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

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

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug</th>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janssen</td>
<td>Prezista</td>
<td>2006</td>
<td>$13,090</td>
</tr>
<tr>
<td>Merck</td>
<td>Isentress</td>
<td>2007</td>
<td>$12,889</td>
</tr>
<tr>
<td>Janssen</td>
<td>Intelence</td>
<td>2008</td>
<td>$10,411</td>
</tr>
<tr>
<td>Janssen</td>
<td>Edurant</td>
<td>2008-2011</td>
<td>$17,078</td>
</tr>
<tr>
<td>Gilead</td>
<td>Stribild</td>
<td>2012</td>
<td>$28,109</td>
</tr>
<tr>
<td>ViiV</td>
<td>Triumeq</td>
<td>2014</td>
<td>$26,488</td>
</tr>
</tbody>
</table>
## HIV Price Increases Since FDA Approval

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug</th>
<th>Price Increase</th>
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<tbody>
<tr>
<td>Janssen</td>
<td>Prezista</td>
<td>2006 56% - 8.5%</td>
</tr>
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<td>Janssen</td>
<td>Intelence</td>
<td>2008 43% - 7.2%</td>
</tr>
<tr>
<td>Janssen</td>
<td>Edurant</td>
<td>2008 22% - 8.9%</td>
</tr>
<tr>
<td>Merck</td>
<td>Isentress</td>
<td>2007 39% - 6.3%</td>
</tr>
<tr>
<td>ViiV</td>
<td>Combivir</td>
<td>1997 118% - 8.1%</td>
</tr>
<tr>
<td>ViiV</td>
<td>Lexiva</td>
<td>2003 96% - 9.6%</td>
</tr>
<tr>
<td>ViiV</td>
<td>Epzicom</td>
<td>2004 78% - 9.1%</td>
</tr>
<tr>
<td>ViiV</td>
<td>Tivicay</td>
<td>2013 4.9% - 4.9%</td>
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<tr>
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<tbody>
<tr>
<td>AbbVie</td>
<td>Norvir</td>
<td>1997 478% - 38%</td>
</tr>
<tr>
<td>AbbVie</td>
<td>Kaletra</td>
<td>2005 50% - 3.7%</td>
</tr>
<tr>
<td>BMS</td>
<td>Sustiva</td>
<td>1998 144% - 9.3%</td>
</tr>
<tr>
<td>BMS</td>
<td>Reyataz</td>
<td>2003 79% - 7.9%</td>
</tr>
<tr>
<td>BMS</td>
<td>Atripla</td>
<td>2006 78% - 9.8%</td>
</tr>
<tr>
<td>Gilead</td>
<td>Viread</td>
<td>2001 168% - 13.4%</td>
</tr>
<tr>
<td>Gilead</td>
<td>Emtriva</td>
<td>2003 107% - 10.2%</td>
</tr>
<tr>
<td>Gilead</td>
<td>Truvada</td>
<td>2004 97.2% - 10.2%</td>
</tr>
<tr>
<td>Gilead</td>
<td>Complera</td>
<td>2011 20.4% - 8.2%</td>
</tr>
<tr>
<td>Gilead</td>
<td>Stribild</td>
<td>2012 4.9% - 2.5%</td>
</tr>
</tbody>
</table>
RECENT PRICE INCREASES:
BRISTOL-MYERS SQUIBB

<table>
<thead>
<tr>
<th>Date of Increase</th>
<th>Drug</th>
<th>Price Increase</th>
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<tbody>
<tr>
<td>January 2013</td>
<td>Sustiva</td>
<td>9.7%</td>
</tr>
<tr>
<td>January 2013</td>
<td>Reyataz</td>
<td>7.9%</td>
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<td>January 2014</td>
<td>Reyataz</td>
<td>7.9%</td>
</tr>
<tr>
<td>June 2014</td>
<td>Sustiva</td>
<td>7%</td>
</tr>
</tbody>
</table>

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 Trumeq 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

<table>
<thead>
<tr>
<th>Company</th>
<th>Patient Assistance Program</th>
<th>Co-payment Assistance Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck</td>
<td>500% of FPL</td>
<td>20% of 12 Rxs - 44 weeks</td>
</tr>
<tr>
<td>Vertex</td>
<td>$100,000 income maximum</td>
<td>$10,000 maximum</td>
</tr>
<tr>
<td>Janssen</td>
<td>500% of FPL</td>
<td>$25 per Rx - $25,000 maximum for OOPs</td>
</tr>
<tr>
<td>Gilead</td>
<td>$100,000 or 500% of FPL</td>
<td>20% of regimen cost - $25 per Rx - $16,800 maximum for OOPs ($5 for 90%)</td>
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# CURRENT 2014 HIV PRICES

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The price of Triumeq is less than the price of its component parts and less than the price of Strivid, 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 + ???

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**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, DE, HI, IL, LA, MD, 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

<table>
<thead>
<tr>
<th>Fair Pricing Coalition: HIV</th>
<th>Fair Pricing Coalition: Hepatitis C</th>
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<tbody>
<tr>
<td>Bill Arnold</td>
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<tr>
<td>Paul Arons</td>
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<tr>
<td>Jeff Berry</td>
<td>Bruce Burkett</td>
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<td>Lanny Cross</td>
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<td></td>
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www.fairpricingcoalition.org