



Payer Options for Managing Specialty Drugs

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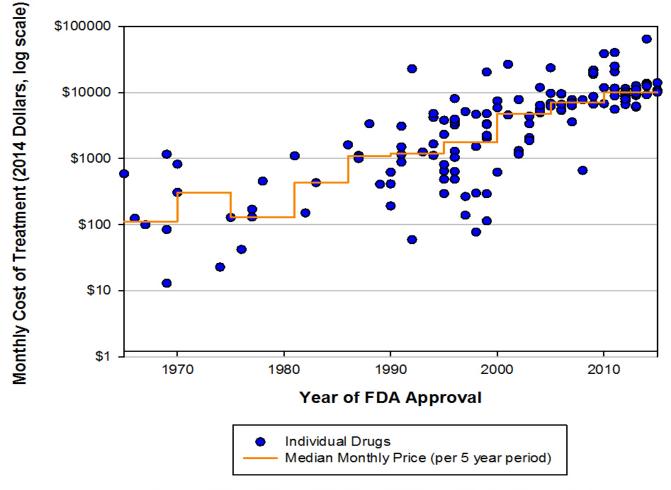


The challenge Payer strategies to date A better way?



Rising Prices at Time of Launch

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965-2015



Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

Price Increases after Launch

Top selling U.S. drug prices over five years

Prices rose 54 percent to 126 percent.

DRUG (COMPANY)	PRICE* Dec. 31, 2010 Present		PRICE GROWTH
Humira (AbbVie) 40 mg/0.8 ml pre-filled syringes	\$1,676.98	\$3,797.10	126.4%
Enbrel (Amgen) 50 mg/ml subcutaneous sol.	\$427.24	\$932.16	118.2%
Copaxone (Teva) 20 mg/ml subcutaneous sol.	\$3,025.04	\$6,593.00	118.0%
Crestor (AstraZeneca) 10 mg tablets	\$350.17	\$745.41	112.9%
Abilify (Otsuka) 10 mg tablets	\$454.07	\$891.97	96.4%
Lantus Solostar (Sanofi SA) 100 units/ml subcutaneous sol.	\$191.96	\$372.76	94.2%
Advair Diskus (GlaxoSmithKline) 250/50 inhalation discs	\$199.90	\$334.63	67.4%
Remicade (Johnson & Johnson) 100 mg IV powder for solution	\$657.87	\$1,071.48	62.9%
Neulasta (Amgen) 6 mg/0.6 ml subcutaneous sol.	\$3,320.00	\$5,155.65	55.3%
Nexium (AstraZeneca) 10 mg oral packets	\$162.55	\$250.94	54.4%

* Reflects wholesale acquisition prices before volume-related rebates and other discounts. Prices are based on most commonly prescribed dose.

Source: Truven Health Analytics

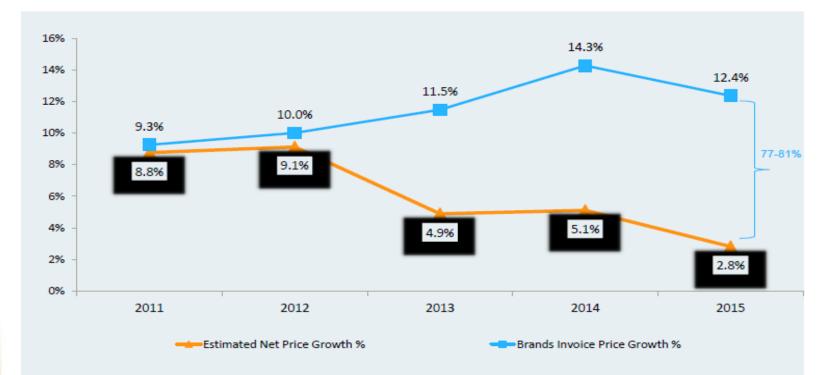
S. Culp, 30/03/2016

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Payers Negotiate Rebates

Although invoice price growth for protected brands was 12.4%, net price growth is estimated at 2.8%

Protected Brand Invoice and Net Price Growth



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Even After Negotiated Rebates, Most Prices Are Higher in US

Average Drug Prices for Top-Selling Drugs in 2015

	Monthly Pric	e, US \$			
	United States				
Drug	Nondis- counted Price	Estimated Discounted Price	Canada	France	Germany
Adalimumab (Humira), 40 mg biweekly	3430.82	2504.50	1164.32	981.79	1749.26
Fluticasone/salmeterol (Advair), 250 µg, 50 µg daily	309.60	154.80	74.12	34.52	37.71
Insulin glargine (Lantus), 50 insulin units daily	372.75	186.38	67.00	46.60	60.90
Rosuvastatin (Crestor), 10 mg daily	216.00	86.40	32.10	19.80	40.50
Sitagliptin (Januvia), 100 mg daily	330.60	168.61	68.10	35.40	39.00
Sofosbuvir (Sovaldi), 400 mg daily	30 000.00	17 700.00	14943.30	16088.40	17 093.70
Trastuzumab (Herceptin), 450 mg every 3 wk	5593.47	4754.45		2527.97	3185.87

AS Kesselheim et al. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform.

JAMA 2016;316(8):858-871.

Payer Strategies to Date



- Formulary restrictions and step therapy
- Consumer cost sharing
- The arms race

Formulary Exclusions and Step Therapy

- Payers are narrowing their drug formularies and tightening prior authorization (PA) and step therapy (ST) requirements
- PA now reaches 'inside' the FDA label
 - 'Successful' in limiting use (HCV, PCSK9)
- PA and ST place major burdens on physicians and patients
- Regulatory backlash is coming
 - Pharma develops MD support programs that increase access, at high cost
 - Pharma increases prices to reflect expected effect of PA and UT on sales



Deductibles and Coinsurance

- Payers are increasing deductibles in the medical benefit (infused drugs) and coinsurance in the pharmacy benefit
- Patient cost sharing is linked to drug's list price, not the (post-rebate) net price
- Major obstacles to patient adherence and increased MD bad debt
- Rising regulatory backlash: mandated OOP max per month, bans on coinsurance
 - Pharma increases copay support
 - Pharma raises prices to reflect the cost of copay support programs and the expected effect of cost sharing on sales

The Arms Race



- 1. Payers increase PA/ST and cost sharing
- 2. Pharma then increases physician practice and patient copay support programs
- 3. Payers further increase PA/ST and cost sharing, and restrict formularies
- 4. Pharma then further increases its programs, fosters patient and regulatory backlash. It factors these costs into its prices
- 5. Drug prices are high, non-transparent, onerous for patients, fodder for politicians



Is There Another Way?

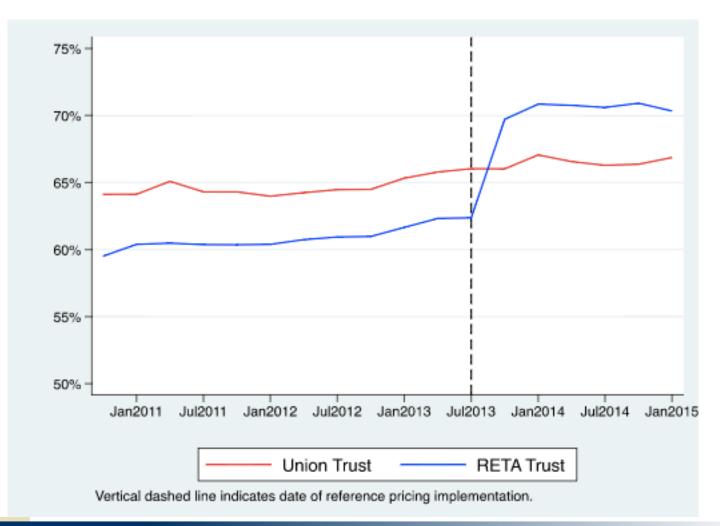
- There is great potential for price competition among specialty drugs: innovation is producing large numbers of therapeutic equivalents
- But potential competition will only result in actual competition if purchasers create incentives for physicians and patients
- Specialty generics and biosimilars are part of the solution, but face obstacles
- Reference pricing has been used successfully for non-specialty drugs. Can it be applied to specialty drugs?



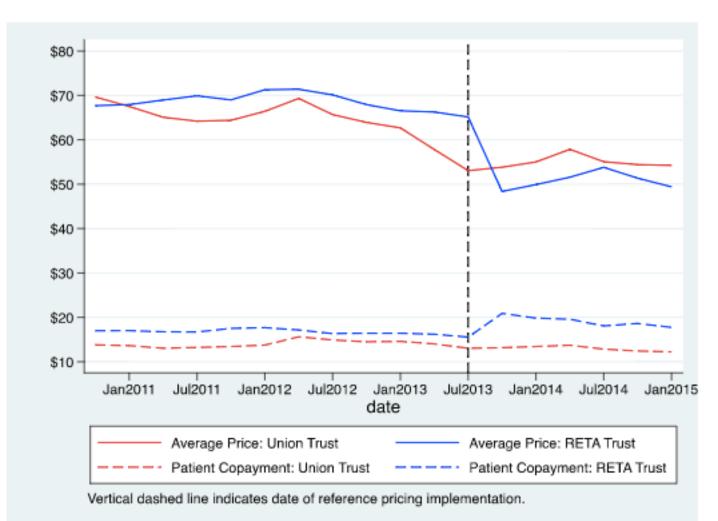
What is Reference Pricing?

- Sponsor (employer, insurer) establishes a maximum contribution (reference price) towards paying for a particular product
 - This limit is set at some point on price range (e.g., minimum, median)
 - Patient must pay the full difference between this and the price charged
 - Patient may reduce cost sharing by switching to low-priced product
- Patient has good coverage for low priced options but *full responsibility for choice*

Reference Pricing and Consumer Choices for Non-Specialty Drugs



Reference Pricing and Spending for Non-Specialty Drugs



Reference Pricing for Pharmacy Benefit (patient-administered) Specialty Drugs

- <u>Therapeutic reference pricing</u>: set payment at level of generic or preferred brand for classes with multiple products
 - Comparative effectiveness can be used to set multiple reference limits for drugs with different MOA within a class
 - Generous, evidence-based clinical exemptions policy is essential
 - Compare to PA/ST: say no then yes, rather than yes then no

Reference Pricing for Medical Benefit (office- infused) Specialty Drugs

- <u>Therapeutic reference pricing</u> (Least Cost Alternative): set payment at level of biosimilar or preferred brand
 - Comparative effectiveness can be used to set multiple reference payment limits for drugs with different MOA
 - Generous, evidence-based clinical exemptions policy is essential

Site of care reference pricing: set payment at rate charged by freestanding, non hospitalowned practices; raise payment rates to freestanding practices



"Geez Louise—I left the price tag on."