HIV/HCV Co-Infection Watch: July 2018

The HIV/HCV Co-Infection Watch is a publication of the Community Access National Network (CANN). It is a patient-centric informational portal serving three primary groups – Patients, Healthcare Providers, and AIDS Service Organizations.

Learn more: http://www.tiicann.org
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Overview

and report on HIV and Hepatitis C (HCV) co-infection in the United States. The HIV/HCV Co-Infection Watch delivers the information from a “patient-centric” perspective on access to care and treatment.

People living with HIV-infection face a higher risk of long-term liver failure as a result of co-infection with HCV. In fact, HCV-related liver failure has become the leading non-AIDS-related cause of death among people living with HIV-infection in the United States – and as such, treating HCV is of paramount importance.

With well over half of the HCV-infected population falling near, at, or below the Federal Poverty Limit (FPL), patients frequently rely on coverage provided by state- and federally-funded programs – such as the AIDS Drugs Assistance Program (ADAP), Medicaid and Medicare. It is for these patients, and those who still, for whatever reason, lack coverage, that the HIV/HCV Co-Infection Watch advocates.

The research component of the HIV/HCV Co-Infection Watch is designed to gather the following information:
• Formulary information in every state and territory covered by ADAP, as it relates to coverage for HCV drug therapies.
• Formulary information for HCV drug therapies covered by the State Medicaid programs.
• Formulary information for HCV drug therapies covered by the Veterans Affairs system.
• Information about patient assistance programs (PAPs).
• State-by-state harm reduction data for HIV, HCV, and HIV/HCV co-infection, as well as relevant public policy changes.
• Up-to-date information as it relates to HCV treatment.
• Statistics related to HIV/HCV co-infection (Existing Diagnoses, New Diagnoses, and Morbidity Rates).

For the purposes of this report, coverage is divided into three categories:
• No Coverage – no HCV treatments are covered
• Basic Coverage – only older HCV regimens (Ribavirin, Pegylated-Interferon, etc.) are covered; no Direct Acting Antivirals
• Expanded Coverage – Direct Acting Antivirals are covered

The HIV/HCV Co-Infection Watch list-serve sign-up form is available online: http://tiicann.org/signup_listserv.html
Findings

The following is a summary of the key findings for July 2018:

- **AIDS Drug Assistance Programs**
  There are 56 State and Territorial AIDS Drug Assistance Programs (ADAPs) in the United States, 44 of which offer some form of coverage for Hepatitis C (HCV) treatment. Of those programs, 38 have expanded their HCV coverage to include the regimens that serve as the current Standard of Care (SOC) for Hepatitis C treatment. Five (5) programs offer only Basic Coverage and 13 programs offer No Coverage. Three (3) territories – American Samoa, Marshall Islands, and Northern Mariana Islands – are not accounted for in this data. A state-by-state Drug Formulary breakdown of coverage is included in Figure 1, with accompanying drug-specific maps in Figures 2 – 13.

  Additionally, patient assistance programs (PAPs) are manufacturer-provided programs that offer coverage to low-income uninsured and/or underinsured patients who are unable to afford the cost of their medications. These programs often cover part or all of the cost of treatment at the manufacturer’s expense.

  Although many (if not most) ADAP clients already meet the income qualifications required for eligibility, our findings suggest that these patients may not be receiving information about or assistance with applying for coverage under these programs: only 19 ADAPs reported that they actively provide clients with this information, 7 states – AL, AK, CT, DE, MN, DC, PR – indicated that they do not provide this information.

- **Medicaid Programs**
  There are 59 State and Territorial Medicaid programs in the United States, and data is represented for all fifty states and the District of Columbia. As of October 01, 2016, all 50 states offer Expanded Coverage. All states will cover at least one of the regimens that serve as the current SOC for Hepatitis C treatment. A state-by-state PDL breakdown of coverage is included in Figure 14, with accompanying drug-specific maps in Figures 15 – 26.

  With respect to PAPs, while many Medicaid clients already meet the income requirements for eligibility, Gilead Sciences, the manufacturer of Sovaldi and Harvoni, automatically decline applicants currently enrolled in Medicaid. This is in response to Medicaid programs actively denying coverage for patients, despite having current or developing pricing negotiations with Gilead for the drugs.
Findings
The following is a summary of the key findings for July 2018:

**Veterans Administration:**
On March 09, 2016, the U.S. Department of Veterans Affairs (VA) announced that it was able to fund care for all Veterans with HCV for Fiscal Year (FY) 2016, regardless of the stage of the patient’s liver disease. VA has treated over 76,000 Veterans infected with Hepatitis C, and approximately 60,000 have been cured since 2014. In FY 2015, VA allocated $696 million for new HCV drugs – 17% of the VA’s total pharmacy budget – and in FY 2016, VA anticipates spending approximately $1 billion on HCV drugs (Office of Public and Intergovernmental Affairs, 2016).

**Harm Reduction Programs:**
Every State and Territory in the United States currently provides funding for low-income people living with substance abuse issues to enter state-funded rehabilitation services (National Center for Biotechnology Information, n.d.). Forty-three (43) States and Territories currently have syringe exchange programs in place, regardless of state. Fifty (50) states and the District of Columbia have expanded access to Naloxone to avert opioid drug overdoses. Forty-eight (48) states have Good Samaritan laws or statutes that provide protection for those rendering emergency services during drug overdoses. Forty-one (41) states have in place Mandatory Prescription Drug Monitoring Programs (PDMPs) that require physicians and/or pharmacists to report prescriptions written or filled to a state agency for monitoring. Thirty-eight (38) states have Doctor Shopping Laws preventing patients from attempting to receive multiple prescriptions from numerous physicians, and/or from withholding information in order to receive prescriptions. Thirty-seven (37) states mandate a Physical Exam Requirement in order for patients to receive a prescription for opioid drugs. Twenty-six (26) states have in place an ID Requirement mandating that people filling opioid prescriptions present a state-issued ID prior to receiving their prescription. Thirty-six (36) states require prescribing physicians to attend mandatory and continuing opioid prescribing education sessions. All but three (3) states – AZ, CA, & SD – have Medicaid doctor/pharmacy Lock-In programs that require patients to receive prescriptions from a single physician and/or fill prescriptions from a single pharmacy. A state-by-state program breakdown is included in Figure 27, with accompanying drug-specific maps in Figures 28 – 36.
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Figure 1. – Figure 13.
### AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

**Figure 1.** (*Indicates “Preferred Drug”)

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## AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

### Figure 1. (∗ Indicates “Preferred Drug”) Con’t.

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

There are currently 44 AIDS Drug Assistance Programs (ADAPs) that cover some form of HCV drug therapies as part of their approved drug formularies. To learn more about ADAPs or their approved drug formularies, please visit http://adap.directory.

Figure 2.
Basic Coverage Map Key:
- Lime Green: Basic Coverage
- Red: No Coverage

[Map of the United States showing basic drug coverage and no coverage areas.]
Figure 3.
Sovaldi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Olysio Coverage Map
July 2018

Figure 4.
Olysio Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Harvoni Coverage Map
July 2018

Figure 5.
Harvoni Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Viekira Pak Coverage Map

July 2018

Figure 6.
Viekira Pak Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Daklinza Coverage Map
July 2018

Figure 7.
Daklinza Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

[Map showing Daklinza coverage across the United States with states colored in lime green (coverage) or red (no coverage).]

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Technivie Coverage Map

July 2018

Figure 8.
Technivie Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Zepatier Coverage Map
July 2018

Figure 9.
Zepatier Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Epclusa Coverage Map
July 2018

Figure 10.
Epclusa Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

Created with mapchart.net ©
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Viekira XR Coverage Map
July 2018

Figure 11.
Viekira XR Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

Created with mapchart.net ©
Figure 12.
Vosevi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Mavyret Coverage Map
July 2018

Figure 13.
Mavyret Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Of the 56 respective State and Territorial ADAPs, only 13 (ID, KS, KY, MS, MT, NV, NM, OH, UT, VT, GU, PW, VI) do not offer any coverage for HCV drug therapies. States whose formularies are not available on the state-run website have been checked against the most recent National Alliance of State and Territorial AIDS Directors (NASTAD) formulary database (last updated February 01, 2018). The data presented are current as of June 15, 2018.

July 2018 Updates:
• New Mexico has moved to an Open Formulary
• Hawaii has expanded treatment to include Daklinza, Technivie, Zepatier, and Vosevi

July 2018 Notes:
• States with Open Drug Formularies: IL, IA, MA, MN, NE, NH, NJ, NM, OH, OR, WA
  • N.B. – Although Ohio is listed by NASTAD as having an open formulary, both NASTAD’s ADAP Formulary Database and Ohio’s ADAP website indicates that the state does not offer any treatment for HCV
• Colorado’s ADAP offers five coverage options – Standard ADAP, HIV Medical Assistance Program (HMAP), Bridging the Gap Colorado (BTGC), HIV Insurance Assistance Program (HIAP), and Supplemental Wrap Around Program (SWAP). ‘Yes’ indications in Figure 1. for Colorado denote that at least one of these programs offers coverage for each respective drug. The Standard ADAP Formulary covers medications only if funds are available to do so
• Louisiana’s ADAP (Louisiana Health Access Program – LA HAP) offers two coverage options – Uninsured (Louisiana Drug Assistance Program – L-DAP) and Insured (Health Insurance Program – HIP). HIP pays for the cost of treatment only if the client’s primary insurance covers the drug under its formulary
Medicaid Programs & HCV Treatments

Figure 14. – Figure 26.
### Medicaid Programs & HCV Treatments

*Figure 14. (* Indicates “Preferred Drug”)*

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## Medicaid Programs & HCV Treatments

*Figure 14. (* Indicates “Preferred Drug”) Con’t.*

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### Medicaid Programs & HCV Treatments

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Medicaid Programs & HCV Treatments

There are currently **50** Medicaid programs that cover some form of HCV-related drug therapies as part of their Preferred Drug Lists. To learn more about Medicaid or their Preferred Drug Lists, please visit [http://medicaiddirectors.org](http://medicaiddirectors.org).

Figure 15.
Basic Coverage Map Key:
- Light Blue: Covered
- Yellow: Not Covered
Medicaid Programs & HCV Treatments
Medicaid Sovaldi Coverage Map
July 2018

Figure 16.
Sovaldi Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments

Olysio Coverage Map

July 2018

Figure 17.
Medicaid Olysio Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Harvoni Coverage Map
July 2018

Figure 18.
Medicaid Harvoni Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments

Viekira Pak Coverage Map

July 2018

Figure 19.
Medicaid Viekira Pak Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 20.
Medicaid Daklinza Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments

Technivie Coverage Map

July 2018

Figure 21.

Medicaid Technivie Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Zepatier Coverage Map
July 2018

Figure 22.
Medicaid Zepatier Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Epclusa Coverage Map
July 2018

Figure 23.
Medicaid Epclusa Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Viekira XR Coverage Map
July 2018

Figure 24.
Medicaid Viekira XR Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments

Vosevi Coverage Map
July 2018

Figure 25.
Medicaid Vosevi Map Key:
- Light Blue: Covered
- Yellow: Not Covered
Medicaid Programs & HCV Treatments
Mavyret Coverage Map
July 2018

Figure 26.
Medicaid Mavyret Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments

All 50 states and the District of Columbia continue to offer some form of HCV coverage. All 50 states and the District of Columbia have expanded their Preferred Drug Lists to include at least one HCV Direct Acting Agent (DAA).

July 2018 Updates:
• Olysio is being removed from formularies following discontinuation by Janssen Therapeutics in 2018
• New Jersey and Rhode Island have both opened up restrictions for HCV DAA treatment (see Latest News section)

July 2018 Notes:
• The following states’ Medicaid programs offer multiple coverage plans for their respective Medicaid clients. An indication of “Y” in Figure 12 for these states indicates that at least one of that state’s Medicaid coverage plans offers coverage for the drug in question. The plan highlighted in bold typeface represents the most comprehensive plan with the most drugs covered in the respective state:
  – Hawaii – (1.) Advantage Plus; (2.) QUEST Integration
  – Kentucky – (1.) Aetna Better Health of Kentucky; (2.) Anthem BlueCross BlueShield; (3.) Humana – CareSource; (4.) Magellan Medicaid; (5.) Passport Health Plan; (6.) WellCare of Kentucky
  – New Jersey – (1.) Aetna; (2.) AmeriGroup NJ; (3.) Horizon NJ Health; (4.) UnitedHealthcare of New Jersey; (5.) WellCare
  – New Mexico – (1.) BlueCross BlueShield of New Mexico; (2.) Molina Healthcare of New Mexico; (3.) Presbyterian Centennial Care; (4.) UnitedHealthcare Community Plan of New Mexico
  – Ohio – (1.) Buckeye Health Plan – MyCare Ohio; (2.) CareSource Ohio Medicaid; (3.) Molina Healthcare of Ohio; (4.) Paramount Advantage; (5.) UnitedHealthcare Community Plan of Ohio.
• No data is has been made available by the Medicaid programs in the U.S. Territories

* Medicaid coverage excludes patients from most drug manufacturer patient assistance programs (PAPs)
Veterans Affairs & HCV Treatments
Veterans Affairs & HCV Treatments

The Veteran’s Administration (VA) currently offers coverage for the following HCV drugs: Sovaldi, Olysio, Harvoni, Viekira Pak, Daklinza, Technivie, Zepatier, Epclusa, and Viekira XR. This is according to the most recent VA National Formulary, dated November 2016. The VA Treatment Considerations and Choice of Regimen for HCV-Mono-Infected and HIV/HCV Co-Infected Patients (Update September, 2016) lists the following therapies as preferred treatments:

**Genotype 1:**
- Treatment-naïve, HCV RNA <6 million IU/mL, HCV-mono-infected, non-cirrhotic – Harvoni (8 weeks)
- Treatment-naïve/experienced (prior Pegylated Interferon (PEG-INF)/Ribavirin only), non-cirrhotic or cirrhotic, CTP A:
  - Zepatier
    - Genotype 1a (GT1a) without baseline Nonstructural Protein SA (NS5A) Resistance-Associated Polymorphisms (RAPs) prior to treatment – Zepatier (12 weeks)
    - GT1a with baseline NS5A RAPs – Zepatier + Ribavirin (16 weeks)
    - GT1b – Zepatier (12 weeks)
  - Harvoni (12 weeks)
    - Add Ribavirin for treatment-experienced cirrhotic patients
  - Viekira Pak / Viekira XR (12 weeks)
    - Test for HIV before using
      - GT1a – Viekira Pak / Viekira XR + Ribavirin (12 weeks)
    - May consider 24 weeks in cirrhotic patients or null responders
      - GT1b – Ribavirin not needed
    - Alternative Option: If Treatment-Experienced, Cirrhotic, and RBV Intolerant/Contraindicated: Epclusa (12 weeks)
- Treatment-naïve/experienced (prior PEG-INF/Ribavirin only), Cirrhotic, CTP B, C:
  - Harvoni + Ribavirin (600mg/day and increase by 200mg/day every 2 weeks only as tolerated) - (12 weeks)
  - If Ribavirin intolerant/contraindicated – Harvoni (24 weeks)
  - Alternative Option: Epclusa + Ribavirin (12 weeks); start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
**Veterans Affairs & HCV Treatments**

- Treatment-experienced (prior NS3/4A Inhibitor + PEG-INF/Ribavirin or Sovaldi + Ribavirin +/- PEG-INF), non-cirrhotic or cirrhotic, CTP A:
  - Zepatier + Ribavirin (NOT FDA approved in prior Sovaldi + Ribavirin +/- PEG-INF treatment failures)
    - GT1a without baseline NS5A RAPs – Zepatier (12 weeks)
    - GT1a with NS5A RAPs – Zepatier (16 weeks)
    - GT1b – Zepatier (12 weeks)
  - Harvoni + Ribavirin – (12 weeks) (NOT FDA approved in prior Sovaldi + Ribavirin +/- PEG-INF treatment failures)
  - Alternative Option: If treatment-experienced, Cirrhotic, and RBV Intolerant/Contraindicated: Epclusa (12 weeks)

- Treatment-experienced (Prior NS3/4A inhibitor + PEG-INF/Ribavirin or Sovaldi + Ribavirin +/- PEG-INF), Cirrhotic, CTP B, C:
  - Harvoni + Ribavirin (600mg/day and increase by 200mg/day every 2 weeks only as tolerated) - (12 weeks)
  - If Ribavirin intolerant/contraindicated – Harvoni (24 weeks)
  - NOT FDA approved in prior Sovaldi + Ribavirin +/- PEG-INF treatment failures
    - Treatment-experienced (Prior NS5A-containing regimen), Non-Cirrhotic/Cirrhotic
      - Alternative Option: Epclusa + Ribavirin (12 weeks); start a lower RBV doses as clinically indicated (e.g., baseline Hgb)

- Treatment-experienced (Prior NS5A-Containing Regimen), Cirrhotic/Non-Cirrhotic:
  - Test for RAS to NS5A prior to re-treatment; consult with an expert based on results

**Genotype 2:**

- Treatment-naïve/experienced (Prior Sovaldi + Ribavirin +/- PEG-INF), Non-Cirrhotic or Cirrhotic, CTP A:
  - Epclusa (12 weeks)
  - If Sovaldi-experienced – Epclusa + Ribavirin (12 weeks)
  - Alternative Options:
    - Daklinza + Sovaldi (12 weeks / 12-16 weeks if CTP A) - *NOT FDA APPROVED*
    - Daklinza + Sovaldi + Ribavirin (12 weeks / 12-16 weeks) - *NOT FDA APPROVED*
Veterans Affairs & HCV Treatments

Genotype 2 Con’t:

- Treatment-naïve/experienced (Prior Sovaldi + Ribavirin +/- PEG-INF), Cirrhotic, CTP B, C:
  - Epclusa + Ribavirin (12 weeks)
  - Start at lower Ribavirin doses as clinically indicated
  - Alternative Option: Daklinza + Sovaldi + Ribavirin (12 weeks or 12-16 weeks if treatment-experienced) - NOT FDA APPROVED

- Treatment-experienced (Prior NS5A-containing regimen), Non-cirrhotic or Cirrhotic:
  - Consult with an expert based on results

Genotype 3:

- Treatment naïve, Non-cirrhotic – Epclusa (12 weeks)
  - Alternative Option: Daklinza + Sovaldi (12 weeks)

- Treatment naïve, Cirrhotic:
  - Epclusa (12 weeks)
  - CTP A: Test for NS5A RAPs and if Y93H is present – Epclusa + Ribavirin (12 weeks)
    - Alternative Option: Daklinza + Sovaldi + Ribavirin (12-16 weeks)
  - CTP B or C – Epclusa + Ribavirin (12 weeks) – Start at lower Ribavirin doses as clinically indicated
    - Alternative Option: CTP B or C – Daklinza + Sovaldi + Ribavirin (12-24 weeks)

- Treatment-experienced (Prior PEG-INF/Ribavirin +/- Sovaldi), Non-Cirrhotic:
  - Epclusa (12 weeks)
  - If PEG-INF/Ribavirin experienced only, test for NS5A RAPs and if Y93H RAP is present – Epclusa + Ribavirin (12 weeks)
  - If Sofosbuvir-experienced – Epclusa + Ribavirin (12 weeks)
    - Alternative Options:
      - Daklinza + Sovaldi (12 weeks)
      - Daklinza + Sovaldi + Ribavirin (12-16 weeks)
Veterans Affairs & HCV Treatments

- Treatment-experienced (Prior PEG-INF/Ribavirin +/- Sovaldi), Cirrhotic:
  - Epclusa (12 weeks)
  - CTP A: Test for NS5A RAPs and if Y93H RAP is present – Epclusa + Ribavirin (12 weeks)
    - Alternative Option: Daklinza + Sovaldi + Ribavirin (12-16 weeks / 12-24 weeks if Sofosbuvir-experienced)
  - If Sofosbuvir-experienced – Epclusa + Ribavirin (12 weeks)
  - CTP B or C – Epclusa + Ribavirin (12 weeks) – start at lower Ribavirin doses as clinically indicated
    - Alternative Option: Daklinza + Sovaldi + Ribavirin (12-24 weeks)
- Treatment-experienced (Prior NS5A-containing regimen), Non-Cirrhotic or Cirrhotic:
  - Test for NS5A RAPs prior to re-treatment
  - Consult with expert based on results

Genotype 4:

- Treatment-naïve, Non-Cirrhotic or Cirrhotic, CTP A:
  - Zepatier (12 weeks)
  - Harvoni (12 weeks)
  - Technivie + Ribavirin (12 weeks) – Dasabuvir not needed
- Treatment-experienced (Prior PEG-INF/Ribavirin only), Non-Cirrhotic or Cirrhotic, CTP A:
  - Zepatier + Ribavirin (16 weeks)
  - Harvoni (12 weeks)
  - Technivie + Ribavirin (12 weeks) – Dasabuvir not needed
    - Alternative Option: Epclusa (12 weeks)
- Treatment naïve or experienced (Prior PEG-INF/Ribavirin only), Cirrhotic, CTP B, C:
  - Harvoni + Ribavirin (600mg/day and increase as tolerated) – (12 weeks)
    - NOT FDA approved with Ribavirin
Veterans Affairs & HCV Treatments

Genotype 4 Con’t:

– Alternative Option: Epclusa + Ribavirin (12 weeks / start at lower RBV doses as clinically indicated)

Genotype 4, 5 or 6:

• Without cirrhosis or with compensated cirrhosis (CTP A) – Epclusa (12 weeks)
• Decompensated cirrhosis (CTP B or C) – Epclusa + Ribavirin (12 weeks)
Patient Assistance Programs (PAPs)
Patient Assistance Programs (PAPs)

The drug manufacturers and various national nonprofit organizations offer a variation of patient assistance programs (PAPs) to assist patients in accessing treatments. They include:

**Support Path (Gilead Sciences):**
- Financial Assistance
  - Provides Co-Pay Coupons for Harvoni and Epclusa; the PAP for Sovaldi is no longer available
  - Co-Pay Coupons cover out-of-pocket costs up to 25% of the catalog price of a 12-week regimen of either Harvoni or Epclusa
  - Excludes patients enrolled in Medicare Part D or Medicaid
- Insurance Support
  - Researches and verifies patient’s benefits, and gives information they need about coverage options and policies
  - Explain Prior Authorization process and works with HCV Specialist’s office so they can submit PA forms to a patient’s insurance company
  - May be able to provide assistance with appeals process
- Website: [http://www.mysupportpath.com/](http://www.mysupportpath.com/)

**CarePath Savings Program (Janssen / Johnson & Johnson)**
- Financial Assistance
  - Eligible patients receive an Olysio Savings Card, allowing them to pay $5 per fill, with a maximum benefit of $50,000/year and expires 12 months after activation (whichever comes first)
  - Excludes patients enrolled in Medicare Part D or Medicaid
- Website: [http://www.janssenprescriptionassistance.com/olysio-cost-assistance](http://www.janssenprescriptionassistance.com/olysio-cost-assistance)
Patient Assistance Programs (PAPs)

AbbVie HCV Co-Pay Card:
- Financial Assistance
  - Card provides covers out-of-pocket costs up to 25% of the catalog price of AbbVie HCV products (Technivie, Viekira Pak, or Viekira XR)
  - Patient pay as little as $5
  - Excludes patients enrolled in Medicare Part D, Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs
- Website: [https://www.viekira.com/content/pdf/copaycard.pdf](https://www.viekira.com/content/pdf/copaycard.pdf)

Patient Support CONNECT™ (Bristol-Myers Squibb):
- Financial Assistance:
  - Covers out-of-pocket costs for Daklinza for up to a maximum benefit of $5,000 per 28-day supply of 30mg or 60mg regimen; maximum benefit of $10,000 per 28-day supply of 90mg regimen
  - Excludes patients enrolled in Medicare Part D, Medicare Advantage, Medicaid, Medigap, Veterans Affairs, or Department of Defense Programs (other programs may apply)
- Website: [https://bmsdm.secure.force.com/patientsupportconnect/patient](https://bmsdm.secure.force.com/patientsupportconnect/patient)

Multiuse Savings Coupon (Merck):
- Financial Assistance
  - Covers out-of-pocket costs for Zepatier for up to a maximum benefit of 25% of catalog price
  - Excludes patients enrolled in Medicare Part D, Medicare Advantage, Medicaid, Medigap, Veterans Affairs, or Department of Defense Programs (other programs may apply)
- Website: [https://www.activatethecard.com/7208/#](https://www.activatethecard.com/7208/#)
Patient Assistance Programs (PAPs)

NeedyMeds:

- NeedyMeds Drug Discount Card
  - Designed to lower cost of prescription medications by up to 80% at participating pharmacies
  - NeedyMeds DOES NOT keep a list of prescription medications covered
  - No eligibility requirements
  - Patients CANNOT be enrolled in any insurance
  - CANNOT be used in combination with government healthcare programs, but CAN be used IN PLACE of program
  - CANNOT be combined with other offers

The Assistance Fund:

- Status: Open
- Website: [https://tafcare.org/patients/covered-diseases/](https://tafcare.org/patients/covered-diseases/)

Patient Advocate Foundation Co-Pay Relief:

- Status: Open
- Maximum award of $24,000
- Eligibility Requirements:
  - Patient must be insured, and insurance must cover prescribed medication
  - Confirmed HCV diagnosis
  - Reside and receive treatment in the U.S.
  - Income falls below 400% of FPL with consideration of the Cost of Living Index (COLI) and the number in the household
- Website: [https://www.copays.org/diseases/hepatitis-c](https://www.copays.org/diseases/hepatitis-c)
Patient Assistance Programs (PAPs)

Patient Access Network (PAN) Foundation:

- Status: **Closed**
- Co-Pay Assistance with a maximum award of $7,200
  - Patients may apply for a second grant during their eligibility period subject to availability of funding
- Eligibility Requirements:
  - Must be being treated for HCV
  - Have insurance that covers HCV prescribed medication
  - Income falls below 500% of FPL
  - Residing and receiving treatment in the U.S. (citizenship NOT required)

HealthWell Foundation:

- Status: **Open**
- Co-Pay Assistance with a maximum award of $30,000
- Minimum Co-Pay Reimbursement Amount: $5
- Eligibility Requirements:
  - Must be being treated for HCV
  - Have insurance that covers HCV prescribed medication
  - Income falls below 500% of FPL
  - Receiving treatment in the U.S.
- Website: [https://www.healthwellfoundation.org/fund/hepatitis-c/](https://www.healthwellfoundation.org/fund/hepatitis-c/)
Harm Reduction Programs

Figure 27. – Figure 36.
Harm Reduction Programs

The HIV/HCV Co-Infection Watch monitors the following Harm Reduction programs nationally:

• **Syringe Exchange:**
  Syringe Exchange (or Needle Exchange) programs exist to provide injection drug users (or those whose prescriptions require injection) with clean syringes and/or in exchange for used ones.

• **Expanded Naloxone:**
  Naloxone is a drug used to counteract the effects of opioid overdoses. Expanded Access refers to one of more of the following conditions: Naloxone purchase without a prescription; availability to schools, hospitals, and emergency response units for use in the event of an overdose.

• **Good Samaritan Laws:**
  Good Samaritan Laws are laws that are designed to protect emergency services personnel, public or private employees, and/or citizens from being held legally liable for any negative healthcare outcomes as a result of providing "reasonable measures" of emergent care.

• **Mandatory PDMP Reporting:**
  Prescription Drug Monitoring Programs (PDMPs) are programs established by state and/or federal law that requires prescribing physicians and the fulfilling pharmacies to report to a state agency one or more of the following data points: Patient Names; Specific Drug(s) Prescribed; Prescription Dosage; Date; Time; Form of State-Issued ID.

• **Doctor Shopping Laws:**
  Doctor Shopping Laws are those laws designed to prevent patients from seeking one or more of the same prescription from multiple doctors through the use of subterfuge, falsifying identity, or any other deceptive means. Some states also include provisions that prohibit patients from seeking a new prescription if another physician has denied a similar prescription within a certain period of time.

• **Physical Exam Required:**
  Physical Exam Requirements are those that mandate that the prescribing physician perform a physical examination on a patient before providing a prescription for a controlled substance to determine if the prescription is medically necessary.
Harm Reduction Programs

• **ID Required for Purchase of Opioid Prescription:**
  Federal law requires anyone purchase a controlled substance to provide a state-issued identification (“I.D.”) in order to fill the prescription. Mandatory ID requirements go further and require that this information be recorded and stored in an effort to prevent the same patient from obtaining multiple or repeated prescriptions in a given period of time.

• **Prescriber Education Required/Recommended:**
  States that require/do not require that prescribing physicians undergo special training related to safer prescribing and utilization practices.

• **Lock-In Program:**
  Lock-In Programs are laws requiring that patients either receive prescriptions from only one physician and/or fill prescriptions from only one pharmacy.
## Harm Reduction Programs

**Figure 27.**

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## Harm Reduction Programs

### Figure 27.

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## Harm Reduction Programs

**Figure 27.**

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Harm Reduction Programs
Syringe Exchange Coverage Map
July 2018

Figure 28.
Syringe Exchange Map Key:
Purple: Syringe Exchange(s)
Red: No Syringe Exchange(s)
Harm Reduction Programs
Expanded Naloxone Coverage Map
July 2018

Figure 29.
Expanded Naloxone Map Key:
Purple: Expanded Naloxone
Red: Restricted Naloxone
Harm Reduction Programs
Good Samaritan Laws Coverage Map
July 2018

Figure 30.
Good Samaritan Laws Map Key:
Purple: Good Samaritan Laws
Red: No Good Samaritan Laws
Harm Reduction Programs
Prescription Drug Monitoring Programs (PDMPs) Coverage Map
July 2018

Figure 31.
PDMPs Map Key:
Purple: Mandatory PDMPs
Red: No Mandatory PDMPs
Harm Reduction Programs
Doctor Shopping Laws Coverage Map
July 2018

Figure 32.
Doctor Shopping Laws Map Key:
Purple: Doctor Shopping Laws
Red: No Doctor Shopping Laws
Harm Reduction Programs
Physical Exam Required Coverage Map
July 2018

Figure 33.
Physical Exam Required Map Key:
Purple: Physical Exam Required
Red: No Physical Exam Required
Harm Reduction Programs
I.D. Required Coverage Map
July 2018

Figure 34.
I.D. Requirement Map Key:
Purple: I.D. Required
Red: No I.D. Required
Harm Reduction Programs
Prescriber Education Required Coverage Map
Julu 2018

Figure 35.
Prescriber Ed Required Map Key:
Purple: Prescriber Ed Required
Red: No Prescriber Ed Required
Harm Reduction Programs
Lock-In Program Coverage Map
July 2018

Figure 36.
Lock-In Program Map Key:
Purple: Lock-In Program
Red: No Lock-In Program
Harm Reduction Programs

Harm Reduction, as it relates to opioid abuse and HCV, are measures designed to serve as preventive or monitoring efforts in combating opioid prescription drug and heroin abuse, and as an effect, helping to prevent the spread of HCV and HIV. The Co-Infection Watch covers the following measures: Syringe Exchange, Expanded Naloxone Access, Good Samaritan Laws, Mandatory PDMP Reporting, Doctor Shopping Laws, Physical Exam Requirements, ID Requirements for Purchase, Required or Recommended Prescriber Education, and Lock-In Programs.

July 2018 Updates:
• No updates

July 2018 Notes:
• The following state has pending legislation that would legalize state-sponsored Syringe Exchanges – IA, MS
• The following states have pending legislation requiring Mandatory PDMP reporting – CO, IA, MO, OR, WY
• The following state has pending legislation imposing Doctor Shopping Laws – MI, MO, PA, VA
• The following state has pending legislation requiring a Physical Examination before Opioid Prescribing – MA
• The following state has pending legislation requiring Prescriber Education – HI
Regional Trends
Hepatitis Treatment in the West South Central Region

Figure 37.
Regional Trends
Hepatitis C Treatment in the West South Central Region – District 07 – West South Central (AR, LA, OK, TX)
The West South Central Region is comprised of four states, including AR, LA, OK, TX.

- **HBV (2016 National Rate – 1.0):**
  This region has a relatively low burden of HBV, with only Arkansas above the national rate of Acute HBV infection with a rate of 1.6. Louisiana is at 1.0, Oklahoma at 0.8, and Texas at 0.6. This generally low rate of infection is more likely due to low utilization of testing/screening services than from an actual low rate of infection. Access to comprehensive healthcare services in this region is limited.

- **HCV (2016 National Rate – 1.0):**
  This region has a relatively low burden of HCV, with no states rising above the national rate of Acute HCV infection. The rates are as follows: AR – 0.0; LA - 0.1; OK – 0.8; TX – 0.1. Again, this generally low rate of infection is likelier a result of weak screening/testing protocols and availability.

- **Overdose Deaths (2016 National Rate – 19.8):**
  Two states in this region (LA, OK) have overdose death rates higher than the national rate (LA – 21.8; OK – 21.5), ranking them 22nd and 24th respectively.

- **ADAP:**
  All four states have expanded their ADAPs to include HCV Direct-Acting Antivirals.

- **Correctional Hepatitis Testing:**
  Only two states in the region responded to our information request regarding Correctional Disease Screening/Testing – OK and TX. Oklahoma offers Opt-Out testing for HBV and HCV if Clinical Criteria are met; Texas offers Opt-In testing for HBV and HCV on request or if clinical criteria are met.
Latest News
**Latest News**

- **PRODUCT DISCONTINUATION for OLYSIO® (simeprevir) 150 mg capsule**

Janssen will be discontinuing commercial availability of OLYSIO® and will be voluntarily withdrawing the New Drug Application (NDA) for OLYSIO® in the United States effective May 25, 2018. OLYSIO® is indicated for the treatment of adults with chronic hepatitis C virus (HCV) infection: in combination with sofosbuvir in patients with HCV genotype 1 without cirrhosis or with compensated cirrhosis; and/or in combination with peginterferon alfa (Peg-IFN-alfa) and ribavirin (RBV) in patients with HCV genotype 1 or 4 without cirrhosis or with compensated cirrhosis (Janssen Therapeutics, 2018).

- **Kansas Settles Suit Over Hepatitis C Coverage For Medicaid Patients**

Kansas has agreed to settle a lawsuit alleging the state’s Medicaid program sets too many barriers for hepatitis C patients to receive potentially life-saving but expensive medications. Terms of the settlement have yet to be finalized, but the parties filed a notice with the court Tuesday afternoon that they had resolved the case after mediation.

“I feel comfortable saying we have a path forward to making sure all people on Medicaid with hep C will be treated, regardless of their fibrosis score,” said Lauren Bonds, legal director of the ACLU of Kansas, which filed the lawsuit on behalf of two Medicaid patients. Jeff Anderson, secretary of the Kansas Department of Health and Environment and a defendant in the lawsuit, said the parties had reached an agreement in principle to resolve the issues in the case (Margolies, 2018).

- **NJ GIVES MEDICAID PATIENTS WITH HEPATITIS C EARLIER ACCESS TO LIFE-SAVING DRUGS**

Tens of thousands of New Jersey Medicaid patients diagnosed with hepatitis C will no longer have to wait until they have liver damage for their insurance to cover potentially life-saving medical treatments, thanks to a new state program and public funding that could also reduce the spread of the infectious disease. State Department of Human Services Commissioner Carole Johnson announced yesterday that, with the fiscal year 2019 budget recently approved, New Jersey has set aside more than $10 million in state and federal dollars for prescription drugs to help prevent liver destruction associated with hep-C. Until now, these treatments were only available to Medicaid patients who already showed some level of fibrosis, or liver damage (Stainton, 2018).
Latest News

• **RI Expands Medicaid Coverage For Hepatitis C**

Rhode Island’s health insurance program for the poor is expanding treatment for people living with hepatitis C. The state Executive Office of Human Services announced Thursday it will cover treatment for all Medicaid patients with the potentially deadly bloodborne virus affecting the liver. Previously, the state limited treatment for Medicaid patients to only those in advanced stages of the disease, citing the high cost of the medication. The change followed discussions with lawyers representing a Medicaid patient denied coverage. The new policy brings Rhode Island in line with federal medical necessity requirements for Medicaid, according to a statement released by the EOHHS (Arditi, 2018).

• **Plan for safe injection site gets dose of reality over federal drug laws**

There’s a reason San Francisco Mayor London Breed announced that she is opening a model of a safe injection center in the Tenderloin: She’s been warned by the city attorney that opening a real injection site, where drug users can shoot up under supervision, could get her in hot water with the federal government.

According to City Hall sources, City Attorney Dennis Herrera had confidentially advised her predecessor, former Mayor Mark Farrell, and members of the the Board of Supervisors that they could be held criminally liable under federal drug statutes if they attempted to move ahead with the injection centers — that was a red flag warning not to proceed.

One City Hall source privy to the conversations told us Herrera was particularly worried about the threats from the Trump administration to go after drug dealers and new guidelines issued by Attorney General Jeff Sessions in March applying the death penalty to numerous drug-related crimes under existing law.

Earlier this year, Barbara Garcia, director of San Francisco’s Department of Public Health, said she expected to have the first of two privately funded injection sites open in July — with more to follow if they proved a success.

But Garcia has since stepped back. Health Department spokeswoman Rachael Kagan told us that “we are still working through legal barriers.”

City officials estimate that as many as 22,000 intravenous drug users shoot up in San Francisco, leaving behind tens of thousands of dirty needles in the process. The city freely dispenses millions of clean needles a year on demand, arguing that it is the best way to prevent the spread of HIV/AIDS and other diseases. But while polling shows that roughly two-thirds of San Franciscans favor the idea of drop-in facilities for intravenous drug users to shoot up safely and receive medical and other services, there is no getting around the threat of legal action against city officials (Matier & Ross, 2018).
Marcus J. Hopkins is a West Virginia native currently living in his familial hometown of Morgantown, WV. In 2005, Marcus was diagnosed HIV-positive.

After thirty years of involvement in the performing arts (vocal and instrumental music, color guard, and Drum Corps International), he currently spends most of his time dedicated to bringing attention, clarity, and comprehensive education to the world of Patient-Centric HIV and Hepatitis C research and reporting. Marcus presently serves as the Project Director for the HIV/HCV Co-Infection Watch, which is a publication of the Community Access National Network (CANN). He also blogs for CANN’s “Hepatitis: Education, Advocacy & Leadership” (HEAL) coalition.

In his spare time, he’s a video game-addicted, cat-loving insomniac who leaves audiobooks playing in the background at all times.
Disclaimer

Any opinions expressed in this report are the opinions of the Community Access Network, and are in no way to be considered the official position of any other party, including any directors, employees, funders or providers of either ADAP- or Medicaid-related services.

The purpose of these presentations is to provide a clearer picture of the state of the HCV treatment landscape for those patients co-infected with HIV/HCV. While the programs that offer limited or no treatment are color coded, these colors do not represent any judgments made about any of the programs, their directors, their employees, or their providers.

Additionally, any conclusions, observations, or recommendations made related to the design, layout, content, or maintenance of these state-run websites are the opinion of the HIV/HCV Co-Infection Watch, and are not intended to serve as a reflection of the programs, their directors, their employees, or their providers.
Methodology

The HIV/HCV Co-Infection research is conducted using the following resources:

• State- and privately-run websites (publicly available information, only).
• Prior research and reporting conducted by for-profit and non-profit organizations (publicly available information).
• Contact lists from state- and privately-run sources (publicly available information, only).
• Responses to a quarterly formulary survey.

Research gathering is conducted from a “patient perspective,” meaning that the project manager performs all tasks from the view of the patient. When conducting research, the researcher is tasked with considering the following questions:

• Is the information readily available?
• Is the information easy to access, clearly laid out, and easy to understand?
• Does the information answer basic questions about coverage options?
• Is the information up-to-date, recent, and accurate?
• Is the website user-friendly?
• Is there current and correct contact information available?

Using the information gathered during the research phase, data is documented, compiled and presented in a way that is clear and easy to understand. Maps are provided to indicate which states’ and territories’ programs offer HCV treatment coverage, and spreadsheets are provided, as well. “Coverage” is broken down into seven categories - Basic Coverage, Sovaldi, Olysio, Harvoni, Viekira Pak, Daklinza, Technivie, Epclusa, Viekira XR, Vosevi, and Mavyret. This will be expanded as newer treatment options become available.

States and territories where no information could be found, whether because it was not readily available or because those entities failed to respond to requests for information by the researcher, are indicated on the maps by being “greyed” out (as opposed to filled in with color); those programs are indicated in the spreadsheets by being left blank, or with the symbol “?”. Regional Trends tracks coverage data, HCV-related statistics, and harm reduction strategies in specific U.S. Census regions. This section uses data gathered from various government, public, and private resources, including data represented elsewhere in the Report.
References


References


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