The Pharmacist’s Role in Managing Oral Oncolytics

Please stand by. The webinar will begin shortly.
The Pharmacist’s Role in Managing Oral Oncolytics

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Adam Peele, PharmD, MHA, BCPS, BCOP
Cone Health
Objectives

• Describe the pros and cons of oral chemotherapy
• Explain challenges encountered with oral chemotherapy management
• Evaluate benefits of pharmacists playing a role in oral chemotherapy management
• Describe Cone Health’s oral chemotherapy pharmacy-run program
Patient Story #1

• 51 year old female was prescribed an oral oncolytic for her breast cancer as neo-adjuvant therapy prior to surgery. Prescription was written and entered into EMR and sent to the specialty pharmacy. Patient returned 2 months later for follow-up prior to her surgery – she never got the prescription filled. Surgery delayed an additional 2 months. The patient never got the prescription filled because of cost and nothing was ever communicated by the specialty pharmacy and no follow up was done with the patient.
Patient Story #2

• 69 year old male was to start an oral agent as part of his chemo-radiation treatment plan. The specialty pharmacy filled the prescription to the patient with a complicated, rigorous instruction sheet. The patient arrived day 1 without any knowledge or education on how to take his medication appropriately. Delayed his start to radiation by an additional week.
History of Chemotherapy

Figure 1. Key advances in the history of cancer chemotherapy

Advances in drug screening
Events with national impact
Advances in cancer therapeutics

1900
Arsenicals (1, 2)
1908
Animal models (1–4)
1910
Transplantable tumors (5–11)
1912
Nitrogen mustard in lymphomas (15–18)
1935
Model development (7)
1943
Antifolates (22)
1948
1950
Antitumor antibiotics (23)
1955
Cancer Chemotherapy National Service Center
1957
L1210 as primary screen (27–30)
1949
Thiopurines (24, 25)
1951
Methotrexate in choriocarcinoma
1958
5-Fluorouracil (26)
1960s
Concept of cure

Cancer Res 2008; 68(21): 8643-8653
solutions@oncologymgmt.com
History of Chemotherapy

1964: Special Virus Cancer Program
1963: Vinca alkaloids (50)
1968–75: Adjuvant chemotherapy (79–83)
1965: Xenografts in nude mice
1971: National Cancer Act
1976: NCI investment in molecular biology
1975: Cure of testicular cancer (86–88)
1984: Cell culture systems
1985: Cancer mortality begins to decline
1990: Molecular profiling
1995: Genome sequenced
2000: Target specific screens
2005: Mortality decline accelerates
2015:

Cancer Res 2008; 68(21): 8643-8653

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Oncology Management Consulting Group
Oral Chemotherapy

• Novel approach to treating cancer
• Approximately 25% - 35% of all cancer agents in pipeline are administered orally
• Can be used as single agent or in combination with intravenous therapy
• Ushered in a new era of patient access to medications
• Creating a paradigm shift in way oncology operations are conducted
Oral Chemotherapy

1953: Methotrexate/Mercaptopurine

2001: Imatinib

1998: Capecitabine

2003: Gefitinib

2008 - 2013
- Everolimus
- Regorafenib
- Abiraterone
- Enzulatamide
- Axitinib
- Pazopanib
- Vemurafenib
- Crizotinib
- Bosutinib
- Ibrutinib
- Ponatinib
- Pomalidomide
Benefits of Oral Chemotherapy

• Convenient for patients
• Improved quality of life in comparison with intravenous products
• Does not require intravenous access
• Minimizes patient clinic visits
Disadvantages of Oral Chemotherapy

- Access to medications
- Out of pocket cost
- Patient/caregiver education
- Complexity of regimens
- Patient accountability and adherence
Why Does Oral Chemotherapy Treatment Get Delayed?

Routing of Prescription
- Specialty pharmacy use
- Oral chemo not filled on-site
- Transfer to other pharmacy within network

Affordability
- High cost of oral chemo drugs
- Prior authorizations

Third-party processing
- Co-pay assistance enrollment
- Insurance denial

Communication Issues
- Uncertainty of who is responsible for oral chemo (provider, nurse, pharmacist)
- Specialty pharmacy unable to contact patient

Lack of Patient Involvement
- Lack of education
- Patient not involved in prescription process
- Lack of understanding of treatment
- Patient not contacting provider

Specialty pharmacy not contacting provider
- Lack of patient education of treatment

Contact:
solutions@oncologymgmt.com
610-597-9799
Patient Co-pays Affect Oral Chemotherapy Use

- Study from West Clinic in Memphis, Tenn. and Avalere Health in Washington, D.C. looked at claims data for 10,508 patients
  - If cost was $\geq 500$:
    - 25% of patients did not fill prescription
  - If cost was $\leq 100$
    - Only 6% of patients did not fill the prescription ($P<0.05$)
  - Lower annual income was also associated with lower fill rates
    - Not statistically significant
  - More than 5 concurrent medications during previous month
    - Abandonment rate of 12%

Reason for Delay in Oral Chemo Rx Fulfillment

- Rx Transferred, 5
- Prior Authorization, 5
- Insurance Denial, 2
- Patient Assistance Program, 4
- Disease Progression, 2
- Other, 3

Cone Health Cancer Center Internal Data 2015
Accreditation Standards

• Quality Oncology Practice Initiative (QOPI) accreditation instituted into oral chemotherapy standards
  – June 2013

• The Commission on Cancer (CoC) require policies and procedures to be in place to monitor administration of chemotherapy including the oral route
Barrier: Adherence

- Adherence rates to oral chemotherapy vary from 20 – 100%
- Reasons for non-adherence include
  - Cost
  - Complexity of regimen
  - Duration of regimen
  - Forgetfulness
  - Patient knowledge/perception
  - Side effects
- Overuse and underuse pose problems
Adherence Rate Effect on Patient Outcomes

Blood. 2011;117:3733-3736
Complexity of Regimens

• Breast Cancer Regimen example with 2 oral chemotherapy agents
  – Lapatinib 1250 mg/day every day (only available as 250 mg tablets) on an empty stomach
  – Capecitabine 2000 mg twice daily for 14 days then 7 days off (only available as 150 and 500 mg tablets). Take within 30 minutes after a meal.
# Medication Calendar

Sample Calendar: Lapatinib + Capecitabine for Invasive Breast Cancer

<table>
<thead>
<tr>
<th>Sunday Date_____</th>
<th>Monday Date_____</th>
<th>Tuesday Date_____</th>
<th>Wednesday Date_____</th>
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<td>Lapatinib bedtime</td>
<td>Lapatinib bedtime</td>
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</tr>
<tr>
<td>Lapatinib bedtime</td>
<td>Begin next cycle as instructed</td>
<td></td>
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</tr>
</tbody>
</table>
Patient Reminders

Hi, this is John your doctor. Reply YES to set up your medication reminder today.

THANKS! What time would you like your medication reminder?

9:00 PM

Great! You are all set! You will get a daily medication reminder at 9:00 PM.
Cost of Medications

- Medication cost
- Health insurance
  - Medicare vs. Private insurance
    - “Donut Holes”
  - Medication coverage
- Patient assistance programs
- Oral Chemotherapy parity
Oral Chemotherapy Parity

• Parity = Equality
• First oral parity law passed in 2008 in Oregon
  – “A benefit plan that provides coverage for chemotherapy treatment must provide coverage for orally administered cancer medications on a basis that is no less favorable than intravenous or injected medications”
• 42 states and District of Columbia have enacted oral chemotherapy parity laws
Pharmacist’s Role in Oral Chemotherapy

• Education and patient counseling
• Screen for drug-drug interactions
• Assist in patient access
• Liaison between clinical team and patient
• Assist in adverse effect management
• Follow-up adherence and compliance
• Reduce nursing workload
• Patient satisfaction as oral chemotherapy department gives patients a point of contact
• Provides an avenue to help dispensing processes
Pharmacist-Run Oral Chemotherapy Clinic

• Pharmacy Resident run oral chemotherapy program
  – 18 month pilot program

• Intervention: Pharmacist counseling program (phone call)
  – Initial session → weekly follow-up x4 → monthly

• 103 patients enrolled

<table>
<thead>
<tr>
<th>Mean Age (Range)</th>
<th>65 years old (28-91)</th>
</tr>
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<tbody>
<tr>
<td>Males</td>
<td>51 (50.6%)</td>
</tr>
</tbody>
</table>
Purpose and Outcomes

- Initiate pharmacist-driven outpatient pilot-program to improve adherence to oral chemotherapy regimens
- Show quality improvement with addition of clinical pharmacist in managing oral chemotherapy
- Primary outcome
  - Patient adherence to oral chemotherapy
- Secondary outcomes
  - Patient satisfaction
  - Physician satisfaction
  - Pharmacist interventions
Patient Adherence

Results: Adherence

- Self-Reports: 92.5%
- Pharmacy Refill Reports: 86%
# Improved Patient Satisfaction

## Results: Patient Satisfaction

<table>
<thead>
<tr>
<th>83/100 Patients Completed Satisfaction Questionnaire</th>
<th>Scale 1-5 (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How would you rate your understanding of your oral chemotherapy regimen since your participation in this study?</td>
<td>4.5</td>
</tr>
<tr>
<td>Were the follow-up sessions convenient for you?</td>
<td>4.6</td>
</tr>
<tr>
<td>During the appointment, was there adequate time to discuss your problem with the pharmacist?</td>
<td>4.8</td>
</tr>
<tr>
<td>If you have questions about your oral chemotherapy medication(s), would you trust an answer from the pharmacist?</td>
<td>4.6</td>
</tr>
<tr>
<td>Since your participation in this study, do you have less problems when it comes to taking your oral chemotherapy medications?</td>
<td>4.2</td>
</tr>
<tr>
<td>How useful was the service provided by the pharmacist in this study?</td>
<td>4.7</td>
</tr>
<tr>
<td>Has the advice given by the pharmacist affected your life in general?</td>
<td>4.1</td>
</tr>
<tr>
<td>Do you agree that the pharmacist should continue his services in the clinic to help patients with their oral chemotherapy medications?</td>
<td>4.7</td>
</tr>
<tr>
<td>How likely is this program to impact your adherence in the future?</td>
<td>4.4</td>
</tr>
<tr>
<td><strong>Overall, how beneficial was the program</strong></td>
<td><strong>4.5</strong></td>
</tr>
</tbody>
</table>

Legend:  1 = Not satisfied  
5 = Very satisfied

Ramanath K.V, et J Young Pharmacists 2012;4:95-100
### Improved Physician Satisfaction

#### Results: Physician Satisfaction

<table>
<thead>
<tr>
<th>Question</th>
<th>Scale 1-5 (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How satisfied are you with patient adherence?</td>
<td>4.6</td>
</tr>
<tr>
<td>How much, if any, improvement did you see with the program?</td>
<td>4.3</td>
</tr>
<tr>
<td>How convenient do you feel the program is for your patients?</td>
<td>4.7</td>
</tr>
<tr>
<td>Overall, how would you rate our service based on your experience?</td>
<td>4.7</td>
</tr>
<tr>
<td>Overall, how would you rate our service based on your patients input?</td>
<td>4.5</td>
</tr>
<tr>
<td>How beneficial do you feel the program is to patients?</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Legend: 1 = Not satisfied  
5 = Very satisfied
## Pharmacist Interventions

<table>
<thead>
<tr>
<th>Oral Agent</th>
<th>Intervention</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capecitabine</td>
<td>Decrease/hold dose in Hand-Foot syndrome</td>
<td>3/36 (8%)</td>
</tr>
<tr>
<td></td>
<td>Decrease dose for mucositis</td>
<td>2/36 (6%)</td>
</tr>
<tr>
<td></td>
<td>Incorrect dose on Rx</td>
<td>1/36 (3%)</td>
</tr>
<tr>
<td>Dasatinib/Erlotinib</td>
<td>D/C PPI (decreases effect of TKI)</td>
<td>7/11 (34%)</td>
</tr>
<tr>
<td>Everolimus</td>
<td>Hold dose for Pneumonitis</td>
<td>2/8 (25%)</td>
</tr>
<tr>
<td>Temozolomide + Radiation</td>
<td>Missing PCP prophylaxis</td>
<td>1/1 (100%)</td>
</tr>
<tr>
<td>Temozolomide</td>
<td>Nausea w/out anti-emetic Rx</td>
<td>1/5 (20%)</td>
</tr>
<tr>
<td>Abiraterone + Prednisone</td>
<td>Decrease prednisone in patient with ↑ blurred vision and hx of glaucoma</td>
<td>1/15 (7%)</td>
</tr>
</tbody>
</table>

**All recommendations were accepted & implemented**
Why Pharmacist’s Role In Oral Chemotherapy is a No Brainer

• Strong clinical background and training
  – Pharmacotherapy
  – Oncology

• Ability to evaluate prescription for accuracy, safety, interactions

• Counseling

• Financial Resource
  – Close contact with pharmaceutical representatives and manufacturers for
    • Samples
    • Starter packs
    • Vouchers

• Strong patient advocate and respected member of health care team
Requirements for Successful Oral Chemotherapy Management

• Accountability
  – Need a “Point-Person” who is in charge
  – Create a work-flow

• Focus should be on:
  – Education
  – Decrease delay for receiving/starting oral chemotherapy
  – Cost/Assistance
  – Follow-Up
Description of Pharmacist-Run Service

Oncology Pharmacist Navigator

- Manage all aspects of care for the patients on oral chemotherapy (Education, follow-up, toxicity assessment)
- Assist with obtaining financial assistance/funding for oral chemotherapy
- Increase outpatient pharmacy prescription capture rates
- Increase outpatient pharmacy revenue
- Improve patient, education, satisfaction and adherence with their oral chemotherapy treatment
Oral Chemotherapy Pharmacist

- All prescriptions for oral chemotherapy filter through
  - Evaluate for accuracy, dosing, interactions, appropriate labs
- Once clinical review is complete Rx is sent to on-site pharmacy
- Oral chemotherapy pharmacist assists with Prior Auth approval if needed
- Once approved through insurance, pharmacy performs benefit analysis
  - Rx sent to specialty pharmacy if dictated by third party payer
- Oral chemotherapy pharmacist assists with financial issues if needed
- Counseling
  - Initial counseling prior to start of therapy
  - Follow up via telephone
Prior Authorization: CoverMyMeds.com

Find the Request You Need

Have a key? Enter it here

Drug

Medication

Begin typing the medication name and select from list

Xeloda

Patient Insurance

Xeloda 150MG tablets

Xeloda 500MG tablets

or, Search using drug insurance ID card

Forms

Form results will display here

CoverMyMeds makes prior authorization forms available for your use from virtually every health plan. However, the use of health plans’ forms and/or names does not imply health plan affiliation, sponsorship or approval of CoverMyMeds or its services. Please feel free to contact us if you have questions.

610-597-9799
solutions@oncologymgmt.com
# On-Site Pharmacy vs. Specialty Pharmacy Delays

<table>
<thead>
<tr>
<th>Days From Rx Written to Rx Received</th>
<th>On-Site Pharmacy</th>
<th>Specialty Pharmacy</th>
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</thead>
<tbody>
<tr>
<td>October 2016</td>
<td>3.4 days</td>
<td>12.5 days</td>
</tr>
<tr>
<td>November 2016</td>
<td>2.75 days</td>
<td>9.25 days</td>
</tr>
<tr>
<td>December 2016</td>
<td>3 days</td>
<td>10 days</td>
</tr>
<tr>
<td>Total 3 month Average</td>
<td>3.15 days</td>
<td>10.8 days</td>
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</tbody>
</table>
Patient Assistance: Commercial

• Usually straight forward
• Manufacturer copay cards available (Max monthly patient cost $10-$25)
  – Manufacturer will often pay up to a certain amount per year per patient ($25,000)
Patient Assistance: Medicare

- Many patients diagnosed with cancer are 65 or older
- Do not qualify for Co-pay cards through Manufacturer
- Must seek outside funding and support for high copays
  - PANF, PSI, Good Days, Cancer Care, LLS, etc.
- What happens when these funds run out during the year?
  - Patient Assistance Programs through manufacturer if available
  - ~15% of our patients started on oral chemotherapy after September 2016 have required and been approved
Independent Charitable Foundations

CancerCare
1-866-552-6729
www.cancercarecopay.org

Healthwell Foundation
1-800-675-8416
www.healthwellfoundation.org

Patient Advocate Foundation
1-866-512-3861
www.copays.org

Chronic Disease Fund
1-877-968-7233
www.cdfund.org

Patient Access Network Foundation
1-866-316-7263
www.panfoundation.org

Patient Services, Inc.
1-800-366-7741
www.patientservicesinc.org

610-597-9799
solutions@oncologymgmt.com
Solutions to Barriers and Challenges

• Patient counseling
• Pharmacist oral chemotherapy programs
  – Need for a “Point of Contact”
• On-site pharmacy
• Increased monitoring
• Increased communication
• Financial assistance
• Follow-Up is Key!!!
Questions

• Any questions not addressed here may be emailed to solutions@oncologymgmt.com
• OMC Group will compile questions and answers and distribute to webinar registrants
Thank You!

Sincere thanks to all of you for joining us today. We hope that you will keep OMC Group in mind when consulting needs arise in the future.

<table>
<thead>
<tr>
<th>Financial and Market Analyses</th>
<th>New Center Development</th>
<th>Hospital/Physician Integration</th>
<th>Strategic Planning</th>
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<tr>
<td>Implementation and Interim Leadership</td>
<td>Performance and Financial Benchmarking</td>
<td>Operational Assessments</td>
<td>Revenue Cycle Reviews</td>
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