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**ADVANCED PRACTICE PROVIDER** 

**February 15, 2023**

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Advanced Practice Provider webinars created and coordinated by **Tommy Trigliano, DNP, ANP-BC, ACPNP**, in partnership with **UNC Lineberger Cancer Network**

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UNC Lineberger Cancer Network

## ADVANCED PRACTICE PROVIDER

February 15, 2023

Oral Chemotherapy:  
 Prescribing, Monitoring, and Safety



Aimee Faso, PharmD, BCOP, CPP

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OUR PRESENTER



**Aimee Faso,**  
PharmD, BCOP, CPP

Aimee Faso, PharmD, CPP, BCOP, is a Clinical Pharmacist Practitioner (CPP) at the North Carolina Basnight Cancer Hospital (NCBCH) who works with the breast oncology team. After completing her Master's degree in physiological psychology at Ohio University, she worked in the pharmaceutical industry for 2 years. She then attended pharmacy school at the University of Florida in Gainesville, FL followed by a pharmacy practice residency at Dartmouth Hitchcock Medical Center.

Dr. Faso started working at the NCBCH in 2008 and in 2014 joined the outpatient breast oncology team. She is Adjuvant Faculty at the Eshelman School of Pharmacy where she teaches breast cancer treatment to pharmacy students and is a preceptor to pharmacy students and pharmacy residents. She is also a Clinical Assistant Professor in the School of Nursing where she teaches oncology pharmacology in the nurse practitioner program.

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**OUR PRESENTER**

5. Preceptor to pharmacy students and pharmacy residents.

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**OUR PRESENTER**

5. Preceptor to pharmacy students and pharmacy residents.
4. Clinical Assistant Professor in the School of Nursing where she teaches oncology pharmacology in the nurse practitioner program.

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**OUR PRESENTER**

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4. Clinical Assistant Professor in the School of Nursing where she teaches oncology pharmacology in the nurse practitioner program.
3. Adjuvant Faculty at Eshelman School of Pharmacy where she teaches breast cancer treatment to pharmacy students.
2. In 2014, joined Lineberger's outpatient breast oncology team.

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**OUR PRESENTER**

1. Since 2008, Clinical Pharmacist Practitioner at the North Carolina Basnight Cancer Hospital.
2. In 2014, joined Lineberger's outpatient breast oncology team.
3. Adjuvant Faculty at Eshelman School of Pharmacy where she teaches breast cancer treatment to pharmacy students.
4. Clinical Assistant Professor in the School of Nursing where she teaches oncology pharmacology in the nurse practitioner program.
5. Preceptor to pharmacy students and pharmacy residents.

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Oral chemotherapy is a drug, normally a tablet or capsule, used to help kill or weaken cancer cells. The drug can be taken at home, versus in a hospital setting.

True **A**

False **B**

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**Oral chemotherapy is a drug, normally a tablet or capsule, used to help kill or weaken cancer cells. The drug can be taken at home, versus in a hospital setting.**

True

False

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# Oral Chemotherapy

## PRESCRIBING, MONITORING, AND SAFETY


FEBRUARY 2023

AIMEE FASO, PHARM.D, BCOP, CPP  
CLINICAL PHARMACIST PRACTITIONER  
UNC HEALTH CARE

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## Oral Chemotherapy Objectives

- Describe the factors involved in safe prescribing practices of oral chemotherapy
- Review how to appropriately monitor patients while on oral chemotherapy
- Discuss the safe handling, storage and disposal of oral chemotherapy



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## Oral chemotherapy

- Oral chemotherapy includes medications taken by mouth that are cytotoxic or target proteins, pathways or receptors that are involved with cancer
- Use of oral chemotherapy has been steadily increasing
  - 18 novel oral chemotherapies have been approved from 2020 to December 2022
  - Estimated that 25-30% of chemotherapy medications in the development pipeline will be oral

New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products. <https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products>. Accessed December 8, 2022  
 Hematology/Oncology Pharmacy Association (HOPA). Oral chemotherapy issue brief. [www.hoparx.org/images/hopa/advocacy/Issue-Briefs/HOPA\\_Oral\\_Chemotherapy\\_Issue\\_Brief.pdf](http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/HOPA_Oral_Chemotherapy_Issue_Brief.pdf).

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## Shifts the care of patients from the provider to the patient

### Benefits

- Patient convenience
- Patient empowerment
- Reduced burden of care
- Efficacious
- Reduced toxicity?

### Concerns

- Adherence
- Safety
- Proper storage/handling
- Monitoring
- Cost

Weingart SN, Toro J, Spencer J, et al: Medication errors involving oral chemotherapy. *Cancer* 116:2455-2464, 2010  
 Weingart SN, et al. NCCN Task Force: Oral Chemotherapy. *J Natl Comp Canc Netw* 2008;6 Suppl 3:S1-14.

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## Wide scope of use

CML	• Imatinib, nilotinib, dasatinib, bosutinib
Metastatic RCC	• Sunitinib, pazopanib, cabozantinib, axitinib
Ph+ AML	• Imatinib, dasatinib (along with cytotoxic chemotherapy)
BRAF-mutant melanoma	• Vemurafenib/cobimetinib, dabrafenib/trametinib
ALK-mutant non-small cell lung cancer	• Crizotinib, alectinib, ceritinib
Multiple myeloma	• Thalidomide, lenalidomide containing regimens
EGFR-mutant NSCLC	• Erlotinib, afatinib, osimertinib, gefitinib
Advanced prostate Cancer	• Abiraterone, enzalutamide, apalutamide
Advanced breast cancer	• Tucatinib, capecitabine, ribociclib
Advanced colon cancer	• Capecitabine, regorafenib, trifluridine + tipiracil

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## Varied mechanisms of action

Cytotoxic	• E.g. Capecitabine
Targeted	• E.g. Imatinib
Endocrine	• E.g. Tamoxifen
Other	• E.g. Lenalidomide

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### Prescribing

Safe prescribing at the institutional level

**Development of institutional policies and procedures**

Standardized ordering practices	Standardized patient monitoring
Standardized symptom management	Consistent documentation

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## Prescribing

### Safe prescribing for patient care

**Review upon initiation of oral chemotherapy**

- Diagnosis
- Co-morbid conditions and past medical history
- Comprehensive medication history and allergies
- Height/weight
- Functional or performance status
- Baseline labs

**Assess at initiation and at each encounter**

- Vital signs
- Weight
- Allergies
- Toxicities
- Medication review
- Functional status
- Labs, as appropriate

Neuss MN et al. 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. JOP 2016;12(12):1262-1271.

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## Prescribing

### Oral chemotherapy prescriptions should include:

- Patient name and demographics
- Drug name
- Dose calculation, if applicable
- Schedule
- Administration instructions
- Quantity
- Refills

Sample Prescription

Medical Center  
100 Medical Center Dr.  
Chapel Hill, NC 27514  
T: 800-555-1212  
F: 800-555-1313

**Name:** Jane Doe  
**DOB:** 1/2/1969  
**MRN:** 000000000  
**Address:** 123 Main St;  
Chapel Hill, NC 27514

**Date:** Feb. 2, 2023

**Capecitabine 500 mg tablets**  
**Sig:** Take 3 tablets (1500 mg) po after breakfast and 3 tablets (1500 mg) po after dinner for 14 days of a 21-day cycle.  
**Qty:** 84 tablets **Refill:** 0 (Zero) **Route:** Oral

**Diagnosis:** Malignant neoplasm of right breast, female (C50.011)

**Pharmacy Note:** Wt=67 kg; Ht=160 cm BSA=1.73  
Dose = 1000 mg/m<sup>2</sup> po BID x 14 days of 21 day cycle

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**Authorizing Provider: Dr. Hemonc**  
NPI: 1000000000  
License # 100

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## Patient education

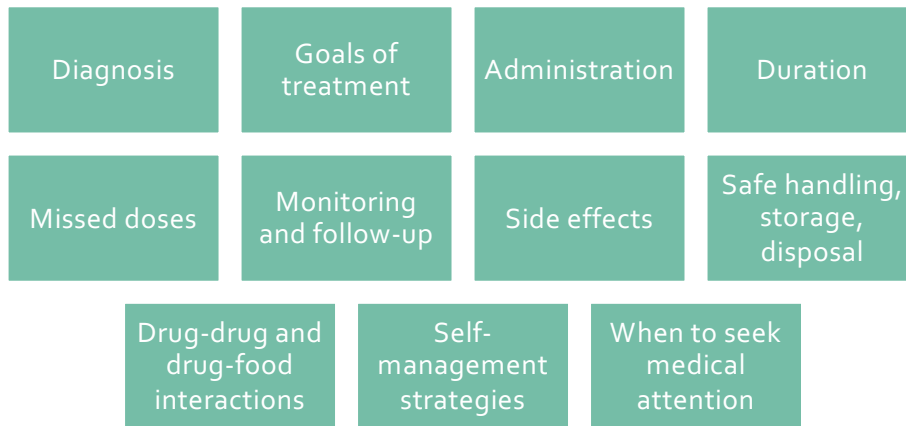
- Patients should be provided education prior to initiation of oral chemotherapy
- Best to use standardized teaching materials
- Should be suitable for patient’s health literacy and language
- Can clarify patient misconceptions
- Will need reinforcement throughout treatment period



Mackler, E et al. 2018 Hematology/Oncology Pharmacist Association Best Practices for the Management of Oral Oncolytic Therapy: Pharmacy Practice Standard. JOP 2018;15(4): e346-e355.

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## Patient education



Neuss MN et al. 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. JOP 2016;12(12): 1262-1277.

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# Patient education

Should also include

- Written care plan
- Specific administration instructions




Morning	Evening
7 am - Lapatinib (Tykerb)	--
8 am - Breakfast	8 pm - Dinner
8:30 am - Capecitabine (Xeloda)	8:30 pm - Capecitabine (Xeloda)

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	Sun	Mon	Tue	Wed	Thu	Fri	Sat
<b>Calendar</b>		<b>30 (Cycle 7, Day 1)</b> Ponatinib 15 mg Doxorubicin IV  Dexamethasone 1.5 tabs in the morning and 1.5 tabs in the afternoon  Mercaptopurine 1 tab	<b>31</b> Ponatinib 15 mg  Dexamethasone 1.5 tabs in the morning and 1.5 tabs in the afternoon  Mercaptopurine 2 tabs	<b>1</b> Ponatinib 15 mg  Dexamethasone 1.5 tabs in the morning and 1.5 tabs in the afternoon  Mercaptopurine 1 tab	<b>2</b> Ponatinib 15 mg  Dexamethasone 1.5 tabs in the morning and 1.5 tabs in the afternoon  Mercaptopurine 2 tabs	<b>3</b> Ponatinib 15 mg  Dexamethasone 1.5 tabs in the morning and 1.5 tabs in the afternoon  Mercaptopurine 1 tab	<b>4</b> Ponatinib 15 mg  Mercaptopurine 2 tabs
	<b>5</b> Ponatinib 15 mg  Mercaptopurine 2 tabs	<b>6</b> Ponatinib 15 mg  Mercaptopurine 1 tab	<b>7</b> Ponatinib 15 mg  Mercaptopurine 2 tabs	<b>8</b> Ponatinib 15 mg  Mercaptopurine 1 tab	<b>9</b> Ponatinib 15 mg  Mercaptopurine 2 tabs	<b>10</b> Ponatinib 15 mg  Mercaptopurine 1 tab	<b>11</b> Ponatinib 15 mg  Mercaptopurine 2 tabs
	<b>12</b> Ponatinib 15 mg  Mercaptopurine 2 tabs	<b>13</b> Ponatinib 15 mg	<b>14</b> Ponatinib 15 mg	<b>15</b> Ponatinib 15 mg	<b>16</b> Ponatinib 15 mg	<b>17</b> Ponatinib 15 mg	<b>18</b> Ponatinib 15 mg
	<b>19</b> Ponatinib 15 mg	<b>20 (Cycle 8, Day 1)</b> Ponatinib 15 mg  Doxorubicin IV  Dexamethasone 1.5 tabs in the morning and 1.5 tabs in the afternoon	Take mercaptopurine at least 1 hour after evening meals. Avoid milk and citrus products				

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## Patient education

-  Education should be provided verbally and in written form
-  Education should include family members, caregivers or others
-  Patients should be encouraged to write down questions and answers

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## Patient education resources

- Website resources that provide handouts specifically for patients
  - Oncolink (<https://www.oncolink.org/>)
  - Chemocare (<https://chemocare.com/>)
  - Oral Chemotherapy Education (<https://www.oralchemoedsheets.com/>)
- Package insert
- Tertiary drug information databases
  - Lexi-Comp, UpToDate®, Facts and Comparisons, Micromedex
  - [www.drugs.com/monograph](http://www.drugs.com/monograph)
    - Free website that obtains drug information from multiple drug information databases including Micromedex and American Society of Health-System Pharmacists

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## Drug interactions

- Oral chemotherapy can interact with other medications, supplements, or foods
- Can result in increased toxicities or reduced efficacy
- Interactions may occur by multiple mechanisms
- Important to assess for interactions at each visit
- Information on interactions and their management may be limited

Segal EM et al. Oral chemotherapy food and drug interactions: A comprehensive review of the literature. *J Oncol Pract* 2015;10: e255-268  
 Rogala BD et al. Oral anticancer therapy: Management of drug interactions. *J Oncol Pract* 2019;15:81-90

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## Pharmacokinetic drug interactions

- Effect the absorption, distribution, metabolism or excretion of another drug
- CYP 3A4 is the most common enzyme that metabolizes oral chemotherapy
  - Drugs that inhibit or induce CYP 3A4 can effect concentrations of drugs that are substrates of this enzyme

### EXAMPLES

- Phenytoin (Dilantin®)
  - Strong 3A4 inducer
  - Can significantly decrease the concentrations of medications that are major substrates of CYP 3A4
- Nirmatrelvir/ritonavir (Paxlovid®)
  - Strong 3A4 inhibitor
  - Can significantly increase the concentration of major substrates of CYP 3A4

Segal EM et al. Oral chemotherapy food and drug interactions: A comprehensive review of the literature. *J Oncol Pract* 2015;10: e255-268  
 Rogala BD et al. Oral anticancer therapy: Management of drug interactions. *J Oncol Pract* 2019;15:81-90

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## Pharmacodynamic drug interactions

Lead to an alteration of pharmacologic effect, which may be additive, synergistic, or antagonistic

**EXAMPLE**

**QTc prolongation**

- Oral chemotherapy agents may prolong QTc and the addition of other drugs that have this side effect result in an additive risk
- Ribociclib (Kisqali<sup>®</sup>) can cause QTc prolongation. Addition of ondansetron (Zofran<sup>®</sup>) or citalopram (Celexa<sup>®</sup>) can increase the risk of this adverse effect



Segal EM et al. Oral chemotherapy food and drug interactions: A comprehensive review of the literature. J Oncol Pract 2015;10: e255-268  
 Rogala BD et al. Oral anticancer therapy: Management of drug interactions. J Oncol Pract 2019;15:81-90

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## Acid suppression therapy interactions

PPIs, H<sub>2</sub> receptor antagonists, and antacids can effect the absorption of some oral chemotherapy

**EXAMPLES**

- Proton pump inhibitors**
  - Due to decreased absorption, PPIs are contraindicated with dasatinib, erlotinib, neratinib and pazopanib
- Histamine H<sub>2</sub> receptor antagonists**
  - Erlotinib, and nilotinib can be taken 10 hours after or 2 hours before taking a histamine H<sub>2</sub>-receptor
- Antacids**
  - Over-the-counter antacids should be administered 2 hours before or after the administration of acalabrutinib, dasatinib, erlotinib, gefitinib, bosutinib, nilotinib, and ponatinib, and 3 hours before neratinib

Segal EM et al. Oral chemotherapy food and drug interactions: A comprehensive review of the literature. J Oncol Pract 2015;10: e255-268  
 Rogala BD et al. Oral anticancer therapy: Management of drug interactions. J Oncol Pract 2019;15:81-90

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## Herbal products

- Herbal supplements have the potential to cause pharmacodynamic or pharmacokinetic interactions
- Drug-herb interactions can be difficult to evaluate due to limited or lack of data

**EXAMPLE**


St. John's Wort

- CYP 3A4 inducer
- Can decrease the concentration of major substrates of CYP 3A4 and should be avoided



Segal EM et al. Oral chemotherapy food and drug interactions: A comprehensive review of the literature. J Oncol Pract 2015;10: e255-268  
 Rogala BD et al. Oral anticancer therapy: Management of drug interactions. J Oncol Pract 2019;15:81-90

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### Food interactions

- Food can impair or improve the absorption of some oral chemotherapies
- Each drug has specific recommendations if it should be taken with food, without food or with/without food.

**EXAMPLES**

- Empty stomach
  - Lapatinib should be taken 1 hour before or 1 hour after a meal
- With food
  - Capecitabine should be taken within 30 minutes of a meal
  - Regorafenib should be taken with a low fat breakfast
- Grapefruit
  - Grapefruit is a 3A4 inhibitor and should be avoided with oral chemotherapy that are substrates of 3A4

Segal EM et al. Oral chemotherapy food and drug interactions: A comprehensive review of the literature. J Oncol Pract 2015;10: e255-268  
 Rogala BD et al. Oral anticancer therapy: Management of drug interactions. J Oncol Pract 2019;15:81-90

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## Drug interaction resources

- Manufacturer package insert
- Tertiary drug information databases
  - Lexi-Comp, UpToDate®, Facts and Comparisons, Micromedex
  - [www.drugs.com/drug\\_interactions.html](http://www.drugs.com/drug_interactions.html)
- Herb information
  - Natural Medicines, available through institutional library
    - [www.naturalmedicines.therapeuticresearch.com](http://www.naturalmedicines.therapeuticresearch.com)
  - Memorial Sloan Kettering Cancer Center website  
*About Herbs, Botanicals & Other Products*
    - [www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine/herbs](http://www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine/herbs)
  - National Center for Complimentary and Integrative Health
    - [www.nccih.nih.gov](http://www.nccih.nih.gov)

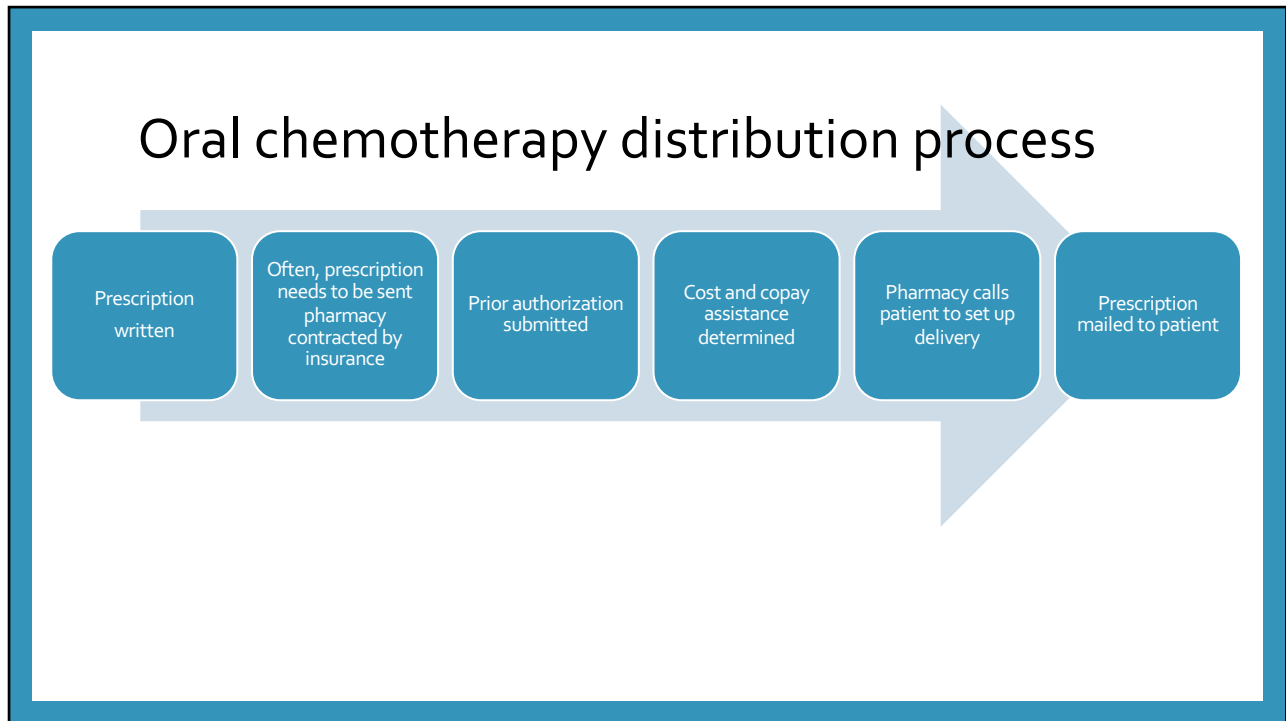
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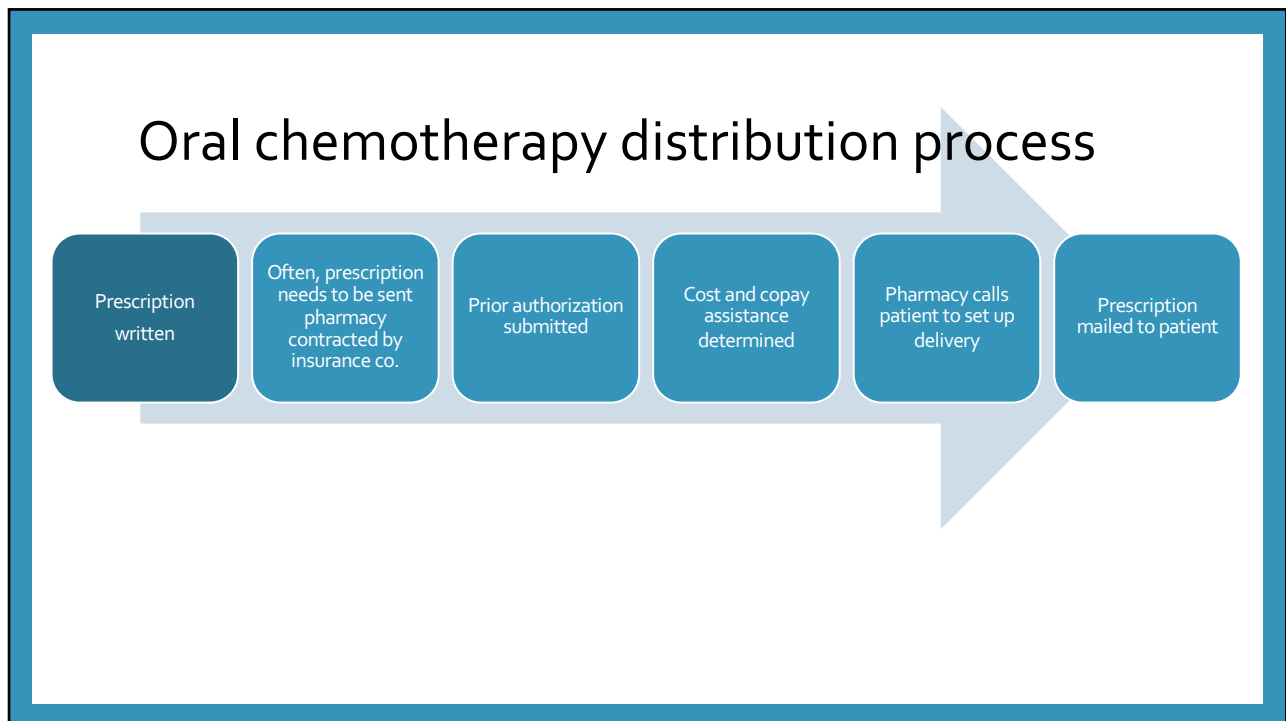
Oral chemotherapy distribution process

- Most oral chemotherapy must be dispensed by a specialty pharmacy
- Provide medications that treat rare or complex diseases and/or are expensive
- Most specialty pharmacies are mail order

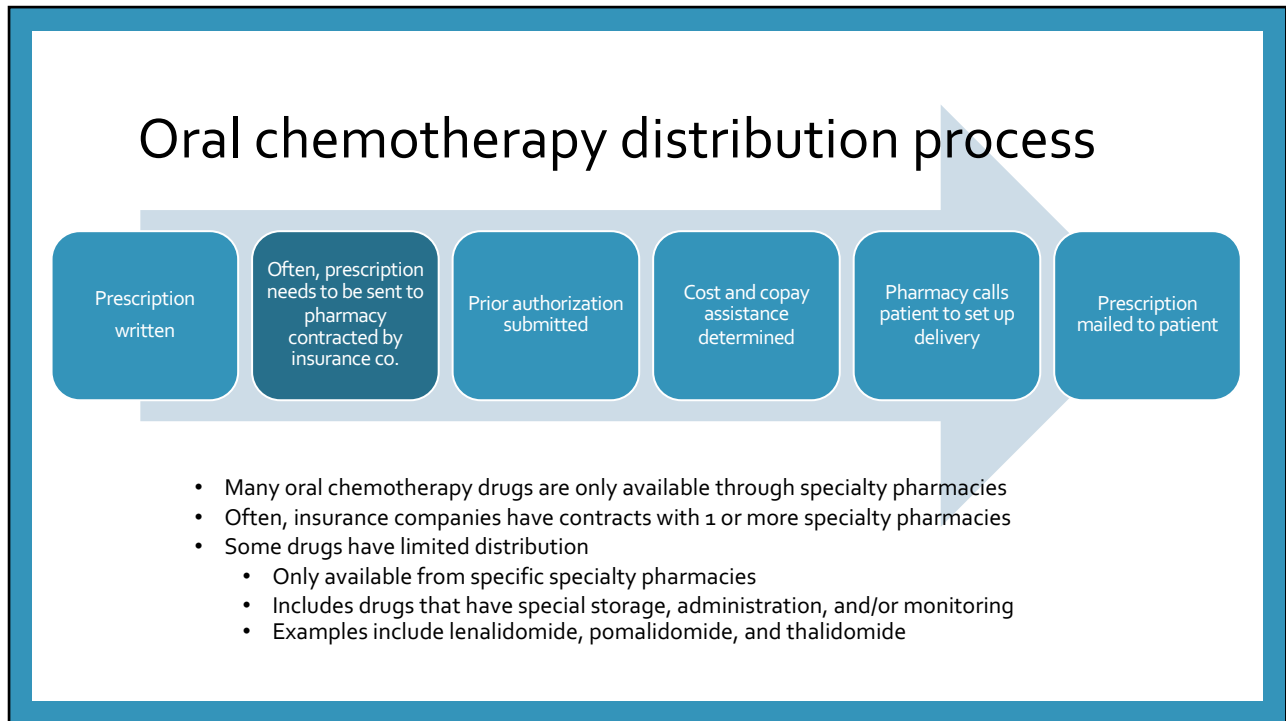
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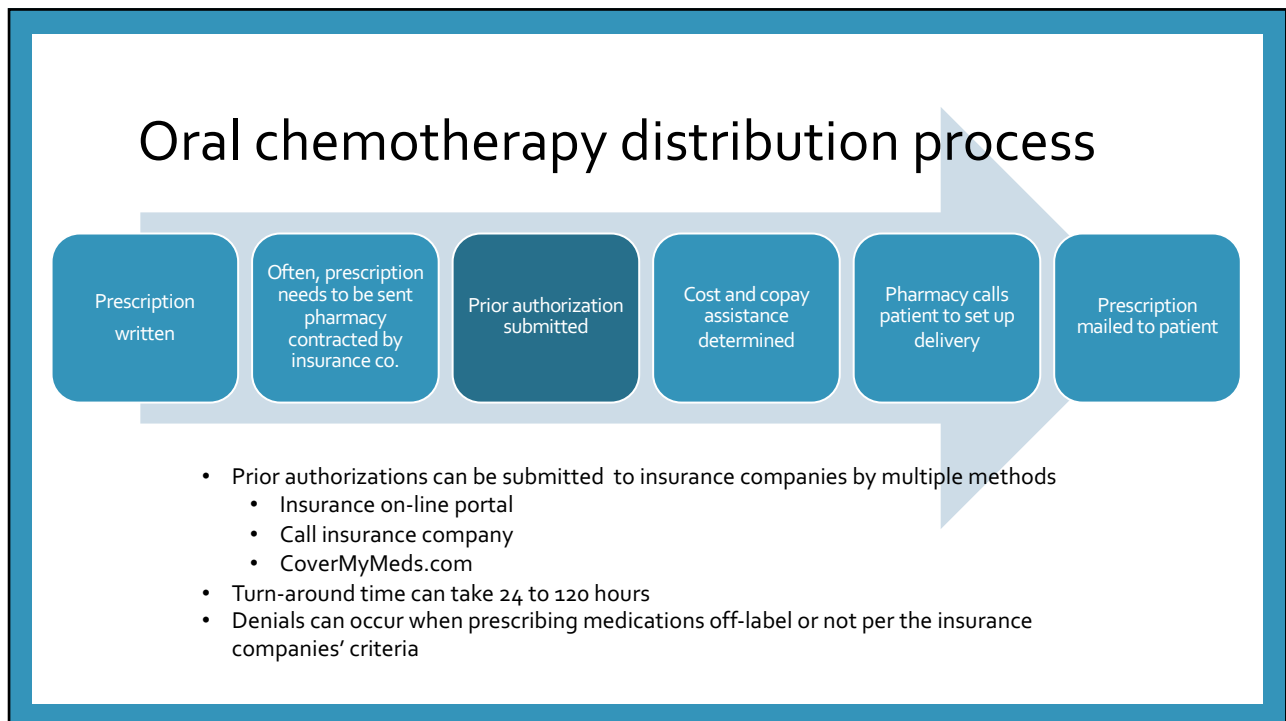
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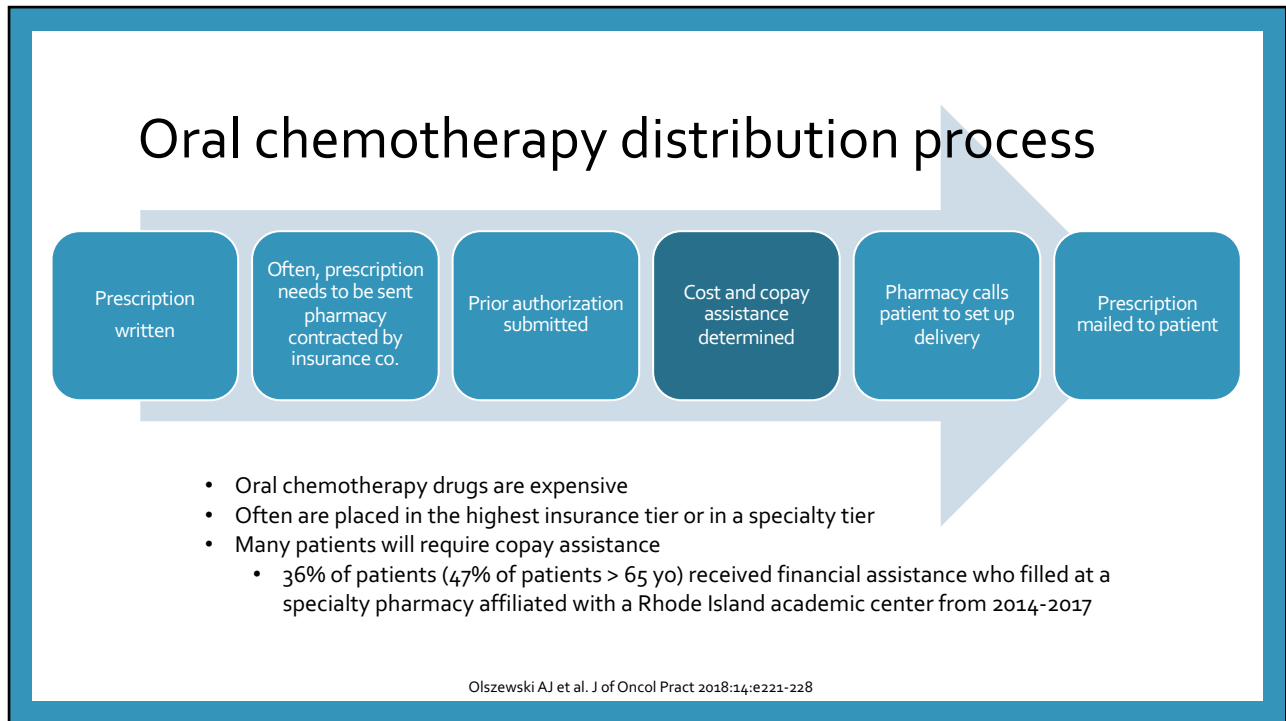
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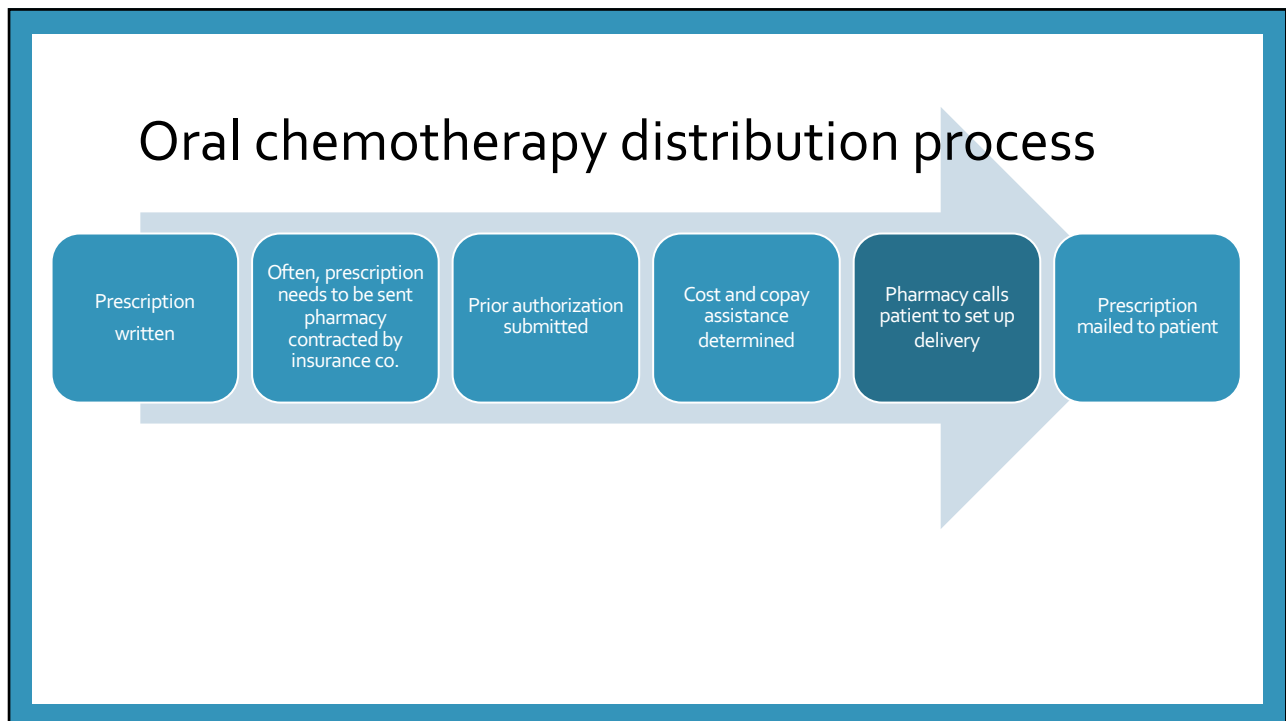
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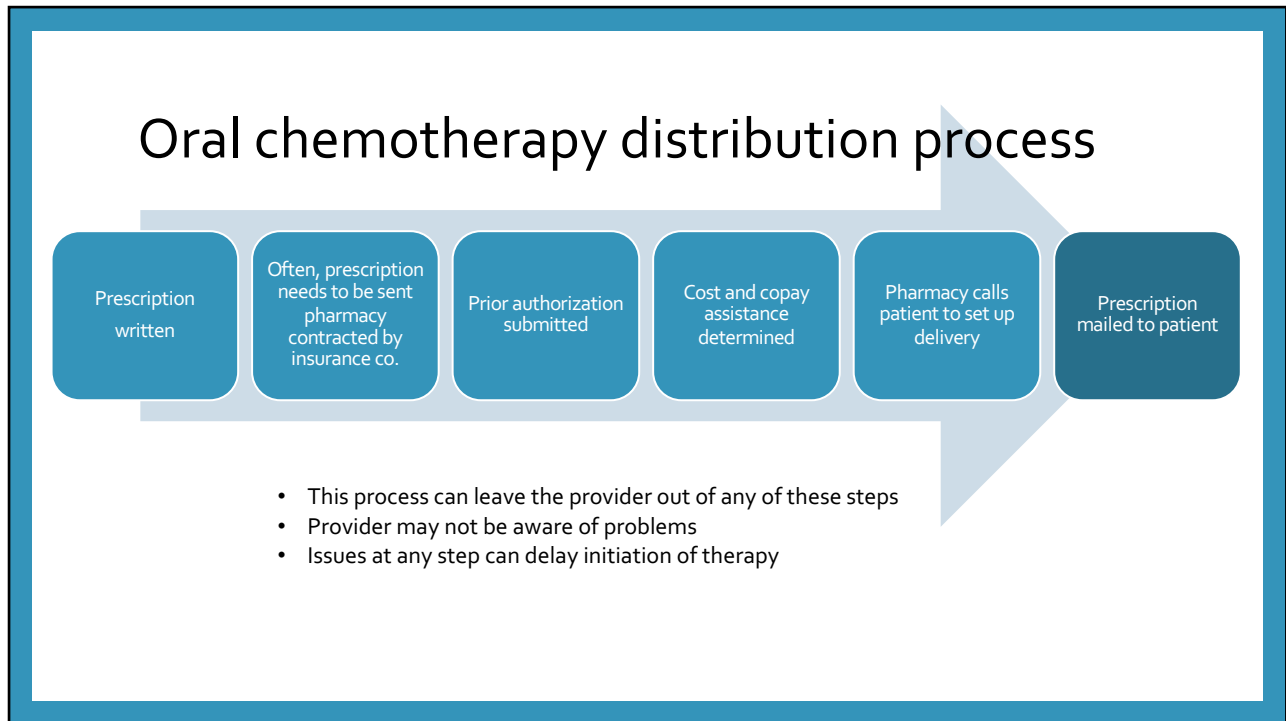
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## Cost

- US patients paid an estimated \$16.2 billion in out-of-pocket cancer care costs and lost nearly \$5 billion in time costs in 2019
- During the first year after a cancer diagnosis
  - Patients aged 65 years or older have an average of \$2700 in both out-of-pocket and lost time costs
  - Patients < 65 years old had an average \$5900 in out-of-pocket and lost time costs
- These costs place a large burden on our cancer patients

Kuehn, B. Cancer care creates substantial costs for US patients. JAMA 2021;326:2251.

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## Resources to help with drug costs

Uninsured	Commercial Insurance	Government insurance
<ul style="list-style-type: none"> <li>• Manufacturer assistance programs</li> </ul>	<ul style="list-style-type: none"> <li>• Copay cards</li> <li>• Charity grants</li> <li>• Manufacturer assistance programs for under-insured</li> </ul>	<ul style="list-style-type: none"> <li>• Medicare Part D Grants</li> <li>• Manufacturer assistance programs</li> </ul>

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## Resources to help with cost

- Charity Grants
  - Patient Access Network Foundation [www.panfoundation.org](http://www.panfoundation.org)
  - Healthwell <https://www.healthwellfoundation.org/>
  - Patient Advocate Foundation <https://copays.org/>
- NeedyMeds [www.needymeds.org](http://www.needymeds.org)
- 1 of US [1ofus.org](http://1ofus.org)
- Leukemia Lymphoma Society [www.lls.org](http://www.lls.org)
- Social Security Compassionate Allowance [www.socialsecurity.gov/compassionateallowances/](http://www.socialsecurity.gov/compassionateallowances/)
- Pharmacists

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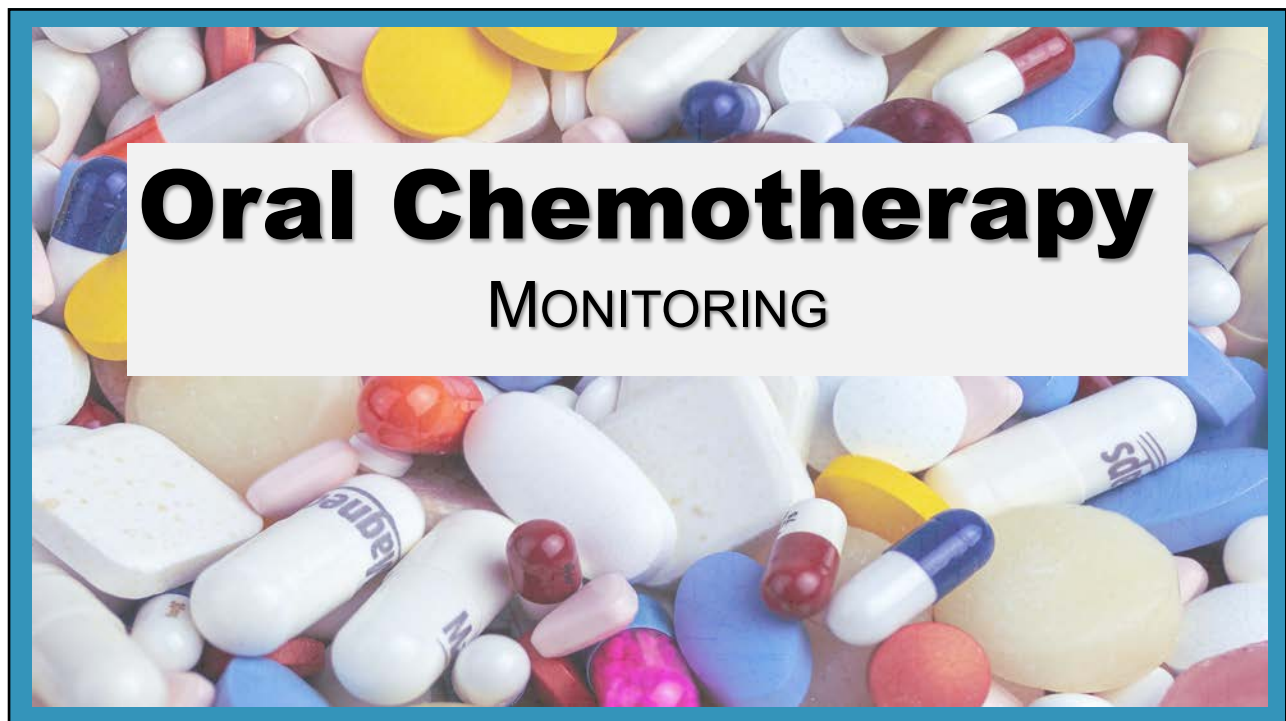
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## Which of the following is not the best resource to determine potential drug-drug or drug-herb interactions with an oral chemotherapy medication?

- Medication package insert
- Tertiary databases such as drugs.com
- Tik Tok
- Memorial Sloan Kettering Cancer Center "About Herbs" website

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## Monitoring

- Oral chemotherapy has many potential adverse effects
- Appropriate monitoring is important to prevent and assess side effects

```

graph TD
    A[Mechanism of Action] --> B[Cytotoxic]
    A --> C[Targeted]
    B --> D[Kidney and/or Liver Function]
    B --> E[Myelosuppression]
    C --> F[Kidney and/or Liver Function]
    C --> G[Many potential labs and varies per drug]
    
```

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## Monitoring

Targeted therapy adverse effects will depend on the drugs "on" targets and "off" targets

Potential toxicities of targeted therapy
Dermatologic
Cardiovascular
Ophthalmologic
Metabolic/Endocrine
Pulmonary
Gastrointestinal
Musculoskeletal
Neurologic
Hematologic
Hepatic
Renal
Other

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## Potential labs/tests to monitor



- CBC/diff
- LFTs
- SCr
- Electrolytes
- Potassium/magnesium
- Lipid panel and glucose
- Lipase/amylase
- Uric acid
- CPK
- TSH
- Pregnancy
- ECG
- ECHO
- Blood pressure

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## Where to find required lab testing and intervals

### Package insert

#### Imatinib (Gleevec®)

##### -----WARNINGS AND PRECAUTIONS-----

- Edema and severe fluid retention have occurred. Weigh patients regularly and manage unexpected rapid weight gain by drug interruption and diuretics. (5.1, 6.1)
- Cytopenias, particularly anemia, neutropenia, and thrombocytopenia, have occurred. Manage with dose reduction, dose interruption, or discontinuation of treatment. Perform complete blood counts weekly for the first month, biweekly for the second month, and periodically thereafter. (5.2)
- Severe congestive heart failure and left ventricular dysfunction have been reported, particularly in patients with comorbidities and risk factors. Monitor and treat patients with cardiac disease or risk factors for cardiac failure. (5.3)
- Severe hepatotoxicity, including fatalities may occur. Assess liver function before initiation of treatment and monthly thereafter or as clinically indicated. Monitor liver function when combined with chemotherapy known to be associated with liver dysfunction. (5.4)
- Grade 3/4 hemorrhage has been reported in clinical studies in patients with newly diagnosed CML and with GIST. GI tumor sites may be the source of GI bleeds in GIST. (5.5)

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/021588s047lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021588s047lbl.pdf)

### Tertiary drug information databases

- Lexi-Comp
- UpToDate®
- Facts and Comparisons
- Micromedex
- Drugs.com
- DailyMed

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## Example: Imatinib

- **Pretreatment Screening**
  - Complete blood cell count (CBC)
  - Baseline liver and renal function
  - Consider performing an echocardiogram and determining serum troponin concentrations in patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL), and in patients with myelodysplastic/myeloproliferative diseases or aggressive systemic mastocytosis associated with high eosinophil levels. If results of the echocardiogram or serum troponin concentrations are abnormal, consider prophylactic use of systemic corticosteroids.
  - Verify pregnancy status in females of reproductive potential
- **Patient Monitoring**
  - Monitor for signs or symptoms of fluid retention (e.g., weight gain) regularly during therapy
  - Monitor CBC weekly for the first month of therapy, every other week during the second month, and periodically (e.g., every 2–3 months) thereafter as clinically indicated
  - Carefully monitor patients with cardiac disease or risk factors for cardiac disease for signs and symptoms of cardiac toxicity or renal failure
  - Carefully monitor patients with a history of renal failure for signs and symptoms of cardiac toxicity or renal failure
  - Monitor liver function monthly or as clinically indicated during therapy
  - Monitor renal function during therapy
  - Monitor serum TSH concentrations in patients receiving levothyroxine replacement therapy following thyroidectomy
  - In pediatric patients, monitor bone growth and development
  - Monitor patients with high tumor burden or those with a high proliferative rate for TLS.

<https://www.drugs.com/monograph/imatinib.html>

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## Monitoring CML TKIs

	Imatinib	Nilotinib	Dasatinib	Bosutinib	Ponatinib	Asciminib
<b>CBC</b>	X (weekly x1 mo → biweekly x1 mo → periodically)	X (biweekly x2mo → monthly)	X (weekly x2 weeks → q3 months)	X (weekly x1mo → monthly)	X (biweekly x3mo → monthly)	X (biweekly x3mo → monthly)
<b>LFTs</b>	X (baseline → monthly)	X (baseline → monthly)	X (baseline → periodically)	X (monthly x3 → periodically)	X (baseline → monthly)	
<b>SCr</b>	X (baseline → periodically)			X (baseline → periodically)		
<b>Electrolytes</b>	X (baseline → periodically)	X (baseline → periodically)	X (baseline → periodically)		X (baseline → periodically)	
<b>Lipid profile &amp; glucose</b>		X (baseline → Periodically)				
<b>Lipase &amp; Amylase</b>		X (baseline → monthly)			X (biweekly x2mo → monthly)	X (baseline → monthly)
<b>Uric Acid</b>		X (baseline)			X (baseline)	
<b>ECG</b>		X (baseline → periodically)	X (baseline → q3mo x2)			
<b>Pregnancy</b>	X	X	X	X	X	X

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### Monitoring CDK 4/6 Inhibitors

	Palbociclib	Abemaciclib	Ribociclib
CBC	X (baseline, biweekly x2 mo, then as indicated)	X (baseline, biweekly x2mo → monthly x 2 mo, then as indicated)	X (baseline biweekly x2 mo → monthly x 4 mo, then as indicated)
LFTs		X (baseline, biweekly x2mo → monthly x 2 mo, then as indicated)	X (baseline biweekly x2 mo → monthly x 4 mo, then as indicated)
SCr		X (baseline → periodically)	
Electrolytes			X (baseline → monthly x 6, then as indicated)
ECG			X (baseline → q2weeks x 2), then as indicated)

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## Adherence

**Definition:**  
 “the degree or extent of conformity of the recommendations about day-to-day treatment by the provider with respect to timing, dosage, and frequency”

Optimal adherence and persistence occurs when a patient follows his/her prescribed treatment regimen

### Consequences of non-adherence

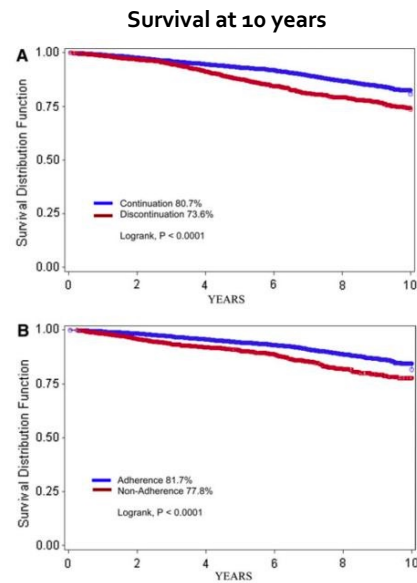
Poor patient outcomes	Increased toxicities	Increased health care costs
-----------------------	----------------------	-----------------------------

Cramer JA et al. Medication compliance and persistence terminology and definitions. Value Health 2008;11:44-47  
 Ruddy, K et al. Patient adherence and persistence with oral anticancer treatment. CA Cancer J Clin 2009;59:56-66

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## Consequences of non-adherence

- Women diagnosed with hormone-sensitive breast cancer prescribed adjuvant endocrine therapy for 5 years
  - N = 8769 women
  - 31.5% discontinued medication early
  - Of the 6000 women who continued the medication for the full time, 28% took < 80% of doses
  - Discontinuation and adherence were independent predictors of mortality

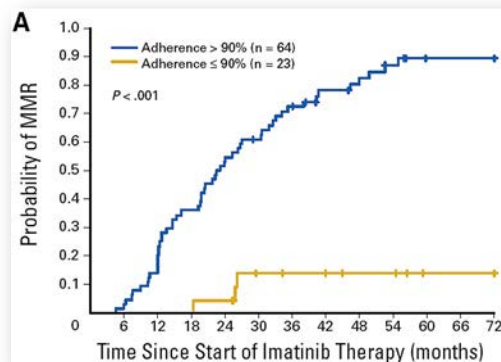


Hershman DL et al. Early discontinuation and non-adherence to adjuvant hormonal therapy are associated with increased mortality in women with breast cancer. *Breast Cancer Res. Treat.* 2011;126:529-537.

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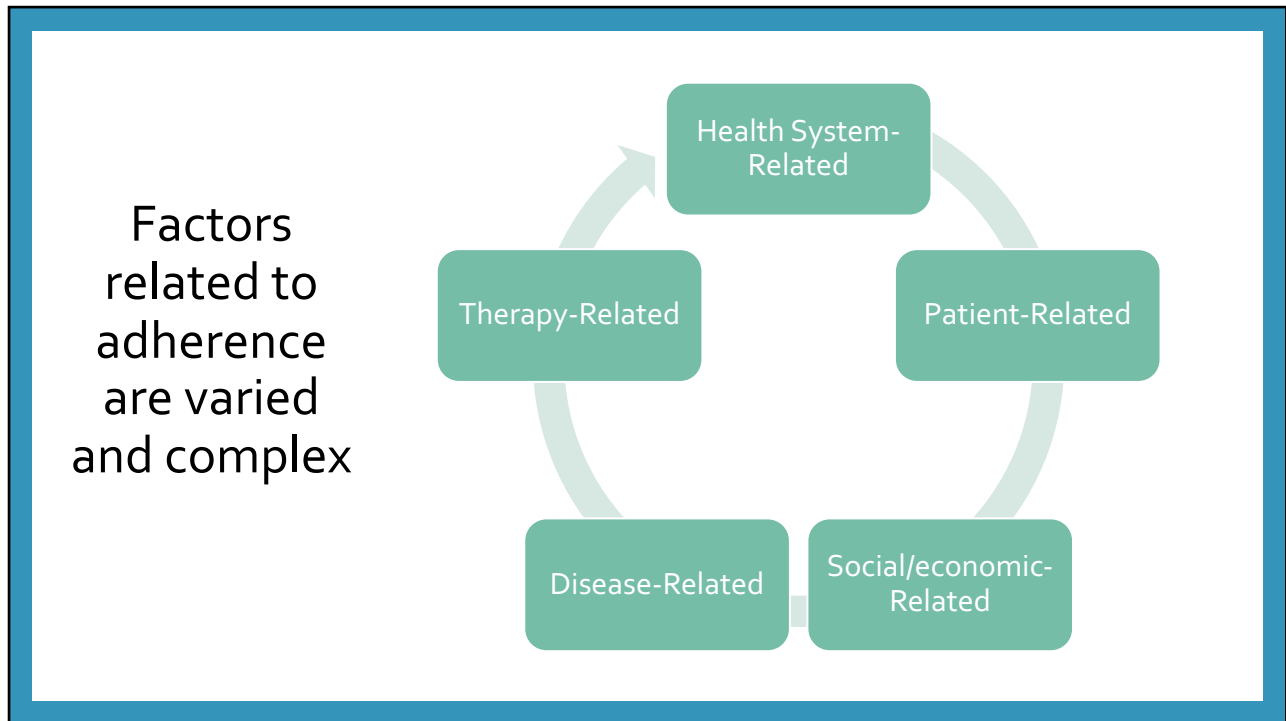
## Consequences of non-adherence

- Patients with CML on imatinib
  - Patients with adherence rate > 90% were associated with a major molecular response (MMR)
    - Probability of MMR in patients with adherence rate of > 90% = 93.7%
    - Probability of MMR in patients with adherence rate of ≤ 90% = 13.9%



Marin D et al. Adherence Is the Critical Factor for Achieving Molecular Responses in Patients With Chronic Myeloid Leukemia Who Achieve Complete Cytogenetic Responses on Imatinib 2010 *JCO* 28:2381-2388

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## Adherence Assessment

**Ask**

Since I last saw you, how many doses of your medication do you think you missed?

**Look for signs/predictors of non-adherence**

- Missed appointments
- Unfilled prescriptions
- Adverse effects
- High medication cost
- Lack of belief or understanding of treatment
- Psychological factors such as depression

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## Improving adherence

Barriers	Solutions
Forgetfulness	Alarm Clock/Phone Alarm
	Phone apps
	Family members
Side Effects	Close Follow-Up
	Early Management
Questions	Re-education
	Empowerment
Cost	Medication Assistance
Complex Regimen	Written Care Plan
	Calendars
	Simplify regimen whenever possible

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**Which of the following is a sign of non-adherence to a medication?**

- Patient tolerates the medication with few adverse effects
- Medication has a high cost
- Patient is engaged in his/her treatment
- Prescriptions are filled regularly and on time

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### Safe handling

Recommendations for health care providers

- Receive and maintain training on safe practices if the practitioner will come into contact with oral chemotherapy
- Follow institutional policies
- Follow guidelines related to oral chemotherapy

Goodin, S etal. Safe handling of Oral Chemotherapeutic agents in Clinical Practice: Recommendations from an International Pharmacy panel. JOP 2011;7(1): 712.

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## Safe handling

Recommendations for patients

- Understand handling and administration instructions
- Tablets/capsules should not be crushed, chewed, or cut
- Use gloves or tip tablets into a disposable medicine cup
- Wash hands thoroughly
- If able to place in a pill box, do not share the pill box with others
- Double flush or use a separate bathroom, if able

Goodin, S etal. Safe handling of Oral Chemterapeutic agents in Clinical Practice: Recommendations from an International Pharmacy panel. JOP 2011;7(1): 712.

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## Safe storage



- Store in a safe place away from children and pets
- Store medications away from sunlight, humid bathrooms, or other areas that may have fluctuations in temperature
- Read labels - some oral chemotherapy must be stored in original container (e.g. regorafenib) or refrigerated (e.g. oral etoposide, trametinib)
- If traveling, store in original, pharmacy-labelled container

<https://www.ncoda.org/wp-content/uploads/2019/03/Safe-Handling-of-Oral-Chemo-1>. Accessed 12/11/22

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## Safe disposal

- Don't discard unused tablets/capsules down the toilet
- Dispose in local medication disposal sites or drop boxes
- May mix whole tablets with something unpalatable (e.g. coffee grounds) and place in a container with lid or double sealable storage bags prior to placing in regular trash
- Celgene provides packaging so patients may return unused lenalidomide, pomalidomide, and thalidomide

<https://www.ncoda.org/wp-content/uploads/2019/03/Safe-Handling-of-Oral-Chemo-1>. Accessed 12/11/22

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## Oral chemotherapy resources


- Hematology/Oncology Pharmacy Association (HOPA)
  - Oral chemotherapy resources  
[www.hoparx.org/images/hopa/resource-library/guidelines-standards/Oral\\_Chemo\\_Resources\\_Web\\_Outline.pdf](http://www.hoparx.org/images/hopa/resource-library/guidelines-standards/Oral_Chemo_Resources_Web_Outline.pdf)
- Oncology Nursing Society
  - Oral Anticancer Medication Toolkit  
[www.ons.org/clinical-practice-resources/oral-adherence-toolkit](http://www.ons.org/clinical-practice-resources/oral-adherence-toolkit)
- Drug.com
  - Drug monographs  
[www.drugs.com/](http://www.drugs.com/)
- Daily Med
  - Drug monographs  
[www.dailymed.nlm.nih.gov/dailymed](http://www.dailymed.nlm.nih.gov/dailymed)
- Pharmacists

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Which of the following is not recommended to patients for safe handling of oral chemotherapy?

- Take tablets by tipping them first into a cup
- Wash hands after handling oral chemotherapy
- Do not share pill boxes with others
- Cut tablets to help make them easier to swallow

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**Oral Chemotherapy**  
PRESCRIBING, MONITORING,  
AND SAFETY

QUESTIONS?


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# Questions/Comments?


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<b>Jon Powell, PhD</b> , Continuing Education Specialist	<b>Nadja Brown</b> , Interim Administrative Support Specialist
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**UPCOMING LIVE WEBINARS**

**PATIENT CENTERED CARE**  
  
**March 8**  
**12:00 PM**


Integrating the Caregiver as a Member of the Multidisciplinary Care Team  
**Erin Kent, PhD, MSc**  
**Loretta Muss, RN, BA**

---

**ADVANCED PRACTICE PROVIDER**  
  
**March 15**  
**4:00 PM**

What Is Cancer Rehabilitation and How Can it Help My Patients?  
**Sasha E. Knowlton, MD**

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**RESEARCH TO PRACTICE**  
  
**March 22**  
**12:00 PM**


Clinical Updates in Breast Oncology  
**Emily Ray, MD, MPH**

Complete details on upcoming LIVE webinars:  
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**February 21**  
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Caring for Patients with Head and Neck Cancers  
**Trevor Hackman, MD, FACS**  
**Catherine J. Lumley, MD**

**March 21**  
**4:00 PM**

Caring for Patients with GI Cancers  
**Melanie N. Allard, DNP, APRN, FNP-BC, CCRN**

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**SELF-PACED, ONLINE COURSES**

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Self-Paced, Online Course

**Occupational Therapy for Cancer Survivors**  
**Farrell Wiggins, MS, OTR/L**  
**Alexis Petteway, MS, OTR/L**

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Self-Paced, Online Course

**Acute Myeloid Leukemia with Myelodysplasia-Related Changes (AML-MRC): An Evolving Poor-risk Subgroup of High Unmet Need**  
**Joshua F. Zeidner, MD**

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**Patti Morfeld, RN, BSN, OCN**

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**THANK YOU FOR PARTICIPATING!**

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