Fair Pricing Coalition Pricing, Access, Advocacy

Lynda Dee & Murray Penner FAPP Meeting September 10, 2014



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



HISTORY

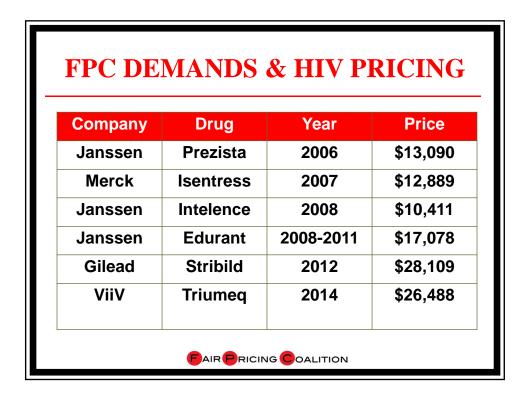
- Worked with ADAP Directors before creation of the ADAP Crisis Task Force (ACTF)
- First ever price freeze (2 years 2002)
 - Resulted in \$50MIL savings for ADAPs
- Currently works in conjunction with ACTF
- Involved in HCV since 2010

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



FAIR PRICING COALITION

HIV PRICE INCREASES SINCE FDA APRROVAL

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 APRROVAL

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%

FAIR PRICING COALITION

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:

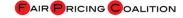
Tivicay: 4.9%Epzicom: 6.9%

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) + 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, <u>DE</u>, HI, IL, LA, <u>MD</u>, NY, VA (≤ \$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 Fair Pricing Coalition: Hepatitis C

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www.fairpricingcoalition.org

