Management of HCV Infection in the Federal Bureau of Prisons

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Hepatitis C Medicaid Affinity Group

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Federal Bureau of Prisons
Objectives

- Describe the demographics of the Federal Bureau of Prisons (BOP)
- Discuss the BOP strategy for management of hepatitis C virus (HCV) infection
- Explain the BOP’s transitional care and release planning for HCV
BOP Inmate Demographics

- Total population at BOP facilities - 151,764
- Average age: 41 years
- Gender: 93% male, 7% female
- Race/ethnicity: white- 58%; black- 38%; Hispanic -33% (all races)
- Citizenship: USA- 80%; Mexico- 13%
- Security levels: high- 12%; medium- 30%; low- 38%; minimum- 17%
- Inmates released: 2018- NA; 2017- 42,638; 2016- 43,864

NA = Not available
Epidemiology of HCV Infection

- Prevalence of chronic HCV in U.S.A.*
  - 2.27 million (0.93% of U.S. population)*
    - 2 million in general population;
    - 9 states have 52% of all HCV cases
  - Approx. 12% to 30% prevalence rates in prison populations
    - 231K incarcerated / institutionalized/homeless
    - Known prevalence in BOP population = 3% to 6%

BOP Strategy for Evaluation & Management of HCV infection

- Current - “Test and Treat”
  - Test all inmates for HCV
    - “Opt-out” approach
    - At intake for newly incarcerated and at various times for inmates not previously tested
  - All sentenced inmates are eligible for treatment
    - Consider pre-trial and pre-sentence inmates with high priority criteria
BOP Strategy for Treatment of HCV infection

Current
- All sentenced inmates are eligible for treatment
  - Consider pre-trial and pre-sentence inmates with high priority criteria
- Prioritize if large numbers of patients to treat
- All HCV DAAs are non-formulary in the BOP
- Regional / Central review and approval required
BOP Priority Criteria

- BOP priority criteria for treatment
  - Priority Level 1: High Priority
  - Priority Level 2: Intermediate Priority
  - Priority Level 3: Low Priority

- Current role of priority criteria
  - Used to prioritize for treatment not to determine eligibility
Priority Level 1: High Priority

- Advanced hepatic fibrosis or cirrhosis
  - APRI ≥ 2, clinical cirrhosis, or liver biopsy stage 3-4 / 4
- Liver transplant recipients
- Hepatocellular carcinoma
- Comorbid conditions associated with HCV
  - Cryoglobulinemia with renal disease or vasculitis
  - Certain lymphomas / hematologic malignancies
  - Porphyria cutanea tarda
- Immunosuppressant Medications
  - Chemotherapy, TNF inhibitors, other immunomodulators
- Continuity of care
  - New BOP intakes arriving on HCV medication
Priority Level 2: Intermediate Priority

- Progressive fibrosis
  - APRI score ≥ 0.7
  - Metavir fibrosis stage ≥ 2 on liver biopsy (if done)
- Medical conditions assoc. with more rapid progression of fibrosis
  - Coinfection with HBV or HIV
  - Comorbid liver disease (autoimmune hepatitis, hemochromatosis, fatty infiltration or steatohepatitis)
  - Diabetes mellitus, & other conditions with insulin resistance
- Chronic kidney disease with GFR < 60
- Birth Cohort 1945-1965
Priority Level 3: Low Priority

- APRI < 0.7
- Stage 0 to 1 on liver biopsy
Selecting An Appropriate DAA Regimen

- Factors that affect regimen selection
  - Genotype
  - HCV treatment history & resistance associated substitutions
  - Presence of cirrhosis, compensated or decompensated
  - Potential drug-drug interactions
  - Cost and ease of administration

- Special considerations required for
  - Decompensated cirrhosis
  - Liver transplant recipients
  - Chronic kidney disease with GFR < 30
Additional Factors for Consideration of Treatment

- **Positive factors**
  - Life expectancy > 18 months
  - Sufficient time to complete tx prior to release
  - Willingness and ability to adhere to tx regimen.

- **Negative factors**
  - Pregnant
  - Ongoing prohibited substance use / high risk behavior
  - Reinfection after HCV treatment while incarcerated
BOP Strategy for Selecting a DAA Regimen

- **Step 1:**
  - Identify AASLD recommended regimens based on genotype, fibrosis stage, and prior treatment experience

- **Step 2:**
  - Assess for drug interactions

- **Step 3:**
  - Use the most cost effective medication from steps 1 and 2
AASLD: “In general, when given a choice between recommended HCV DAA regimens, the less costly regimen is preferred as a more efficient use of resources (even if it requires multiple tablet dosing).”*

Cost of DAA medications may vary based on individual contracts

* [https://www.hcvguidelines.org/](https://www.hcvguidelines.org/)
HCV Treatment Options in 2019

- **3 Classes of HCV DAA Medications**
  - NS₃/₄A Protease Inhibitors (-previr)
  - NS₅A Inhibitors (-asvir)
  - NS₅B (Polymerase) Inhibitors (-buvir)

- **DAA combination therapy options**
  - Elbasvir/grazoprevir (Zepatier®)
  - Glecaprevir/pibrentasvir (Mavyret®)
  - Ledipasvir/sofosbuvir (Harvoni®)
  - Paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira XR™)
  - Sofosbuvir/velpatasvir (Epclusa®)
  - Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)
Selecting a DAA Regimen*  
Genotype 1, 4, 5, or 6

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>GENOTYPES 1A AND 1B&lt;sup&gt;E,F,G&lt;/sup&gt;</th>
<th></th>
<th>GENOTYPE 4</th>
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<tbody>
<tr>
<td></td>
<td>NO CIRRHOSIS</td>
<td>COMPENSATED CIRRHOSIS</td>
<td>NO CIRRHOSIS</td>
<td>COMPENSATED CIRRHOSIS</td>
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<td>Treatment-Naive</td>
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<td></td>
<td>EBR/GZR: 12 wks</td>
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<td>EBR/GZR: 12 wks</td>
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<td>GLE/PIB: 8 wks</td>
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<td>LDV/SOF: 12 wks</td>
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<td>SOF/VEL: 12 wks</td>
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<td>SOF/VEL: 12 wks</td>
<td>SOF/VEL: 12 wks</td>
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<tr>
<td>Treatment-Experienced w/ PEG-IFN + RBV</td>
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<td></td>
<td>EBR/GZR: 12 wks</td>
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<td>GLE/PIB: 12 wks</td>
<td>GLE/PIB: 12 wks</td>
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<td></td>
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<td>SOF/VEL: 12 wks</td>
<td>SOF/VEL: 12 wks</td>
<td>SOF/VEL: 12 wks</td>
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<tr>
<td>Treatment-Experienced w/ PI + PEG-IFN + RBV</td>
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<td></td>
<td></td>
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<td></td>
<td>GLE/PIB: 12 wks</td>
<td>GLE/PIB: 12 wks</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td></td>
<td>LDV/SOF: 12 wks</td>
<td>LDV/SOF: 12 wks</td>
<td></td>
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<tr>
<td></td>
<td>SOF/VEL: 12 wks</td>
<td>SOF/VEL: 12 wks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-Experienced w/ SOF + RBV + PEG-IFN OR SOF + PI +/-RBV</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>GLE/PIB: 12 wks (1a or 1b)</td>
<td>GLE/PIB: 12 wks (1a)</td>
<td>SOF/VEL/VOX: 12 wks (1a)</td>
<td>SOF/VEL/VOX: 12 wks</td>
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<tr>
<td></td>
<td>SOF/VEL: 12 wks (1b)</td>
<td>SOF/VEL: 12 wks (1b)</td>
<td>SOF/VEL/VOX: 12 wks (1b)</td>
<td>SOF/VEL/VOX: 12 wks</td>
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<tr>
<td>Treatment-Experienced w/ NSSA inhibitor</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SOF/VEL/VOX: 12 wks</td>
<td>SOF/VEL/VOX: 12 wks</td>
<td>SOF/VEL/VOX: 12 wks</td>
<td>SOF/VEL/VOX: 12 wks</td>
</tr>
</tbody>
</table>

- Refer to the AASLD/IDSA website for most current recommendations, www.hcvguidelines.org

+ An 8 week course of LDV/SOF may be considered for TN who are non-black race, not HIV infected, and have an HCV RNA < 6 million IU/ml.
## HCV Statistics: Expenditures

<table>
<thead>
<tr>
<th>FY</th>
<th>Approvals</th>
<th>Treated</th>
<th>Expenditure</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>363</td>
<td>N/A</td>
<td>$1,950,026</td>
<td>Peg/RBV</td>
</tr>
<tr>
<td>2011</td>
<td>494</td>
<td>277</td>
<td>$1,931,064</td>
<td>Late 2011 added BOC, TVR</td>
</tr>
<tr>
<td>2012</td>
<td>371</td>
<td>348</td>
<td>$4,378,238</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>387</td>
<td>366</td>
<td>$4,168,807</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>180</td>
<td>138</td>
<td>$5,917,436</td>
<td>Added SOF, SOF/SMV, Harvoni</td>
</tr>
<tr>
<td>2015</td>
<td>222</td>
<td>227</td>
<td>$13,646,354</td>
<td>Added DCV, Technivie, Viekira XR</td>
</tr>
<tr>
<td>2016</td>
<td>311</td>
<td>342</td>
<td>$14,033,347</td>
<td>Added Zepatier, Epclusa</td>
</tr>
<tr>
<td>2017</td>
<td>904</td>
<td>765</td>
<td>$27,581,085</td>
<td>Added Mavyret</td>
</tr>
<tr>
<td>2018</td>
<td>1683</td>
<td>NA</td>
<td>$24,982,235</td>
<td>Added Vosevi</td>
</tr>
</tbody>
</table>
HCV Statistics: Outcomes

- Population of inmates available for 12 week post-treatment viral load (Genotypes 1, 2, and 3)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR</td>
<td>88%</td>
</tr>
<tr>
<td>D/C</td>
<td>1%</td>
</tr>
<tr>
<td>Failure</td>
<td>8%</td>
</tr>
<tr>
<td>Refused on treatment</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
</tbody>
</table>

- SVR < 90% likely due to high numbers with cirrhosis prioritized for treatment
- D/C: ADR/labs, noncompliance, other reasons
# HCV Statistics: BOP Liver-Related Mortality

<table>
<thead>
<tr>
<th>Liver-related deaths</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total numbers</td>
<td>42</td>
<td>52</td>
<td>22</td>
<td>15</td>
</tr>
<tr>
<td>Percentage of all deaths</td>
<td>8.6%</td>
<td>11%</td>
<td>5.6%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Rank order</td>
<td>4th</td>
<td>3rd</td>
<td>4th</td>
<td>7th</td>
</tr>
</tbody>
</table>
Barriers and Best Practices

- Administrative hurdles
  - Check lists and order sets
  - Team medicine
- Cost
  - Non-formulary requests
  - Pharmaceutical contracts
  - Budget project codes / set-asides
- Knowledge deficits / lack of experience
  - Clinical Guidance & education
  - Co-management
  - HCV pharmacist consultants
Data Mining and Analytics

- Data drives decision-making
  - Intake screening for HCV / prevalence rates
  - Prevalence rates of each genotype
  - Treatment outcomes
  - Clinical care utilization evaluation
  - Mortality reviews
Transitional Care / Release Planning
(1 of 3)

- HCV treatment ordinarily not started if insufficient time to complete before release.
  - If started, will usually send enough medication with patient to finish treatment after release

- Social worker involved in release planning for ill / medically disabled inmates (Care 3 or 4)
  - Facilitates application for health care coverage, medical appointments, placement, etc.
  - Not specific for follow up of HCV
Numerous challenges facing inmates releasing from prison

Health coverage for incarcerated people
If you're incarcerated, some special rules apply to your health care options.

Incarceration and the Marketplace
For purposes of the Marketplace, "incarcerated" means serving a term in prison or jail.

- Incarceration doesn't mean living at home or in a residential facility under supervision of the criminal justice system, or living there voluntarily. In other words, incarceration doesn't include being on probation, parole, or home confinement.
- You're not considered incarcerated if you're in jail or prison pending disposition of charges. In other words, being held but not convicted of a crime.

If you're incarcerated, you can't use the Marketplace to buy a private insurance plan. But after you're released you can.
Status of State Action on the Medicaid Expansion Decision

- Adopted
- Not Adopted
Opt-out HCV screening for all BOP inmates
All sentenced BOP inmates eligible for treatment consideration
Review of all HCV treatment requests
DAA regimen selection based follows AASLD guidelines.
Management of HCV Infection in the Federal Bureau of Prisons

- Discussion
  - Comments or
  - Questions