Managing Specialty Pharmaceuticals: What’s on the Horizon?
2016 Health Care Cost and Utilization Report

A review of trends in health care spending, utilization, and price among Americans with employer-sponsored insurance
Drugs contributing to overall spending

Figure 2: Annual Change in Spending per Person, 2012-2016
Potential Elements in Determining a Reasonable Launch Price for Pharmaceuticals

- Costs of development and/or production plus “reasonable” profit
  - Potential for negative effects if applied to all new drugs
  - Often considered for older generic drugs without barrier to entry

- Budget impact for drugs affecting large populations
  - Public health opportunities
  - Cost-plus or other mechanisms sometimes considered

- Added “value” to patients and health systems
  - More apt for new drugs with limited or no competition
  - Cost-effectiveness analysis is the accepted approach in the US and abroad
Cost-effectiveness thresholds (Cost per QALY)

Cost ($)

Effectiveness (QALYs)

Cost-effectiveness Threshold

Even more effective
Higher cost

More effective
Higher cost
ICER’s Value-based Price Benchmarks
### ICER’s Value-based Price Benchmarks (examples)

<table>
<thead>
<tr>
<th>Drug category</th>
<th>Recommended Discount*</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCSK9 inhibitors for high cholesterol</td>
<td>50%</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>5%</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>25%</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>15%</td>
</tr>
<tr>
<td>Atopic dermatitis</td>
<td>0%</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>50-80%</td>
</tr>
<tr>
<td>TKIs for lung cancer</td>
<td>0%</td>
</tr>
<tr>
<td>PD-1s for lung cancer</td>
<td>50%</td>
</tr>
<tr>
<td>Abuse-deterrent opioids</td>
<td>40%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug category</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Ovarian cancer PARP drugs</td>
<td>50%</td>
</tr>
<tr>
<td>Tardive dyskinesia</td>
<td>85-90%</td>
</tr>
<tr>
<td>Gene therapy for inherited blindness</td>
<td>50-75%</td>
</tr>
<tr>
<td>Emicizumab for hemophilia A</td>
<td>Cost-saving</td>
</tr>
<tr>
<td>CAR-T for cancer</td>
<td>0%</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td>67-75%</td>
</tr>
<tr>
<td>Chronic migraine</td>
<td>TBD</td>
</tr>
<tr>
<td>Elagolix for endometriosis</td>
<td>TBD</td>
</tr>
<tr>
<td>Apalutamide for prostate cancer</td>
<td>TBD</td>
</tr>
</tbody>
</table>

* For new drugs, discount from list price needed to meet common thresholds of cost-effectiveness. For drugs already in use, discount is from **post-rebate price**
Use of ICER Assessments

• **For policy makers:** independent evaluation of value and suggested value-based prices figure in multiple proposals

• **For payers and provider groups:** helps guide coverage decisions and pricing negotiations

• **For drug makers and payers:** helps negotiation over prices in conjunction with appropriate access
Payers and Provider Groups

• VA using ICER reports to negotiate prices

• New York Medicaid
  • New law establishing drug spending targets for Medicaid
  • When exceeded, drugs can be identified for supplemental rebates
  • New York panel used ICER report on cystic fibrosis drug Orkambi to determine target price: 70% discount from list price
  • What will the impact be?
Drug makers and payers

- Dupixent for severe atopic dermatitis
- Pre-launch, manufacturer agrees to align price with ICER’s value-based benchmark
- ICER recommends price of $31K (far below market expectation of $60K)
- Manufacturer uses value-based price w/ payers to negotiate “reasonable” access
Drug makers and payers: Praluent for high cholesterol

- One of two PCSK9 inhibitors
- Initial launch at $14,350 judged not cost-effective by ICER; payers erect daunting prior authorization requirements
- Patients and clinicians struggle for access; PCSK9i’s greatly “disappoint” on revenue

New clinical data available on Praluent:
- Shared with ICER in-confidence before public release
- Updated value-based price benchmarks calculated for overall population ($2,300-$3,400) and high-risk subgroup ($4,500-$8,000)
- Regeneron/Sanofi commit publicly to ICER price range for the high-risk subgroup in conjunction with “streamlined” access from payers
- Express Scripts and drug makers announce deal….
Coming Soon?
Value-Based Plan Designs/Formularies

• Option 1 (private payers): Special tier, step therapy, or exclusion for drugs whose best negotiated price remains above the value-based price benchmark

• Option 2 (public or private payers): Include drugs on formulary but only pay up to the value-based price benchmark. Any residual gap between price charged and reimbursement is the responsibility of the patient/manufacturer.

• Option 3 (public payers): Include drugs on formulary but only pay up to the value-based price benchmark. Manufacturer forbidden from balance billing; has choice to list or not list the drug at a price not exceeding the value-based price.