Managing Specialty Pharmaceuticals: What's on the Horizon?

INSTITUTE FOR CLINICAL
AND ECONOMIC REVIEW

HCCI HEALTH CARE COST INSTITUTE

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

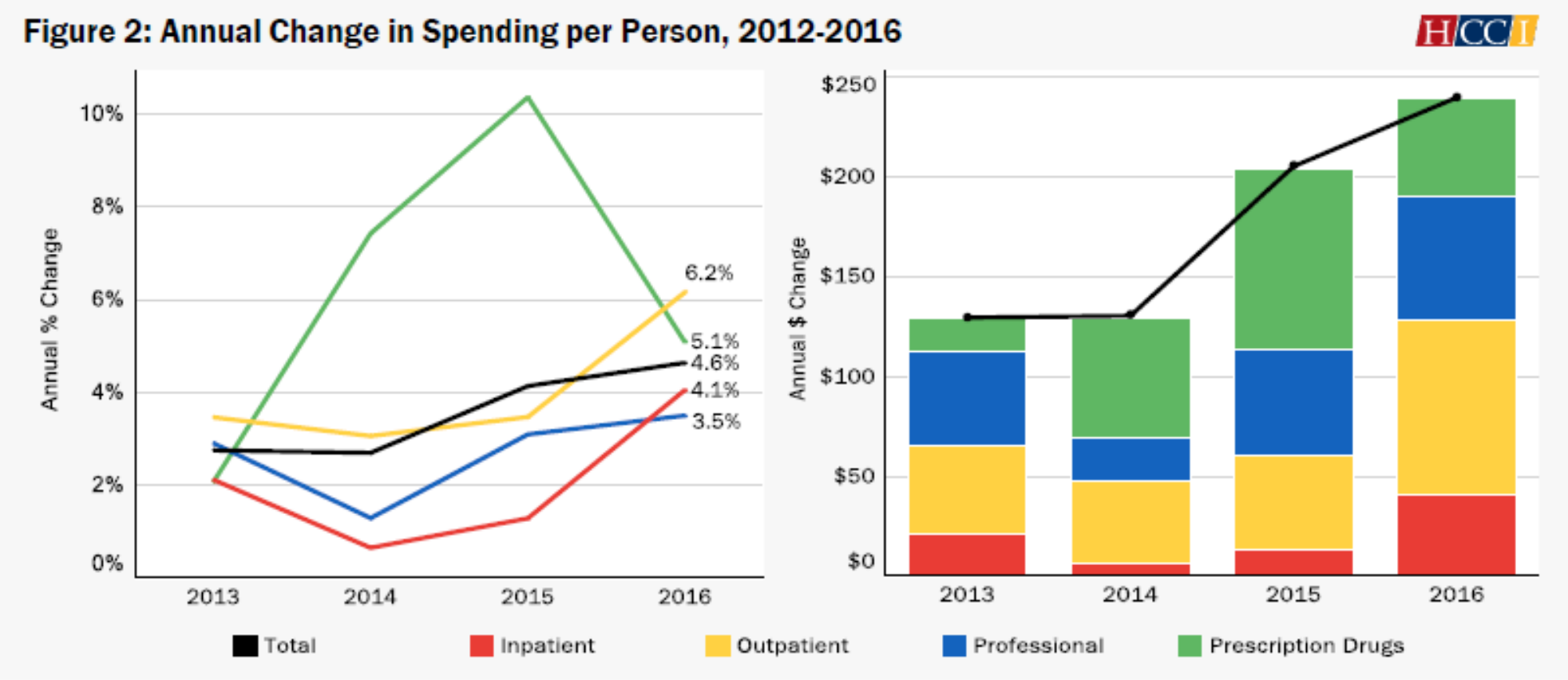
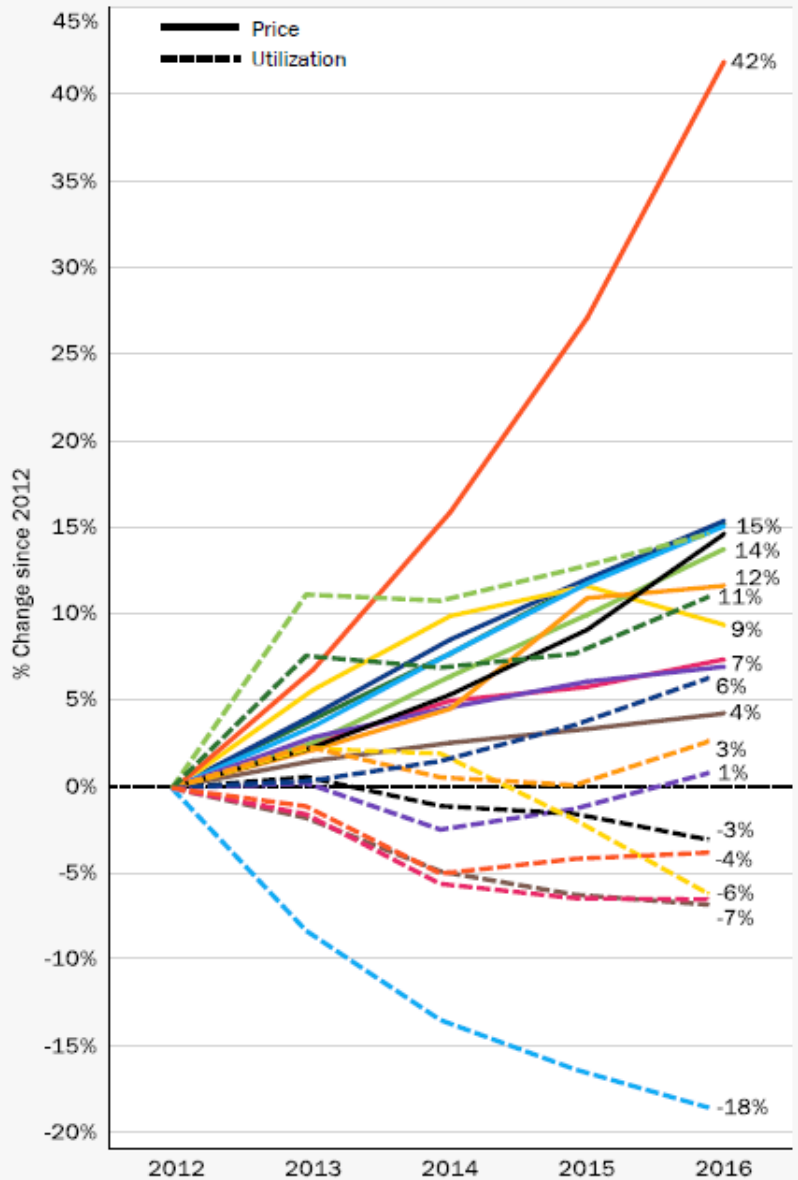


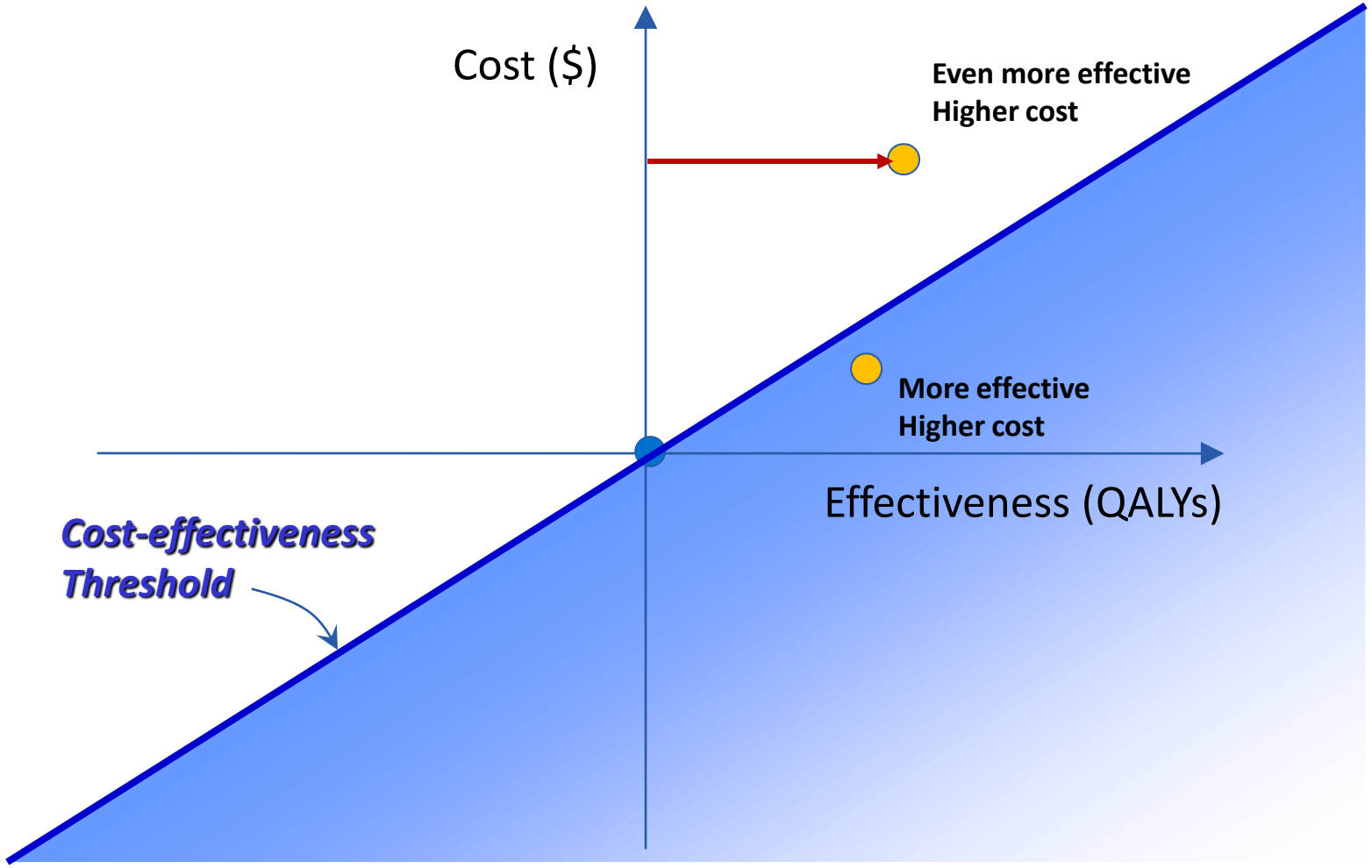
Figure 17: Cumulative Change in Professional Services Price and Utilization



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)



ICER's Value-based Price Benchmarks

ICER's Value-based Price Benchmarks (examples)

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

Drug category	Recommended Discount*
Ovarian cancer PARP drugs	50%
Tardive dyskinesia	85-90%
Gene therapy for inherited blindness	50-75%
Emicizumab for hemophilia A	Cost-saving
CAR-T for cancer	0%
Cystic fibrosis	67-75%
Chronic migraine	TBD
Elagolix for endometriosis	TBD
Apalutamide for prostate cancer	TBD

** 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

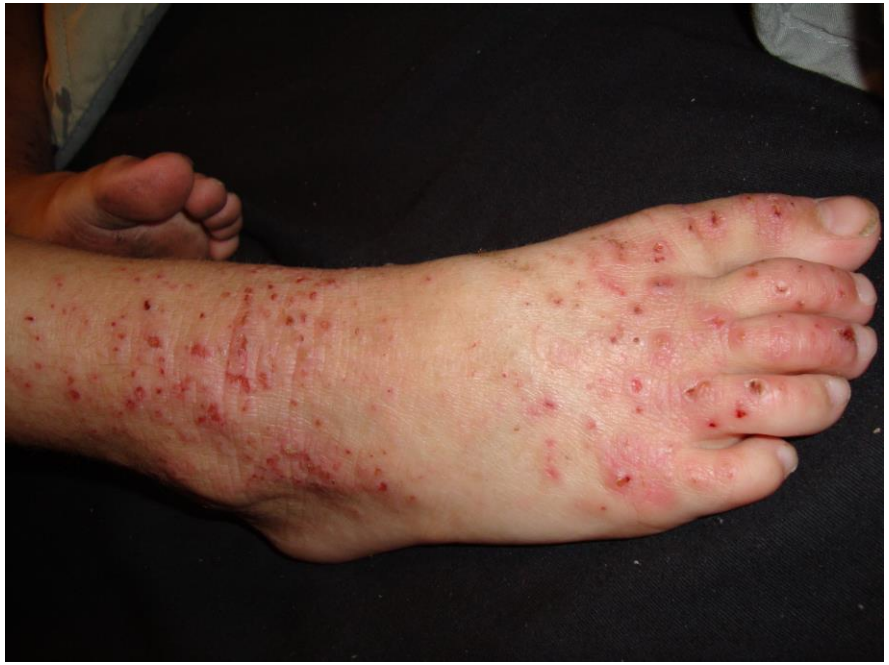
- **For policy makers:** independent evaluation of value and suggested value-based prices figure in multiple proposals
- **For payers and provider groups:** helps guide coverage decisions and pricing negotiations
- **For drug makers and payers:** helps negotiation over prices in conjunction with appropriate 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.