## HIV/HCV Co-Infection Watch: November 2019



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: <a href="http://www.tiicann.org">http://www.tiicann.org</a>



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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 under the U.S. Department of Veterans Affairs.
- Statistics related to HIV/HCV co-infection (i.e., 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: <a href="http://tiicann.org/signup\_listserv.html">http://tiicann.org/signup\_listserv.html</a>



#### **Findings**

The following is a summary of the key findings for November 2019:

#### AIDS Drug Assistance Programs

There are <u>56</u> State and Territorial AIDS Drug Assistance Programs (ADAPs) in the United States, <u>47</u> of which offer some form of coverage for Hepatitis C (HCV) treatment. Of those programs, <u>43</u> have expanded their HCV coverage to include the regimens that serve as the current Standard of Care (SOC) for Hepatitis C treatment. Four (<u>4</u>) programs offer only Basic Coverage and 9 programs offer No Coverage. Three (<u>3</u>) 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 <u>59</u> 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 <u>50</u> 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 November 2019:

#### 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-four (44) States and Territories currently have syringe exchange programs in place, regardless of state. Fifty-one (51) states and the District of Columbia have expanded access to Naloxone to avert opioid drug overdoses. Fifty (50) states have Good Samaritan laws or statutes that provide protection for those rendering emergency services during drug overdoses. Forty-five (45) 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. Forty (40) 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. Forty (40) 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. Forty-three (43) 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.



Figure 1. – Figure 12.



Figure 1. (\* Indicates "Preferred Drug")

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Alabama	Υ	N	N	N	N	Υ	N	N	Υ			Х
Alaska	Υ	N	N	N	N	N	No Info	No Info	No Info			Х
Arizona	Υ	Υ	Υ	N	Υ	Υ	Υ	N	Υ			Х
Arkansas	Υ	N	Υ	N	N	Υ	Υ	N	Υ			Х
California	Y	Υ	Υ	N	N	Y	Υ	Υ	Υ	Υ	Υ	Х
Colorado	Υ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ			Х
Connecticut	Υ	N	Υ	N	N	N	Υ	Υ	Υ			Х
Delaware	Υ	N	Υ	N	N	N	N	N	N			Х
Florida	Y	N	Υ	N	N	Y	N	N	Υ			Х
Georgia	Υ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ			X
Hawaii	Y	Υ	Υ	Υ	Y	Y	Υ	Υ	Υ			X
Idaho	N	N	N	N	N	N	N	N	N			X
Illinois	Υ	Υ	Υ	Υ	Y	Y	Υ	Y	Υ	Υ	Υ	Х
Indiana	Υ	Υ	Υ	N	N	N	Υ	No Info	Υ			X
lowa	Y	Υ	Y	Υ	Υ	Y	Y	Υ	Y	Y	Υ	X
Kansas	N	N	N	N	N	N	N	No Info	No Info			Х
Kentucky	N	N	N	N	N	N	N	No Info	No Info			Х
Louisiana	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
Maine	Y	Υ	Υ	N	N	Y	Υ	N	Y	Υ	Υ	Х



Figure 1. (\* Indicates "Preferred Drug") Con't.

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Maryland	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
Massachusetts	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Michigan	Υ	N	Υ	N	N	Υ	Υ	N	Υ			Х
Minnesota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Mississippi	N	N	Υ	N	N	Υ	Υ	N	Υ			Х
Missouri	Υ	N	N	N	N	Υ	N	N	Υ			Х
Montana	N	N	N	N	N	N	N	N	Υ			Х
Nebraska	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Nevada	Υ	Υ	Y	Υ	Υ	Υ	Υ	Υ	Υ			Х
New Hampshire	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
New Jersey	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Y	Υ	Υ	Х
New Mexico	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
New York	Υ	N	N	Υ	Υ	Υ	N	N	Υ			Х
North Carolina	Υ	N	Υ	Υ	Υ	Υ	N	N	Υ			Х
North Dakota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Ohio	N	N	N	N	N	N	N	No Info	No Info			Х
Oklahoma	Υ	Υ	Υ	N	N	N	Υ	No Info	No Info			Х
Oregon	Υ	Υ	Y	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Pennsylvania	Υ	Υ	Y	N	Υ	Υ	Υ	N	Υ	Υ	Υ	Х



Figure 1. (\* Indicates "Preferred Drug") Con't.

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Rhode Island	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
South Carolina	Υ	N	N	N	N	N	N	N	N			Х
South Dakota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
Tennessee	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ	Υ			Х
Texas	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Y	Υ			Х
Utah	N	N	N	N	N	N	N	No Info	No Info			Х
Vermont	N	N	N	N	N	N	N	No Info	No Info			Х
Virginia	Υ	Υ	Υ	N	Υ	Υ	Υ	N	Υ			Х
Washington	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
West Virginia	Υ	N	N	N	N	Υ	N	N	N			Х
Wisconsin	Υ	N	N	Υ	N	Υ	Υ	N	N			Х
Wyoming	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ	Υ			Х
Washington, DC	Υ	Υ	Υ	Υ	Υ	Υ	N	N	Υ			Х
												Х
Fed. St. Micronesia	Υ	N	N	N	No Info	No Info	No Info	No Info	No Info			Х
Guam	N	N	N	N	N	N	N	N	N			Х
Palau	N	N	N	N	N	No Info	No Info	No Info	No Info			Х
Puerto Rico	Υ	Υ	Υ	N	Υ	Υ	N	Υ	Υ			Х
U.S. Virgin Islands	N	N	N	N	N	N	N	No Info	No Info			Х



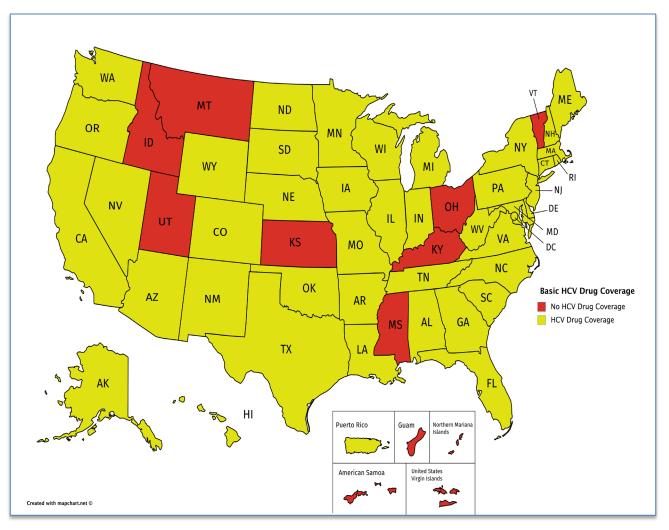
There are currently <u>46</u> AIDS Drug Assistance Programs (ADAPs) that cover some form of HCV drug therapies as part of their approved drug formularies. To learn more about ADAPs or their approved drug formularies, please visit <a href="http://adap.directory">http://adap.directory</a>.

Figure 2.

Basic Coverage Map Key:

Lime Green: Basic Coverage

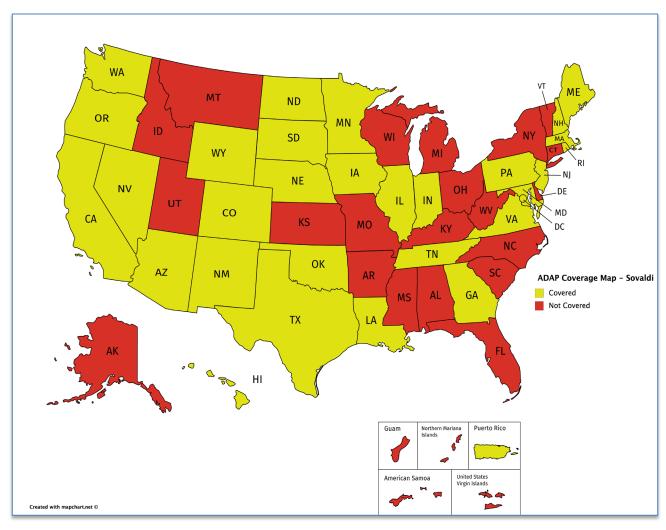
Red: No Coverage





Sovaldi Coverage Map November 2019

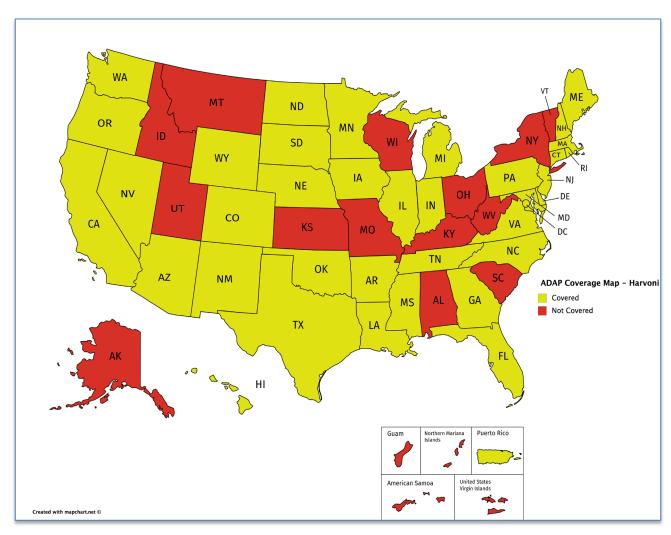
Figure 3.
Sovaldi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage





Harvoni Coverage Map November 2019

Figure 4.
Harvoni Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

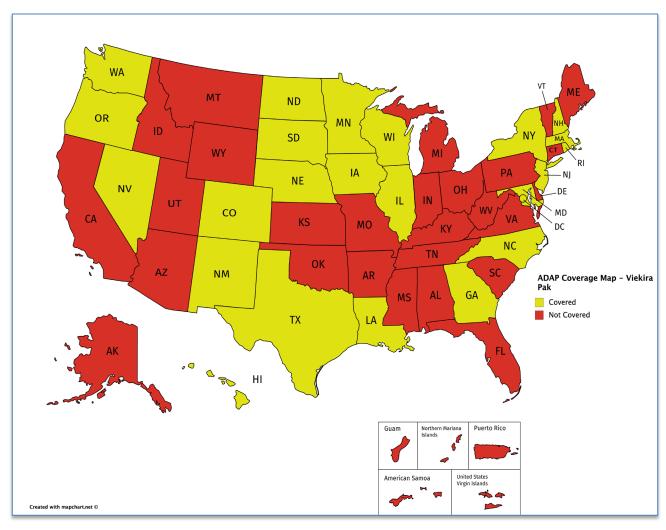




Viekira Pak Coverage Map November 2019

**Figure 5.**Viekira Pak Coverage Map Key:
Lime Green: Coverage

Red: No Coverage

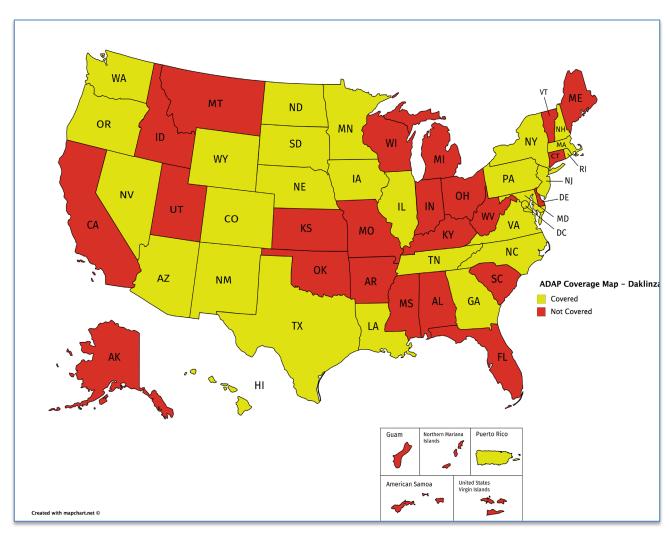




Daklinza Coverage Map November 2019

Figure 6.

Daklinza Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

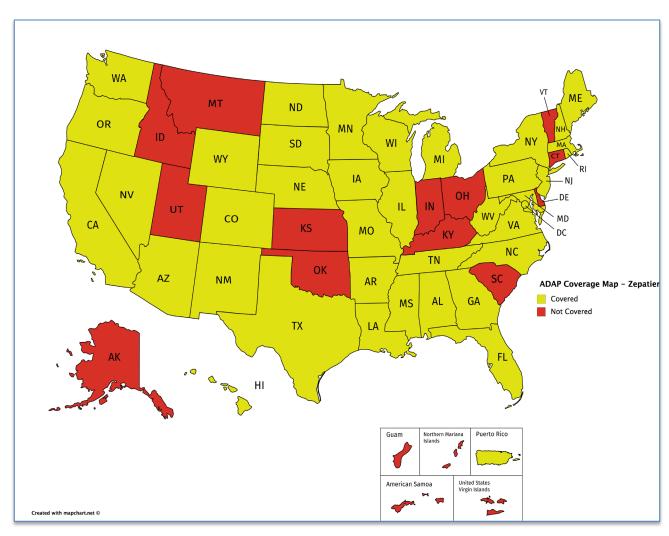




Zepatier Coverage Map November 2019

Figure 7.

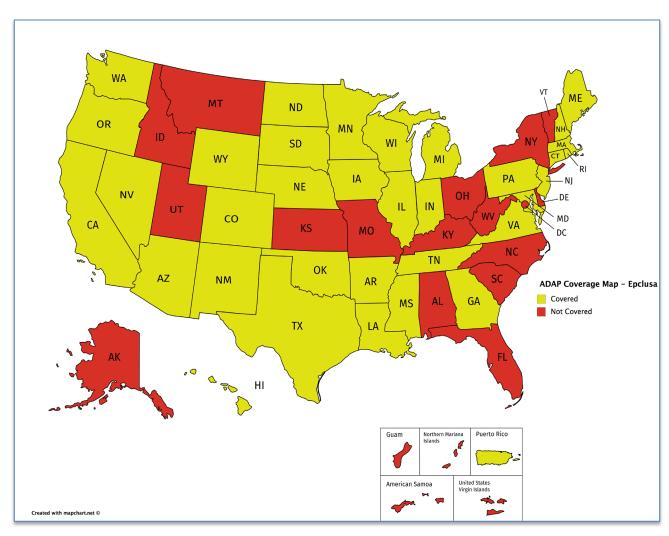
Zepatier Coverage Map Key:
Lime Green: Coverage
Red: No Coverage





Epclusa Coverage Map November 2019

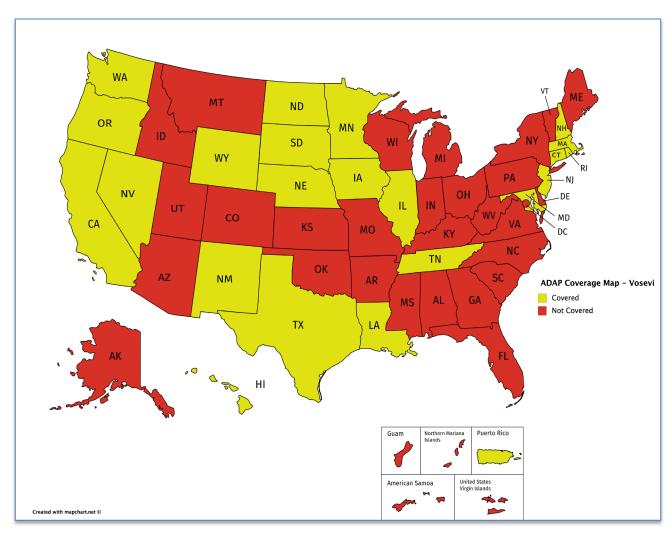
Figure 8.
Epclusa Coverage Map Key:
Lime Green: Coverage
Red: No Coverage





Vosevi Coverage Map November 2019

Figure 9.
Vosevi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

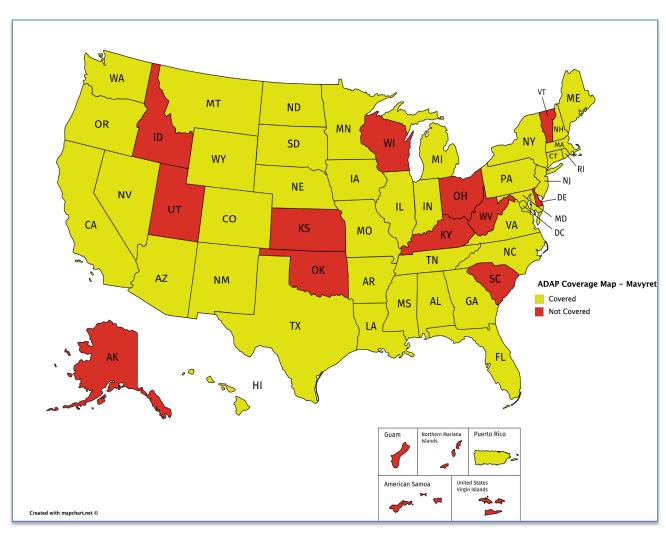




Mavyret Coverage Map November 2019

Figure 10.

Mavyret Coverage Map Key:
Lime Green: Coverage
Red: No Coverage

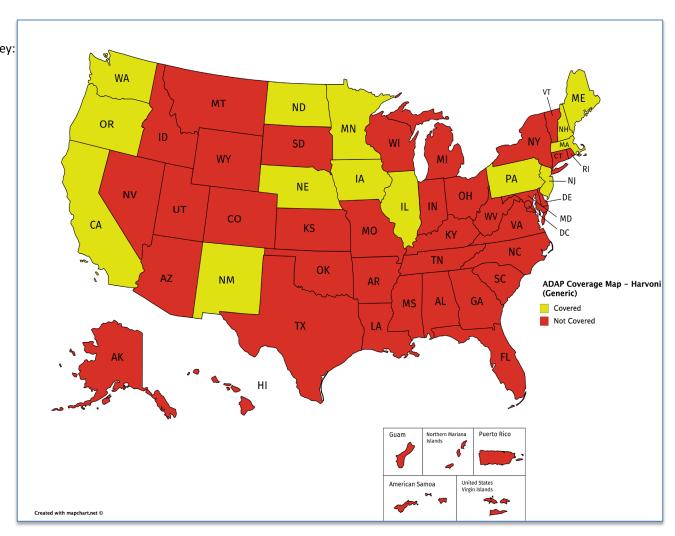




Harvoni *Generic* Coverage Map November 2019

**Figure 11.**Harvoni *Generic* Coverage Map Key:

Lime Green: Coverage Red: No Coverage

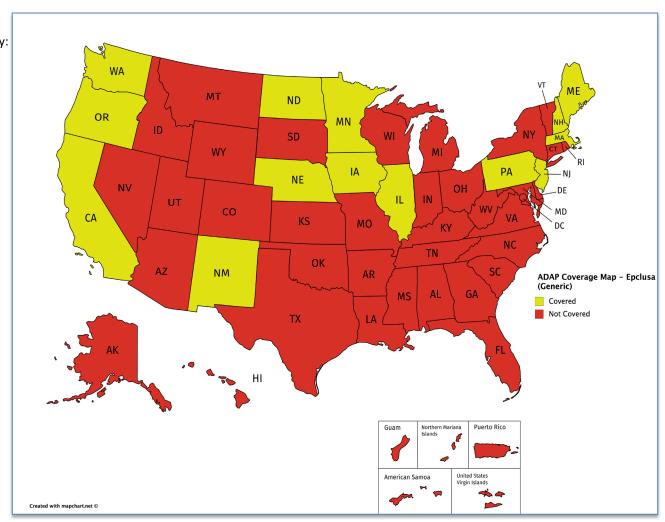




Epclusa *Generic* Coverage Map November 2019

Figure 12.

Epclusa *Generic* Coverage Map Key: Lime Green: Coverage Red: No Coverage





Of the 56 respective State and Territorial ADAPs, only <u>9</u> (ID, KS, KY, OH, UT, VT, GU, PW, VI) do <u>not</u> 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 15, 2019). The data presented are current as of October 15, 2019.

#### November 2019 Updates:

- Connecticut has expanded their ADAP Formulary to include the following HCV DAA Drugs: Harvoni, Epclusa, Vosevi, Mavyret
- States that have added Harvoni (Generic) to their ADAP Formularies: CA, IL, IA, ME, MA, MN, NE, NH, NJ, NM, ND, OR, PA,

#### WA

• States that have added Epclusa (Generic) to their ADAP Formularies: **CA, IL, IA, ME, MA, MN, NE, NH, NJ, NM, ND, OR, PA, WA** 

#### November 2019 Notes:

- States with Open Formularies: IL, IA, MA, MN, NE, NH, NJ, NM, ND, OH, OR, WA, WY
- 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
- N.B. Although North Dakota has adopted an open formulary, they provide only co-pay and deductible assistance for HCV medications
- N.B. Wyoming's ADAP Open Formulary document, the following disclaimer related to HCV is made: Hepatitis C treatment medications (i.e. Harvoni, Viekira XR, Sovaldi, Ribavirin, Zepatier, Technivie, Daklinza, Epclusa) must be prior authorized. To be eligible, clients must have applied for prior authorization from their insurance plan and the WY ADAP Hepatitis C Treatment checklist must be completed and signed by the provider and client
- 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



Figure 13. – Figure 24.



Figure 13. (\* Indicates "Preferred Drug")

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Alabama	Υ	N	Υ*	N	N	Υ*	γ*	N	γ*	γ*	γ*	Х
Alaska	Y	Υ	Υ	Υ	Υ	γ*	γ*	Υ	γ*	Υ	Υ	Х
Arizona	Y	N	N	N	N	N	N	N	γ*		γ*	Х
Arkansas	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	γ*			Х
California	Y	Υ*	Υ*	Υ*	N	γ*	γ*	N	Υ*	γ*	γ*	Х
Colorado	Υ	Υ	Υ*	Υ	Υ	Υ	γ*	Υ	γ*	Υ	Υ	Х
Connecticut	Y	N	N	N	N	N	γ*	γ*	Υ*	N	N	Х
Delaware	Υ	Υ	N	Υ	Υ	γ*	N	Υ	γ*	Υ	γ*	Х
Florida	Y	N	N	N	N	N	N	γ*	Υ*			Х
Georgia	Υ	Υ	Υ	N	Υ	γ*	γ*	γ*	Υ*			Х
Hawaii	Y	Υ	Υ	Υ	N	N	Υ	Υ	Υ	Υ	Υ	Х
Idaho	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ*			Х
Illinois	Υ	Υ	Υ	Υ	Υ	Υ	γ*	Υ	γ*	Υ	Υ	Х
Indiana	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	Υ*	Υ	Υ	Х
Iowa	Υ	Υ	Υ	N	Υ	Υ	γ*	Υ	γ*	Υ	γ*	х
Kansas	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*			х
Kentucky	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	х
Louisiana	Y	Υ	Υ	Υ	Υ	Υ	γ*	γ*	γ*	Υ	γ*	Х
Maine	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	γ*			Х



Figure 13. (\* Indicates "Preferred Drug") Con't.

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Maryland	Υ	Υ	N	Υ	Υ	γ*	N	γ*	γ*	γ*	γ*	Х
Massachusetts	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
Michigan	Υ	Υ	Υ	Υ	Υ	γ*	Υ*	γ*	γ*	Υ	Υ	Х
Minnesota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	Υ*	Υ	Υ	Х
Mississippi	Y	Υ	Υ	Υ	Υ	γ*	Υ*	Υ	γ*		γ*	Х
Missouri	Υ	Υ	Υ	Υ	Υ	γ*	Υ*	γ*	Υ*	Υ	Υ	Х
Montana	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ	γ*	Υ	Υ	Х
Nebraska	Υ	Υ	N	Υ	Υ	Υ	N	γ*	Υ*	Υ	Υ	Х
Nevada	Υ	Υ*	γ*	Υ	Υ	γ*	Υ*	Υ	Υ*	γ*	γ*	Х
New Hampshire	Υ	Υ	Υ*	N	N	Υ	γ*	γ*	γ*	γ*	γ*	Х
New Jersey	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
New Mexico	Υ	N	N	N	N	N	N	N	Υ	N	Υ	Х
New York	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	γ*	Х
North Carolina	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	Υ*	Υ	γ*	Х
North Dakota	Υ	Υ	Υ	Υ	N	γ*	Υ*	Υ	γ*	Υ	Υ	Х
Ohio	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ	Υ	N	Υ	Х
Oklahoma	Υ	Υ*	Υ*	Υ	γ*	γ*	Υ*	γ*	γ*	Υ	Υ	Х
Oregon	Υ	N	N	N	N	Υ*	Υ*	γ*	γ*	N	γ*	Х
Pennsylvania	Υ	Υ	γ*	Υ	Υ	γ*	Υ*	Υ	γ*	Υ	Υ	Х



Figure 13. (\* Indicates "Preferred Drug") Con't.

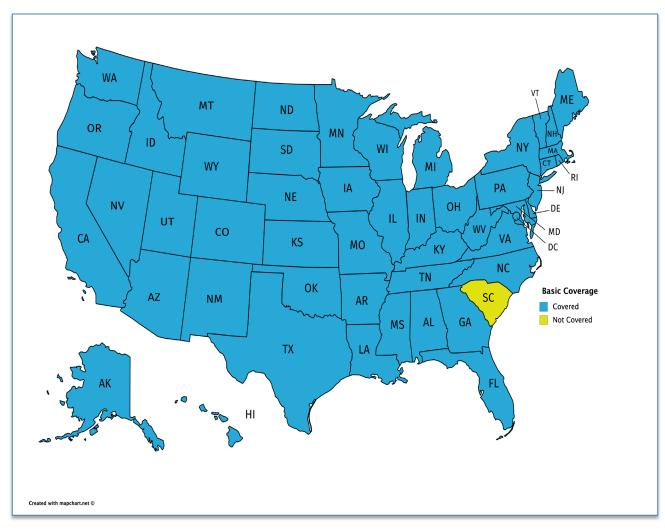
State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Rhode Island	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	Υ	Х
South Carolina	N	N	N	N	N	N	γ*	γ*	Υ*			Х
South Dakota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Tennessee	Υ	Υ	Υ*	Υ	Υ	Υ	γ*	Υ	Υ*	Υ	Υ	Х
Texas	Υ	Υ	Υ	Υ	Υ	Υ	Υ*	γ*	γ*	Υ	Υ	Х
Utah	Υ	Υ	Υ*	Υ	Υ	γ*	γ*	Υ	γ*	Υ	Υ	Х
Vermont	Υ	Υ	Υ	Υ	Υ	Υ	γ*	Υ	Υ*	Υ	Υ	Х
Virginia	Υ	Υ	Υ	Υ	N	Υ	Υ	Υ	γ*	Υ	γ*	Х
Washington	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	Υ	Υ	Х
West Virginia	Υ	Υ	Υ*	Υ	Υ	γ*	γ*	Υ	γ*	Υ	Υ	Х
Wisconsin	Υ	Υ	Υ*	N	Υ	γ*	γ*	Υ	Υ*	Υ	Υ	Х
Wyoming	Υ	Υ	Υ*	Υ	Υ	Υ	γ*	Υ	γ*			X
Washington, DC	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*			Х
												Х
Fed. St. Micronesia												X
Guam												Х
Palau												Х
Puerto Rico												Х
U.S. Virgin Islands												Х



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.

Figure 14.

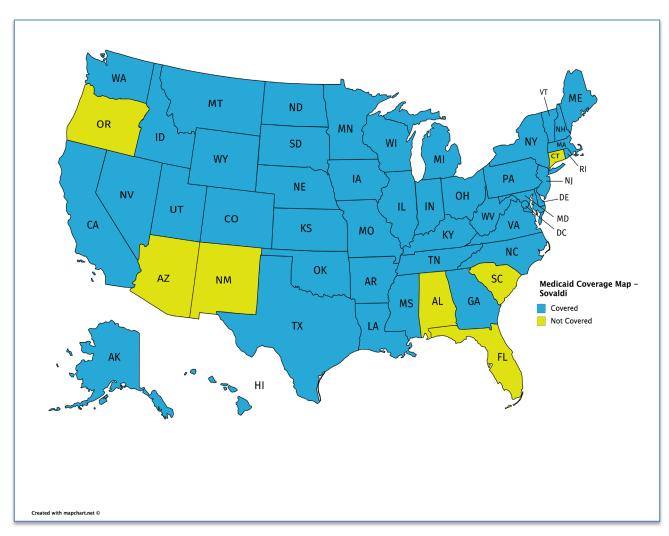
Basic Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Sovaldi Coverage Map November 2019

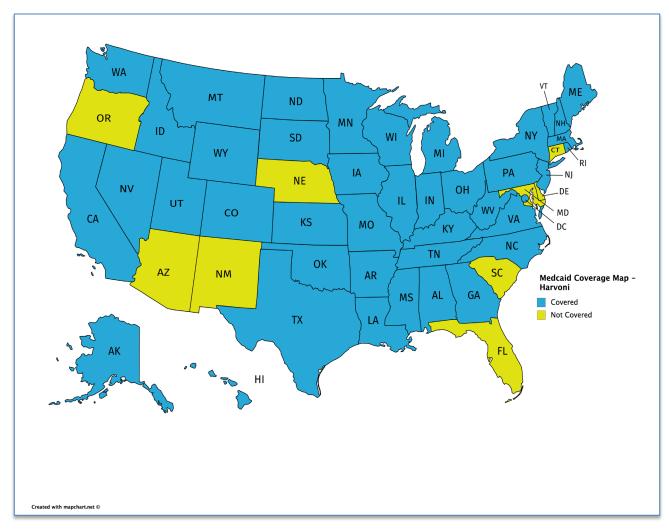
Figure 15.
Sovaldi Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Harvoni Coverage Map November 2019

Figure 16.
Harvoni Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered

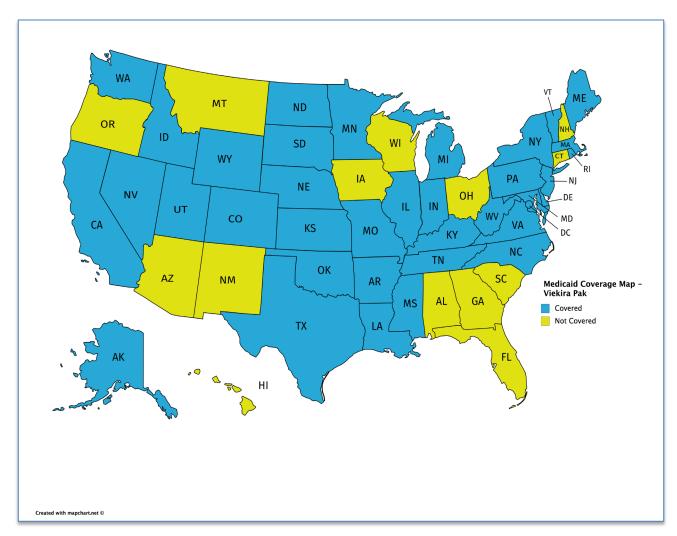




Viekira Pak Coverage Map November 2019

Figure 17.
Viekira Pak Coverage Map Key:

Light Blue: Covered Yellow: Not Covered

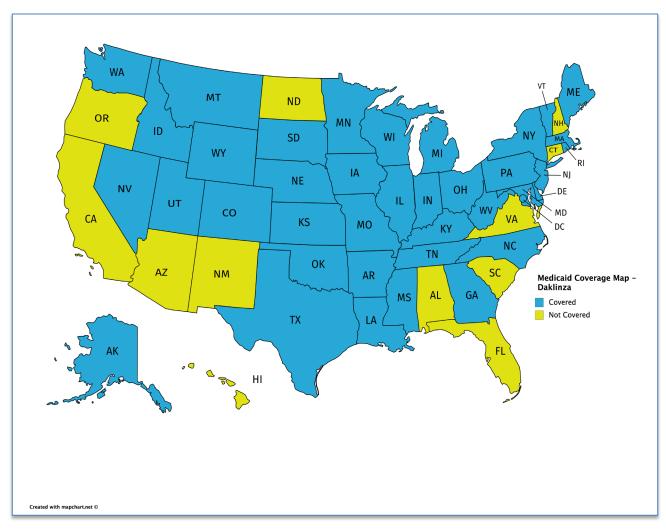




Daklinza Coverage Map November 2019

Figure 18.

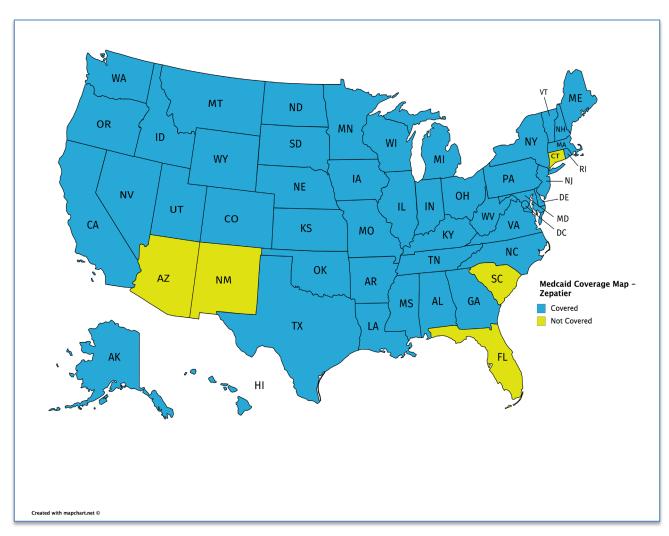
Daklinza Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Zepatier Coverage Map November 2019

Figure 19.
Zepatier Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered

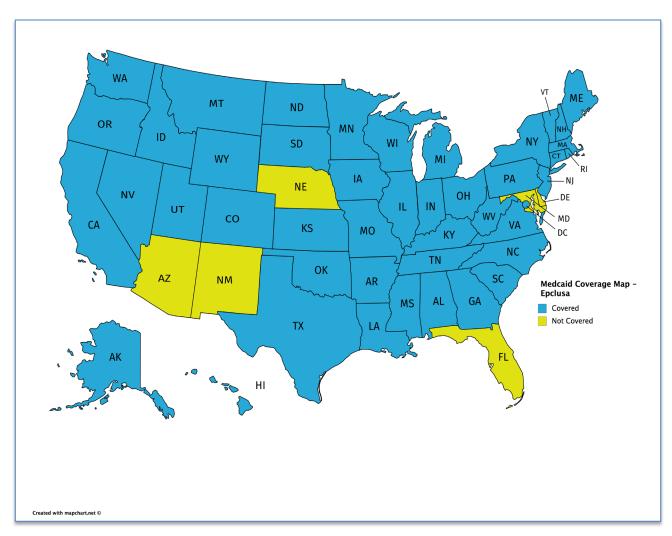




Epclusa Coverage Map November 2019

Figure 20.

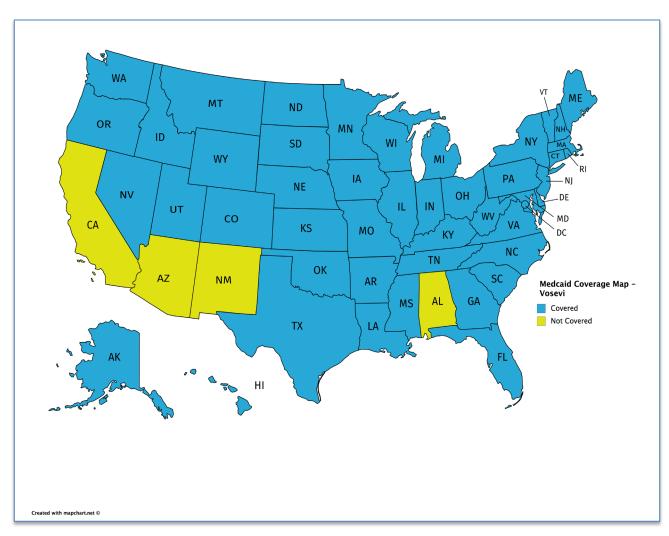
Epclusa Coverage Map Key: Light Blue: Covered Yellow: Not Covered





Vosevi Coverage Map November 2019

Figure 21.
Vosevi Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered

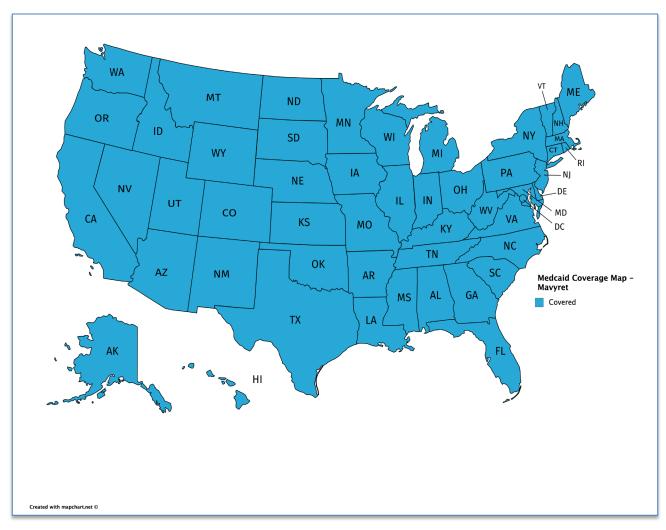




Mavyret Coverage Map November 2019

Figure 22.

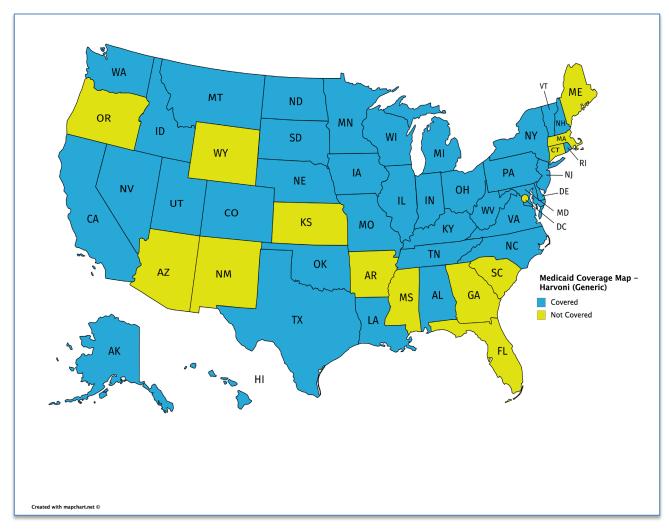
Mavyret Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Harvoni *Generic* Coverage Map November 2019

Figure 23.
Harvoni *Generic* Map Key:
Light Blue: Covered
Yellow: Not Covered



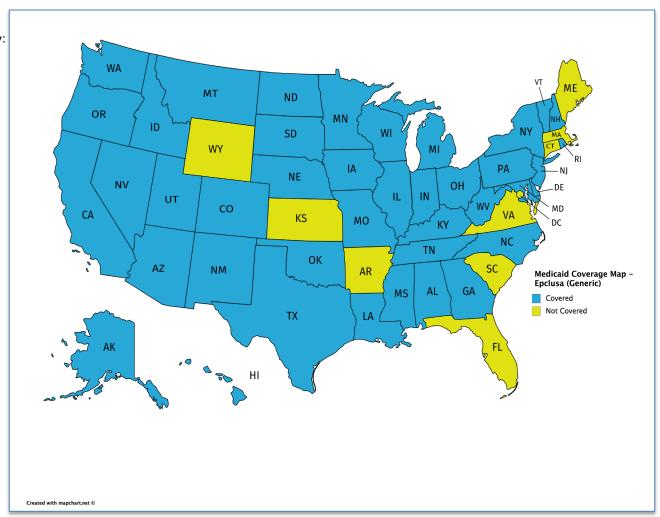


Epclusa *Generic* Coverage Map November 2019

Figure 24.

Epclusa *Generic* Coverage Map Key:

Light Blue: Covered Yellow: Not Covered





# **Medicaid Programs & HCV Treatments**

All <u>50</u> 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).

### November 2019 Updates:

- States that have included Harvoni (Generic) in their PDLs: AL, AK, CA, CO, DE, HI, ID, IL, IN, IA, KY, LA, MD, MI, MN, MO, MT, NE, NV, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV, WI
- States that have included Epclusa (Generic) in their PDLs: AL, AK, CA, CO, CT, DE, HI, ID, IL, IN, IA, KY, LA, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV, WI

### November 2019 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.) Presbyterian Centennial Care
  - -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



<sup>\*</sup> Medicaid coverage excludes patients from most drug manufacturer patient assistance programs (PAPs)



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 coinfected: 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)



### 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



### 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



# 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 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 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)



### 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





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 Sovaldi, Harvoni, Harvoni (Generic), Epclusa, Epclusa (Generic), and Vosevi
  - Co-Pay Coupons cover out-of-pocket costs up to 25% of the catalog price of a 12-week regimen (3 bottles/packages)
    of Sovaldi, Harvoni, Harvoni (Generic), Epclusa, Epclusa (Generic), or Vosevi
  - 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/

### AbbVie Mavyret Co-Pay Savings Card:

- Financial Assistance
  - Patient may be eligible to 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.mavyret.com/copay-savings-card



### 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.
- Website: <a href="http://ow.ly/fEJo309cJ7Z">http://ow.ly/fEJo309cJ7Z</a>

### The Assistance Fund:

Status: Closed

Website: https://tafcares.org/patients/covered-diseases/

# **Patient Advocate Foundation Co-Pay Relief:**

- Status: Closed
- 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



### 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
  - Medication must be listed on PAN's list of covered medications:
     <a href="https://www.panfoundation.org/index.php/en/patients/medications-covered">https://www.panfoundation.org/index.php/en/patients/medications-covered</a>
  - Income falls below 500% of FPL
  - Residing and receiving treatment in the U.S. (citizenship NOT required)
- Website: <a href="https://www.panfoundation.org/index.php/en/patients/assistance-programs/hepatitis-c">https://www.panfoundation.org/index.php/en/patients/assistance-programs/hepatitis-c</a>

### **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: <a href="https://www.healthwellfoundation.org/fund/hepatitis-c/">https://www.healthwellfoundation.org/fund/hepatitis-c/</a>



Figure 25. – Figure 34.



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. (N.b. – states listed as "Y" indicate only that a Syringe Services Program (SSP) exists within the state, regardless of the legality of SSPs under state law).

### 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.



### • 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.



Figure 27.

State	Syringe	Naloxone	Samaritan	PDMP	Doc Shop	Phy Exam	I.D.	Prescriber Ed	Lock-In
Alabama – AL	N	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Alaska – AK	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Arizona – AZ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	N
Arkansas – AR	Υ	Υ	Υ	Υ	N	Υ	N	Υ	Υ
California – CA	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	N
Colorado – CO	Υ	Υ	Υ	Pending	Υ	Υ	N	Υ	Υ
Connecticut – CT	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Delaware – DE	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Florida – FL	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Georgia – GA	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Hawaii – HI	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Idaho – ID	Υ	Υ	Υ	N	N	Υ	Υ	Υ	Υ
Illinois – IL	Y	Y	Y	Y	Y	Υ	Y	Υ	Υ
Indiana – IN	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Iowa – IA	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Kansas – KS	Υ	Υ	Υ	N	N	N	N	N	Υ
Kentucky – KY	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Louisiana – LA	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
Maine – ME	Υ	Υ	N	Υ	Υ	Υ	Υ	Υ	Υ



Figure 27.

State	Syringe	Naloxone	Samaritan	PDMP	Doc Shop	Phy Exam	I.D.	Prescriber Ed	Lock-In
Maryland – MD	Υ	Υ	Υ	Υ	Υ	N	N	Υ	Υ
Massachusetts – MA	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ	Υ
Michigan – MI	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ	Υ
Minnesota – MN	Υ	Υ	Υ	Υ	N	Υ	Υ	Pending	Υ
Mississippi – MS	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Missouri – MO	Υ	Υ	Υ	Pending	N	Υ	N	N	Υ
Montana – MT	Υ	Υ	Υ	N	Υ	N	N	N	Υ
Nebraska – NE	N	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Nevada – NV	Υ	Υ	Υ	Y	Υ	Υ	Y	Υ	Υ
New Hampshire –NH	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
New Jersey – NJ	Y	Y	Y	Y	Y	Y	N	Υ	Υ
New Mexico – NM	Υ	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ
New York – NY	Y	Y	Y	Y	Y	N	Y	Υ	Υ
North Carolina – NC	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
North Dakota – ND	Y	Y	Y	Y	Y	Υ	Y	N	Y
Ohio – OH	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Oklahoma – OK	N	Υ	Y	Υ	Υ	Υ	Y	N	Υ
Oregon – OR	Υ	Υ	Υ	Υ	N	N	Y	Υ	Υ
Pennsylvania – PA	Y	Y	Y	Y	Y	Υ	N	Υ	Y



Figure 27.

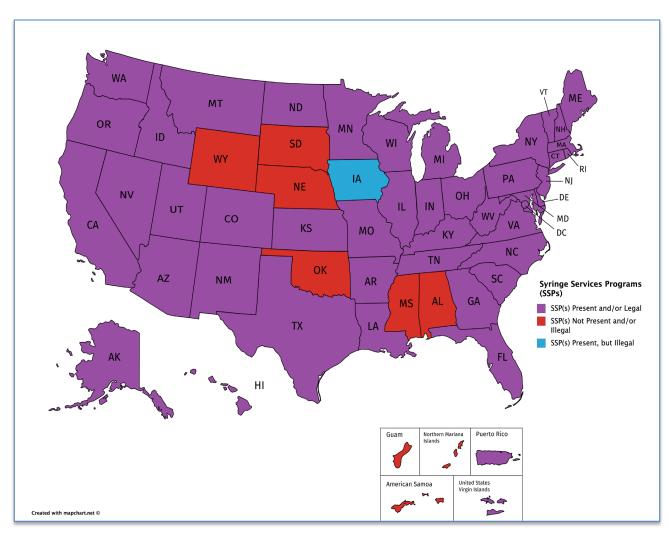
State	Syringe	Naloxone	Samaritan	PDMP	Doc Shop	Phy Exam	I.D.	Prescriber Ed	Lock-In
Rhode Island – RI	Υ	Υ	Υ	Υ	N	Y	N	Υ	Υ
South Carolina – SC	Υ	Υ	Pending	Υ	Υ	Υ	Υ	Υ	N
South Dakota – SD	N	Υ	Υ	N	Υ	N	N	N	N
Tennessee – TN	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Texas – TX	Υ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ
Utah – UT	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Vermont – VT	Υ	Υ	Y	Υ	Υ	N	Y	Y	Υ
Virginia – VA	Υ	Υ	Υ	Υ	Pending	Υ	Υ	Υ	Υ
Washington – WA	Y	Y	Y	Y	N	Y	N	Y	Υ
West Virginia – WV	Υ	Υ	Υ	Υ	Υ	Y	Υ	Υ	Υ
Wisconsin – WI	Υ	Υ	Y	Υ	Υ	N	Y	Y	Υ
Wyoming – WY	N	Υ	Υ	Υ	Υ	N	N	N	Υ
District of Columbia	Υ	Υ	Y	N	N	Y	N	Υ	Υ
American Samoa	N	?	?	?	N	N	?	?	?
Guam	N	?	?	Υ	N	N	?	?	?
N. Mariana Islands	N	?	?	?	N	N	?	?	?
Puerto Rico	Υ	?	?	?	N	N	?	?	?
U.S. Virgin Islands	Υ	?	?	?	N	N	?	?	?



Syringe Exchange Coverage Map November 2019

Figure 28.

Syringe Exchange Map Key: Purple: Syringe Exchange(s) Red: No Syringe Exchange(s)

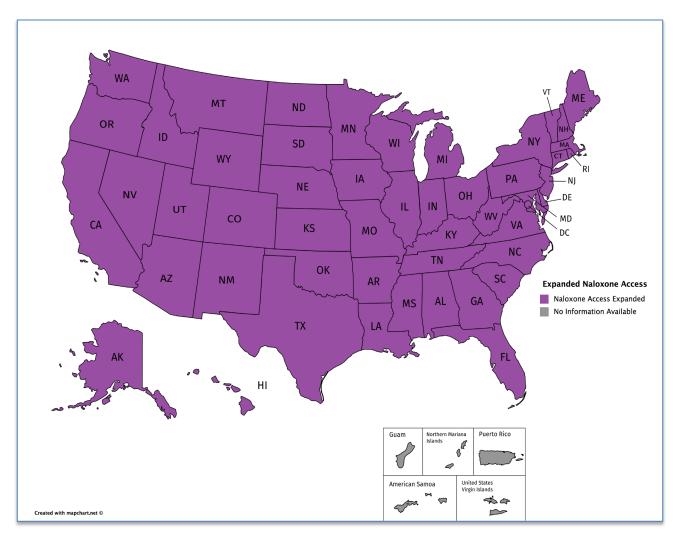




Expanded Naloxone Coverage Map November 2019

Figure 29.

Expanded Naloxone Map Key: Purple: Expanded Naloxone Red: Restricted Naloxone

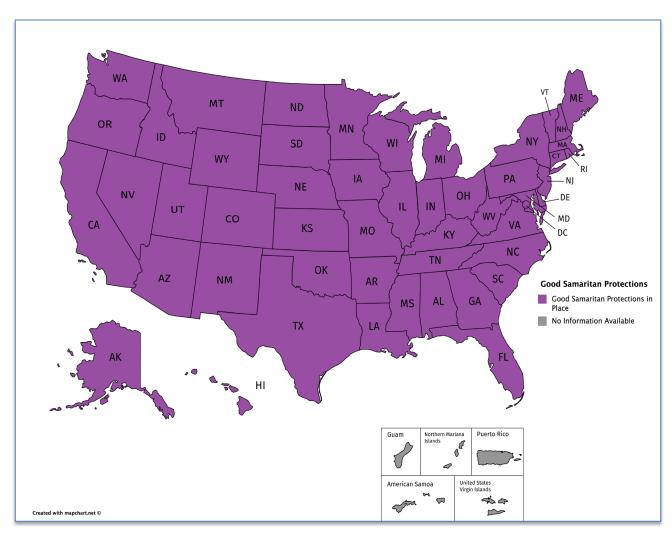




Good Samaritan Laws Coverage Map November 2019

Figure 30.

Good Samaritan Laws Map Key: Purple: Good Samaritan Laws Red: No Good Samaritan Laws

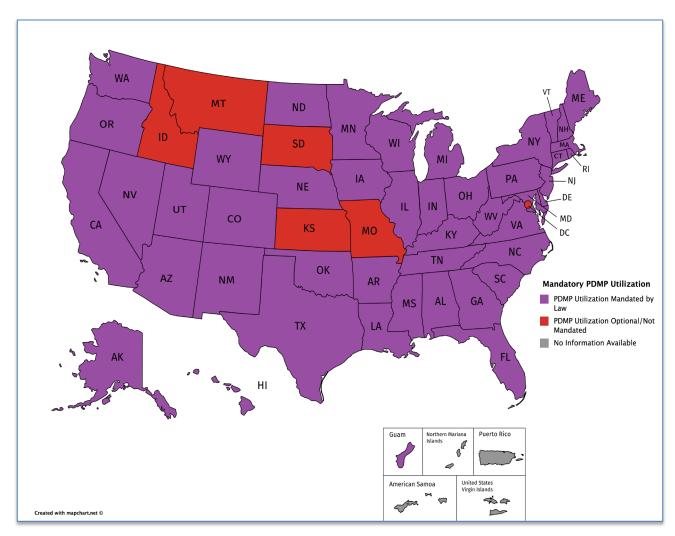




Prescription Drug Monitoring Programs (PDMPs) Coverage Map November 2019

**Figure 31.** PDMPs Map Key:

Purple: Mandatory PDMPs Red: No Mandatory PDMPs



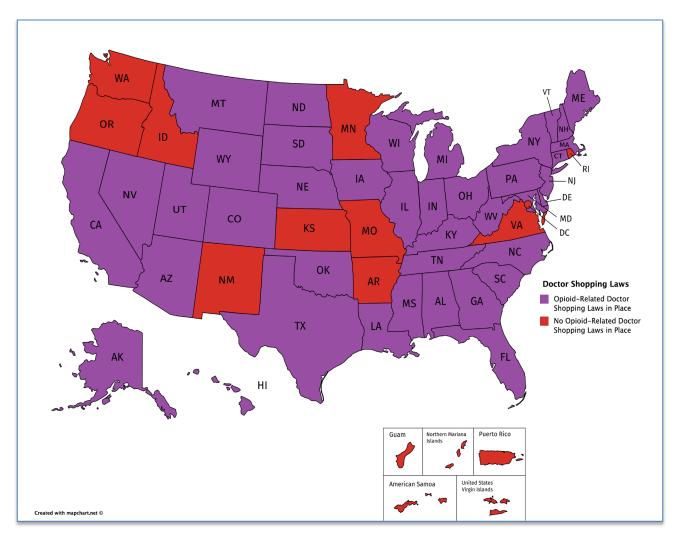


Doctor Shopping Laws Coverage Map November 2019

Figure 32.

Doctor Shopping Laws Map Key:

Purple: Doctor Shopping Laws Red: No Doctor Shopping Laws



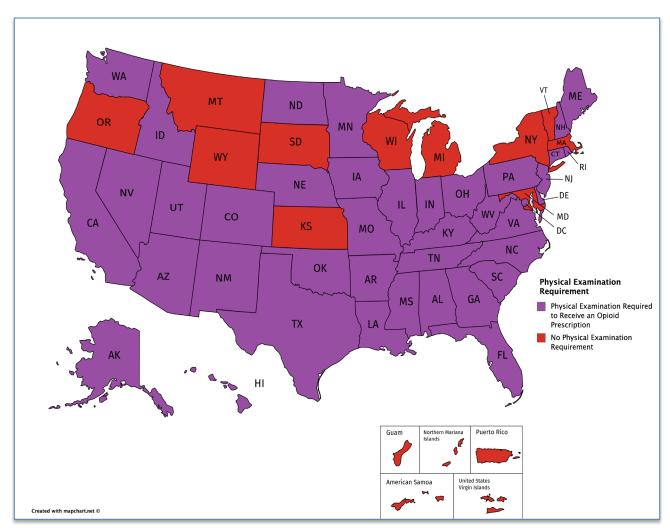


Physical Exam Required Coverage Map November 2019

Figure 33.

Physical Exam Required Map Key:

Purple: Physical Exam Required Red: No Physical Exam Required

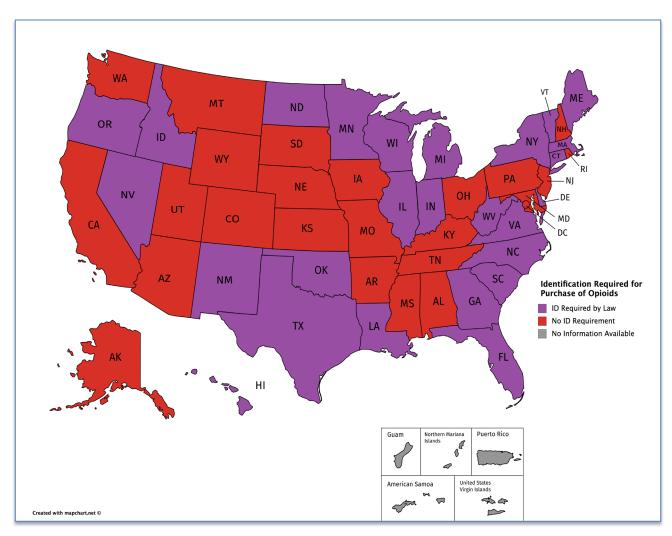




I.D. Required Coverage Map November 2019

Figure 34.

I.D. Requirement Map Key: Purple: I.D. Required Red: No I.D. Required





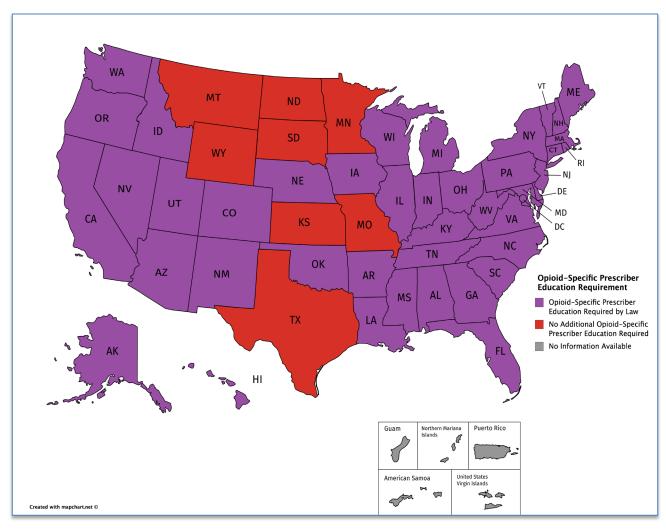
Prescriber Education Required Coverage Map November 2019

Figure 35.

Prescriber Ed Required Map Key:

Purple: Prescriber Ed Required

Red: No Prescriber Ed Required

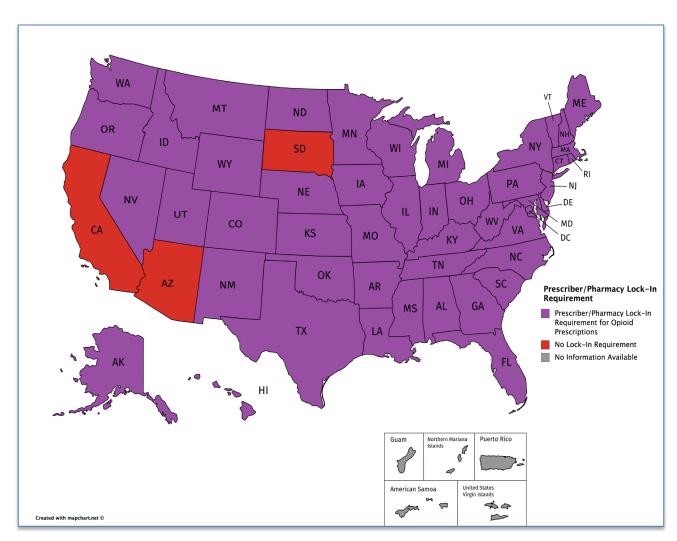




Lock-In Program Coverage Map November 2019

Figure 36.

Lock-In Program Map Key: Purple: Lock-In Program Red: No Lock-In Program





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.

### November 2019 Updates:

No updates

### November 2019 Notes:

- The following state has pending legislation that would legalize state-sponsored Syringe Exchanges FL, IA, MO, ND
- The following states have pending legislation requiring Mandatory PDMP reporting MO
- The following state has pending legislation implementing Doctor Shopping Laws (None)
- The following state has pending legislation requiring a Physical Examination before Opioid Prescribing MA
- The following state has pending legislation requiring Prescriber Education MN



# Regional Trends National Trends:

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# **Regional Trends**

### **National Trends:**

### HIV (2017 Preliminary National Rate - 11.8):

Since 2012, the overall number of new HIV infections continues to decline on an annual basis. In all age groups, except for people aged 25-29, the number of new HIV infections either declined, or remained stable; for people aged 25-29, new infections have been steadily increasing since 2013, particularly within Hispanic/Latinx populations. New HIV infections via Injection Drug Use (IDU) has declined, nationally, but in certain states, HIV via IDU has increased exponentially. A prime example of this is the state of West Virginia, which is currently experiencing its fourth HIV outbreak in three calendar years. From 2013-2017, West Virginia saw an annual average of 77 total new HIV infections. In 2018, that number increased to 87; in 2019, as of October 18, 2019, the state has seen 112 new HIV infections, of which 72 – 64.3% – of which have been linked to IDU as the primary risk factor for infection. The outbreak in Cabell County, WV – which borders both Kentucky and Ohio – will also impact new HIV infections in both Kentucky and Ohio, as many of the 82 cases identified in the Cabell County Cluster of HIV infections are non-residents of either the county or the state. Despite being diagnosed in West Virginia, it is likely that these patients whose infections were the likely result of IDU may have already engaged in IDU practices back in their counties and states of residence and may have spread HIV within their user networks. It can safely be assumed that, as more testing efforts get underway, that we will continue to see HIV infections via IDU increase in 2018 reporting and beyond until these patients have better access to preventive services.

### HBV (2017 National Rate – 1.1):

While the overate rate of new Hepatitis B (HBV) infections remained relatively stable from 2016 to 2017, certain states saw increases in new HBV infections, many of which appear to be related to IDU. Maine saw the most dramatic year-over-year increase of new HBV infections from 2016 to 2017, increasing their rate from 4.0 to 5.8, replacing Kentucky as having the second-highest rate of new HBV infections (after West Virginia). This increase is likely a result of IDU as, along with the rest of New England, the state continues to grapple with prescription and illicit opioid drug addiction. West Virginia, which has had the highest rate of new HBV infections in the country since at least 2010, saw its second consecutive decrease in new HBV infection since 2015, from 14.7 to 14.6 to 11.7. The rate of new infections is, however, still more than double that of the second-highest rate in Maine. As with Hepatitis C (HCV), IDU continues to be the leading driver for new HBV infections, particularly in rural and suburban areas of the country.



# Regional Trends Con't.

### **National Trends:**

### HCV (2017 National Rate – 1.0):

The overall rate of new HCV infections remained relatively stable from 2016 to 2017 while continuing the trend of new HCV infections being largely driven by IDU, particularly in rural and suburban parts of the U.S. In 2017, West Virginia replaced Massachusetts has having the highest rate of new HCV infections (WV – 5.6, up from 5.1 in 2016; MA – 4.8, down from 6.2 in 2016), as new HCV infections continue to mount in West Virginia as a result of the opioid crisis-related IDU. Delaware saw a drastic decrease in new HCV infections, from 2.6 in 2016 to 0.4 in 2017. This decrease should not be considered a trend, however, as Delaware's rate of new HCV infections was 0.4 in 2015, which could indicate that fewer people were testing from year to year. Indiana's rate of new infections jumped from 2.2 in 2016 to 2.9 in 2017 which is likely the result of IDU transmission. It should also be noted that methamphetamine is making a comeback, particularly in IN, OH, PA, WV, and KY – areas where addiction to opioid drugs has led to increased scrutiny and attention paid to illicitly obtained prescription opioid and the heroin markets. This is leading to an increased number of new HIV, HBV, and HCV infections as a result of IDU of methamphetamine, rather than opioid drugs.

### Overdose Deaths (2017 National Rate - 21.7):

The rate of drug overdose deaths increased from 19.8 in 2016 to 21.7 in 2017. Of those overdose deaths, 67.8% involved opioid drugs, particularly synthetic opioids such as fentanyl. From 2016 to 2017, synthetic opioid-involved overdose deaths saw an increase of 45.2%. Synthetic opioids (other than methadone), specifically fentanyl, have increasingly been finding their way into counterfeit prescription and illicit drug (primarily methamphetamine and heroin) supplies. Fentanyl has been coming into the U.S. either directly from China in its completed formulation, or indirectly from China via Mexico, where cartels and drug warehouses receive the components from China needed to manufacture fentanyl. Twenty-three states (AL, AR, CA, CO, DE, FL, GA, IL, IN, KY, LA, MD, ME, MI, NC, NJ, NY, OH, PA, SC, TN, WI, WV) saw statistically significant increases in the overdose death rates from 2016 to 2017, with New Jersey seeing a 29.3% increase, Indiana seeing a 22.5% increase, and North Carolina seeing a 22.3% increase. West Virginia continues to have the highest rate of overall drug overdose deaths, seeing an increase from 52.0 in 2016 to 57.8 in 2017. The next highest rate of overdose deaths is 46.3 in Ohio. As the rate of overall overdose deaths continues to climb, we expect to see similar climbing trends in new HIV, HBV, and HCV infections related to IDU.



# **Latest News**



# **Latest News**

### New HCV infection less common in MSM initiating PrEP

New incidences of hepatitis C virus infection among men who have sex with men, or MSM, who are actively using pre-exposure prophylaxis for HIV prevention appeared to be less common than previously shown, according to data presented at The Liver Meeting 2019.

"There have been a number of studies showing that once pre-exposure prophylaxis for HIV became available, risk-taking associated with sexual transmission and previously associated with trying to reduce the risk of HIV transmission started to go down," Jordan J. Feld, MD, MPH, FAASLD, from the University of Toronto University Health Network, said during a press conference highlighting the finds. "And so, PrEP clinics have reported high incidences of acute HCV infection both through sexual transmission and through drug use at the time associated with sex" (Healio, 2019).

## Educational Intervention Improves HBV Care, More Needed for Underserved Populations With HCV

A patient-centered educational intervention for hepatitis B virus (HBV) infection can improve overall HBV care in underserved safety-net populations1, according to study results presented at the American Association for the Study of Liver Disease' The Liver Meeting, held November 8 to 12, 2019, in Boston, Massachusetts.

Between July 2017 and July 2018, adults with chronic HBV were recruited at a single safety-net liver clinic to evaluate the effects of an in-person, language-concordant HBV educational intervention on appropriate HBV care, including clinic follow-up, laboratory monitoring, hepatocellular carcinoma (HCC) surveillance, and HBV treatment. Patients who participated in the educational intervention (n=102; 54.9% men; mean age, 52.0±13.8 years; 83.3% Asian) were compared in a 1:1 ratio with age- and sexmatched controls receiving usual care for HBV at the same clinic (Beairsto, 2019).



# Latest News Con't.

### Sex, ethnicity drive disparities in successful linkage to HCV care

Researchers observed sex-specific and ethnicity-specific disparities in successful linkage to care for chronic hepatitis C, including poor health literacy, lack of insurance, and fear of stigma that ultimately lowers screening and treatment rates, according to data presented at the American College of Gastroenterology Annual Meeting.

"These results confirm that disparities exist within the HCV care cascade," Chantal Gomes, DO, from Highland Hospital in Oakland, California, told Healio Gastroenterology and Liver Disease.

"In an effort to eliminate HCV, these disparities need to be addressed. It will be difficult to identify the exact cause of these disparities but knowing they exist and targeting ethnically diverse safety net populations with increased screening, HCV education and linkage to care are ideas."

Between 2014 and 2018, researchers observed 54,173 individuals who underwent HCV Ab testing and noted that during this period, the percentage of patients with both positive HCV Ab and HCV RNA tests decreased from 74% to 44%. They also reported that rates were higher among men than women (58% vs. 44%; P < .001).

Successful linkage to care was most successful among women than men (38.3% vs. 30.6%; P = .034) and Asian (66.7%) and African American patients (33.3), compared with white patients (27.4%) and other ethnicities (27.1%; P = .003) (Gomes, 2019).



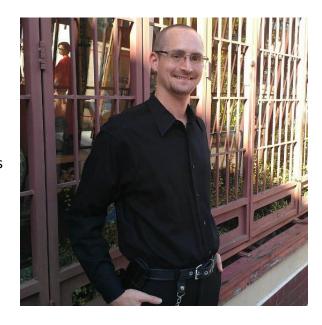
# **Contact**

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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 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.



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