

Management of HCV Infection in the Federal Bureau of Prisons

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Hepatitis C Medicaid Affinity Group

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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

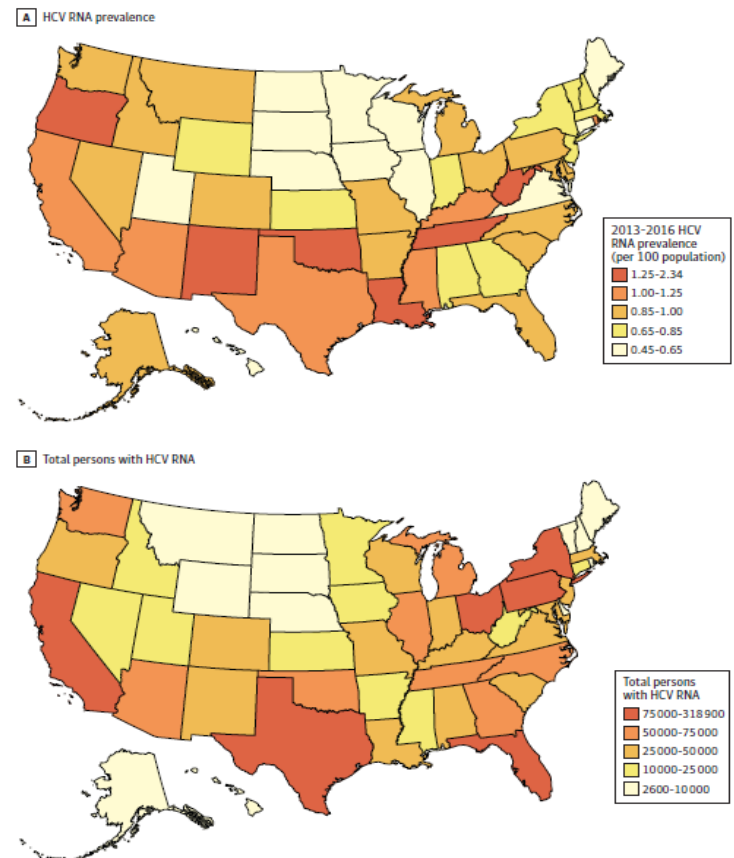
- Total population at BOP facilities - 151,764
- Average age: 41 years
- Gender: 93% male, 7% female
- Race/ethnicity: white- 58%; black- 38%; Hispanic -33% (all races)
- Citizenship: USA-80%; Mexico-13%
- Security levels: high-12%; medium-30%; low-38%; minimum-17%
- Inmates released: 2018- NA; 2017-42,638;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

Figure 1. Estimated Hepatitis C Virus (HCV) RNA Prevalence and Total Persons With HCV RNA, Indicating Current Infection, United States and District of Columbia, 2013 to 2016



*<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719137><https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719137>

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

HCV Medication Costs

- 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/>

HCV Treatment Options in 2019

- *3 Classes of HCV DAA Medications*
 - NS_{3/4A} Protease Inhibitors (-previr)
 - NS_{5A} Inhibitors (-asvir)
 - NS_{5B} (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

CONDITION	TREATMENT OPTIONS BY HCV GENOTYPE ^D			
	GENOTYPES 1A AND 1B ^{E,F,G}		GENOTYPE 4	
	NO CIRRHOSIS	COMPENSATED CIRRHOSIS	NO CIRRHOSIS	COMPENSATED CIRRHOSIS
Treatment-Naïve	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 8 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 12 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 8 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 12 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks
Treatment-Experienced w/ PEG-IFN + RBV	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 8 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 8 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ EBR/GZR: 12 wks ▶ GLE/PIB: 12 wks ▶ SOF/VEL: 12 wks
Treatment-Experienced w/ PI + PEG-IFN + RBV	<ul style="list-style-type: none"> ▶ GLE/PIB: 12 wks ▶ LDV/SOF: 12 wks ▶ SOF/VEL: 12 wks 	<ul style="list-style-type: none"> ▶ GLE/PIB: 12 wks ▶ SOF/VEL: 12 wks 	NA	NA
Treatment-Experienced w/ SOF + RBV + PEG-IFN OR SOF + PI +/-RBV	<ul style="list-style-type: none"> ▶ GLE/PIB: 12 wks (1a or 1b) ▶ SOF/VEL/VOX: 12 wks (1a) ▶ SOF/VEL: 12 wks (1b) 	<ul style="list-style-type: none"> ▶ GLE/PIB: 12 wks (1a or 1b) ▶ SOF/VEL/VOX: 12 wks (1a) ▶ SOF/VEL: 12 wks (1b) 	<ul style="list-style-type: none"> ▶ SOF/VEL/VOX: 12 wks 	<ul style="list-style-type: none"> ▶ SOF/VEL/VOX: 12 wks
Treatment-Experienced w/ NS5A inhibitor	<ul style="list-style-type: none"> ▶ SOF/VEL/VOX: 12 wks 	<ul style="list-style-type: none"> ▶ SOF/VEL/VOX: 12 wks 	<ul style="list-style-type: none"> ▶ SOF/VEL/VOX: 12 wks 	<ul style="list-style-type: none"> ▶ SOF/VEL/VOX: 12 wks

- Table excerpted from BOP Clinical Guidance, available at https://www.bop.gov/resources/health_care_mngmt.jsp.
- 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

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

HCV Statistics: Outcomes

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

Outcome	Total
SVR	88%
D/C	1%
Failure	8%
Refused on treatment	1%
Other	2%

- 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

Liver-related deaths	2014	2015	2016	2017
Total numbers	42	52	22	15
Percentage of all deaths	8.6%	11%	5.6%	3.9%
Rank order	4 th	3 rd	4 th	7 th

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

Transitional Care / Release Planning (2 of 3)

- Numerous challenges facing inmates releasing from prison

The screenshot shows the HealthCare.gov website. At the top, there is a navigation bar with the HealthCare.gov logo, a search bar, and links for 'ESPAÑOL', 'LOG IN', 'Get Coverage', 'Keep or Update Your Plan', 'See Topics', and 'Get Answers'. Below the navigation bar, the main content area is titled 'Health coverage for incarcerated people'. A sub-header reads 'Incarceration and the Marketplace'. A paragraph explains that for Marketplace purposes, 'incarcerated' means serving a term in prison or jail. A bulleted list provides details: incarceration doesn't mean living at home or in a residential facility under supervision; and you're not considered incarcerated if you're in jail or prison pending disposition of charges. A red circle highlights a paragraph stating that incarcerated individuals cannot use the Marketplace to buy a private insurance plan, but they can after release. On the right side, there are sections for 'START HERE' (with links for enrollment, Medicaid & CHIP info, and document sending) and 'RELATED CONTENT' (with links for dates & deadlines and Medicaid expansion).

HealthCare.gov

ESPAÑOL
LOG IN

Get Coverage Keep or Update Your Plan See Topics Get Answers Search

EMAIL PR

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.

START HERE

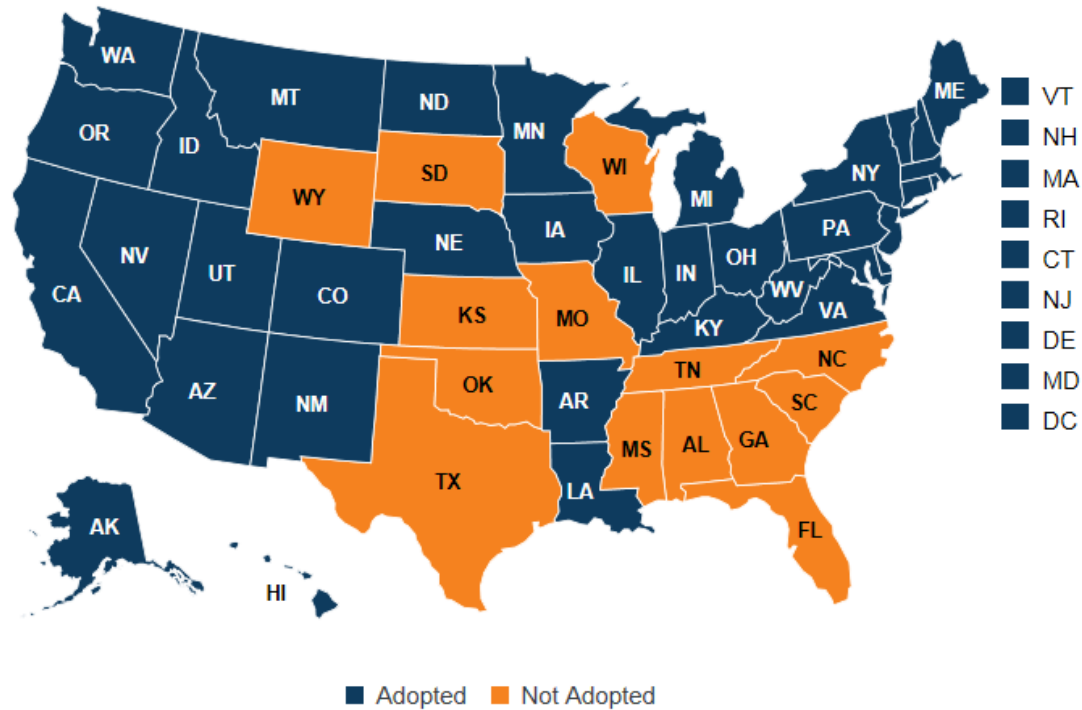
- [See if you can enroll](#)
- [Get Medicaid & CHIP info](#)
- [Send documents](#)

RELATED CONTENT

- [Dates & deadlines](#)
- [Medicaid expansion & you](#)

Transitional Care / Release Planning (3 of 3)

Status of State Action on the Medicaid Expansion Decision



Summary

BOP HCV Management

- 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