HIV/HCV Co-Infection Watch: October 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

The HIV/HCV Co-Infection Watch is a project of the Community Access National Network (CANN) designed to research, monitor 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.

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](http://tiicann.org/signup_listserv.html)
Findings

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

•  **AIDS Drug Assistance Programs**

There are 56 State and Territorial AIDS Drug Assistance Programs (ADAPs) in the United States, 45 of which offer some form of coverage for Hepatitis C (HCV) treatment. Of those programs, 39 have expanded their HCV coverage to include the regimens that serve as the current Standard of Care (SOC) for Hepatitis C treatment. Six (6) programs offer only Basic Coverage and 11 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 – 12.

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 program: 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 13 – 24.

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 October 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 25 – 34.
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Figure 1. – Figure 12.
## 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 45 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](http://adap.directory).

Figure 2.
Basic Coverage Map Key:
- Lime Green: Basic Coverage
- Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Sovaldi Coverage Map
October 2018

Figure 3.
Sovaldi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
Figure 4.
Harvoni Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Viekira Pak Coverage Map
October 2018

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

Daklinza Coverage Map
October 2018

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

Technivie Coverage Map
October 2018

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

![Technivie Coverage Map](image-url)
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Zepatier Coverage Map
October 2018

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

Epclusa Coverage Map

October 2018

Figure 9.

Epclusa Coverage Map Key:
- Lime Green: Coverage
- Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Viekira XR Coverage Map

Figure 10.

Viekira XR Coverage Map Key:
- Lime Green: Coverage
- Red: No Coverage
**AIDS Drug Assistance Programs (ADAPs) & HCV Treatments**

Vosevi Coverage Map

October 2018

**Figure 11.**
Vosevi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

![Vosevi Coverage Map](image-url)
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Mavyret Coverage Map
October 2018

Figure 12.
Mavyret Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

[Map showing coverage and non-coverage of Mavyret across states]
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 October 15, 2018.

October 2018 Updates:
• No updates

October 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 13. – Figure 24.
**Medicaid Programs & HCV Treatments**

*Figure 13. (* Indicates “Preferred Drug”)*

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### Medicaid Programs & HCV Treatments

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### Medicaid Programs & HCV Treatments

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Medicaid Programs & HCV Treatments

There are currently **51** 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 14.**
Basic Coverage Map Key:
- Light Blue: Covered
- Yellow: Not Covered
Medicaid Programs & HCV Treatments
Medicaid Sovaldi Coverage Map
October 2018

Figure 15.
Sovaldi Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 16.
Medicaid Harvoni Map Key:
Light Blue: Covered
Yellow: Not Covered

Medicaid Programs & HCV Treatments
Harvoni Coverage Map
October 2018
Medicaid Programs & HCV Treatments

Viekira Pak Coverage Map
October 2018

Figure 17.
Medicaid Viekira Pak Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Daklinza Coverage Map
October 2018

Figure 18.
Medicaid Daklinza Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 19.
Medicaid Technivie Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Medicaid Zepatier Map Key:
Light Blue: Covered
Yellow: Not Covered

Figure 20.

Medicaid Zepatier Coverage Map
October 2018
Medicaid Programs & HCV Treatments
Epclusa Coverage Map
October 2018

Figure 21.
Medicaid Epclusa Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 22.
Medicaid Viekira XR Map Key:
- Light Blue: Covered
- Yellow: Not Covered
Medicaid Programs & HCV Treatments
Vosevi Coverage Map
October 2018

Figure 23.
Medicaid Vosevi Map Key:
Light Blue: Covered
Yellow: Not Covered

[Map showing Medicaid Vosevi coverage by state, with states like California, Arizona, and Oklahoma marked in yellow for not covered, and others in light blue for covered.]

Figure 24.
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).

October 2018 Updates:
• No updates

October 2018 Notes:
• The follow 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 all HCV drugs. This is according to the most recent VA National Formulary, dated July 2018 (U.S. Dept. of V.A., 2018a). The VA Treatment Considerations and Choice of Regimen for HCV-Mono-Infected and HIV/HCV Co-Infected Patients (U.S. Dept. of V.A., 2018b) lists the following therapies as preferred treatments:

Abbreviations:
- CTP – Child-Turcotte-Pugh (score used to assess severity of cirrhosis)
- IU/mL – International Units Per Milliliter
- PEG-IFN/IFN – Peginterferon/Interferon
- RAS – Resistance-associated substitutions
- RBV – Ribavirin

Genotype 1:
- Treatment-naïve without or with cirrhosis (CTP A):
  - Zepatier: 1 tablet orally daily for 12 weeks if GT1a without baseline NS5A RAS or GT1b
  - Mavyret: 3 tablets orally daily with food
- If non-cirrhotic: 8 weeks
- If cirrhotic: 12 weeks
  - Harvoni: 1 tablet orally daily
- If HCV-monoinfected, non-cirrhotic, and baseline HCV RNA <6 million IU/mL: 8 weeks
- If cirrhotic, baseline HCV RNA ≥6 million IU/mL or HIV/HCV coinfect: 12 weeks
- Consider adding RBV in cirrhotic patients
  - Epclusa: 1 tablet orally daily for 12 weeks
- Treatment-naïve with decompensated cirrhosis (CTP B or C):
  - Harvoni: 1 tablet orally daily + RBV (600 mg/day and increase by 200 mg/day every 2 weeks only as tolerated) for 12 weeks
  - Epclusa: 1 tablet orally daily + RBVd for 12 weeks; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
Veterans Affairs & HCV Treatments

Genotype 1 (Cont.):

- Treatment-experienced (NS5A- and SOF-naïve [e.g., failed PEG-IFN/RBV ± NS3/4A PI]) without or with cirrhosis (CTP A)
  - Zepatier: 1 tablet orally daily for 12 weeks if GT1b, or if failed only PEG-IFN/RBV and GT1a without baseline NS5A RAS
  - Mavyret: 3 tablets orally daily with food
- If PEG-IFN/RBV-experienced: 8 weeks if non-cirrhotic or 12 weeks if cirrhotic
- If NS3/4A PI + PEG-IFN/RBV-experienced: 12 weeks
  - Harvoni: 1 tablet orally daily for 12 weeks; add RBVd if cirrhotic
  - Epclusa: 1 tablet orally daily for 12 weeks
- Treatment-experienced (NS5A-naïve and SOF-experienced) without or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food
- If PEG-IFN/RBV + Sovaldi-experienced: 8 weeks if non-cirrhotic or 12 weeks if cirrhotic
- If Olysio + Sovaldi-experienced: 12 weeks
  - Epclusa: 1 tablet orally daily for 12 weeks if GT1b
- Treatment-experienced (prior NS5A-containing regimen) without or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food for 16 weeks if failed only an NS5A inhibitor without NS3/4A PI (e.g., Harvoni)
  - Vosevi: 1 tablet orally daily with food for 12 weeks
- Treatment-experienced with decompensated cirrhosis (CTP B or C)
  - Epclusa: 1 tablet orally daily + RBV; start at lower RBV doses as clinically indicated (e.g., baseline Hgb);
- If NS5A-naïve: 12 weeks
- If NS5A-experienced: 24 weeks; NOT FDA approved for 24 weeks
Veterans Affairs & HCV Treatments

**Genotype 2:**

- Treatment-naïve or treatment-experienced (PEG-IFN/IFN ± RBV or Sovaldi + RBV ± PEG-IFN) without or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food
- If non-cirrhotic: 8 weeks
- If cirrhotic: 12 weeks
  - Epclusa: 1 tablet orally daily for 12 weeks
- Treatment-experienced (NS5A-experienced) without or with cirrhosis (CTP A)
  - Vosevi: 1 tablet orally daily with food for 12 weeks
- Treatment-naïve or treatment-experienced patients with decompensated cirrhosis (CTP B or CTP C)
  - Epclusa: 1 tablet orally daily + RBV; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
- If NS5A-naïve: 12 weeks
- If NS5A-experienced: 24 weeks

**Genotype 3:**

- Treatment-naïve without cirrhosis or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food for 12 weeks
  - Epclusa: 1 tablet orally daily for 12 weeks
- If CTP A, test for NS5A RAS
- Add RBV if Y93H RAS present
- Treatment-experienced (PEG-IFN ± RBV or Sovaldi + RBV ± PEG-IFN) without or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food for 16 weeks
Veterans Affairs & HCV Treatments

Genotype 3 (Cont.):

- Treatment-experienced (NS5A-experienced) without or with cirrhosis (CTP A)
  - Vosevi: 1 tablet orally daily with food for 12 weeks
- If CTP A, consider adding RBV (no supporting data)
- Treatment-naïve or treatment-experienced with decompensated cirrhosis (CTP B or C)
  - Epclusa: 1 tablet orally daily + RBV; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
- If NS5A-naïve: 12 weeks
- If NS5A-experienced: 24 weeks

Genotype 4:

- Treatment-naïve without or with cirrhosis (CTP A)
  - Zepatier: 1 tablet orally daily for 12 weeks
  - Mavyret: 3 tablets orally daily with food
- If non-cirrhotic: 8 weeks
- If cirrhotic: 12 weeks
  - Harvoni: 1 tablet orally daily for 12 weeks
  - Epclusa: 1 tablet orally daily for 12 weeks
- Treatment-naïve with decompensated cirrhosis (CTP B or C)
  - Harvoni: 1 tablet orally daily + RBV (600 mg/day and increase by 200 mg/day every 2 weeks only as tolerated) for 12 weeks
  - Epclusa: 1 tablet orally daily + RBV for 12 weeks; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
Veterans Affairs & HCV Treatments

Genotype 4 (Cont.):

- Treatment-experienced (Sovaldi-experienced and NS5A-naïve) without or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food for 12 weeks
  - Epclusa: 1 tablet orally daily + RBV for 12 weeks; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)

- Treatment-experienced (NS5A-experienced) without or with cirrhosis (CTP A)
  - Vosevi: 1 tablet orally daily with food for 12 weeks

- Treatment-experienced with decompensated cirrhosis (CTP B or CTP C)
  - Epclusa: 1 tablet orally daily + RBV; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
    » If NS5A-naïve: 12 weeks
    » If NS5A-experienced: 24 weeks; NOT FDA approved for 24 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: Closed
- Website: [https://tafcares.org/patients/covered-diseases/](https://tafcares.org/patients/covered-diseases/)

**Patient Advocate Foundation Co-Pay Relief:**
- Status: Open
- Maximum award of $15,000
- 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: None
- Minimum Premium Reimbursement Amount: None
- **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 25. – Figure 34.
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
October 2018

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

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

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

Figure 32.
Doctor Shopping Laws Map Key:
Purple: Doctor Shopping Laws
Red: No Doctor Shopping Laws

[Map of the United States showing states with Doctor Shopping Laws and those without.]
Harm Reduction Programs
Physical Exam Required Coverage Map
October 2018

Figure 33.
Physical Exam Required Map Key:
Purple: Physical Exam Required
Red: No Physical Exam Required
Figure 34.
I.D. Requirement Map Key:
Purple: I.D. Required
Red: No I.D. Required
Harm Reduction Programs
Prescriber Education Required Coverage Map
October 2018

Figure 35.
Prescriber Ed Required Map Key:
Purple: Prescriber Ed Required
Red: No Prescriber Ed Required

[Map of the United States with states colored in purple and red to indicate prescriber education requirements.]
Harm Reduction Programs
Lock-In Program Coverage Map
October 2018

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

[Map of the United States showing states with and without Lock-In Programs, with purple states indicating Lock-In Program and red states indicating 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.

October 2018 Updates:
• No updates

October 2018 Notes:
• The following state has pending legislation that would legalize state-sponsored Syringe Exchanges – (None)
• The following states have pending legislation requiring Mandatory PDMP reporting – (None)
• The following state has pending legislation implementing Doctor Shopping Laws – PA
• The following state has pending legislation requiring a Physical Examination before Opioid Prescribing – MA
• The following state has pending legislation requiring Prescriber Education – (None)
Regional Trends
Special Focus:
Low HCV Treatment Utilization
Regional Trends

Special Focus: Low HCV Treatment Utilization

Since the release of HCV Direct-Acting Antivirals in 2013, Hepatitis advocates and activists have hailed the drugs as the revolutionary therapies they are. We are able to cure the deadliest disease in America, and sure, it costs a lot of money, but that’s to be expected. What quickly became apparent was that the cost would prove to be the biggest barrier to treatment. If patients weren’t being denied coverage outright by private insurers or public payors (e.g. – Medicaid, Ryan White), it was co-pays in the thousands if they were approved for treatment.

And so advocates and activists fought tooth and nail to convince or force payors to offer coverage for these expensive, yet effective medications, regardless of cost concerns. Payors responded by expanding their formularies and Preferred Drug Lists (PDLs) to cover DAAs…at least nominally. So, what do I mean by “nominally?”

The adding of these drugs to formularies and PDLs has been largely “in name only.” Evidence continues to mount that, despite offering “coverage” for HCV treatment, treatment utilization – actually gaining access to and using the medications – is still an issue. A study published in June 2018 showed that patients with commercial insurance were denied coverage 52.4% of the time (between January 2016 and April 2017); those with Medicaid coverage were denied 34.5% of the times; those with Medicare, 14.7% of the time (Gowda, et al., 2018).

DAA utilization in ADAP programs has been extremely low. According to Amanda Bowes from the National Alliance of State and Territorial AIDS Directors (NASTAD), in calendar year 2016, over 1,000 (2%) ADAP clients across 15 ADAPs were reported as being co-infected with HCV at some point during the year. Of those, just 336 (32%) of these clients received treatment for their HCV, and of those who were treated, 160 (48%) were reported as cured (Bowes, 2018). When asked why utilization of DAAs is so low among ADAP programs, Bowes responded that neither NASTAD, nor any other organization for that matter, could accurately and concisely pinpoint the reason.

So, despite “coverage” being offered for these drugs, the only patients who seem to be getting them with any real regularity are those who receive coverage under Medicare, which isn’t terribly surprising considering that a majority of people living with Chronic HCV infection are covered under Medicare. That said, it does not explain (or excuse) the low utilization of drugs by other payors, especially with the introduction of the far more competitively priced Mavyret (AbbVie). Moreover, with the introduction of authorized Harvoni and Epclusa generics in January 2019, should payors continue to restrict coverage, it will prove disastrous to U.S. efforts to eliminate HCV by 2030.
Latest News
Latest News

• **Authorized Generics of Epclusa, Harvoni Will Soon Be Available for HCV Treatment**

Gilead Sciences announced that its subsidiary, Asegua Therapeutics, will launch authorized generic versions of Epclusa (sofosbuvir, velpatasvir) and Harvoni (ledipasvir, sofosbuvir), both indicated for the treatment of hepatitis C virus (HCV) infection. Epclusa combines sofosbuvir, an HCV NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor. It is indicated to treat HCV genotype 1, 2, 3, 4, 5, or 6 infection in adults without cirrhosis or with compensated cirrhosis; or with decompensated cirrhosis for use in combination with ribavirin (RBV).

Harvoni combines ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV NS5B polymerase inhibitor. It is indicated to treat HCV genotype 1, 4, 5, or 6 infection in patients without cirrhosis or with compensated cirrhosis; genotype 1 with decompensated cirrhosis, in combination with ribavirin; or genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin (Hee Han, 2018).

• **The Current State of Hepatitis C Virus Treatment in the United States**

A meet-the-professor session at the 2018 ID Week Annual Meeting in San Francisco, CA, covered a wide swath by providing an overview of updated recommendations on testing for hepatitis C virus infection, strategies to check for drug-drug interactions (DDIs)—summarizing DDIs of particular concern for direct-acting antivirals (DAAs)—DAAs that are applicable for special populations (such as patients with renal impairment or those with decompensated cirrhosis), and the management of hepatitis C virus infection for persons who inject drugs (PWID).

The 4 cases that were discussed highlighted the challenges clinicians face in terms of heterogeneity in symptoms, risk factors, treatment compliance, and treatment affordability. The consensus is that it is definitely not a one-size-fits-all landscape.

Testing for hepatitis C virus infection can be based on the risk of exposure. A partial list of the risks includes current or former injection drug use, certain medical conditions, blood transfusion, and organ transplantation. Individuals exposed to hepatitis C virus-positive blood and children born to hepatitis C virus-positive women should definitely be tested (Hoyle, 2018).
Latest News

• Sustained Hepatitis C Treatment Associated With Lower Risk for Cardiovascular Events

Treatment for hepatitis C (HCV) is associated with a reduction in cardiovascular events, according to results of a study presented at ID Week 2018 held October 3 to 7, 2018, in San Francisco, California.

Previous research has shown inconsistent results when evaluating the association between HCV and cardiovascular disease (CVD) and the effect of HCV treatment on the future risk for CVD developing. Researchers used the Electronically Retrieved Cohort of HCV Infected Veterans to identify individuals who had been treated for HCV for >7 weeks, and each of these patients was matched with an untreated person.

A total of 32,575 patients received treatment and were matched with an equal number of untreated patients. The median age was 58 years; 27% were black and a significant majority (96%) were male. The findings showed that the incidence rate for CVD events/1000 person-years in the treated group was 19.10 (95% CI, 17.79-20.50) vs an incidence of 32.37 (95% CI, 30.51-34.33) for the untreated cohort (P < .01). Treatment with a direct-acting antiretroviral regimen was associated with a lower risk for an incident CVD event compared to treatment with a peginterferon/ribavirin regimen (hazard ratio [HR] .68; 95% CI, .53-.88). This lower risk association was also demonstrated for achieving sustained virologic response (HR .76; 95% CI, .63-.92). Patients who were untreated also had a shorter CVD event-free survival during 30 months of follow-up compared to those who received treatment (log rank P < .0001) (Nelson, 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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