AM + Dabrafenib PM</td>
</tr>
</tbody>
</table>

**SAMPLE CALENDAR 2: Ixazomib + Lenalidomide + Dexamethasone for Multiple Myeloma after ≥ 1 prior therapy**

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ixazomib</td>
<td>Lenalidomide</td>
<td>Dexamethasone</td>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
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</tr>
<tr>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
<td>Ixazomib</td>
<td>Lenalidomide</td>
<td>Dexamethasone</td>
<td>Lenalidomide</td>
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<tr>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
<td>Ixazomib</td>
<td>Lenalidomide</td>
<td>Dexamethasone</td>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
</tr>
<tr>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
<td>Ixazomib</td>
<td>Lenalidomide</td>
<td>Dexamethasone</td>
<td>Lenalidomide</td>
<td>Lenalidomide</td>
</tr>
<tr>
<td>Rest</td>
<td>Rest</td>
<td>Begin next cycle as instructed</td>
<td>Rest</td>
<td>Rest</td>
<td>Rest</td>
<td>Rest</td>
</tr>
</tbody>
</table>

**SAMPLE CALENDAR 3: Lapatinib + Capecitabine for Invasive Breast Cancer**

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
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<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
<td>Capecitabine AM + Lapatinib at bedtime</td>
</tr>
<tr>
<td>Lapatinib at bedtime</td>
<td>Lapatinib at bedtime</td>
<td>Lapatinib at bedtime</td>
<td>Lapatinib at bedtime</td>
<td>Lapatinib at bedtime</td>
<td>Lapatinib at bedtime</td>
<td>Lapatinib at bedtime</td>
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</tbody>
</table>

**SOURCE:**


# Factors Influencing Adherence

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Barriers</th>
</tr>
</thead>
</table>
| Personal and Patient Factors | • Emotional and mental status  
• Physical status and comorbid conditions  
• Social supports  
• Feelings about disease, self-efficacy and outcome expectation  
• Socioeconomic status |
| Treatment-Related Factors | • Goal of therapy  
• Complexity of treatment regimen  
• Immediacy and evidence of benefit  
• Short- and long-term side effects  
• Cost of medication and copay |
| Healthcare System       | • Relationship with providers  
• Communication with providers  
• Education of patient and caregivers  
• Satisfaction with care  
• Insurance coverage  
• Access to convenient and efficient clinic |

NOTE: Based on information from
Methods Used to Encourage Patient Adherence

A variety of tools and techniques have been shown to help improve adherence to oral anticancer therapy.

**Reminder Tools**

- Calendar or daily medication checklist
- Pill diaries
- Patient and family education
- Establishing routine, which includes drug administration
- Home psychological support
- Pillboxes with multiple compartments (as packaging form and storage needs permit)
- Electronic reminders
  - Alarms on clocks, timers and cell phones
  - Smartphone applications
  - Glowing or electronic pillboxes
  - Text message reminder
  - Automated voice recording (phone call) reminder
- Medication-dispensing machines

**Sources:**

## Traditional Counseling Versus Motivational Interviewing

<table>
<thead>
<tr>
<th>Traditional Counseling</th>
<th>Motivational Interviewing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HCP is the healthcare expert</td>
<td>• HCP develops partnership with patient</td>
</tr>
<tr>
<td>• Assumes patient lacks knowledge</td>
<td>• Exchanges information to facilitate an informed decision</td>
</tr>
<tr>
<td>• Tells patient what to do</td>
<td>• Patient has the right to decide own care</td>
</tr>
<tr>
<td>• Hopes patient follows instructions</td>
<td>• HCP provides information to patient for the purpose of developing discrepancy between present behavior and goal</td>
</tr>
<tr>
<td>• HCP provides definitive information</td>
<td>• HCP and patient negotiate behavior and reach agreement</td>
</tr>
<tr>
<td>• Directives are presumed to be non-negotiable</td>
<td>• Goal is to access motivation and elicit patient’s commitment to change behavior</td>
</tr>
<tr>
<td>• HCP dictates healthcare behavior</td>
<td>• HCP understands and accepts patient’s action</td>
</tr>
<tr>
<td>• Goal is to motivate the patient</td>
<td>• HCP expects respect from patient</td>
</tr>
<tr>
<td>• HCP persuades patient to change behavior</td>
<td>• HCP must earn respect from patient</td>
</tr>
</tbody>
</table>

HCP: healthcare provider.

**SOURCES:**


Medication Reconciliation

Maintain a current list of patient medications and supplements, both prescription and over-the-counter, through a process of medication reconciliation. Medication reconciliation involves comparing medication orders against the medications a patient has been taking in an effort to avoid medication errors such as omissions, duplications, dosing errors or drug interactions. It should be done across the continuum of care, at every clinical encounter or transition of care in which new medications are ordered or existing orders are rewritten.

The 5-step process includes

1. Develop a list of current medications
2. Develop a list of medications to be prescribed
3. Compare the medications on the two lists
4. Make clinical decisions based on the comparison
5. Communicate the new list to appropriate caregivers and to the patient and pharmacy

SOURCES:


Developing a Process of Medication Tracking

When a team of healthcare professionals cares for a patient through their cancer treatment, responsibility for medication tracking can be confusing. The interprofessional team should establish a process to ensure medication reconciliation is completed consistently and concerns are acted upon promptly. Consider discussing the following questions as a team.

- Who is responsible for obtaining the medication history?
- What medications are included?
- Is a standardized form used?
- Who adds this form or information to the chart?
- Who identifies variances?
- What is the time frame to act upon variances?
- When medications are changed, how is it documented?
- How are medication changes communicated between specialties?
- Who communicates changes to patients and caregivers?
- How is the process monitored?

SOURCES:

A treatment regimen that is not a good lifestyle fit may result in poor adherence to therapy, and changing one’s lifestyle can be challenging. Begin by assessing the individual’s readiness to change.

**Readiness to Change Scale**

![Readiness Ruler](image)

**Instructions for Use**

1. Ask patient to rate how ready he or she is for change by drawing an arrow to or circling a number in the appropriate area on the scale.

2. A score >5 indicates patient is ready to work toward changing behavior.

3. Discuss the patient’s ranking on the scale with the following questions:
   a. How important is this change to you?
   b. How confident are you that you can make this change?
   c. Why did you choose a ____, not a 10?
   d. What would have to happen to make it a ____?
      [next highest number from the one stated in question “c”]

**Sources**


<table>
<thead>
<tr>
<th>Resource Name</th>
<th>Website URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abramson Cancer Center of the University of Pennsylvania, OncoLink</td>
<td><a href="http://www.oncolink.org">www.oncolink.org</a></td>
</tr>
<tr>
<td>American Cancer Society</td>
<td><a href="http://www.cancer.org">www.cancer.org</a></td>
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<tr>
<td>American Society of Health-System Pharmacists</td>
<td><a href="http://www.ashp.org">www.ashp.org</a></td>
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<tr>
<td>Association of Cancer Online Resources</td>
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<td>Association of Community Cancer Centers</td>
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<td>ChemoCare</td>
<td><a href="http://www.chemocare.com">www.chemocare.com</a></td>
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<td>Lexi-Comp, Inc.</td>
<td><a href="http://www.lexi.com">www.lexi.com</a></td>
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<td>Micromedex</td>
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<td>National Cancer Institute</td>
<td><a href="http://www.cancer.gov">www.cancer.gov</a></td>
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<td>National Coalition for Cancer Survivorship</td>
<td><a href="http://www.canceradvocacy.org">www.canceradvocacy.org</a></td>
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<td>National Comprehensive Cancer Network</td>
<td><a href="http://www.nccn.org">www.nccn.org</a></td>
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<td>Patient Compliance</td>
<td><a href="http://www.patientcompliance.net">www.patientcompliance.net</a></td>
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<tr>
<td>Patients Equal Access Coalition</td>
<td><a href="http://peac.myeloma.org/oral-chemo-access-map">http://peac.myeloma.org/oral-chemo-access-map</a></td>
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<td>Stand Up to Cancer</td>
<td><a href="http://www.standuptocancer.org">www.standuptocancer.org</a></td>
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<td>UpToDate® information resource</td>
<td><a href="http://www.uptodate.com">www.uptodate.com</a></td>
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<tr>
<td>U.S. Food and Drug Administration</td>
<td><a href="http://www.fda.gov">www.fda.gov</a></td>
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