HIV/HCV Co-Infection Watch: October 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: 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 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: http://tiicann.org/signup_listserv.html



Findings

The following is a summary of the key findings for October 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 October 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	X
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	Υ	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			X
Louisiana	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
Maine	Y	Υ	Υ	N	N	Y	Υ	N	Y	Υ	Υ	X



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	Υ	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	Υ	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	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Pennsylvania	Υ	Υ	Υ	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



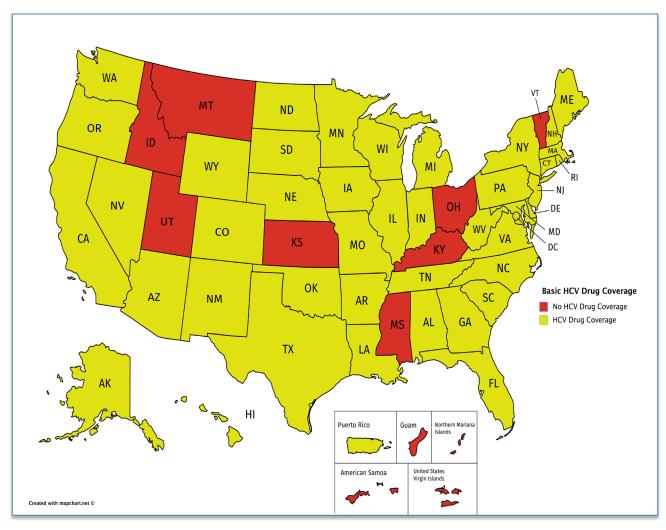
There are currently <u>46</u> AIDS Drug Assistance Programs (ADAPs) that cover some form of HCV drug therapies as part of their approved drug formularies. To learn more about ADAPs or their approved drug formularies, please visit http://adap.directory.

Figure 2.

Basic Coverage Map Key:

Lime Green: Basic Coverage

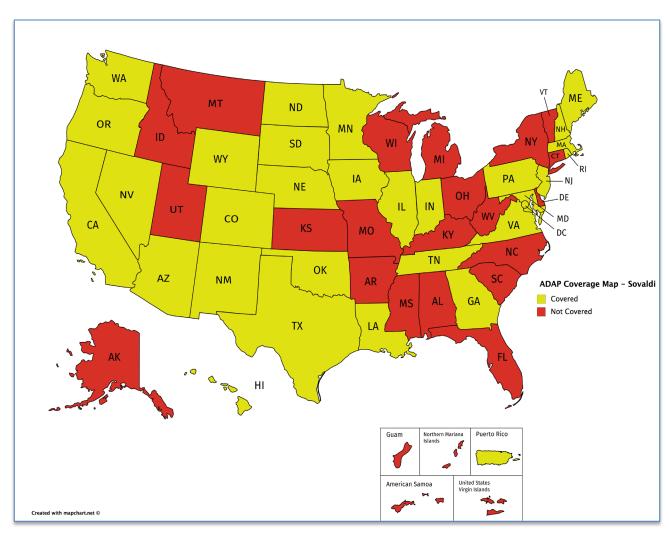
Red: No Coverage





Sovaldi Coverage Map October 2019

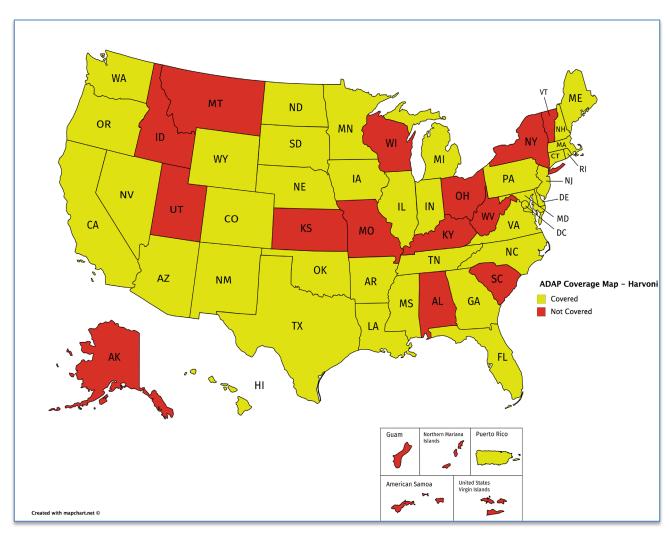
Figure 3.
Sovaldi Coverage Map Key:
Lime Green: Coverage
Red: No Coverage





Harvoni Coverage Map October 2019

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

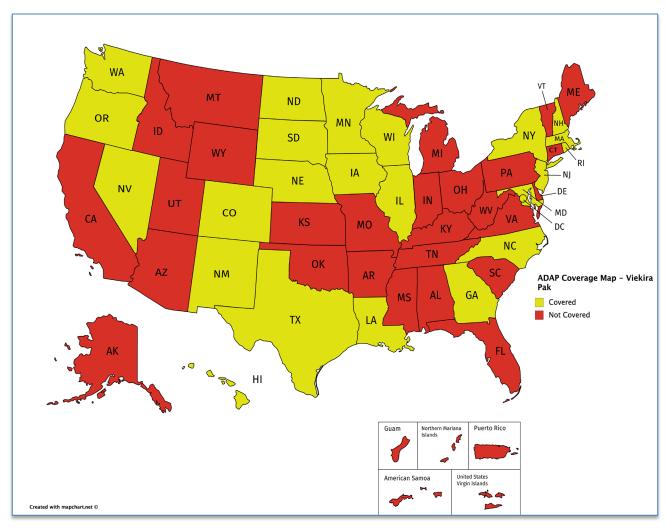




Viekira Pak Coverage Map October 2019

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

Red: No Coverage

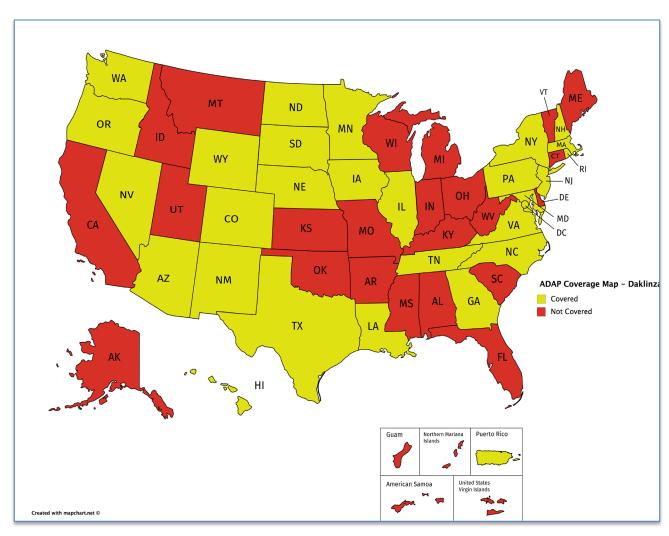




Daklinza Coverage Map October 2019

Figure 6.

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

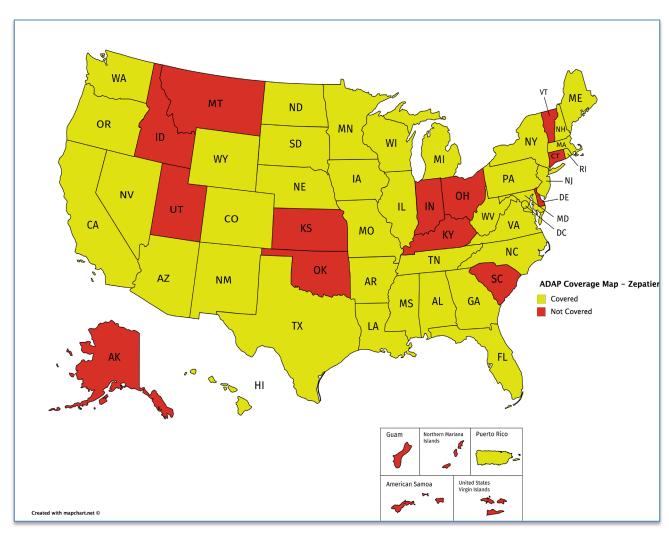




Zepatier Coverage Map October 2019

Figure 7.

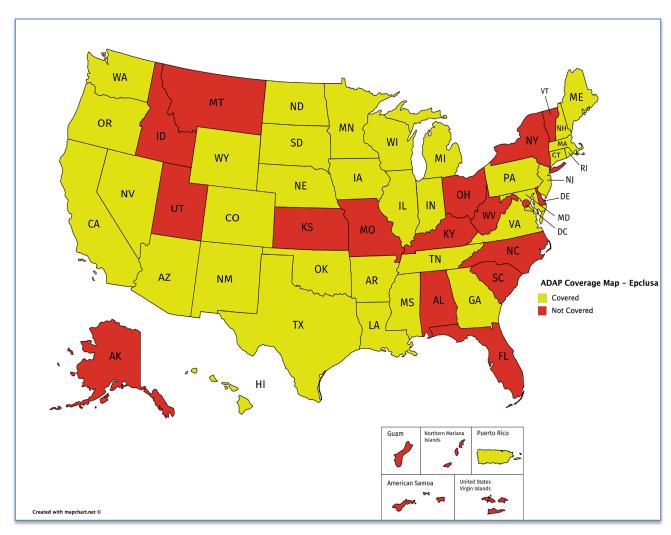
Zepatier Coverage Map Key:
Lime Green: Coverage
Red: No Coverage





Epclusa Coverage Map October 2019

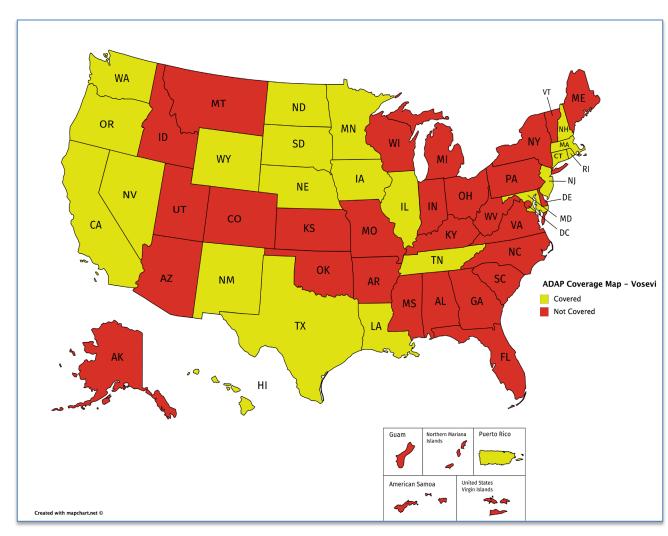
Figure 8.
Epclusa Coverage Map Key:
Lime Green: Coverage
Red: No Coverage





Vosevi Coverage Map October 2019

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

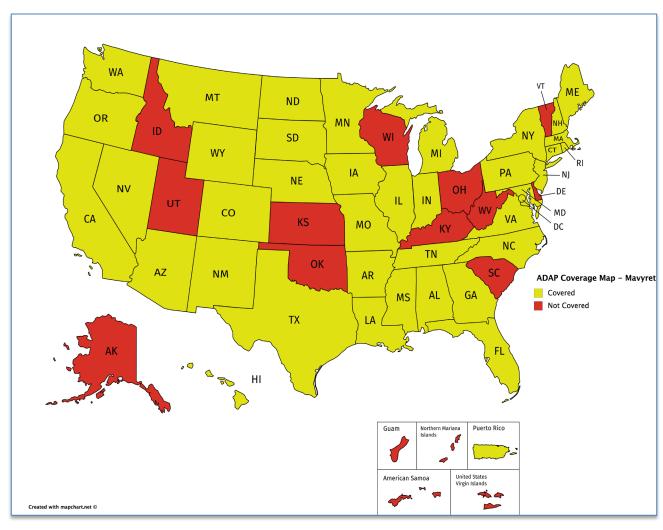




Mavyret Coverage Map October 2019

Figure 10.

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

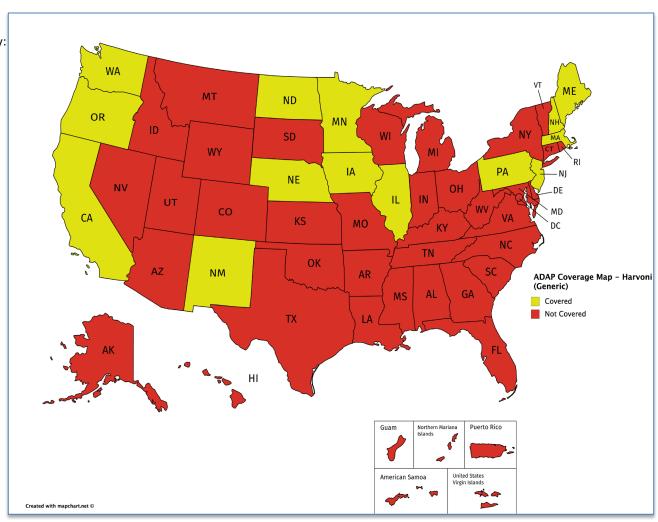




Harvoni *Generic* Coverage Map October 2019

Figure 11.Harvoni *Generic* Coverage Map Key:

Lime Green: Coverage Red: No Coverage



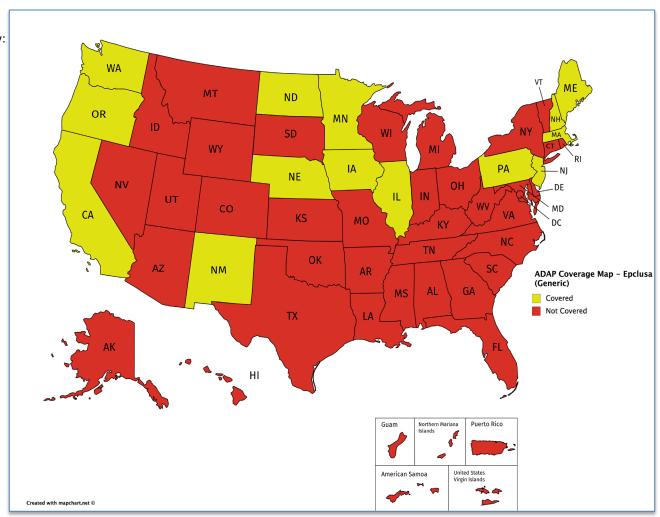


Epclusa *Generic* Coverage Map October 2019

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 September 15, 2019.

October 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**

October 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	γ*	γ*	N	γ*	γ*	γ*	Х
Alaska	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	Υ*	Υ	Υ	Х
Arizona	Υ	N	N	N	N	N	N	N	Υ*		γ*	Х
Arkansas	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	γ*			Х
California	Υ	Υ*	Υ*	Υ*	N	Υ*	γ*	N	γ*	γ*	γ*	Х
Colorado	Υ	Υ	Υ*	Υ	Υ	Υ	γ*	Υ	γ*	Υ	Υ	Х
Connecticut	Υ	N	N	N	N	N	Υ*	γ*	γ*	N	N	Х
Delaware	Υ	Υ	N	Υ	Υ	γ*	N	Υ	γ*	Υ	γ*	Х
Florida	Υ	N	N	N	N	N	N	γ*	γ*			Х
Georgia	Υ	Υ	Υ	N	Υ	Υ*	γ*	γ*	γ*			Х
Hawaii	Υ	Υ	Υ	Υ	N	N	Υ	Υ	Υ	Υ	Υ	Х
Idaho	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	γ*			Х
Illinois	Υ	Υ	Υ	Υ	Υ	Υ	γ*	Υ	γ*	Υ	Υ	Х
Indiana	Υ	Υ	Υ	Υ	Υ	γ*	Υ*	Υ	γ*	Υ	Υ	Х
Iowa	Υ	Υ	Y	N	Υ	Υ	γ*	Υ	γ*	Υ	γ*	Х
Kansas	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*			Х
Kentucky	Υ	Y	Y	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Louisiana	Υ	Υ	Y	Υ	Υ	Υ	γ*	Υ*	γ*	Υ	γ*	Х
Maine	Υ	Y	Y	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	Υ*	γ*	γ*	γ*	Х
Massachusetts	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ			Х
Michigan	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ*	γ*	Υ	Υ	Х
Minnesota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	Υ	Х
Mississippi	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	γ*		γ*	Х
Missouri	Υ	Υ	Υ	Υ	Υ	γ*	γ*	γ*	γ*	Υ	Υ	Х
Montana	Υ	Υ	Υ	N	Υ	Υ	Υ	Y	γ*	Υ	Υ	X
Nebraska	Υ	Υ	N	Υ	Υ	Υ	N	γ*	γ*	Υ	Υ	Х
Nevada	Υ	Υ*	Υ*	Υ	Υ	γ*	γ*	Υ	γ*	Υ*	γ*	Х
New Hampshire	Υ	Υ	Υ*	N	N	Υ	γ*	γ*	γ*	Υ*	γ*	Х
New Jersey	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Y	Υ	Υ	X
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*	γ*	Υ	γ*	Х
North Dakota	Υ	Υ	Υ	Υ	N	γ*	γ*	Υ	γ*	Υ	Υ	Х
Ohio	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ	Υ	N	Υ	Х
Oklahoma	Υ	Υ*	Υ*	Υ	Υ*	γ*	Υ*	γ*	Υ*	Υ	Υ	Х
Oregon	Υ	N	N	N	N	γ*	γ*	γ*	γ*	N	γ*	Х
Pennsylvania	Υ	Υ	γ*	Υ	Υ	γ*	γ*	Υ	γ*	Υ	Υ	Х



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

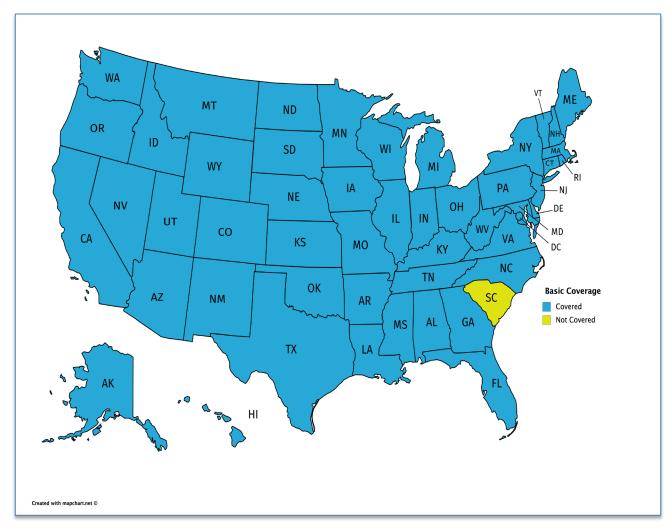
State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni <i>Generic</i>	Epclusa Generic	х
Rhode Island	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	Υ	Υ	Х
South Carolina	N	N	N	N	N	N	γ*	γ*	Υ*			Х
South Dakota	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Х
Tennessee	Υ	Υ	Υ*	Υ	Υ	Υ	γ*	Υ	Υ*	Υ	Υ	Х
Texas	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*	γ*	Υ	Υ	Х
Utah	Υ	Υ	γ*	Υ	Υ	γ*	γ*	Υ	Υ*	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	Υ*	Υ	Υ	Х
West Virginia	Υ	Υ	γ*	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	γ*	Υ	Υ	Υ	γ*	Υ	Υ*			Х
Washington, DC	Υ	Υ	Υ	Υ	Υ	Υ	Υ	γ*	γ*			Х
												Х
Fed. St. Micronesia												Х
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.

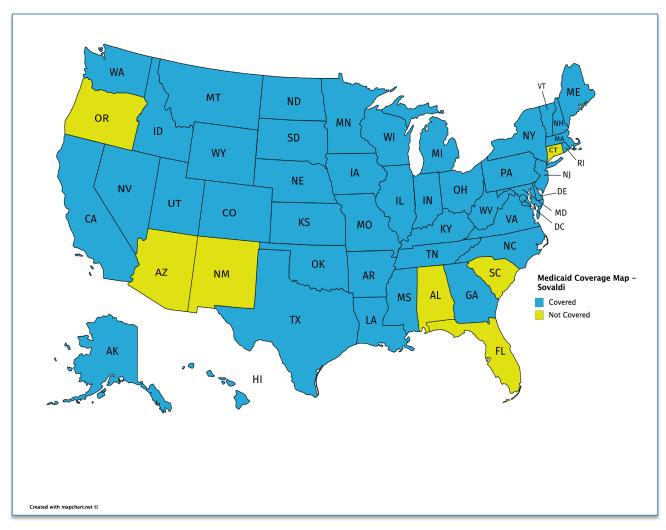
Basic Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Sovaldi Coverage Map October 2019

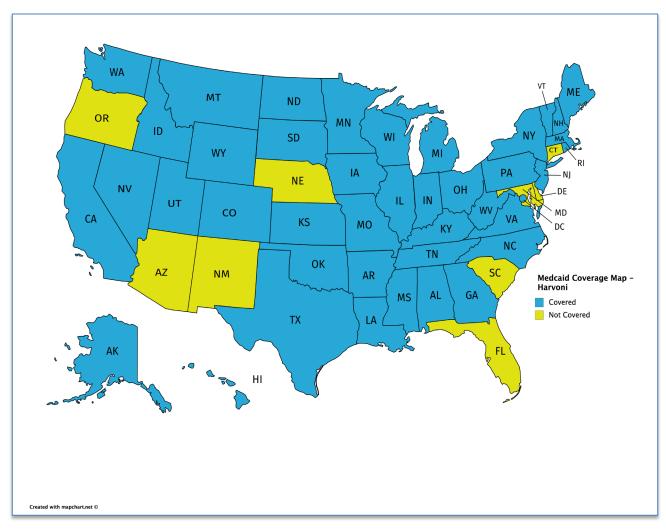
Figure 15.
Sovaldi Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Harvoni Coverage Map October 2019

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

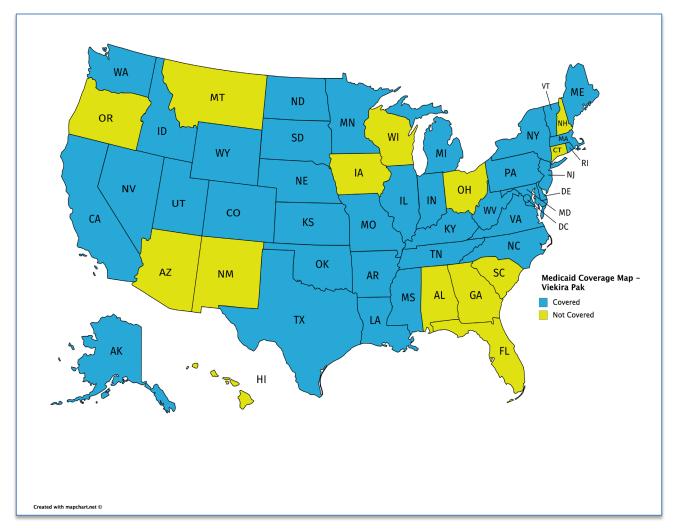




Viekira Pak Coverage Map October 2019

Figure 17.Viekira Pak Coverage Map Key:

Light Blue: Covered Yellow: Not Covered

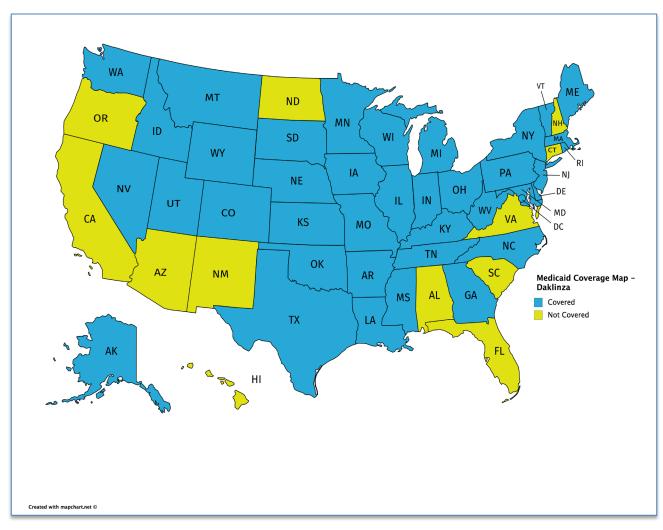




Daklinza Coverage Map October 2019

Figure 18.

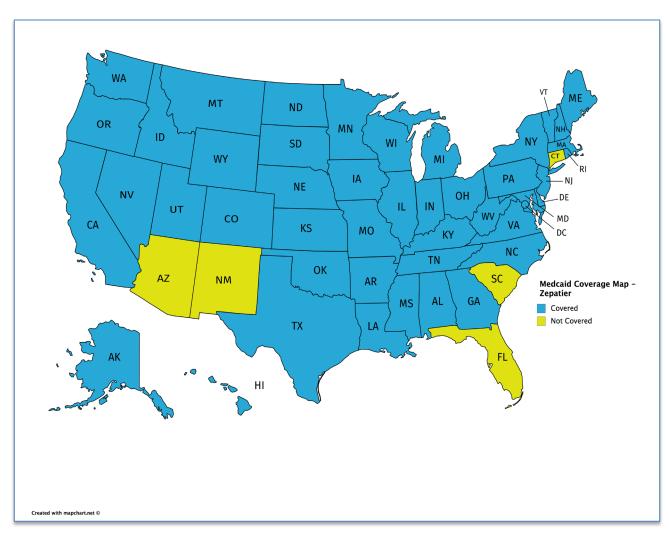
Daklinza Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Zepatier Coverage Map October 2019

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

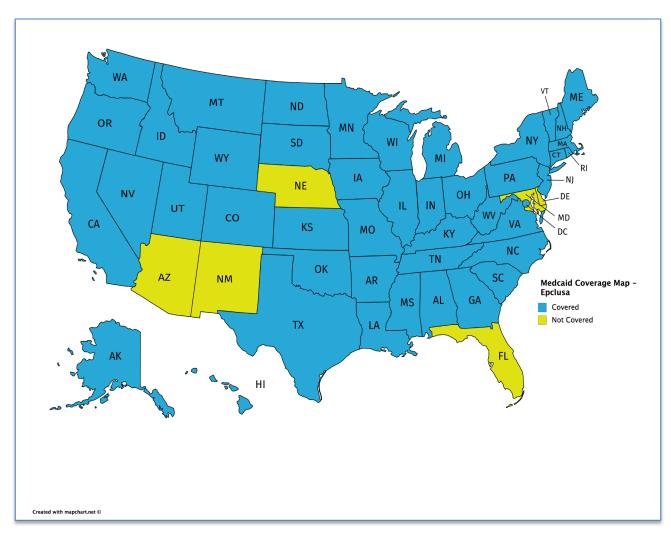




Epclusa Coverage Map October 2019

Figure 20.

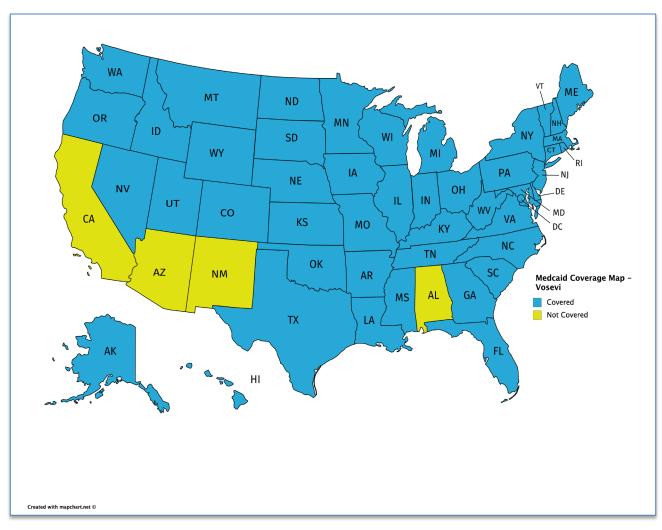
Epclusa Coverage Map Key: Light Blue: Covered Yellow: Not Covered





Vosevi Coverage Map October 2019

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

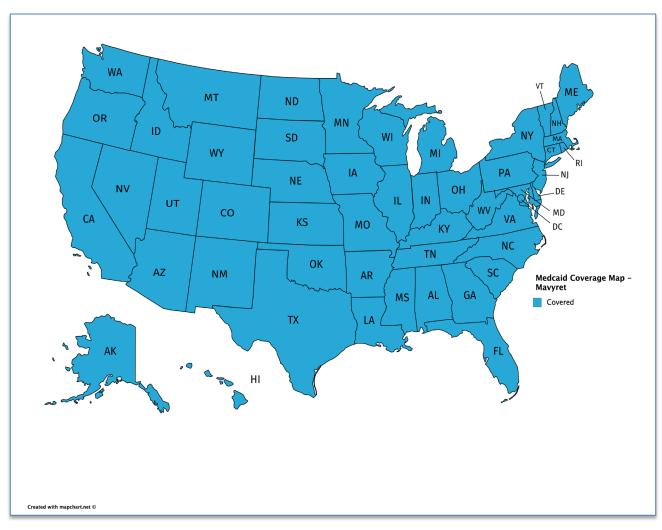




Mavyret Coverage Map October 2019

Figure 22.

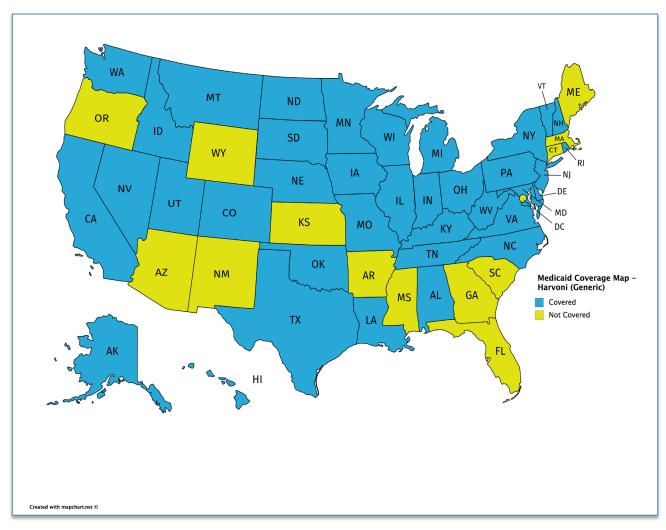
Mavyret Coverage Map Key:
Light Blue: Covered
Yellow: Not Covered





Harvoni *Generic* Coverage Map October 2019

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



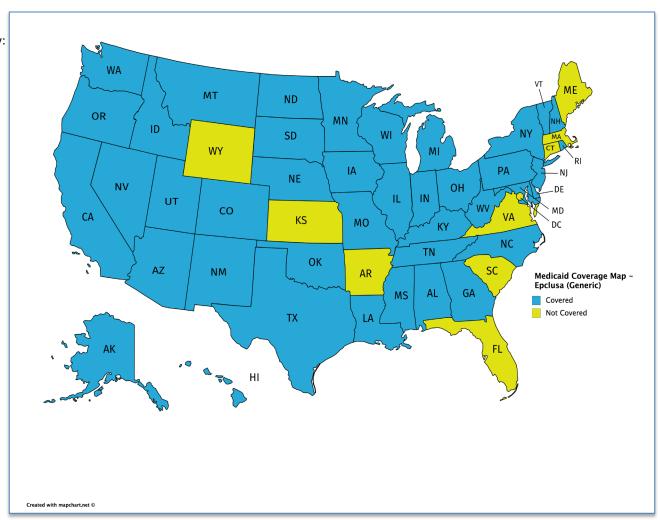


Epclusa *Generic* Coverage Map October 2019

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).

October 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

October 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



^{*} 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: http://ow.ly/fEJo309cJ7Z

The Assistance Fund:

Status: Closed

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

Patient Advocate Foundation Co-Pay Relief:

- Status: Open
- Maximum award of \$15,000
- Eligibility Requirements:
 - Patient must be insured, and insurance must cover prescribed medication
 - Confirmed HCV diagnosis
 - Reside and receive treatment in the U.S.
 - Income falls below 400% of FPL with consideration of the Cost of Living Index (COLI) and the number in the household
- Website: https://www.copays.org/diseases/hepatitis-c



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:
 https://www.panfoundation.org/index.php/en/patients/medications-covered
 - Income falls below 500% of FPL
 - Residing and receiving treatment in the U.S. (citizenship NOT required)
- Website: https://www.panfoundation.org/index.php/en/patients/assistance-programs/hepatitis-c

HealthWell Foundation:

- Status: Open
- Co-Pay Assistance with a maximum award of \$30,000
- Minimum Co-Pay Reimbursement Amount: None
- Minimum Premium Reimbursement Amount: None
- Eligibility Requirements:
 - Must be being treated for HCV
 - Have insurance that covers HCV prescribed medication
 - Income falls below 500% of FPL
 - Receiving treatment in the U.S.
- Website: https://www.healthwellfoundation.org/fund/hepatitis-c/



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	Y	Υ	Υ	Y	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	Υ	Υ	Υ	Υ	Υ	Υ	Υ	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	Y	Υ	Y	Y	Υ	Y	Υ	Y
New Hampshire –NH	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
New Jersey – NJ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
New Mexico – NM	Υ	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ
New York – NY	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ	Υ
North Carolina – NC	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ
North Dakota – ND	Υ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ
Ohio – OH	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Oklahoma – OK	N	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ
Oregon – OR	Υ	Υ	Υ	Υ	N	N	Υ	Υ	Υ
Pennsylvania – PA	Y	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ



Figure 27.

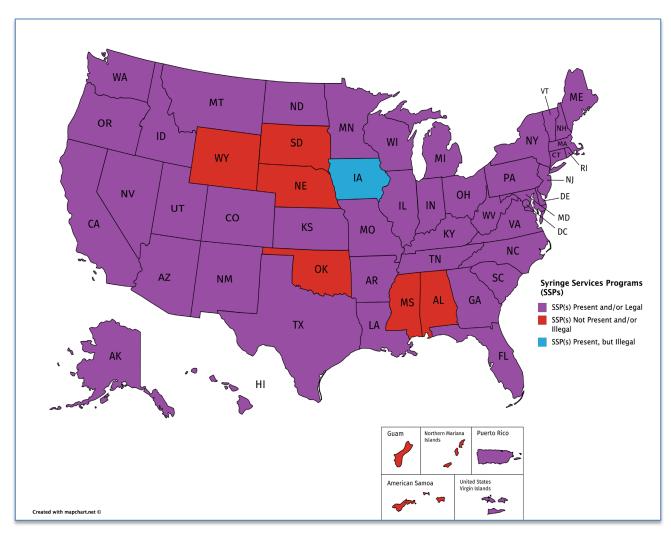
State	Syringe	Naloxone	Samaritan	PDMP	Doc Shop	Phy Exam	I.D.	Prescriber Ed	Lock-In
Rhode Island – RI	Υ	Υ	Υ	Υ	N	Y	N	Υ	Υ
South Carolina – SC	Υ	Υ	Pending	Υ	Υ	Υ	Υ	Υ	N
South Dakota – SD	N	Υ	Υ	N	Υ	N	N	N	N
Tennessee – TN	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Texas – TX	Υ	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ
Utah – UT	Υ	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Vermont – VT	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	Y	?	?	?	N	N	?	?	?



Syringe Exchange Coverage Map October 2019

Figure 28.

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

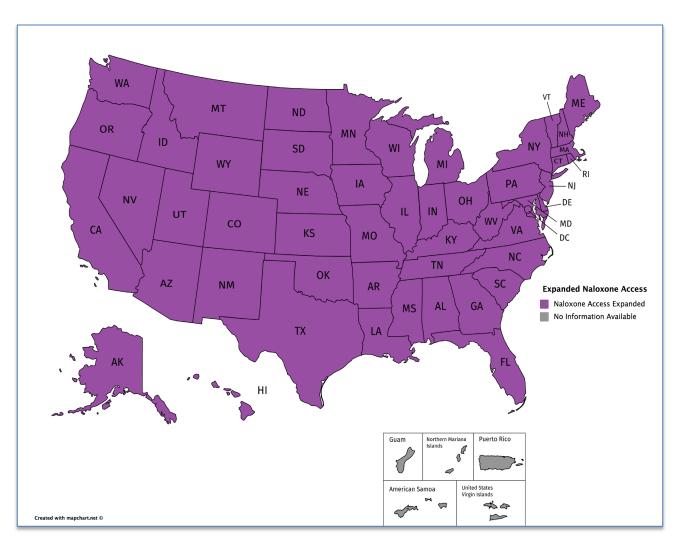




Expanded Naloxone Coverage Map October 2019

Figure 29.

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

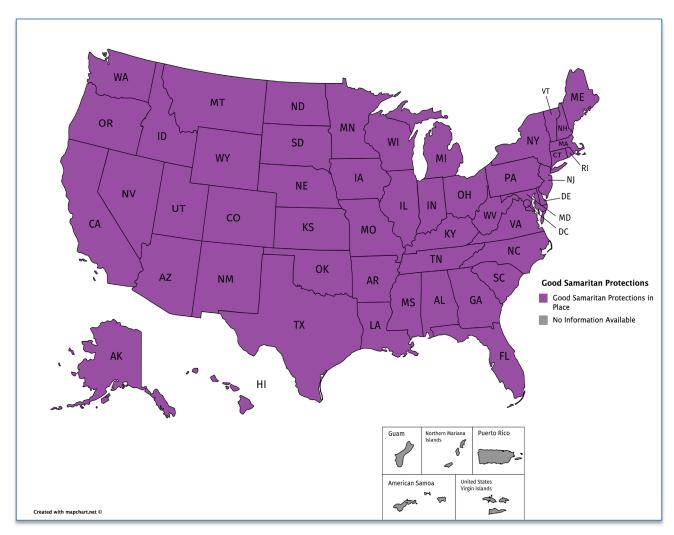




Good Samaritan Laws Coverage Map October 2019

Figure 30.

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



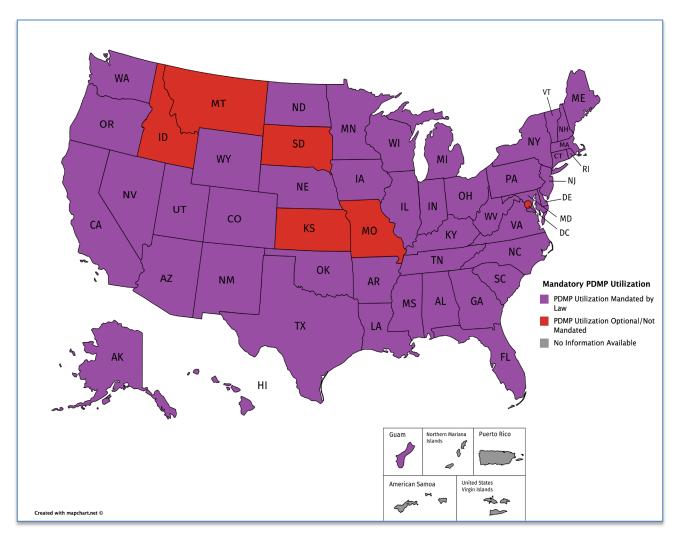


Prescription Drug Monitoring Programs (PDMPs) Coverage Map October 2019

Figure 31.

PDMPs Map Key:

Purple: Mandatory PDMPs Red: No Mandatory PDMPs

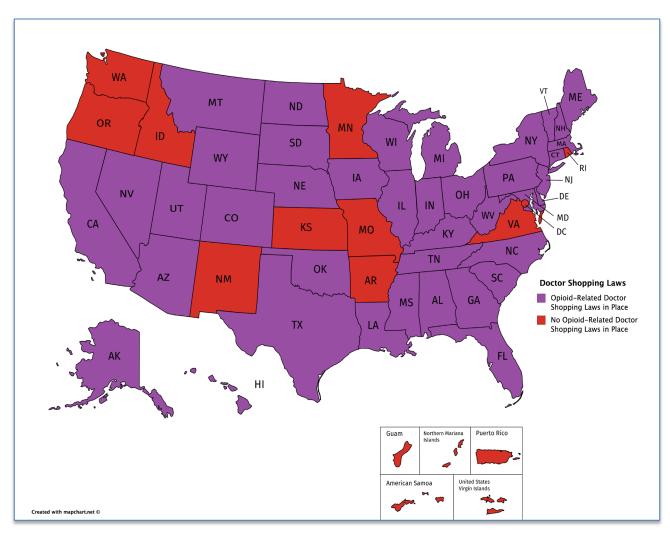




Doctor Shopping Laws Coverage Map October 2019

Figure 32.Doctor Shopping Laws Map Key:

Purple: Doctor Shopping Laws Red: No Doctor Shopping Laws



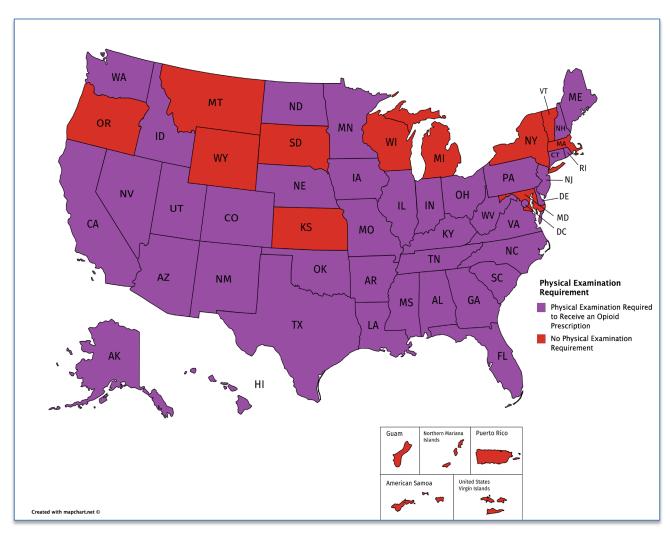


Physical Exam Required Coverage Map October 2019

Figure 33.

Physical Exam Required Map Key:

Purple: Physical Exam Required Red: No Physical Exam Required

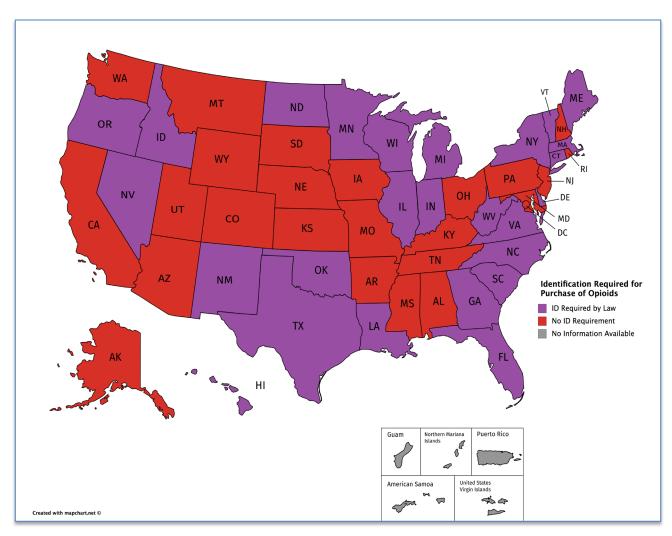




I.D. Required Coverage Map October 2019

Figure 34.

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





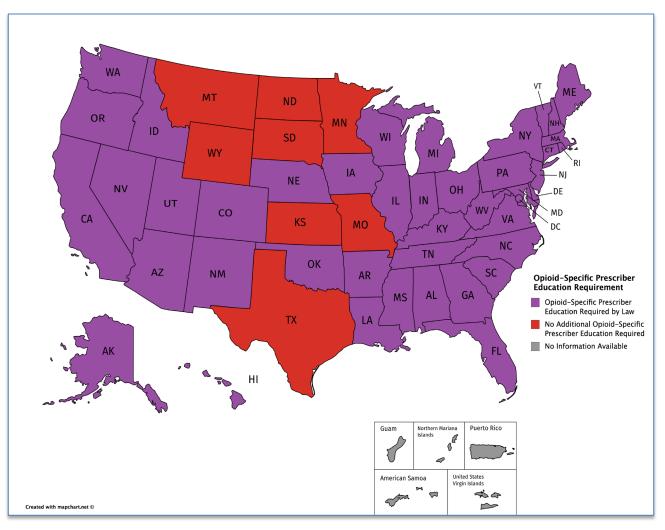
Prescriber Education Required Coverage Map October 2019

Figure 35.

Prescriber Ed Required Map Key:

Purple: Prescriber Ed Required

Red: No Prescriber Ed Required

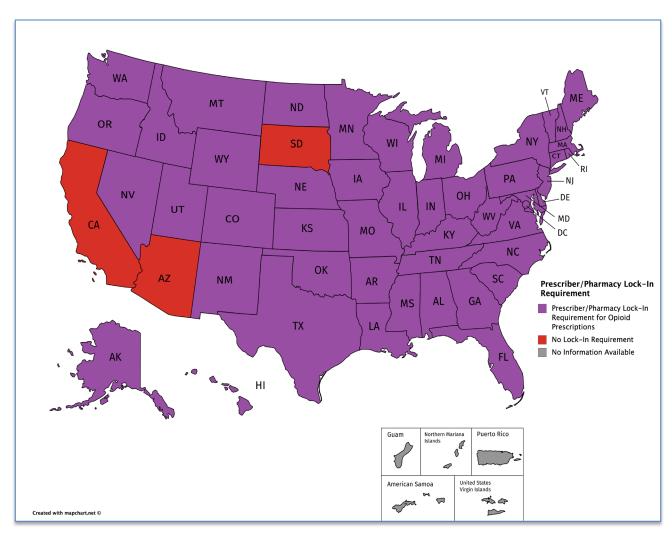




Lock-In Program Coverage Map October 2019

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.

October 2019 Updates:

No updates

October 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 District 09 – Pacific (AK, CA, HI, OR, WA):

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Regional Trends

District 09 - Pacific (AK, CA, HI, OR, WA):

HIV (2016 National Rate - 12.3):

• This region has a low burden of HIV, with only one state (California – 11.4; 15th highest rate in the U.S.) coming near the national rate of new infections of 11.8 (per 100,000).

HBV (2016 National Rate – 1.0):

• This region has a low burden of HBV, with only one state (Alaska – 1.2; 12th highest in the U.S.) having a rate of new infections above the national rate of 1.0 (per 100,000).

HCV (2016 National Rate - 1.0):

• This region has a low burden of HCV, with no states having rates of new infections higher than the national rate of 1.0 (per 100,000). Neither Alaska, nor Hawaii list Hepatitis C as a reportable condition.

Overdose Deaths (2016 National Rate – 21.7):

• This region has a low burden of overdose deaths, with only one state (Alaska – 20.2) having a rate of overdose deaths near the national rate of 21.7 (per 100,000).

Opioid-Related Overdose Deaths (2017 National Rate – 14.5):

• This region has a low burden of opioid-related overdose deaths, with only one state (Alaska – 13.9) having a rate of opioid-related overdose deaths near the national rate of 14.5 (per 100,000)

Opioid Prescribing Rates (2017 National Rate – 58.7 per 100 persons):

• This regional has a moderately rate of opioid prescriptions, with only one state (Oregon – 66.1) having a rate of opioid prescriptions per 100 persons. Washington state (57.2) and Alaska (52.0) have rates near the national prescribing rate.

ADAP HCV Coverage:

• All but one state (Alaska) have expanded their ADAP Formularies to include coverage of HCV DAAs. California requires a Clinical Prior Authorization; Hawaii has a limited number of slots for HCV treatment; Oregon requires a Denial and Appeal letter.



Regional Trends Con't.

District 09 - Pacific (AK, CA, HI, OR, WA):

Medicaid Prior Authorization Requirements:

- All five states require Prior Authorizations (Pas) in order for Medicaid recipients to receive treatment for HCV.
- AK Prescriber Restrictions; Patient Non-Compliance Rejections; No replacement of lost/stolen medications; Child-Pugh Score Requirement of B or C; HBV and HIV co-infection considerations; No Sobriety requirements: Mandatory Drug and Alcohol screening; Referral to a Substance Use Treatment (SUT) program
- CA PA required, but few restrictions
- HI PAs required by the following Managed Care Organization plans: Alohacare Advantage Plus, HMSA, Ohana (WellCare of HI). HMSA has the most restrictive requirements
- OR Prescriber Restrictions; Requested Child-Pugh score; HBV and HIV co-infection considerations
- WA Prior Authorization required

Correctional HIV and Viral Hepatitis Testing:

- All five states responded to CANN requests for screening/testing data:
 - California, Oregon, and Washington make HIV testing compulsory during the Intake process with Alaska and Hawaii testing upon request. AK, HI, and OR use an Opt-In delivery method, while CA and WA use an Opt-Out delivery method
 - Only Oregon and Washington make HBV testing compulsory, with Alaska and Hawaii testing upon request, and California testing based upon Clinical Criteria. AK, CA, HI, and OR use an Opt-In deliver method, while WA uses an Opt-Out delivery method
 - California, Oregon, and Washington make HCV testing compulsory, with Alaska and Hawaii testing upon request. AK,
 HI, and OR use an Opt-In delivery method, while CA and WA use an Opt-Out delivery method



Regional Trends Con't.

District 08 - Mountain (AZ, CO, ID, MT, NV, NM, UT, WY):

Correctional Hepatitis Testing:

- Neither Arkansas, nor Louisiana responded to CANN's information requests regarding Correctional HIV, HBV, and HCV Testing.
- Of the two responding states, both Oklahoma and Texas have made HIV testing compulsory upon intake with No Refusals possible.
- Neither Oklahoma, nor Texas require HBV testing upon entry, though Oklahoma does offer testing upon request. Both states test based upon Clinical Criteria, with Oklahoma using an Opt-Out delivery model and Texas using Opt-In.
- Neither Oklahoma, nor Texas require HCV testing upon entry, though Oklahoma does offer testing upon request. Both states test based upon Clinical Criteria, with Oklahoma using an Opt-Out delivery model and Texas using Opt-In.



Latest News



Latest News

Integrated HCV care in HIV centers reaches more PWID than usual care

Results from a real-world study of implementing hepatitis C testing into integrated care centers that deliver HIV services to people who inject drugs demonstrated superior infection awareness, testing and treatment compared with usual care.

"Calls have been made for integrating HCV testing with existing services including harm reduction and HIV prevention and treatment particularly for drug using populations, but there are few empirical trials to date," Sunil Suhas Solomon, PhD, from Johns Hopkins University School of Medicine in Baltimore, Maryland, and colleagues wrote. "Over a short duration, we observed significant impact on community-level HCV testing and awareness of HCV status among PWID."

Solomon and colleagues recruited 11,993 PWID at baseline in 2013 from six integrated care centers (ICCs) and six centers providing usual care, with 11,721 available for follow-up evaluation between 2016 and 2017. The ICCs were within either a government facility or nongovernment organization and provided services for PWID in a single PWID-friendly venue (Healio, 2019a).

Combined HCV, opioid use disorder increasing among pregnant women

The rates of hepatitis C infection at delivery among pregnant women in the U.S. increased between 2000 and 2015, especially among women with concomitant opioid use disorder, the prevalence of which also increased during that period.

Increases in HCV among both the general U.S. population and pregnant women during the last decade have correlated with the opioid epidemic, according to Jean Y. Ko, PhD, from the National Center for Chronic Disease Prevention and Health Promotion at the CDC, and colleagues, as approximately 68% of pregnant women with HCV have opioid use disorder.

"Current U.S. Preventive Services Task Force and CDC guidelines recommend hepatitis C testing for persons at high risk (eg, persons who inject drugs); however, epidemiologic changes in HCV infection in the United States have prompted a review of the evidence informing HCV testing," they wrote. "Treatment of opioid use disorder should include screening and referral for related conditions such as HCV infection" (Healio, 2019b).



Latest News Con't.

Antiretroviral Switches in HIV/HCV: No Increased Risk for Virologic Failure

HIV treatment and virologic failure, and sustained viral response at 12 and 24 weeks were not different between individuals with HIV/hepatitis C co-infection who did or did not switch antiretroviral medication regimens before treatment with direct antiretroviral medication, according to study results presented at IDWeek 2019, held from October 2- October 6, in Washington, DC.

In HIV/hepatitis C virus co-infection, direct-acting antivirals (DAA) and antiretroviral medications pose treatment challenges, and the management of contraindicated treatment combinations varies from practice to practice. Because antiretroviral therapy regimen switches may increase the risk of HIV virologic failure and treatment failure and has been reported to increase DAA treatment failure risk, this retrospective cohort study was designed to assess how antiretroviral therapy regimen switches affect treatment outcomes in adult patients with stable HIV/hepatitis C co-infection (HIV RNA<50 for ≥6 months) who received DAA hepatitis C therapy. Data analyzed were obtained by using the Centers for AIDS Research Network of Integrated Clinical Systems.

Participants switching antiretroviral therapy regimen within 6 months before DAA treatment were defined as the antiretroviral therapy switch cohort, and those with no change in the same time period were defined as the no-switch cohort. The primary study outcome was HIV treatment failure (including HIV virologic failure, progression to AIDS, discontinuation/change of antiretroviral therapy regimen, or death).

Of the 256 total participants, 25% were in the switch cohort. The most common baseline regimen in this group was protease inhibitor-based, while the most common baseline regimen for the no-switch group was integrase strand transfer inhibitor-based. The HIV/hepatitis C transmission risk factors, hepatitis C genotype, and alanine aminotransferase/aspartate aminotransferase (ALT/AST) were similar between the switch and no-switch groups. The percentage of participants with HIV treatment and virologic failure were also similar between the 2 groups, as were the proportions achieving sustained viral response at week 12 and sustained viral response at week 24 (Infectious Disease Advisor, 2019).



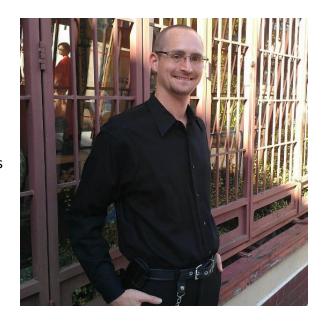
Contact

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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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