

Fair Pricing Coalition

Pricing, Access, Advocacy

Lynda Dee & Murray Penner

FAPP Meeting

September 10, 2014

F **AIR** **P** **RICING** **C** **OALITION**

FAIR PRICING COALITION

- **FPC History**
- **Programs and Initiatives**
- **Pre-ACA and ACA Pricing, Access and Advocacy**
- **HIV and HCV Pipeline and Pricing**
- **FPC members and contact information**

Fair Pricing Coalition

FAIR PRICING COALITION

Martin Delaney

Linda Grinberg

1999



HISTORY

- **Worked with ADAP Directors before creation of the ADAP Crisis Task Force (ACTF)**
- **First ever price freeze (2 years - 2002)**
 - **Resulted in \$50MIL savings for ADAPs**
- **Currently works in conjunction with ACTF**
- **Involved in HCV since 2010**

PROGRAMS & INITIATIVES

- **Negotiates with HIV & HCV drug companies for:**
 - **Initial pricing after FDA approval**
 - **Price freezes and annual increases**
 - **Medical CPI for price increases (3%)**
 - **Patient Assistance Programs (PAPs)**
 - **Co-Pay Programs for the privately insured**
 - **Co-Pay Programs for the publicly insured**
 - **PAP coverage for the underinsured???**
 - **Other access programs (HarborPath, PAN)**

Pricing, Access and Advocacy

FPC DEMANDS & HIV PRICING

Company	Drug	Year	Price
Janssen	Prezista	2006	\$13,090
Merck	Isentress	2007	\$12,889
Janssen	Intelence	2008	\$10,411
Janssen	Edurant	2008-2011	\$17,078
Gilead	Stribild	2012	\$28,109
ViiV	Triumeq	2014	\$26,488

HIV PRICE INCREASES SINCE FDA APPROVAL

Company	Drug	Price Increase
Janssen	Prezista 2006	56% - 8.5%
Janssen	Intelence 2008	43% - 7.2%
Janssen	Edurant 2008	22% - 8.9%
Merck	Isentress 2007	39% - 6.3%
ViiV	Combivir 1997	118% - 8.1%
ViiV	Lexiva 2003	96% - 9.6%
ViiV	Epzicom 2004	78% - 9.1%
ViiV	Tivicay 2013	4.9% - 4.9%

HIV PRICE INCREASES SINCE FDA APPROVAL

Company	Drug	Price Increase
AbbVie	Norvir 1997	478% - 38%
AbbVie	Kaletra 2005	50% - 3.7%
BMS	Sustiva 1998	144% - 9.3%
BMS	Reyataz 2003	79% - 7.9%
BMS	Atripla 2006	78% - 9.8%
Gilead	Viread 2001	168% - 13.4%
Gilead	Emtriva 2003	107% - 10.2%
Gilead	Truvada 2004	97.2% - 10.2%
Gilead	Complera 2011	20.4% - 8.2%
Gilead	Stribild 2012	4.9% - 2.5%

RECENT PRICE INCREASES: BRISTOL-MYERS SQUIBB

Date of Increase	Drug	Price Increase
January 2013	Sustiva	9.7%
January 2013	Reyataz	7.9%
January 2014	Sustiva	9.7%
January 2014	Reyataz	7.9%
June 2014	Sustiva	7%

Sustiva price increases inflate Atripla prices.

GILEAD & ViiV PRICE INCREASES

- **Gilead**
 - **Price increases taken between 2009-2012**
 - **Viread: 31.81%**
 - **Emtriva: 24.4%**
 - **Truvada: 24.5%**
 - **Atripla: 27.2%**
- **ViiV**
 - **Price increases taken in 2014:**
 - **Tivicay: 4.9%**
 - **Epzicom: 6.9%**
 - **Added \$1,500 to Triumeq price**

PAP ELIGIBILITY CRITERIA

- **Patient Assistance Programs:
Fairpricingcoalition.org/projects/**
 - **500% of Federal Poverty Level (FPL)**
 - **\$4,862.50 per month/\$58,350 per year**
 - **Janssen: 200% FPL with exception process**
 - **Part D co-pay assistance with varying criteria**
 - **HarborPath for ADAP waiting list patients**

CO-PAY PROGRAMS

- **Co-pay Assistance Programs:**
Fairpricingcoalition.org/projects/
 - **\$200 (single drug) to \$400 (FDCs) per month**
 - **Merck: Isentress & ViiV: Tivicay - \$400**
 - **Janssen: 100% after first \$5.00**
 - **AbbVie (Norvir): \$50 only per prescription**

HARBORPATH

- **PAP concept with “one-stop shopping”**
- **Licensed in all 50 states**
 - **One portal**
 - **Clinics register with access for case managers**
- **All companies participate with HP, except Janssen**
- **HarborPath.org/ - 855-300-8916**

COMMON PAP FORM

- **Standardizes the application form for PAPs:**
 - **Patient name & contact information**
 - **Healthcare coverage**
 - **Physician's name and contact information**
 - **Alternate shipping information**
 - **Prescription information**
 - **Signature of patient and provider**
- **www.bit.ly/CommonPAPForm**

HCV ACCESS PROGRAMS

Company	Patient Assistance Program	Co-payment Assistance Program
Merck	500% of FPL	20% of 12 Rxs - 44 weeks
Vertex	\$100,000 income maximum	\$10,000 maximum
Janssen	500% of FPL	\$25 per Rx - \$25,000 maximum for OOPs
Gilead	\$100,000 or 500% of FPL	20% of regimen cost - \$25 per Rx - \$16,800 maximum for OOPs (\$5 for 90%)

CURRENT 2014 HIV PRICES

Company	Drug	Price
Merck	Isentress	\$12,889
ViiV	Tivicay	\$14,105
Gilead	Stribild	\$28,109
ViiV	Triumeq	\$26,488

The price of Triumeq is less than the price of its component parts and less than the price of Stribild, Tivicay + Truvada and Tivicay + Epzicom.

HIV PIPELINE

- **Single Drugs:**
 - **Gilead: Cobicistat, elvitegravir (two of the component parts of Stribild)**
 - **Merck: MK1439 (doravirine) - NNRTI**
 - **BMS: 663068 - attachment inhibitor**
 - **BMS: 955176 - maturation inhibitor**
 - **BMS: 936559 - anti-PDL1 for cure research**

HIV PIPELINE

- **Single tablet regimens (STRs), AKA fixed dose combinations (FDCs):**
 - **ViiV and Janssen: Tivicay + Edurant**
 - **Gilead and BMS: Cobi + Reyataz**
 - **Gilead and Janssen: Cobi + Prezista**
 - **GSK and Janssen: Long-acting injectables
GSK1265744 + TMC278 - AEs, adherence?**

2014 HCV PRICES

- **Vertex Incivek \$66,152 21.8% 2011-13**
- **Merck Victrelis \$40,118 25% 2011-13**
- **Janssen Olysio \$66,360 0% Nov 2013**
- **Gilead Sovaldi \$1000/\$84,000**
- **Gilead 2 drug regimen - \$84,000 + ???**
- **AbbVie 4 or 5 regimen (3 or 4 pills) ± RBV???**
- **BMS 2 drug regimen + Sovaldi - \$84,000 + ???**

12 WEEK HCV PIPELINE

- **Gilead: Sovaldi (nuc) + ledipasvir (polymerase)??**
- **AbbVie: ABT450/r (PI - paritaprevir + Norvir) + ABT267 (ombitasvir) + ABT333 (NS5A - dasabuvir) ± RBV???**
- **BMS: Daclatasvir (Daklinza) + Sovaldi??**
- **90-100% cure rate (SVR) - interferon free - no SAEs**
- **Cost-effectiveness, not if drugs are not accessible**

8-24 WEEK HCV PIPELINE

- **BMS: Asunaprevir (Sunvepra) + Daklinza (NS5A polymerase) + BMS791325 (NS5B) - 12 wks**
- **BMS: Asunaprevir (Sunvepra) + Daklinza - 24 wks**
- **Merck: MK5172 + RBV, (PI) 12 wks vs 24 wks**
- **Merck: MK5172 + MK8742 (NS5A) \pm RBV 8 vs 12**
- **Sovaldi + ledipasvir 8 wks???**
- **Treatmentactiongroup.org/pipeline-report/2014s**

ACA ACCESS ISSUES

- **Lack of capacity: ADAPs vs all states and payers**
- **ACA mandated OOP maximums - \$6,350/\$12,700 = underinsured. (FCP Ask: \$6350 for OOPs. Gilead has agreed to cover \$6000 for HIV OOPs.)**
- **Specialty Tiering: Tier 4 and 5**
 - **Cost sharing and preauthorization**
 - **Adherence issues and discrimination**
- **Co-pay programs in jeopardy - federal programs?**

ACA ADVOCACY

- **FPC: \$6350 vs Gilead's \$6000 vs PAN's \$4000???**
- **Patient Access Network Foundation (PAN) - ViiV**
- **Co-Pay program for Medicare/Medicaid patients**
 - **Avoids OIG inducement issues**
- **Underinsured program coverage for all patients:**
 - **Eligibility criteria: 500% of FPL**
 - **Provides up to \$4,000 for annual OOPs**
 - **Privately underinsured subject to funds**

MEDICAID ACCESS ISSUES: HIV MEDICATIONS - SECT 1937

- **Pre-ACA: Drugs from all companies participating in Medicaid rebate programs are covered**
- **Fewer drugs available to ACA designated Medicaid expansion clients because of a switch in CMS policy on Essential Health Benefits (EHBs) - 2013**
- **States may now cover a minimum of one drug per class consistent with the state's "benchmark" plan**
- **Dramatically limits required number of drugs to be covered by state ACA Exchange plans**
- **At worst only, one drug per therapeutic class might be included on a state Exchange formulary**

MEDICAID ACCESS ISSUES: HEPATITIS C MEDICATIONS

- **Medicaid Utilization Management Examples:**
 - **Prescribed by Hepatologist, GI or ID specialists**
 - **No illicit drug and/or alcohol: 3, 6 or 12 months**
 - **Testing before or during treatment; counseling**
 - **Evidence of Stage 3 or 4 fibrosis**

PRICING/ACCESS ADVOCACY

- **Direct Actions:**
 - **AIDS Healthcare Foundation (AHF)**
 - **Treatment Action Group, Vocal NY, Health GAP, 1199SEIU United Healthcare Workers East**
- **Media and Web Actions:**
 - **AHF, Campaign for Rx Affordability, FPC**
- **Access Actions:**
 - **CHLPI & PI; IDSA, HIVMA and AAHIVMA**
 - **FPC: Co-Pay Programs for Medicare/Medicaid and PAP coverage for the underinsured**

LEGISLATIVE ADVOCACY

- **Senate Investigation of Gilead**
- **Federal and State Legislation**
- **Federal: Patients' Access to Treatment Act of 2013 H.R. 460 - David B. McKinley (R-WV)**
 - **Limits specialty tiering and cost sharing**
 - **10% difference between same tier drugs**
 - **Avalere: \$3 annual premium increase**
 - **3% chance passing - ACA lobbying???**
- **State: CA, DE, HI, IL, LA, MD, NY, VA (\leq \$150)**

ACA ADVOCACY

- **Discrimination lawsuits:**
 - **Federal vs state court actions**
 - **Federal: HHS vs DOJ actions**
 - **State Actions: State by state**
 - **CHLPI: Louisiana**
 - **AIDS Institute: Florida**
 - **County vs county differences: Ohio**
- **Medicaid expansion in ALL states**

FAIR PRICING COALITION

Fair Pricing Coalition: HIV

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www.fairpricingcoalition.org

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