Oncology Pharmacy Management Techniques:
Emerging Strategies for Managed Care Professionals

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Outline

- Current issues and trends in oncology pharmacy management
- Formulary and benefit design considerations for oncology pharmacy
- Value-based design and other emerging strategies
- Summary
Cancer Is Now on the Table

- Status of oncology treatments has changed from a position where the price and value of therapies was rarely questioned
- Now, there is an environment of broader debate around the health, pharmacoeconomic, and societal value of the treatment
- Payers are actively applying payment reforms and quality measurement to cancer services
Plans Need to Find Balance Between Shifting Costs and Compliance/Noncompliance

- **Member decision factors**
  - Cost-share
  - Compliance
  - Efficacy/tolerability

- **Benefit design factors**
  - Medical vs pharmacy
  - Copay vs co-insurance
  - Specialty tiers
Drug and Disease Cost Issues and Trends

- **Drug costs**
  - Drug acquisition
    - Pipeline burgeoning with novel biologic agents
    - Patients are living longer with cancer and there is a shift towards more expensive oral, chronic, daily therapies

- **Administrative burden**
  - Elusiveness of data to determine total costs due to lack of transparency driven by medical/pharmacy benefit designs
  - Patient education/health management programs
  - Management of safety monitoring

- **Total costs need to be evaluated**
  - Direct and indirect
Current Issues in Clinical Management

• Complexity of treatment regimens
  – Levels of evidence
  – Bioethics
    • Curable, improved survival, palliation, occasional response
  – Variable endpoints and outcomes
• Off-label use of drugs
• Lack of consensus among guidelines and pathways with multiple compendia
• Patient education and supportive care, particularly end of life counseling
Current Issues in Provider Relations

- Fee schedules and reimbursement
- Location/place of therapy
- Route of administration – incentives
- Support for mandated clinical pathways
- Politics and other network issues
  - Managing oncology networks must be done carefully so oncologists are not dissatisfied, which can affect the plan’s attractiveness to potential clients
Current Trends and Issues in Benefit Design

- **Medical vs pharmacy**
  - Migration of coverage from medical to pharmacy benefit
  - Expect more drugs covered by the medical benefit to be reviewed by plan pharmacy and therapeutics (P&T) committees

- **Plan sponsors have been hesitant to implement changes for oncology**
  - Growing interest driven by cost
  - Emerging delivery channels/channel complexity
  - Copay vs co-insurance
  - Specialty tiers
Cancer Treatments Are Third Largest Specialty Category Under Pharmacy Benefit

With many drugs in the FDA pipeline for cancer, cancer therapies may soon comprise the highest percentage of spending in the specialty pharmacy category.

Express Scripts 2009 Drug Trend Report
Basic Tenets of Benefit Plan Design

- Manage costs by restricting utilization of resources
  - Medical and pharmacy designs usually independent
- Cost-sharing used to influence utilization patterns
  - Patient cost-share related to acquisition cost of service or product
  - Assumes inelastic demand or willingness to pay

Benefit Design Issues for Oncology Pharmacy

• No single standard in the marketplace
• Most plans use traditional cost-management methods applied to other chronic diseases (eg, asthma, hypertension)
  – Adaptation of existing tiered formulary methodology
  – Demand management through cost-sharing and other barrier to access
• Most current designs do not consider patients’ total out-of-pocket burden
  – Is oncology a “value-based” disease state?

Considerations for Oncology Pharmacy Management Strategies

- **Incentive programs**
  - Member
  - Physician: differential reimbursement, pay-for-performance (P4P)
- **Specialty Pharmacy integration**
- **Coordination/collaboration**
  - Data management/widespread use of IT
- **Case management**
  - Needs to be more active and educated
- **Patient support programs**
  - Mandatory?
  - Use of Pharma’s?
Considerations for Oncology Pharmacy Benefit Design

• **Benefit design**
  – Tiers
    • Evaluating out-of-pocket expenses and distribution
  – Biosimilars
    • First follow-on biologics or biosimilars may be available mid-decade or even earlier

• **Application of guidelines/algorithms/disease management**
  – More than just NCCN or other consensus

NCCN=National Comprehensive Cancer Network.
Considerations for Oncology Pharmacy Formulary Management

• **More formulary control**
  – Need for data: Comparative Effectiveness Research?
  – Prior Authorizations (PAs) – levels of evidence
  – Quantity Limits (QLs)

• **Contracts**
  – Work with pharma – Outcomes-based
    • J&J money-back guarantee to British National Health Service: Cost of bortezomib reimbursed for each patient whose tumors did not shrink
  – Net effective pricing

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Impact of Patient Cost-Sharing on Total Costs

- **Oncology drug use largely insensitive to cost-sharing**
  - High variation in the willingness of patient to pay for care
  - Once treatment has begun, out-of-pocket cost changes have little effect on ongoing treatment
    - Patients often find alternative ways to access medications (eg, Patient Assistance Programs)
- **Co-insurance has little effect on total plan sponsor costs unless there is no cap on patient out-of-pocket costs**
- **Patient adherence declines once out-of-pocket costs reach $1,000**
  - However, there is little documentation of poor outcomes due to high out-of-pocket costs

1. Goldman DP. Health Serv Res. 2010;45:115-1132.
Value-Based Oncology Pharmacy Management Approach

- Focus is on long-term outcome of improved functional health
- Total cost picture to include indirect costs
- Subsidizes effective services through lowered out-of-pocket exposure
- Varied financial subsidy based on specific disease/clinical scenarios

Value-Based Insurance Design

• Multiple definitions and interpretations in today’s marketplace
  – Emerging concept

• Original definition:

Value-Based Insurance Design (VBID) explicitly acknowledges and responds to patient heterogeneity. It encourages the use of services when the clinical benefits exceed the cost and likewise discourages the use of services when the benefits do not justify the cost.

Application of Value-Based Approach

- Waive or reduce out-of-pocket costs to achieve specific goals
- Prevention
  - Evidence-based preventive care/services/products
- Condition
  - Promote medication adherence for individuals on maintenance medication for chronic conditions (eg, diabetes)
- Service Provider
  - Incent utilization of a specific provider or service (ie, condition management)

Application of Value-Based Design

- Currently in use by some employer plan sponsors
  - Full integration of medical and pharmacy benefits
  - Uniform plan design
    - Lowered cost-sharing if patient uses most effective resource
    - High cost-sharing for utilizing non-network resources
  - Typically involves co-insurance with an out-of-pocket limit
Value-Based Benefit Design

- Value-based design is an engagement tool for the consumer, plan sponsor, and provider
- Value-based design uses data to invest in incentives that
  - Change behaviors to improve health, productivity, quality, and financial trends

## Initial Data Building for Value-Based Design

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## Advanced Data Building for Value-Based Design

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**Diagram:**
- **Safety**
- **Absenteeism**
- **Biometrics**
- **Behavioral Health**
- **Disability**
- **Medical Claims**
- **Pharmacy**
- **HRAs**
- **Demographics**

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HRA=Health Reimbursement Account.
Application of Value-Based Design to Oncology Drugs

- Primary focus of value-based design is on outcomes
  - Outcomes are driven by
    - Adherence to medication
    - Compliance with treatment management
- Value-based designs may be used to influence patient/provider interaction
  - Documented applications in several chronic conditions (ie, asthma) and specialty pharmacy management in rheumatoid arthritis (RA) and multiple sclerosis (MS)
  - More Oncology applications needed

Application of Value-Based Design to Oncology Drugs

- Potential for good fit with future trends
  - Outcomes-based contracting
  - Integrated care management
  - Implementation with comparative effectiveness research results (CER)

Comparative Effectiveness Research (CER)

- More than $1 billion in the stimulus package is allocated for CER
  - These findings will be used to inform clinical guidelines, provider reimbursement, coverage decisions, and cost-sharing
- CER will not make care decisions, but rather enable better informed decision-making
- Idea is to reduce treatment variability for a given tumor, while maintaining appropriate clinical outcomes coupled with lower cost to the payer and the patient
- Potential implementation of CER
  - Initiate access denials based on use of CER

Pathways for breast, colorectal, and lung cancers have been in place with commercial payers for the past several years

- Trend is increasing for development of more pathways across additional tumor types

Most pathway initiatives to date have been based upon collaboration between physicians and payers utilizing the framework of tumor-specific guidelines from the NCCN

- Result has been selection of a limited number of treatment regimens for each tumor type and/or stage of disease

NCCN=National Comprehensive Cancer Network.

Outcomes-Based Reimbursement

• Potential reporting metrics
  – Adoption of Evidence-Based Guidelines: identify and show compliance for a pathway (NCCN)
    • % compliance reported quarterly
  – Adopt and use standard delivery of chemotherapy regimens
    • % compliance reported quarterly
  – Adopt and verify compliance with safety guidelines (NIOSH)
    • % compliance reported quarterly
  – Adopt and use standard Anti-Emetic Guidelines (ASCO/NCCN)
    • % compliance reported quarterly

NCCN=National Comprehensive Cancer Network.
NIOSH=National Institute for Occupational Safety and Health.
ASCO=American Society of Clinical Oncology.
Oncology Pay-for-Performance (P4P)

- **Limited/localized pilots**
  - UnitedHealthcare and several BlueCross BlueShield (BCBS) plans
  - A lot of data gathering
  - Few dollars have actually changed hands

- **PQRS measures include oncology**¹
  - Voluntary program rewards eligible HCP for reporting on quality measures
  - Reward is 1% of total allowed Medicare charges for services, excluding drugs
  - 27 of 190 measures are cancer-related
  - Viewed as preparation for future pay-for-performance programs
    - A 1.5% reduction in payment is scheduled to begin in 2014

PQRS=Physician Quality Reporting System.

UnitedHealthcare Pay-for-Performance (P4P)

- Adherence to NCCN Clinical Practice guidelines for chemotherapy administration began in 2008
- Episode-of-care payment pilot with 5 practices and 19 clinical conditions began in 2009
  - Up-front lump sum payment for following pathways
    - Drug costs reimbursed separately
  - Covers all aspects of need, based on disease stage and patient status
  - Outcomes are compared and contrasted

NCCN=National Comprehensive Cancer Network.

**Percent of Physicians Rewarded for Using “P4 Pathways” and Preferred Regimens Based on NCCN**

<table>
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<tr>
<th>Pathways</th>
<th>Year 1</th>
<th>Year 2</th>
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<tr>
<td>Breast, lung, and colon cancer treatment</td>
<td>65%</td>
<td>80%</td>
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<tr>
<td>Anemia, neutropenia, and nausea and vomiting</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Prostate, ovarian, multiple myeloma, and lymphomas (CLL, mantle cell, follicular, large B cell)</td>
<td>n/a</td>
<td>80%</td>
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</table>

NCCN=National Comprehensive Cancer Network.
CLL=Chronic Lymphocytic Leukemia.

Value-Based Purchasing (VBP)

- CMS plans to transition PQRI from pay-for-reporting to VBP
  - Value = Quality ÷ Cost
- Payment methods may align incentives for providers to collaborate via PCMH, ACO, Center of Excellence, or other models
  - Potential methods:
    - Pay-for-performance (P4P)
    - Bundled or global payments
    - Episode-of-care payments
    - fee-for-service
    - gain-sharing, with appropriate adjustments

CMS=Centers for Medicare & Medicaid Services. PQRI=Physician Quality Reporting Initiative. PCMH=Patient-Centered Medical Home. ACO=Accountable Care Organization.

Future Needs

• Customization of health plan and plan design to socioeconomic and demographic factors
• Application of predictive modeling to oncology outcomes and plan design
  – Role of comparative effectiveness
• Payers and plans need consistency of care
  – If you can predict what the costs of cancer care are, then you will be better able to set premiums
• Demonstration of value-based design driving provider behavior in oncology care
Summary

• Limited outcomes data, bioethic concerns, and limited resources challenge patients, providers, and plans

• Oncology pharmacy is a key current and future concern for plan sponsors and patients

• With a focus on innovation and adaptability, managed care is in a position to develop solutions

• Current plan designs are based on older premises which often do not apply to the needs of oncology pharmacy

• Newer plan approaches including value-based design should be considered