Oncology Drug Shortages: Issues & Opportunities

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Experience Related to Drug Shortages

Have drug shortages improved?

- Protecting the supply chain includes adequacy of supply

- Oncology drug shortages remain a critical issue
  - 82.7% of oncologists were unable to prescribe the preferred chemotherapy agent at least once in past six months
  - Substitutions are typically more expensive products

- Drug shortages impact access, cost & quality

- Health care providers, suppliers and distributors are working together to better manage drug shortages

Response of Oncologists to the Shortage of Chemotherapy Drugs

<table>
<thead>
<tr>
<th>Adaptation</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Switched chemotherapy regimen</td>
<td>78.4%</td>
</tr>
<tr>
<td>Substituted a drug partway through treatment regimen</td>
<td>76.7%</td>
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<tr>
<td>Delayed treatment</td>
<td>43.2%</td>
</tr>
<tr>
<td>Excluded some patients</td>
<td>36.9%</td>
</tr>
<tr>
<td>Omitted doses</td>
<td>29.0%</td>
</tr>
<tr>
<td>Reduced doses</td>
<td>19.9%</td>
</tr>
<tr>
<td>Referred patients to another practice</td>
<td>16.5%</td>
</tr>
</tbody>
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Factors impacting drug shortages
What are factors contributing to drug shortages

- Manufacturing quality challenges
- Manufacturing complexity and cost
- Pricing constraints
- Limited market capacity
- Maturing Product Portfolio
- Reimbursement Constraints
Economic & regulatory environment impacts shortages

How does reimbursement relate to drug shortages?

- The reimbursement & regulatory environment has constrained the supply chain for injectable generics and some oral generics.

- Reimbursement for generic and low-cost products is significantly constrained in current environment.
  - Current reimbursement methods lead to constrained reimbursement for lower cost products.

- Normal supply/demand is impacted since manufacturer price increases then create significant reimbursement gaps.
  - How can we attract manufacturers to this market?
  - Incentives versus mandates?
  - Align economic and regulatory environment to expand access to low cost treatment options.
Strategies to support patient access

How to ensure that patients in underserved communities aren’t disproportionately affected by drug shortages?

Providers, manufacturers and pharmaceutical distributors have improved how supply issues are managed

• Work to prevent supply issues
• Coordinate together to manage patient access
• Prevent hoarding or behaviors that can compound product supply issues

“Fair Share” allocation system have helped to mitigate impact of supply issues

• Manage supply based on typical product use
• Efficient and fair process across all providers
• Discourage and prevent hoarding
How can we impact drug shortages quickly?

Are there common sense economic and regulatory changes that can be made quickly:

- Accelerate or prioritize regulatory support for generic injectable manufacturing sites
  - Expand manufacturer capacity and quality

- Some private payers now incent use of generic injectable with higher reimbursement
  - Higher reimbursement rates for low cost products

- Need all payers to increase reimbursement when prices increase to match how quickly reimbursement is lowered when price decline
  - Lags in reimbursement updates may act as “virtual price controls” and thus impact normal economic factors
Where knowledge, reach and partnership shape healthcare delivery.