Health Systems Integration for HIV and Hepatitis
Discriminatory Design
HIV Treatment in the Marketplace
Public Health and Insurance Partnerships to Ensure Access to HIV and HCV Medications

Virginia’s Experience
Diana Jordan, RN MS
Director, Division of Disease Prevention
• Population 8.3M
• Politically red and blue, jurisdiction by jurisdiction
  • Democratic Governor and Republic General Assembly
• Adjacent to the nation’s capitol
• Heavy military infrastructure
• 24,853 people living with HIV (298.5/100K)
  • 929 new HIV cases in 2015
ADAP Clients Enrolled and Receiving Medications: Unduplicated 2014 to 2016

Number of ADAP Clients (Unduplicated)

- Enrolled (Unduplicated)
- Received a Medication/Copayment Charged to ADAP**
Virginia’s Third Party Payer Environment Prior to Patient Protection and Affordable Care Act (ACA) Implementation

- No high risk insurance pool
- Virginia implemented the first HIV specific State Pharmaceutical Assistance Program (SPAP)
  - ADAP covers Medicare D premiums and cost shares
Health Care Reform
ADAP Enrolled by Program: 2014 to 2016
One Insurance Carrier has 67% of VA ADAP Clients

Collaboration

- Client data exchange
- Re-enrollment support
- Resolution of pharmacy issues at point of sale
- Refunds of cost shares to ADAP rather than client
  - Reconciliation of Maximum Out Of Pocket costs

Challenges

- Requested changes to our enrollment practices across carriers
- Requested access to our 340B discount
- Requested we enroll all clients in Gold Plans
Addressing Challenges: Engage New Stakeholders

- Elected and appointed officials
- Legislative staff
- Lobbyists

- Professional Associations
  - Medical Societies

- Medical Service Providers

- Consumers
- Vulnerable Population

- Other Service Providers

- Insurance Carriers
  - Pharma Manufacturers
  - Medicaid
  - Insur.
  - Regulators

- Health System Administrators
- ACA enrollment proponents
Addressing Challenges: Learn the Insurance Regulatory Structure

- Bureau of Insurance
- State Corporation Commission
- General Assembly
- Office of Licensure and Certification
- Virginia Department of Health
- Secretary of Health and Human Resources
- Governor
Assess Impact-Year 1: ACA-associated with improved HIV VL suppression

Affordable Care Act Qualified Health Plan Coverage: Association With Improved HIV Viral Suppression for AIDS Drug Assistance Program Clients in a Medicaid Nonexpansion State

Kathleen A. McManus, Anne Rhodes, Steven Bailey, Lauren Yerkes, Carolyn L. Engelhard, Karen S. Ingersoll, George J. Stukensborg, and Rebecca Dillingham

1Division of Infectious Diseases and International Health, Departments of 2Public Health Sciences, and 3Psychology and Neurobehavioral Sciences, University of Virginia, Charlottesville, and 4Virginia Department of Health, Richmond

Affordable Care Act Qualified Health Plan Enrollment for AIDS Drug Assistance Program Clients: Virginia’s experience and best practices

Running Title: Best Practices for ACA Enrollment of ADAP Clients

Kathleen A. McManus, MD, MSCR1, Robert C. Rodney BSW2, Anne Rhodes, MS, PhD3, Steven Bailey, LCSW3, and Rebecca Dillingham, MD, MPH1

1Division of Infectious Diseases and International Health, University of Virginia, Charlottesville, VA, 2University of Virginia Ryan White HIV Clinic, Charlottesville, VA, 3Virginia Department of Health, Richmond, VA
APCD Hepatitis C Treatment Data (top) compared to Surveillance data (bottom)

**Hepatitis C Treatment** prescriptions per 100 new HCV diagnoses (2014)

- 0 - 10.3
- 10.4 - 31.1
- 31.2 - 63.4
- 63.5 - 123.1
- 123.2 - 200.0
- 200.1 - 333.3
- 333.4 - 650.0

**Hepatitis C Diagnoses** per 100,000 excluding incarcerated individuals

- 0 - 52.4
- 52.5 - 105.5
- 105.6 - 206.1
- 206.2 - 374.6
- 374.7 - 712.9
Addressing Gaps: Collaboration With Medicaid

• Provision Try-1115 Waiver for People Living with HIV did not move forward
• Some Success-ADAP providing HCV treatment for individuals Medicaid denied
• Next Adventure-HIV Health Improvement Affinity Group
  – HIV screening policy
  – Viral load suppression
Think “upstream”

Diana.Jordan@vdh.virginia.gov
Terry Leach
Amida Care
Public Health and Medicaid Partnerships to Ensure Access to HIV and HCV Medications

Terry Leach, PharmD.
VP Pharmacy Services
Background

• HIV SNP
  – ~6200 Members in NYC
• Top Co-morbid Conditions
  – Severe Mental Illness
  – Substance Abuse Disorder
  – Hep C

• Regulatory Challenges
  – Specialty Pharmacy Limits
  – Timely Rate Adjustments
  – Rebate restrictions
• HIV & HCV
• Significant FWA Concerns
HIV

- ARV Rebates
- Pharmacy Efficiency Adjustments - *Proposed*
  - MAC Pricing
  - Clinical Edits
    - Quantity Limits
      - ART
    - Dosing limits
    - Age Edits
    - Therapeutic Duplication
      - ART Single Drug Therapy
      - All within a 30 day period
- War on Opioids
2015-2016 Hep C Monthly Requests/Projected Cost

- **Approved**
- **Denied**
Hep C Cost as % of Invoice

Jan-15: 12%
Feb-15: 18%
Mar-15: 23%
Apr-15: 24%
May-15: 24%
Jun-15: 24%
Jul-15: 21%
Aug-15: 16%
Sep-15: 14%
Oct-15: 14%
Nov-15: 13%
Dec-15: 12%
Jan-16: 12%
Feb-16: 4%
Mar-16: 11%

% of Hep C Invoice Cost
• HCV drug Prior Authorization Approval Rate (95%)
  – 450 requests in 2015
    • 410 approved (1<sup>st</sup> request)
    • 19 approved (2<sup>nd</sup> request)
• Outcomes
  ~ 97% Cure rate for those who completed therapy
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 52-26-12
Baltimore, Maryland  21244-1850

Center for Medicaid and CHIP Services

NOVEMBER 5, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.
In the News:
NY Attorney General Sues Health Plans

The Washington Post
Business

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Help us show you better ads by updating your ads settings.

Insurers Expand Hepatitis C Drug Coverage After N.Y. Probe (3)
Rebecca Spalding, Zachary Tracer and Christie Smythe
Apr 28, 2016 6:47 am ET
(Bloomberg) — Seven insurers including Anthem Inc. and Affinity Health Plan reached an agreement with New York Attorney General Eric Schneiderman to cover hepatitis C drugs for patients in the early stages of the disease and for drug and alcohol users.
Five of the insurers have covered only patients who also had liver scarring or other serious effects of the disease, according to a statement Tuesday by Schneiderman. Four have denied coverage to alcohol and drug users even though dirty needles are a main mode of transmission.
New treatments for the disease are highly effective and can cost as much as $94,500 before discounts, according to court documents. Some insurers have denied coverage to those in the early stages of the disease on the basis that treatment is not "medically necessary" until they have more advanced liver scarring.
In a lawsuit against an insurer not a part of Tuesday’s deal, Schneiderman said these denials were motivated by cost considerations rather than medical advice. Five of the seven insurers in Tuesday’s agreement had similar policies in place and have now agreed to cover the drugs for patients in early stages of the disease.
"New Yorkers diagnosed with hepatitis C deserve to be treated, and these agreements will vastly improve access to the medications needed to cure their disease," Schneiderman said in the statement. "My office will do everything possible to ensure treatment for hepatitis C is available, so that patients can be cured and we can minimize the spread of the disease to others."
Companies Covered
The agreement announced Tuesday was the result of an earlier probe into health insurers' hepatitis C coverage in the state. The agreement was reached with Affinity Health Plan, Anthem’s Empire BlueCross BlueShield, Excellus Health Plan, HealthNow, Independent Health, United Healthcare/Oxford and MVP Health Plan, the attorney general said.
Melissa Golen, a spokeswoman for HealthNow, said the company "has cooperated fully" with the state and has modified policies in light of new research. An MVP spokeswoman, Jo Ann LeSage Nelson, said the agreement is consistent with "principles and practices already in place at the company."
A spokesperson for Schneiderman's office said in a statement that the agreement is "in the public interest and is reflective of a properly


2015 Prior Authorization Analysis

40 cases denied

- 16 denied
- 1 Disenrolled
- 19 approved
- 2 prescribed withdrew request
- 2 additional information needed
Denial Reasons (16 cases)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Total</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV unsuppressed</td>
<td>6</td>
<td>TAP Referral, CM</td>
</tr>
<tr>
<td>Lack of efficacy</td>
<td>5</td>
<td>Hepatocellular CA - Previously treated</td>
</tr>
<tr>
<td>Incomplete data received from provider</td>
<td>1</td>
<td>Lab data</td>
</tr>
<tr>
<td>Preferred alternative recommended</td>
<td>4</td>
<td>IFN based treatment preferred</td>
</tr>
</tbody>
</table>
Future Treatment Opportunities
Future Treatment Opportunities

Reinfection/Retreatment
Future Treatment Opportunities

Reinfection/Retreatment

<table>
<thead>
<tr>
<th>PATIENT TREATMENT &amp; EDUCATION READINESS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Readiness:</strong> (documentation required)</td>
</tr>
<tr>
<td>□ Patient demonstration of readiness, willingness, and ability to adhere to the regimen</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Education Readiness: (documentation required)</th>
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<tr>
<td>□ Patient understands reinfection of Hepatitis C is still possible after being cured of Hepatitis C</td>
</tr>
<tr>
<td>□ Patient understands not to engage in risky and unhealthy behaviors which would lead to reinfection.</td>
</tr>
</tbody>
</table>

**Amida Care resources are available to support member adherence and lifestyle modification. Please check below to request any additional type of support or services for member**

□ Additional support needed for member by Amida Care (Please specify type of support or education needed):
Future Treatment Opportunities

New Drug -
• Sofosbuvir (Sof) + velpatasvir (Vel)-Sof/Vel
• Pan-genotypic NS5A inhibitor
• Once daily oral
• Approved – June 28, 2016
• Official label:
  – w or w/o ribavirin
  – 12 week therapy
• ~74,000 for 12 weeks
Discussion
Questions