HIV/HCV Co-Infection Watch: September 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.
• 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 September 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 September 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
September 2018

Figure 3.
Sovaldi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Harvoni Coverage Map
September 2018

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

Viekira Pak Coverage Map

September 2018

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

Daklinza Coverage Map
September 2018

Figure 6.
Daklinza Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Technivie Coverage Map
September 2018

Figure 7.
Technivie Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Zepatier Coverage Map
September 2018

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

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

Figure 10.
Viekira XR Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Figure 11.
Vosevi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
Mavyret Coverage Map
September 2018

Figure 12.
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.

September 2018 Updates:
• No updates

September 2018 Notes:
• States with Open Drug FormulariesIL, 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

**Figure 13. (Indicates “Preferred Drug”) Con’t.**

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## Medicaid Programs & HCV Treatments

**Figure 13. (* Indicates “Preferred Drug”) Con’t.**

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<th>Viekira</th>
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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
September 2018

Figure 15.
Sovaldi Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 16.
Medicaid Harvoni Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 17.
Medicaid Viekira Pak Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments
Daklinza Coverage Map
September 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
Zepatier Coverage Map
September 2018

Figure 20.
Medicaid Zepatier Map Key:
Light Blue: Covered
Yellow: Not Covered
Medicaid Programs & HCV Treatments

Epclusa Coverage Map
September 2018

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

Figure 22.
Medicaid Viekira XR Map Key:
Light Blue: Covered
Yellow: Not Covered
Figure 23.
Medicaid Vosevi Map Key:
Light Blue: Covered
Yellow: Not Covered

Vosevi Coverage Map
September 2018
Medicaid Programs & HCV Treatments
Mavyret Coverage Map
September 2018

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).

September 2018 Updates:
• No updates

September 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 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 5A (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/

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
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

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

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/#
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://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 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
September 2018

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

Figure 29.
Expanded Naloxone Map Key:
Purple: Expanded Naloxone
Red: Restricted Naloxone

[Map showing expanded naloxone coverage across the United States]
Harm Reduction Programs
Good Samaritan Laws Coverage Map
September 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
September 2018

Figure 31.
PDMPs Map Key:
Purple: Mandatory PDMPs
Red: No Mandatory PDMPs
Harm Reduction Programs
Doctor Shopping Laws Coverage Map
September 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
September 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
September 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
September 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 Lock-In Programs and those without, with a key indicating purple for Lock-In Program and red for 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.

September 2018 Updates:
• No updates

September 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
Hepatitis Treatment in the Pacific Region
Regional Trends

Hepatitis C Treatment in Pacific Region – District 09 – Pacific (AK, CA, HI, OR, WA)
The Pacific Region is comprised of five states, including AK, CA, HI, OR, WA.

- **HBV (2016 National Rate – 1.0):**
  This region has a low burden of HBV, with all states that track and report HBV below the national rate of infection. Alaska has the highest, at 0.8.

- **HCV (2016 National Rate – 1.0):**
  This region has a relatively low burden of HCV, with no states that track and report HCV below the national rate of infection. Washington state has the highest rate at 0.9. Neither Alaska, nor Hawaii report HCV.

- **Overdose Deaths (2016 National Rate – 19.8):**
  No states have overdose death rates higher than the national average. Alaska has the highest with a rate of 16.8.

- **ADAP:**
  Only one state – Alaska – has not expanded its formulary to include HCV Direct-Acting Agents.

- **Correctional Hepatitis Testing:**
  All five states replied to our information request re: screening/testing guidelines for HBV and HCV. Only two (2) states – OR, WA – require compulsory HBV screening; only Washington state uses Opt-Out delivery. Only three (3) states – CA, OR, WA – require compulsory HCV screening; two states – California and Washington state – use Opt-Out delivery.
Latest News
Latest News

• **Study finds kidney transplant recipients do not contract hepatitis C if receiving kidneys from donors with a history of hepatitis C**

Researchers at Loma Linda University Health found that kidney transplantation can be safely performed using organs testing positive for the hepatitis C virus (HCV) antibody but negative for active viral infection. Their findings, published July 24 in the American Journal of Transplantation, could expand the number of kidneys available for those in need.

“One way of increasing the kidney donor pool is to utilize more organs from HCV positive donors,” said the study’s lead author, Michael E. de Vera, MD, director of Loma Linda University (LLU) Transplant Institute. “Currently, HCV positive donors are defined by donors that have previously had HCV even if they were cured. Now there has been a call to redefine the definition of an HCV positive donor in hopes that more organs can be used from these donors” (Jackson, 2018).

• **HCV Eradication in HIV/HCV-Coinfection Decreases Immune Activation**

For patients with HIV/hepatitis C virus (HCV) coinfection, eradicating HCV decreases levels of immune activation markers, proviral HIV DNA load, microbial translocation markers, and D-dimers, according to results published in the Journal of Infectious Diseases. These results support treating HCV in all patients with HIV/HCV coinfection, even patients with low-grade fibrosis. The study included participants with HIV/HCV coinfection who received antiretroviral treatment and achieved a sustained virologic response with interferon-free regimens (n=97) (Dellabella, 2018).
Latest News

• **Doctors Largely Ignore CDC’s Birth Cohort HCV Screening Guidelines**

Doctors are not screening Baby Boomers for hepatitis C at high rates, according to a new study; however, the implementation of electronic reminders could help solve the problem.

The US Centers for Disease Control and Prevention (CDC) recommends that all individuals born between 1945 and 1965 be screened for hepatitis C (HCV), as roughly three-quarters of the 3.2 million Americans infected with HCV were born in that time frame. Yet, a paucity of research exists to discern whether individuals in that age cohort are indeed being tested.

The new study looked at data from NorthShore University Health System, in Illinois, between 2010 and 2015. Of the 106,753 commercially-insured Baby Boomer outpatients seen over the 5-year time span, the overall HCV-antibody screening rate was 11.2% (Kaltwasser, 2018).

• **Ribavirin Use in Conjunction with DAA Therapy Predicts Mental Health Decline in Patients with HCV**

Concomitant ribavirin use is an independent predictor of mental health-related quality-of-life in patients with hepatitis C virus (HCV) infection and an inherited bleeding disorder who are on a direct-acting antiviral (DAA) regimen, according to a prospective cohort study led by Joop E. Arends, MD, of the University Medical Center Utrecht Affiliated to Utrecht University. Scores on the mental component of the Short Form-36 (SF-36) also appear to decrease transiently during concomitant therapy.

“In a time of increasing health care costs, it is important to evaluate patient outcomes especially with expensive DAAs,” Arends told MD Magazine®. “Real-world data with PROs [patient-reported outcomes] have not yet been published and that is one of the important contributions of our study. In addition, it still shows the effects of ribavirin [RBV] on patient outcomes, and although in Western world settings we now switch to second generation DAAs in which RBV is not needed anymore, there is still a place for RBV.”

Patients with HCV infection who received an oral DAA therapeutic regimen at a single center in The Netherlands during 2015–2016 were recruited for analysis (n = 68). Approximately 85% of patients were receiving sofosbuvir-based DAA regimens compared with 15% of patients who received a DAA regimen comprised of ombitasvir/paritaprevir/ritonavir/dasabuvir (May, 2018).
Contact

Marcus J. Hopkins
Project Director, HIV/HCV Co-Infection Watch
mhopkins@tiicann.org

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


References


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References


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