Oral Chemotherapy
And The Wide Ranging
Implications

Please stand by. The webinar will begin shortly.
Oral Chemotherapy

And The Wide Ranging Implications

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Objectives

• Understand the pre-certification process for oral chemotherapy
• Understand the billing of oral chemotherapy
• Identify options for Patient Assistance Programs
• Impacts on staffing from oral chemotherapy
• Impact of REMS programs on staffing
• Patient education and medication adherence
Emerging Trends in Cancer

- Increasing approvals of oral chemotherapy
- Targeted vs. traditional chemotherapy (cytostatic vs. cytotoxic)
- Considering some new cancer types as a chronic disease with new emphasis on ongoing therapy
- Longer survival times may require long-term daily medication
- Changing needs for patients and caregivers to monitor and manage side effects
- Patient responsible for adherence to oral therapy

Weingart SN et al NCCN Task Force Report Oral Chemotherapy. JNCCN 2008; 6 (supp3) S1-S14
# Overview of Targeted Agents Used To Treat Cancer Patients

<table>
<thead>
<tr>
<th>Drug</th>
<th>Mechanism</th>
<th>Major Indications</th>
<th>Key Toxicities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dasatinib</td>
<td>Multikinase inhibitor, ABL, SRC family, KIT, PDGFRβ</td>
<td>CML; Ph+ ALL</td>
<td>Myelosuppression; fluid retention; headache, dyspnea; rash; fatigue</td>
</tr>
<tr>
<td>Erlotinib</td>
<td>EGFR tyrosine kinase inhibitor</td>
<td>Advanced NSCLC and pancreatic cancer</td>
<td>Rash; diarrhea; fatigue; anorexia</td>
</tr>
<tr>
<td>Everolimus</td>
<td>mTOR inhibitor</td>
<td>Advanced renal cell carcinoma</td>
<td>Oral ulcerations; infections; fatigue; diarrhea; cough; asthenia</td>
</tr>
<tr>
<td>Gefitinib</td>
<td>EGFR tyrosine kinase inhibitor</td>
<td>Advanced NSCLC</td>
<td>Dry skin; diarrhea; rash; nausea and vomiting</td>
</tr>
<tr>
<td>Imatinib</td>
<td>ABL, KIT, PDGFα</td>
<td>Ph+ CML and ALL, GIST</td>
<td>Fluid retention; muscle cramps;</td>
</tr>
<tr>
<td>Lapatinib</td>
<td>Dual EGFR/HER2 TKI</td>
<td>HER2 overexpressing BrCa</td>
<td>Diarrhea; rash; nausea; fatigue</td>
</tr>
<tr>
<td>Nilotinib</td>
<td>Multikinase inhibitor, ABL, PDGFR, KIT, CSF-1R, DDR</td>
<td>Ph+ CML</td>
<td>Myelosuppression; headache, irregular heartbeat; rash; fatigue, myalgia, GI events</td>
</tr>
<tr>
<td>Pazopanib</td>
<td>Multikinase inhibitor, VEGFR, PDGFR, FGFR</td>
<td>Advanced renal cell carcinoma</td>
<td>Diarrhea; hypertension; nausea; vomiting; anorexia; hair color changes, SGOT elevation</td>
</tr>
<tr>
<td>Sorafenib</td>
<td>Multikinase inhibitor, RAF, KIT, FLT3, VEGFR, PDGFRβ</td>
<td>Advanced renal cell carcinoma; unresectable hepatocellular carcinoma</td>
<td>Weight loss; fatigue; rash; hand-foot synfrome; hypertension; GI events</td>
</tr>
<tr>
<td>Sunitinib</td>
<td>Multikinase inhibitor, PDGFRs, VEGFR, KIT, FLT3</td>
<td>GIST; advanced renal cell carcinoma</td>
<td>Fatigue; GI events; mouth sores; rash; hypertension</td>
</tr>
</tbody>
</table>
Oral chemotherapy – Landscape

• Current oral drugs on the market
  – Some have been around for decades
• New Oral Drugs in the pipeline
  – Emerging area of focus
Current Oral Chemotherapy Options

• Everolimus (Afinitor)  Renal cell carcinoma, Pancreatic neuroendocrine tumor, Astrocytoma
• Melphalan (Alkeran)   Multiple myeloma, Ovarian cancer
• Anagrelide           CML, Thrombocytosis, Polycythemia vera
• Anastrozole          Breast cancer
• Exemestane (Aromasin) Breast cancer
• Bicalutamide (Casodex) Prostate cancer
• Lomustine (CeeNU)     Hodgkin’s disease, Malignant glioma
• Cyclophosphamide     ALL, AML, Breast cancer, Burkitt’s lymphoma, CLL, CML, CTCL, Hodgkin’s disease, Multiple myeloma, Mycosis fungoides, Neuroblastoma, NHL, Ovarian cancer, Retinoblastoma
• Estramustine (Emcyt)  Prostate cancer
• Aprepitant (Emend)    Nausea/Vomiting
Current Oral Chemotherapy Options

- Vismodegib (Erivedge) - Metastatic basal cell carcinoma
- Toremifene (Fareston) - Breast cancer
- Letrozole (Femara) - Breast cancer
- Flutamide (Eulexin) - Prostate cancer
- Imatinib (Gleevec) - ALL, CML, GIST, CEL, MDS, Systemic mastocytosis
- Granisetron - Nausea/Vomiting
- Altretamine (Hexalen) - Ovarian cancer
- Topotecan (Hycamtin) - Relapsed small cell lung cancer
- Hydroxyurea - CML, Head and neck cancer, Malignant melanoma, Ovarian cancer
- Chlorambucil (Leukeran) - CLL, NHL, Hodgkin’s disease
Current Oral Chemotherapy Options

- Mitotane (Lysodren) - Adrenal cancer
- Procarbazine (Matulane) - Hodgkin’s disease
- Mercaptopurine - ALL
- Sorafenib (Nexavar) - Hepatocellular, Renal cell
- Nilutamide (Nilandron) - Prostate Cancer
- Fludarabine oral (Oforta) - CLL, NHL
- Ondansetron (Ondansetron ODT) - Nausea/Vomiting
- Eltrombopag (Promacta) - ITP, Thrombocytopenia
- Lenalidomide (Revlimid) - Multiple myeloma, MDS
- Dasatinib (Sprycel) - ALL, CML
Current Oral Chemotherapy Options

• Sunitinib (Sutent)    GIST, Renal cell carcinoma, Pancreatic neuroendocrine tumor
• Tamoxifen            Breast Cancer
• Erlotinib (Tarceva)  Lung, Pancreatic Carcinoma
• Bexarotene (Targretin) CTCL
• Nilotinib (Tasigna)  Philadelphia chromosome positive CML
• Temozolomide (Temodar) Astrocytoma, Malignant glioma
• Thalidomide T(halomid) Multiple myeloma
• Tretinoin            APL
• Lapatinib (Tykerb)   Breast Cancer
• Pazopanib (Votrient) Renal Cell Carcinoma
Current Oral Chemotherapy Options

- Capecitabine (Xeloda) Breast cancer, Colorectal cancer
- Vemurafenib (Zelboraf) Malignant melanoma
- Vorinostat (Zolinza) Cutaneous T-cell lymphoma
- Abiraterone (Zytiga) Prostate Cancer
FDA is anticipated to approve 25 specialty drugs in 2014

- Oral Oncology agents approved
  - idelalisib (Zydelig)  Relapsed CLL
  - trametinib (Mekinist)  Metastatic melanoma
  - dabrafenib (Tafinlar)  Metastatic melanoma
  - ibrutinib (IMBRUVICA)  CLL
  - ceritinib (ZYKADIA)  NSCLC

- Of the 125 drugs in phase III development 38 are oral cancer drugs
Current FDA List of Chemotherapy Approvals

[Image of FDA website page]

- FDA approved ramucirumab (Cyramza, Eli Lilly and Company) for use in combination with paclitaxel for the treatment of patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma. Ramucirumab was approved in April, 2014 as a single agent for the treatment of patients with advanced gastric or GEJ adenocarcinoma refractory to or progressive following first-line therapy with platinum or fluoropyrimidine chemotherapy. More Information. November 5, 2014

- FDA granted accelerated approval to pembrolizumab (KEYTRUDA, Merck Sharp & Dohme Corp.) for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. More Information. September 4, 2014

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm
Formulary Adoption, Ordering and Billing Process

1. FDA Approval
2. Physician Request
3. P&T Approval
4. Order set Development
5. Complete I.T. entry checklist
6. Add to Charge Description Master
7. Patient Assessment
8. M.D. Orders drugs
9. Prior Authorization
10. Obtain Drug & compound
11. Patient Encountered & Receives Drug
12. Encounter billed to Ins & Patient
13. Payment Received
14. Denials to Revenue Cycle
15. Implement Corrective Measures
16. Establish New Policies

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PRE-VERIFICATION AND PRIOR AUTHORIZATION

1. Receive/Access the patient schedule from time to time
2. Benefit Verification
3. Contact Patient for more info and make them understand their Financial obligation
4. Contacts the Care Management and obtains the Pre-authorization
5. Pre-Authorization Team verifies the Schedule
6. Update Benefit information in the Software
7. Report the schedule to Physician Office and confirm the schedule or reschedule
8. Patient receives the service

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Reimbursement

• Parenteral drugs are billed by hospital/MD practice – Revenue stream
• Oral drugs are covered under Part D of Medicare and filled by Mail order (90 day supply), community pharmacies, hospital outpatient pharmacies (30 day supply) or specialty pharmacies – no revenue stream unless physician dispensing in office practice.
• Oral drugs for which an equivalent injectable exists can be billed under Part B (e.g. Capecitabine)
• Infamous doughnut hole coverage gap in Part D
• Expensive Co-Pays
Patient Assistance Programs

• Insource or outsource
  – Distributors have drug recovery programs
    • 20% - 30% of drug dollars recovered
  – Drug specific information available at each site
    • Training issue – Med Assistants, pharmacy techs, social workers, pharmacists
  – Co-Pay assistance
Don’t qualify for this program? Visit the DBAs to look for financial assistance based on your diagnosis.

Program 1 of 6.
Scroll down to see them all.

Gleevec

Novartis Oncology Patient Assistance Program
This program provides brand name medications at no or low cost.

Provided by: Novartis Pharmaceuticals

Languages Spoken:
English, Others By Translation Service

Program Website

Novartis Oncology Patient Assistance Program
PO Box 66978
St. Louis, MO 63166-6978

TEL: 866-884-5906

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Cover My Meds.com
NaviNet has partnered with CoverMyMeds to deliver NaviNet Drug Authorizations, a free, electronic solution to help providers submit drug prior authorizations for any drug and nearly all health plans. NaviNet Drug Authorizations streamlines the prior authorization (PA) process by eliminating administrative waste, which can immediately translate into operational savings, increased provider satisfaction and most importantly, better patient care with quicker access to prescribed medications. NaviNet Drug Authorizations can decrease costs by streamlining workflows and reducing the time staff spends on the phone, while, at the same time, improving customer satisfaction with a more efficient, paperless PA request process that takes just minutes per submission. Join the thousands of offices submitting PAs faster online and enjoy benefits such as:

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The New Standard for Electronic Prior Authorization

April 10, 2014
Pharmacy Town Hall Series
What You Can Do To Accelerate EPA Adoption

• Spread awareness about new SCRIPT standard for electronic prior authorization and its value
• Learn more about ePA
  o [www.NCPCP.org](http://www.NCPCP.org)
  o [www.CompletEPA.com](http://www.CompletEPA.com)
  o [www2.caremark.com/epa/epa-faq.pdf](http://www2.caremark.com/epa/epa-faq.pdf)

Prioritize the ePA SCRIPT standard with your EHR, health plan, PBM or pharmacy information network

Educate your legislators about this ePA standard and improved care opportunities
Pharmaceutical Specific Assistance Programs

- Co-Pay Assistance
- Referrals to independent Foundations
- Reminder calls about medication refills and appointments
- Reduced medication costs for qualified pts.
- Insurance reimbursement/billing support
- Educational Materials
Automated Prior Authorization

Real Time Results Diagram Chart

Prior Auth
Automated Prior Authorization (APA)
& Audit
Real Time Audit (RTA)

Verify Eligibility
Up-To-Date Rules

Database Rules Engine

Real Time Process
✓ Insurance Benefits
✓ Best Practice Rules
✓ Facility Rules

APA Results
Pass
Fail

Override
Doctor may request an “Override” for Manual Review

Approved “Override” Updates the “Rules”

Doctor & Patient

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NCCN Task Force Report: Specialty Pharmacy

Figure 1

Traditional community pharmacy medication distribution model. Abbreviations: Rx, prescription.
NCCN Task Force Report: Specialty Pharmacy

Drug Procurement

Drug Manufacturer

Wholesaler or Specialty Distributor

Drug Dispensing/Administration

Prescription for oral anticancer agents, self-injectible medications, etc.

Oncology Care Team

Monitoring for adherence, outcomes, etc.

Specialty Pharmacy

Clinical services
- Assessment
- Monitoring
- Patient education
- Etc.

Dispensing functions
- Mail-order
- Community pick-up

Patient

Dispensed to patient

Figure 2

Specialty pharmacy distribution model.
Specialty Pharmacy Controversy

• Fragmentation of care versus ensuring supply
  – Cancer treatment team
  – Primary care physician
  – Primary care/community pharmacists
• Revenue – who gets the revenue?
• Coordination with primary team and Special Pharmacy oral chemo monitoring services
  – Who is monitoring the patient?
• Mail delivery – 90 day supply
Risk Evaluation and Mitigation Strategies (REMS)

• 2007 FDA Amendments Act to improve safety and post marketing monitoring of high risk medications
• Designed in conjunction with AHRQ
• Started with Risk Maps
• Originated in 2002 with PDUFA – Thalidomide
• 52 drugs with REMS including 30 drugs with original Risk Maps by 2009
Drugs Impacted

- ESAs
- Opioids
- NSAIDS
- New molecular entities – targeted therapies with novel mechanisms
REMS – 3 core elements

- Medguide or Patient Package Insert
- Communication plan for health care providers
- Elements to assure safe use (ETASUs)
  - Highest level of REMS
  - Requires prescribers to have specific training or credentials
  - Requires dispenser to be specifically certified
  - Dispensing can only occur in certain settings

- May not require all 3 components

[Note: The text mentions "Specialty Pharmacy", which is not directly related to the core elements of REMS but could be a related concept or a reference to a specific type of pharmacy.]
Challenges with REMS

- Training requirements not standardized
- ETASU protocols not standardized
- No centralized reporting – manufacturers responsible
- No reimbursement for increased administrative burden
- Potential for almost all new oral cancer drugs to be affected
- Unknown if REMS will achieve improved drug safety
- Providers not monitored for adherence to REMS
- Concerns over appropriate off-label use

Johnson PE, JNCCN 2010; 8 (suppl 7); S7-S27
Figure 1: Familiarity with REMS regulation and the different components of REMS.

<table>
<thead>
<tr>
<th>Category</th>
<th>Overall (n = 599)</th>
<th>Physician practicing in a cancer specialty (n = 222)</th>
<th>Advanced Practitioner (PA, NP) or nurse (n = 204)</th>
<th>Pharmacist (n = 87)</th>
<th>Other practicing clinician (n = 57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not familiar</td>
<td>20%</td>
<td>24%</td>
<td>19%</td>
<td>7%</td>
<td>23%</td>
</tr>
<tr>
<td>Somewhat familiar</td>
<td>32%</td>
<td>33%</td>
<td>38%</td>
<td>18%</td>
<td>30%</td>
</tr>
<tr>
<td>Moderately familiar</td>
<td>26%</td>
<td>25%</td>
<td>24%</td>
<td>40%</td>
<td>23%</td>
</tr>
<tr>
<td>Very familiar</td>
<td>22%</td>
<td>18%</td>
<td>20%</td>
<td>34%</td>
<td>25%</td>
</tr>
</tbody>
</table>

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Figure 3  Perceived impact of REMS on patient safety.
Non-Adherence in Oncology

- Historically not a problem
  - Parenteral therapy managed and administered by oncology professionals
- Currently a growing concern
  - New oral medications available in several tumor types
  - Patients manage medication administration
- Considered a “priority research topic” by Oncology Nursing Society

Goodin S. Am J Health SystPharm. 2007;64(suppl 5):S3
Aisne J. Am J Health Syst Pharm. 2007;64(suppl 5):S4-7
Definition of Medication Adherence

• (synonymous with Compliance) – is the “extent to which a person’s behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendation from a health care provider.” (WHO, 2003)
Scope of the Problem

- Approximately 41% of seniors take > 5 medications
- 50% – 60% of patients do not take their medications appropriately
- Medication non-adherence cost the health care system $290 billion in avoidable medical care annually
Long-term adherence to adjuvant tamoxifen therapy in eligible patients from 1991 index year cohort.

Overall % Adherence (mean)

<table>
<thead>
<tr>
<th>Year</th>
<th>Overall Adherence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st (N=492)</td>
<td>83 ± 68</td>
</tr>
<tr>
<td>2nd (N=329)</td>
<td>68 ± 61</td>
</tr>
<tr>
<td>3rd (N=309)</td>
<td>61 ± 50</td>
</tr>
<tr>
<td>4th (N=309)</td>
<td>50 ± 43</td>
</tr>
</tbody>
</table>
Medication Non-adherence Types

– Primary non-adherence - non-adherence to a new prescription
– Secondary non-adherence - non-adherence to both new prescriptions and refills
– Intentional non-adherence – when a patient makes a conscious decision to not take a medication as prescribed
– Non-intentional non-adherence – when a patient has good intentions of taking their medication as prescribed but for one reason or another they do not
Consequences of Medication Non-Adherence

- Increase use of medical resources including hospital admissions
- Increase healthcare expenditures
- Poly-pharmacy
- Treatment failure
- Poor health
- Increased morbidity and mortality
Five Dimensions of Patient Adherence

1. Social & Economic
2. Health Care System
3. Condition Related
4. Therapy Related
5. Patient Related

The 5 Dimensions of Adherence

ACPM, WHO 2003
1. Social and Economic Dimension

- Factors affecting adherence
  - Language and Cultural Barriers
    - English proficiency
    - Cultural beliefs about illness
  - Support Barriers
    - Family
    - Living conditions
    - Schedule
    - Elder abuse
  - Cost/Access Barriers
    - Insurance
    - Access to health care
    - Medication cost – co-pays
Patient Co-pays Affect Oral Chemotherapy Use

- Study from the West Clinic in Memphis Tenn and Avalere Health in Washington, D.C. looked at claims data for 10,508 patients
- If patients were required to pay $500 or more, 25% did not get the prescription filled; If patients had copays of $100 or less, 6% did not fill the prescription = $P<0.05$
- Patients with more than 5 concurrent prescriptions during the previous month had an abandonment rate of 12%
- Lower annual income was also associated with lower fill rates but not statistically significant

Journal of Oncology Practice 2011;7:46s-51s. American Journal of Managed Care 2011;
2. Health Care System Dimension

• Factors affecting adherence
  – Physician - Patient relationship
  – Knowledge gaps
    • Minimal capacity to education patients and follow up on plan of care
    • Minimal knowledge on patient side regarding adherence
    • Handouts not written at appropriate reading level
  – Restricted Formularies
  – Poor access to services
  – Poly pharmacy
  – Transitions of care
    • Lack of continuity of care
3. Condition Related Dimension

• Factors affecting adherence:
  1. Multiple chronic conditions
  2. Lack of symptoms of a disease
  3. Depression
  4. Psychiatric disorders
4. Therapy Dimension

• Factors affecting adherence
  – Complexity of medication regimens - simple is better
  – Schedule – reminders
  – Medications with social stigma, side effects, life style interferences.
5. Patient Related Dimension

• Factors affecting adherence
  1. Age
  2. Gender
  3. Ethnicity/race
  4. Physical
     a. Impaired mobility of dexterity
     b. Difficulty in swallowing Medications
     c. Sensory Impairment
        – Visual, Hearing, Cognitive
Risk Factors for Non-adherence to Oral Chemotherapy

• Complex treatment regimens
• Inconvenience
• Inadequate supervision
• Substantial behavior change required
• Poor communication with health care providers
• Patient dissatisfaction with care
• Patient health beliefs
• Inadequate social support
• History of non-adherence
• History of mental illness

Association of Community Cancer Centers (ACCC) Identified Best Practices

• Only prescribe one month at a time
• Extensive patient and significant other education and counseling
  – Therapy
    • Drug, dosing., and interactions
  – Side effect management
ACCC Identified Best Practices

• Home and family assessment
• Bring medications every visit and count
• Nutrition consult
• Pharmacist consult
• Easy and timely access to team
ACCC Identified Best Practices

- Same day provider/midlevel assessment
- Partner with other agencies such as specialty pharmacies
- Frequent long term monitoring via appointments and phone
ACCC Identified Best Practices

• Timely lab monitoring
• Coordination of care
  – Nurse navigators
  – Case managers
  – Cancer conferences and tumor boards
• Program support services
• Financial counseling
ACCC Identified Best Practices

- Quality monitoring program
  - Patient satisfaction
  - Outcomes
- Annual provider training
- Written patient and significant other education materials
- Active outreach programs and activities to patients
Cycle of Care for Oral Therapy: Practice View

1. Notification of oral protocol
   - Informed consent obtained
   - Orders written and sent to pharmacy

2. Nursing staff screens for drug interactions

3. Appointment made for patient education
   - Patient education conducted

4. Medications added to EHR/chart

5. Rx and patient diary given to patient

6. Pre-authorization

7. Patient reminded to bring all medications to every visit
   - Note placed in computer to "trigger" staff that patient is on oral therapy

8. Nurse checks Rx bottles at each visit to monitor patient adherence

9. Patient called weekly first month, monthly thereafter to promote adherence

Electronic Wi-Fi Enabled Devices

- Variety of device price ranges ($250 - $800) and monthly PMPM costs ($16 - $300 PMPM)
- Presently insurers are not paying costs
- Some are medication blister pack compatible
- Some are blue tooth enabled to collect other data in the home and transmit via Wi-Fi
- Data can be transmitted via text, e-mail, phone call to caregiver or next of kin
Tools for Improvement

MedSentry
PharmAdva
Vaica Medical
MedFolio
Vaica Medical
MedMinder

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Electronic Wi-Fi Enabled
Tools for Improvement

AMAC Medsmart

CompuMed

TabSafe

MedSignals

Abiogenix

CleverCap
Staff Roles: Oral Oncology Team

**Staff**
- Triage and education
- Intra-departmental communications

**Quality Assurance**
- Quality improvement process
- Outcomes management
- Adherence

**Finance**
- Reimbursement (claims, prior authorization)
- Patient assistance
- Intra-departmental communications

**Patient and Caregiver**
- Consent to treatment
- Identification of symptoms
- Symptom management
- Determine impact on QoL
- Adherence to medication and regimen

**Clinicians/Providers**
- Patient selection
- Treatment plan development
- Routine monitoring
- Symptom management
- Education
- Documentation
- Intra-departmental communications
- Consent

**Pharmacy**
- Dispensing
- Monitoring
- Reimbursement
- Education monitoring
- Review for possible interactions
- Intra-departmental communications

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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
• Questions may also be directed to: ernestanderson1130@gmail.com
QUESTIONS ???
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.

• Financial and Market Analyses
• New Center Development
• Hospital/Physician Integration
• Strategic Planning

• Implementation and Interim Leadership
• Performance and Financial Benchmarking
• Operational Assessments
• Revenue Cycle Reviews
Appendix
# Advantages and Disadvantages of Oral Compared With Parenteral Chemotherapies

<table>
<thead>
<tr>
<th></th>
<th>Patient</th>
<th>Physician/Health Care Team</th>
<th>Health Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety/Adherence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Patients assume greater responsibility and control</td>
<td>Difficult for clinicians to monitor adherence and toxicity</td>
<td>Poor adherence or overadherence can lead to acute inpatient admissions and diminished effectiveness</td>
</tr>
<tr>
<td>Parenteral</td>
<td>Adherence based on controlled administration in clinic or office</td>
<td>Tight control of adherence; robust system of checks and balances to reduce medication errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Busy cancer centers may have hazards related to high-volume, high-intensity setting</td>
<td></td>
</tr>
<tr>
<td><strong>Convenience</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Convenience gain only if oral chemotherapy is NOT given with parenteral therapy</td>
<td>Convenience of oral therapy is over simplified for some regimens; patient appropriateness must be carefully considered</td>
<td></td>
</tr>
<tr>
<td>Parenteral</td>
<td>Often has shorter duration of therapy than oral</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Advantages and Disadvantages of Oral Compared With Parenteral Chemotherapies

<table>
<thead>
<tr>
<th>Drug Supply and Distribution</th>
<th>Patient</th>
<th>Physician/Health Care Team</th>
<th>Health Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Can receive from hospital pharmacy, mail order, or specialty pharmacy</td>
<td>Specialty pharmacy may be required</td>
<td>Oral drugs can be tightly controlled through pharmacy benefit</td>
</tr>
<tr>
<td>Parenteral</td>
<td>Requires office visit</td>
<td>Direct control by oncologist</td>
<td>May be cost savings with 90 day supply</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Drug waste may be an issue</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Payors have limited ability to directly manage parenteral therapy</td>
</tr>
</tbody>
</table>

## Communication Issues

| Oral                        | Requires new patient education | Expanding role for mid-level providers in patient education | Patient education time not compensated |
| Parenteral                  | Infusion sessions allow for prolonged contact of the patient with the health care team. | | |

### Advantages and Disadvantages of Oral Compared With Parenteral Chemotherapies

<table>
<thead>
<tr>
<th></th>
<th>Patient</th>
<th>Physician/Health Care Team</th>
<th>Health Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oncology Infrastructure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Potentially fewer office visits; follow up may occur at specialty monitoring clinics</td>
<td>Adequate space for patient counseling not always available</td>
<td>Improved information systems and integrated electronic medical record may improve safety</td>
</tr>
<tr>
<td>Parenteral</td>
<td>Office set up specifically for parenteral therapy</td>
<td>Infusion centers must be maintained; most patients receive parenteral therapy at some point</td>
<td></td>
</tr>
<tr>
<td><strong>Financing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>May face significant cost sharing, including Medicare Part D “donut hole”</td>
<td>No revenue for dispensing/administering oral therapy</td>
<td>Both oral and parenteral biologic or targeted therapies are considered costly; consideration of new benefit designs may be needed</td>
</tr>
<tr>
<td>Parenteral</td>
<td>May have better coverage compared with oral</td>
<td>Approximately 80% of community oncologists’ revenue is from dispensing/administering parenteral chemotherapy</td>
<td></td>
</tr>
</tbody>
</table>

### CMS OPPS Appendix A - Billing codes


<table>
<thead>
<tr>
<th>Group Title</th>
<th>Relative Weight</th>
<th>Payment Rate</th>
<th>National Unadjusted Copayment</th>
<th>Minimum Unadjusted Copayment</th>
<th>Indicates a Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sr98 strontium</td>
<td>K</td>
<td>$1,130.06</td>
<td>.</td>
<td>$226.02</td>
<td>*</td>
</tr>
<tr>
<td>Dexamethasone HCI injection</td>
<td>K</td>
<td>$144.86</td>
<td>.</td>
<td>$28.98</td>
<td>*</td>
</tr>
<tr>
<td>Sargramostim injection</td>
<td>K</td>
<td>$30.13</td>
<td>.</td>
<td>$6.03</td>
<td>*</td>
</tr>
<tr>
<td>Amphotericin b liposome inj</td>
<td>K</td>
<td>$16.83</td>
<td>.</td>
<td>$3.37</td>
<td>*</td>
</tr>
<tr>
<td>Rasburicase</td>
<td>K</td>
<td>$218.75</td>
<td>.</td>
<td>$43.75</td>
<td>*</td>
</tr>
<tr>
<td>Chlorothiazide sodium inj</td>
<td>K</td>
<td>$122.65</td>
<td>.</td>
<td>$24.53</td>
<td>*</td>
</tr>
<tr>
<td>Mechlorethamine hcl inj</td>
<td>K</td>
<td>$189.63</td>
<td>.</td>
<td>$37.93</td>
<td>*</td>
</tr>
<tr>
<td>Daclizumab injection</td>
<td>K</td>
<td>$807.19</td>
<td>.</td>
<td>$161.44</td>
<td>*</td>
</tr>
<tr>
<td>Naltrexone, depot form</td>
<td>K</td>
<td>$2.88</td>
<td>.</td>
<td>$0.58</td>
<td>*</td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td>K</td>
<td>$829.72</td>
<td>.</td>
<td>$165.95</td>
<td>*</td>
</tr>
<tr>
<td>Etoposide oral</td>
<td>K</td>
<td>$57.09</td>
<td>.</td>
<td>$11.42</td>
<td>*</td>
</tr>
</tbody>
</table>
## CMS OPPS Appendix A - Billing codes

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates-Items/2014-October-Addendum-B.html?DLPage=1&DLSort=2&DLSortDir=descending

<table>
<thead>
<tr>
<th>Addendum B: Final OPPS Payment by HCPCS Code for CY 2014</th>
<th>SI</th>
<th>APC</th>
<th>Relative</th>
<th>Payment</th>
<th>National</th>
<th>Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>J8501 Oral aprepitant</td>
<td>K</td>
<td>0688</td>
<td></td>
<td>$7.68</td>
<td>.</td>
<td>$1.54</td>
</tr>
<tr>
<td>J8520 Capecitabine, oral, 150 mg</td>
<td>K</td>
<td>7042</td>
<td></td>
<td>$8.67</td>
<td>.</td>
<td>$1.74</td>
</tr>
<tr>
<td>J8521 Capecitabine, oral, 500 mg</td>
<td>K</td>
<td>0934</td>
<td></td>
<td>$28.63</td>
<td>.</td>
<td>$5.73</td>
</tr>
<tr>
<td>J8560 Etoposide oral 50 mg</td>
<td>K</td>
<td>0802</td>
<td></td>
<td>$57.09</td>
<td>.</td>
<td>$11.42</td>
</tr>
<tr>
<td>J8650 Nabimone oral</td>
<td>K</td>
<td>1424</td>
<td></td>
<td>$28.42</td>
<td>.</td>
<td>$5.68</td>
</tr>
<tr>
<td>J8700 Temozolomide</td>
<td>K</td>
<td>1086</td>
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<td>$5.39</td>
<td>.</td>
<td>$1.08</td>
</tr>
<tr>
<td>J8705 Topotecan oral</td>
<td>K</td>
<td>1238</td>
<td></td>
<td>$94.74</td>
<td>.</td>
<td>$18.95</td>
</tr>
<tr>
<td>J9010 Alemtuzumab injection</td>
<td>K</td>
<td>9110</td>
<td></td>
<td>$582.30</td>
<td>.</td>
<td>$116.46</td>
</tr>
</tbody>
</table>