HCV Pharmacy Management Techniques: Emerging Strategies for Managed Care Professionals

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Faculty Disclosure

• The *faculty* reported the following financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this CME activity:
  – Jeffrey D. Dunn, PharmD, MBA
    • Consulting Fees: Johnson & Johnson and Vertex Pharmaceuticals Inc.
Objective

- Identify the issues related to hepatitis C virus (HCV) specific to managed care organizations (MCOs)
- Evaluate pharmacy benefit management programs including
  - Methods that MCOs can implement to improve overall patient outcomes for patients with HCV
Outline

• Current issues in HCV pharmacy management
• Benefit design considerations for HCV pharmacy
• Value-based design
• Summary
Chronic Hepatitis C: Challenges for Managed Care

- **Disease with a long, indolent course**
  - Aging of a large pool of enrollees
  - Many patients are undiagnosed or are not on therapy
    - Survey: 1/3 of US physicians are “warehousing” patients
    - By end of 2007, only 21% of infected individuals had cumulatively received antiviral therapy
  - Hepatitis C is usually asymptomatic

- **Cornerstone therapies are expensive**

Hoggatt J. [www.in-thought.com/resources/HepCSurvey](http://www.in-thought.com/resources/HepCSurvey).
Chronic Hepatitis C: Challenges for Managed Care (Continued)

- Improved methods to enhance identification and treatment of affected patients are needed
  - Role of active screening?
- Patient adherence to therapy is suboptimal
  - Regimens are complex
- Long-term monitoring of patients necessary to enhance outcomes
- Associated with significant comorbidities, ie, HIV, etc.
- Current therapies have limitations

Hoggatt J. www.in-thought.com/resources/HepCSurvey.
Management of Chronic Hepatitis C: Unanswered Questions

• Will the initial expense of therapy be offset by cost savings from the prevention of future disease burden?
  – If so, how can MCOs assure patients are receiving the best care with the most efficient use of healthcare resources?
• What methods can be used during treatment to further reduce total HCV costs?
• What can be done to ensure diagnosis and appropriate treatment of infected patients, which will reduce future health burden?

Goals of HCV Treatment

• **Goal of treatment:**
  – Eradicate the virus
  – Prevent progression to end-stage liver disease

• **Standard of care:**
  – Peginterferon alfa injection + oral ribavirin
  – Significant unmet need: adverse events, contraindications, efficacy

• **Predictors of sustained response:**
  – HCV genotype 2 and 3, low viral load, age <40 years, female sex, no fibrosis, and compliance

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 coinsurance
  – Specialty tiers
Drug and Disease Cost Issues

• **Drug costs**
  - Drug acquisition
    • Emerging agents
    • Emergence of more expensive chronic oral therapies

• **Clinical burden**
  - Appropriate diagnosis, maintaining adherence, and routine monitoring is difficult
  - Patient education/health management programs
  - Management of safety monitoring

• **Total costs need to be evaluated**
  - Direct and indirect
HCV Drug Spend Is Projected to Nearly Triple in the Next Few Years

Pipeline

- **Protease Inhibitors (>10)**
  - Triple therapy
    - Can we eliminate interferon?
  - Increased efficacy
  - Increased treatment regimen complexity

- **Others**
  - Polymerase inhibitors
    - Nucleoside and Non-Nucleoside
  - Entry inhibitors
  - Vaccines?

- **Increased pharmacy cost**
  - Decreased total cost?
  - Improved long-term outcomes?

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

Common Components of HCV Benefit Design

- **Cost management**
  - Drug discounts
  - Channel management
  - Rebates
  - Benefit design options

- **Utilization management**
  - Medical necessity review
  - Clinical management via treatment algorithms/patient eligibility/duration of therapy
  - Prior authorization
  - Formulary management (tiers, utilization caps)

Considerations for HCV 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 HCV Pharmacy: Benefit Design

• **Benefit design**
  – Tiers
    • Evaluating out-of-pocket expenses and distribution
  – Biosimilars
    • The first follow-on biologics or biosimilars are in late stage development

• **Application of guidelines/algorithms/disease management**
  – Need information concerning retreatment
  – What to do for patients intolerant to or having contraindications to peginterferon or ribavirin
Considerations for HCV Pharmacy: Patient Behavior

- Complex therapy
- Tolerability and efficacy issues
- Asymptomatic disease

- Education
- Strengthening patient-provider relationships
- Patient empowerment
- Integrated communication channels
- Medication Therapy Management (MTM)
- Telephonic counseling
- Medication reminders
Considerations for HCV Pharmacy: Formulary Management

• **More formulary control**
  – Need for data: Comparative Effectiveness Research?
  – Prior Authorizations: levels of evidence
  – Quantity limits
  – Start/stop rules

• **Contracts**
  – Work with pharma; outcomes-based
  – Net effective pricing
## Prior Authorization Criteria: SelectHealth

Please check “Yes” or “No” or answer the following questions:

<table>
<thead>
<tr>
<th>1. Is the prescribing physician a gastroenterologist or an infectious disease physician (or has a GI or ID specialist been consulted)?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Which drug is being requested? Peg-Intron (S0148) Pegasys (S0145) <strong>Note:</strong> X is the preferred pegylated interferon-alfa product, letter of medical necessity is required when requesting Y</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3. Is the patient diagnosed with chronic <strong>hepatitis C</strong> virus (HCV) with compensated liver disease?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>a. Has the patient been treated previously with pegylated interferon-alfa ± ribavirin?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>b. Has the patient had a liver biopsy showing bridging fibrosis or cirrhosis?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>c. What is the HCV genotype? _____________________ (please attach chart &amp; lab notes)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>d. What is the HCV RNA viral load? _______________________ Date: _________________</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Note:</strong> Ribavirin does not require preauthorization</td>
<td></td>
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</tr>
<tr>
<td>• Genotype 1, 4, 5, or 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Therapy will be authorized for 14 weeks (includes 2 weeks for lab results)</td>
<td></td>
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<tr>
<td>• If there is an EVR (&gt;2 log 10 drop in HCV RNA after 12 weeks), therapy will</td>
<td></td>
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<tr>
<td>• be authorized for a total of 48 weeks</td>
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<tr>
<td>• If an EVR is not achieved, but there is clearance of HCV RNA by 24 weeks, therapy will be authorized for a total of 72 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Genotype 2 and 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Therapy will be authorized for 24 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If there is an RVR (HCV RNA is negative after 4 weeks) or patient is intolerant to therapy, therapy may be discontinued between weeks 12 and 16</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> Retreatment with peginterferon in patients who did not achieve an SVR after a prior full course of peginterferon plus ribavirin is not covered.</td>
<td></td>
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</tr>
<tr>
<td>4. Is the patient diagnosed with chronic hepatitis B virus (HBV) with compensated liver disease?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>a. Are the patient’s pre-treatment HBV DNA levels &gt;20,000 IU/mL? (please attach chart &amp; lab notes)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>b. Will this be used as monotherapy?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Therapy will be authorized for 26 weeks initially (includes 2 weeks for lab results)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Therapy will be extended for 48 weeks after documented HBeAg seroconversion</td>
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Impact of Patient Cost Sharing on Total Costs

- **HCV drug use largely insensitive to cost sharing**\(^1,2\)
  - High variation in the willingness of patient to pay for care\(^1,2\)
  - Once treatment is begun, out-of-pocket cost changes have little effect on ongoing treatment\(^1\)
    - Often find alternative ways to access medications, eg, Patient Assistance Programs\(^1,2\)

- **Coinsurance has little effect on total plan sponsor costs unless there is no cap on patient out-of-pocket costs**\(^2\)

- **Patient adherence declines once out-of-pocket costs reach $1,000**\(^2\)

- **However, there is little documentation of poor outcomes due to high out-of-pocket costs**\(^1\)

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2. Willey VJ. *Health Aff.* 2008;27:824-834.
### Value-based Design

<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>Focus on long-term outcome of improved health</td>
</tr>
<tr>
<td>Assess total cost picture including medical spending and productivity</td>
</tr>
<tr>
<td>The more beneficial the therapy, the lower the patient’s cost share</td>
</tr>
<tr>
<td>Adjust out-of-pocket costs for specific services based on patient characteristics</td>
</tr>
</tbody>
</table>

Multiple Definitions of Value-based Design

- Value-based design is an 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.

Components of Value-based Benefit Design

- **Components include**
  - Disease management
  - Patient education
  - Clinician training/awareness
  - Adherence enhancement
  - Management of adverse events
  - Quality of life assessment
  - Coordinated care
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 (e.g., diabetes)
• Service Provider
  – Incent utilization of a specific provider or service (i.e., 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 coinsurance 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**

<table>
<thead>
<tr>
<th>Data</th>
<th>Integration of data points for a full picture of functional risk to the individual and the organization</th>
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</thead>
<tbody>
<tr>
<td>Design</td>
<td>Identify and fill the gaps in data, care, support, and outcomes across the total realm of influence</td>
</tr>
<tr>
<td>Delivery</td>
<td>Promote the intersection of health, finance, community for economic sustainability</td>
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<tr>
<td>Dividends</td>
<td>Align incentives for improved outcomes</td>
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[Pharmacy](#)  [Medical Claims](#)

## Advanced Data Building for Value-based Design

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Application of Value-based Design to HCV 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 RA and MS

Application of Value-based Design to HCV Drugs (Continued)

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

Comparative Effectiveness Research

- >$1 billion in the stimulus package is allocated for CER
  - Used to inform clinical guidelines, provider reimbursement, coverage decisions, and cost sharing
- CER will enable better informed decision-making
- Goal: reduce treatment variability 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

Issues

- Will have more agents
- Algorithms will need to evolve rapidly
- Will see increased utilization and more members
- Formulary decisions
  - Contracting
- Coordination of care
- Benefit design needs to evolve
Summary

• Managed care will be required to develop novel solutions to meet the anticipated growth of the symptomatic HCV population
• Limited resources challenge patients, providers, and payers
• HCV pharmacy is a current and future concern for plan sponsors and patients
• Current plan designs based on older premises often do not apply to the needs of HCV pharmacy
• Newer approaches, including value-based design should be considered