HIV/HCV Co-Infection Watch: April 2020

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 April 2020:

- **AIDS Drug Assistance Programs**

There are 56 State and Territorial AIDS Drug Assistance Programs (ADAPs) in the United States, 47 of which offer some form of coverage for Hepatitis C (HCV) treatment. Of those programs, 44 have expanded their HCV coverage to include the Direct-Acting Antiviral (DAA) regimens that serve as the current Standard of Care (SOC) for Hepatitis C treatment. 3 programs offer only Basic Coverage and 9 programs offer No Coverage. Three (3) territories – American Samoa, Marshall Islands, and Northern Mariana Islands – are not accounted for in this data. A state-by-state Drug Formulary breakdown of coverage is included in Figure 1, with accompanying drug-specific maps in Figures 2 – 12.

- **Medicaid Programs**

There are 59 State and Territorial Medicaid programs in the United States, and data is represented for all fifty states and the District of Columbia. As of October 01, 2016, all 50 states and the District of Columbia offer Expanded Coverage. A state-by-state PDL breakdown of coverage is included in Figure 13, with accompanying drug-specific maps in Figures 14 – 24.

- **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.). 47 States and Territories currently have Syringe Services Programs (SSPs) in place, regardless of the legality. 50 states and the District of Columbia have expanded access to Naloxone to avert opioid drug overdoses. 50 states and the District of Columbia have Good Samaritan laws or statutes that provide some level of protection for those rendering emergency services during drug overdoses. 38 states make reporting to Prescription Drug Monitoring Programs (PDMPs) mandatory, requiring physicians and/or pharmacists to report prescriptions written or filled to a state agency for monitoring. 40 states have Opioid-Specific Doctor Shopping Laws preventing patients from attempting to receive multiple prescriptions from numerous physicians, and/or from withholding information in order to receive prescriptions. 40 states mandate a Physical Exam Requirement in order for patients to receive a prescription for opioid drugs. 27 states have in place an ID Requirement mandating that people filling opioid prescriptions present a state-issued ID prior to receiving their prescription. 45 states require prescribing physicians to attend mandatory and continuing opioid prescribing education sessions. 44 states have Medicaid doctor/pharmacy Lock-In programs that require patients to receive prescriptions from a single physician and/or fill prescriptions from a single pharmacy. A state-by-state program breakdown is included in Figure 27, with accompanying drug-specific maps in Figures 28 – 36.

AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Figure 1. – Figure 12.

AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Figure 1. (* Indicates "Preferred Drug")

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni *Generic*	Epclusa *Generic*	X
Alabama	Y	N	N	N	N	Y	N	N	Y	N	N	X
Alaska	Y	N	N	N	N	N	N	N	N	N	N	X
Arizona	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	X
Arkansas	Y	N	Y	N	N	Y	Y	N	Y	Y	Y	X
California	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	X
Colorado	Y	Y	Y	Y	Y	Y	Y	N	Y	N	N	X
Connecticut	Y	N	Y	N	N	N	Y	Y	Y	N	Y	X
Delaware	Y	N	Y	N	N	N	N	N	N	N	N	X
Florida	Y	N	Y	N	N	Y	N	N	Y	Y	N	X
Georgia	Y	Y	Y	Y	Y	Y	Y	N	Y	N	N	X
Hawaii	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	X
Idaho	N	N	N	N	N	N	N	N	N	N	N	X
Illinois	N	N	N	N	N	N	N	N	N	N	N	X
Indiana	Y	Y	Y	N	N	N	Y	Y	Y	N	N	X
Iowa	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	X
Kansas	N	N	N	N	N	N	N	N	N	N	N	X
Kentucky	N	N	N	N	N	N	N	N	N	N	N	X
Louisiana	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	X
Maine	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y	X

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

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

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

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

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

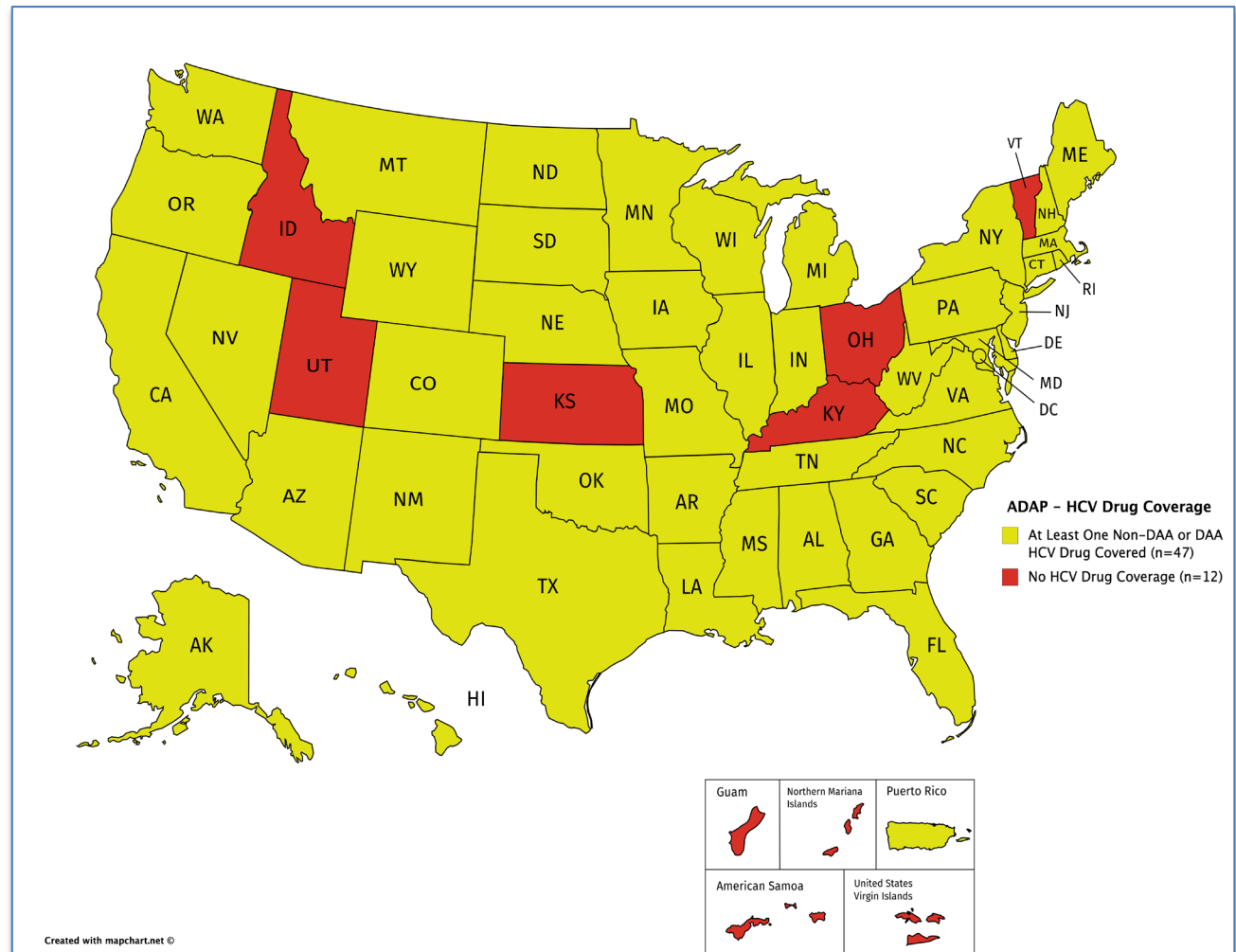| State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni *Generic*	Epclusa *Generic*	X
Rhode Island	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	X
South Carolina	Y	N	N	N	N	N	N	N	N	Y	Y	X
South Dakota	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	X
Tennessee	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	X
Texas	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	X
Utah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

AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

There are currently **46** 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

ADAP – HCV Drug Coverage

At Least One Non–DAA or DAA HCV Drug Covered (n=47)

No HCV Drug Coverage (n=12)

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Sovaldi Coverage Map
April 2020

Figure 3.

Sovaldi Coverage Map Key:
  Lime Green: Coverage
  Red: No Coverage
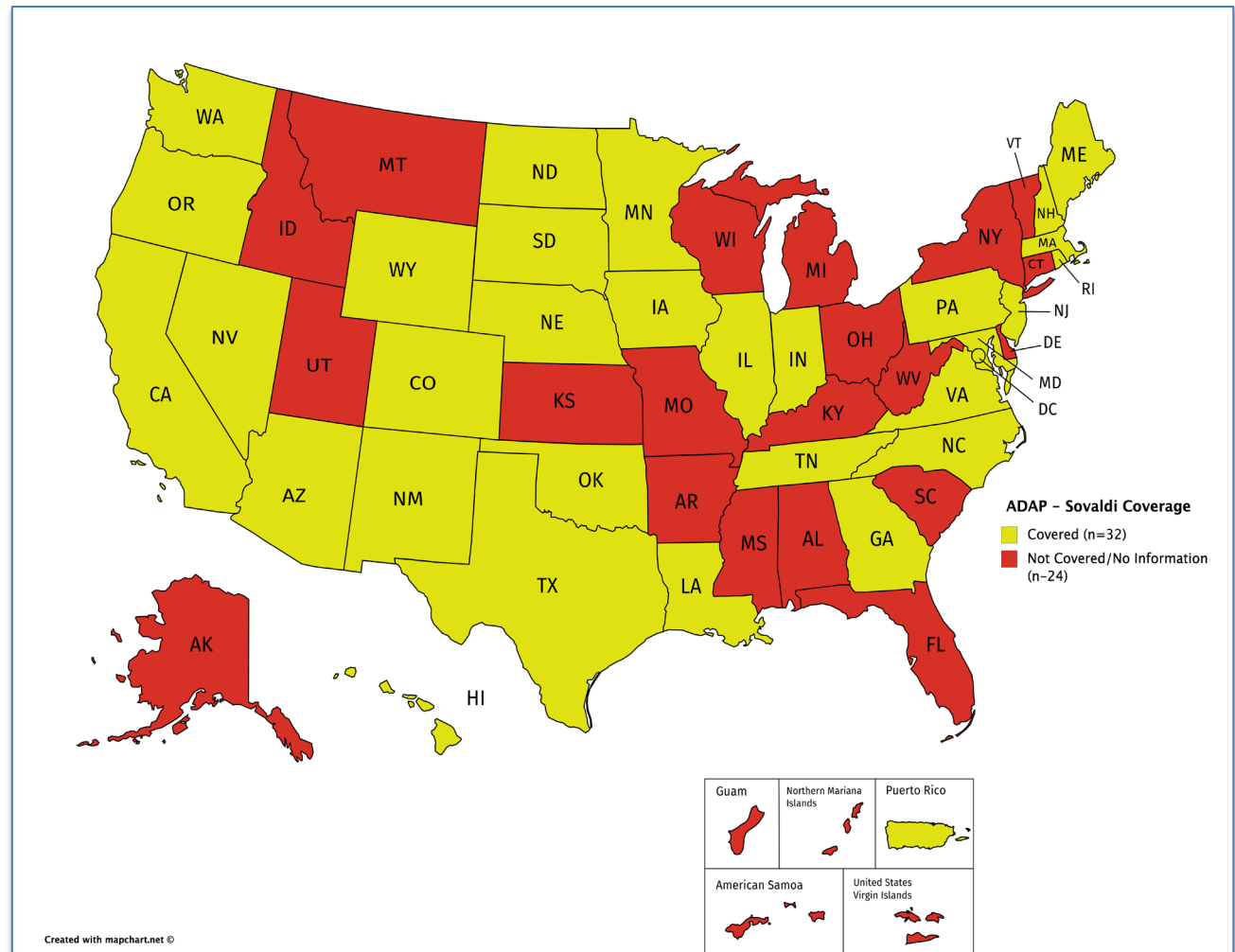
ADAP – Sovaldi Coverage
  Covered (n=32)
  Not Covered/No Information (n-24)

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Harvoni Coverage Map
April 2020

Figure 4.

Harvoni Coverage Map Key:
  Lime Green: Coverage
  Red: No Coverage
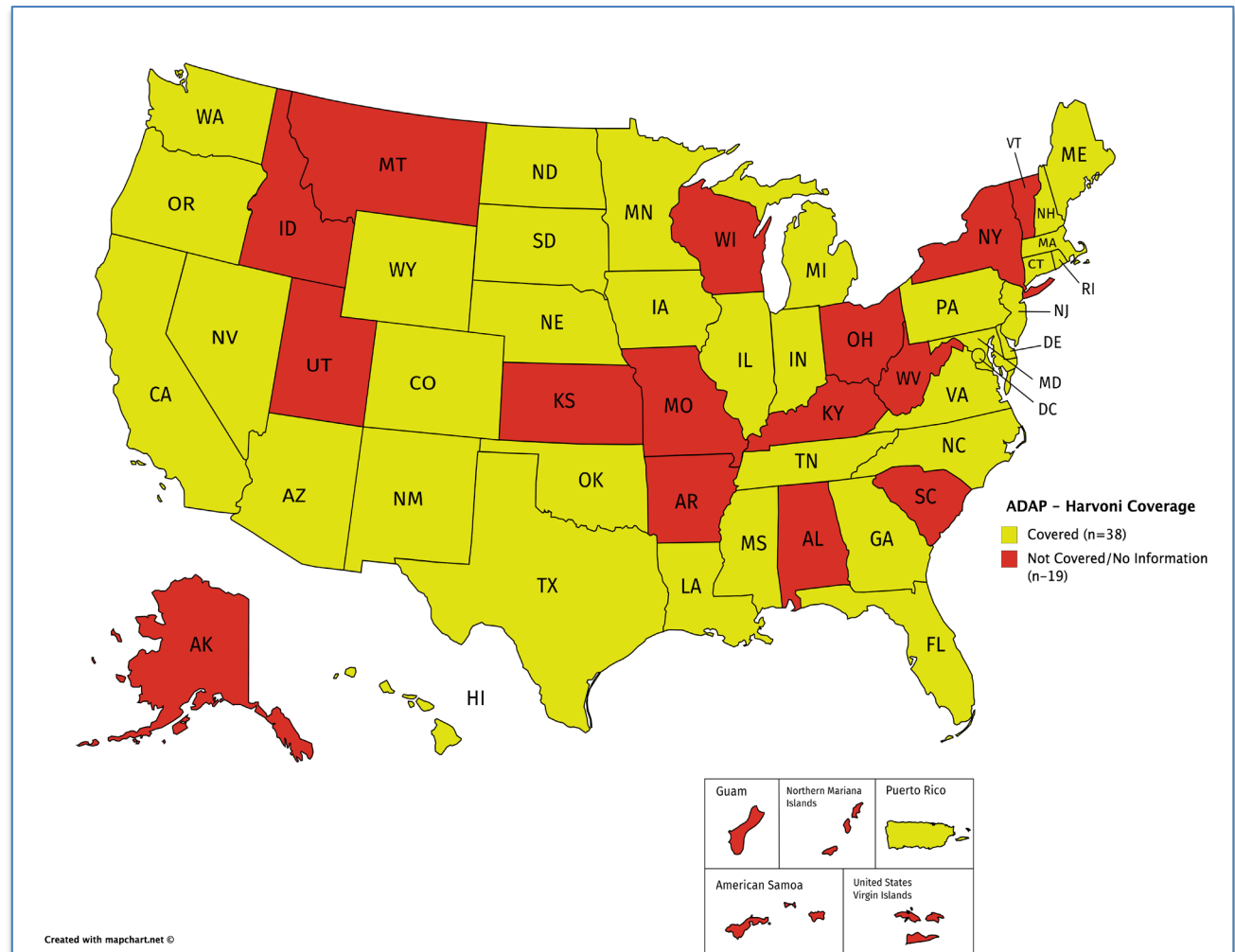
ADAP – Harvoni Coverage
Covered (n=38)
Not Covered/No Information (n–19)

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Viekira Pak Coverage Map
April 2020

Figure 5.

Viekira Pak Coverage Map Key:
  Lime Green: Coverage
  Red: No Coverage

ADAP – Viekira Pak Coverage
Covered (n=24)
Not Covered (n=35)

AIDS Drug Assistance Programs (ADAPs) & HCV Treatments
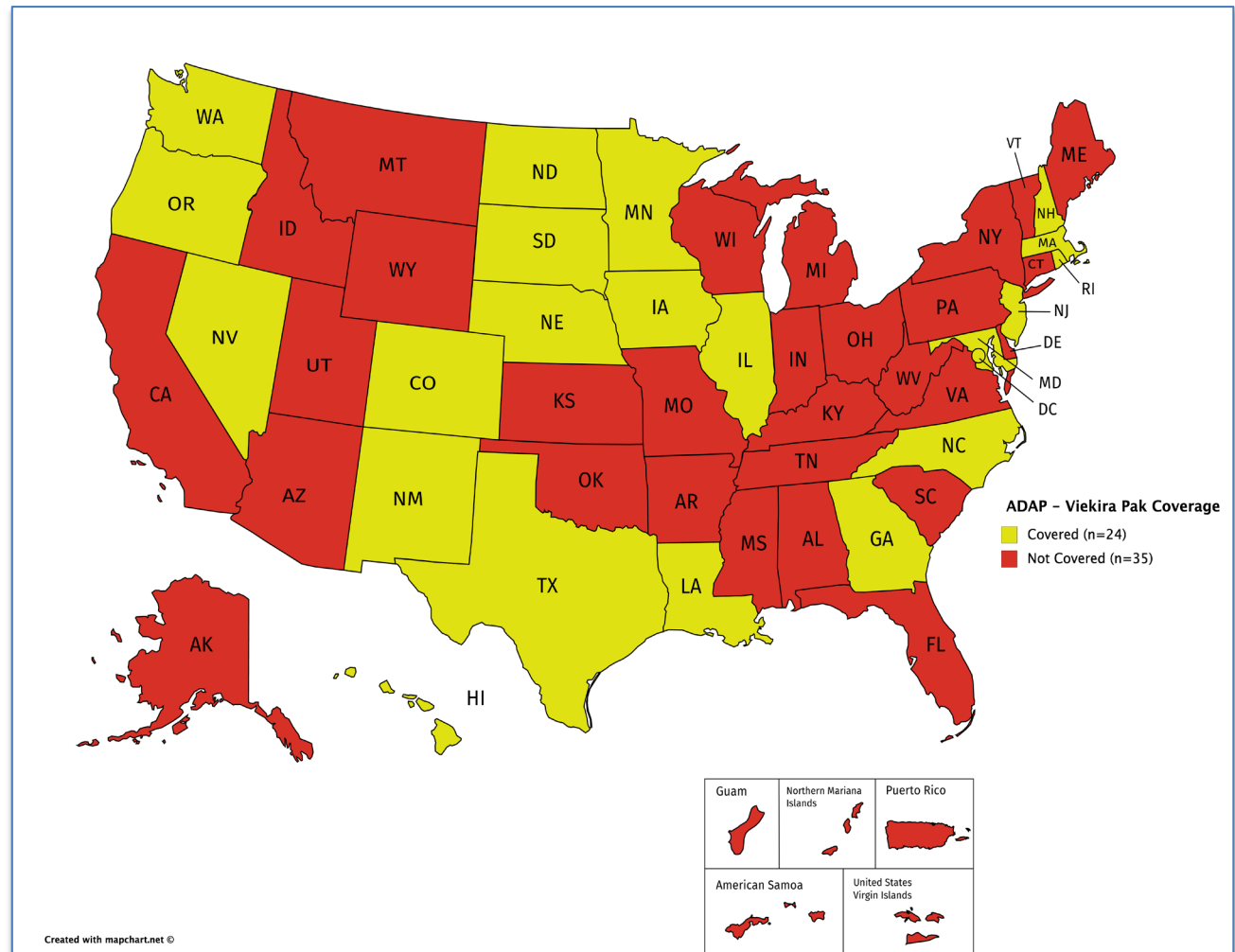
Daklinza Coverage Map
April 2020

Figure 6.

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

ADAP – Daklinza Coverage
Covered (n=29)
Not Covered (n=30)
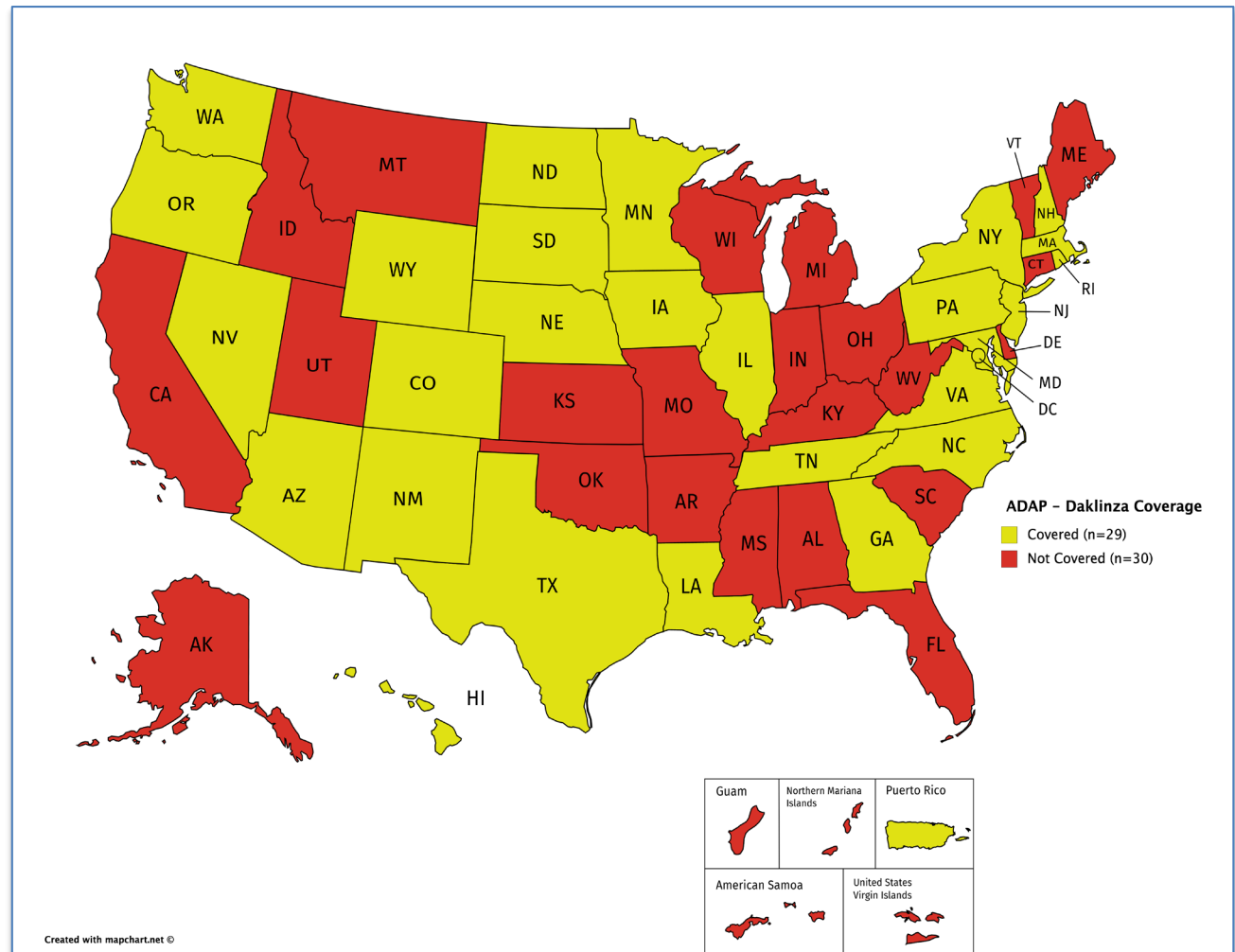
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Zepatier Coverage Map
April 2020

Figure 7.

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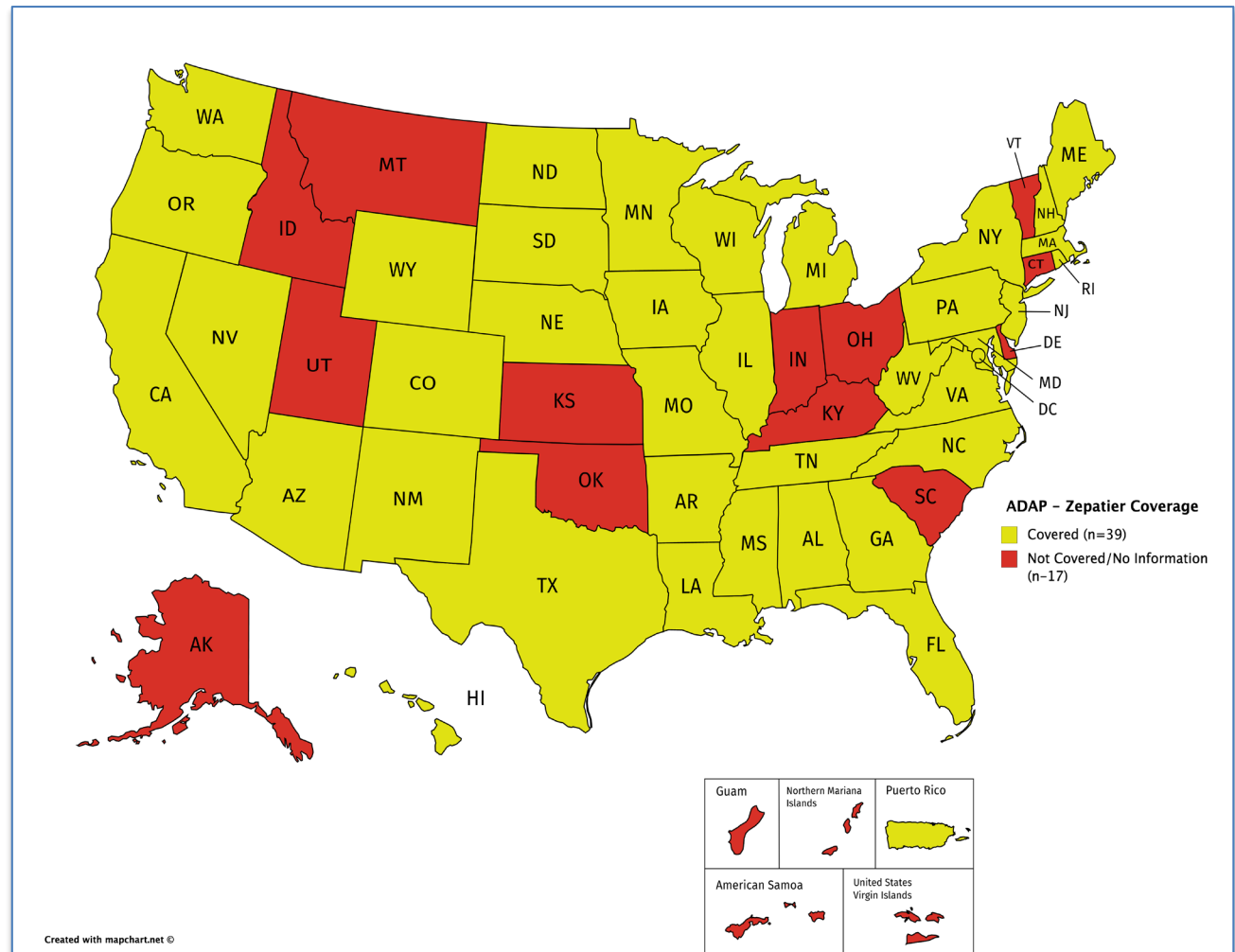
ADAP – Zepatier Coverage

- Covered (n=39)
- Not Covered/No Information (n–17)

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Epclusa Coverage Map
April 2020

Figure 8.

Epclusa Coverage Map Key:
  Lime Green: Coverage
  Red: No Coverage
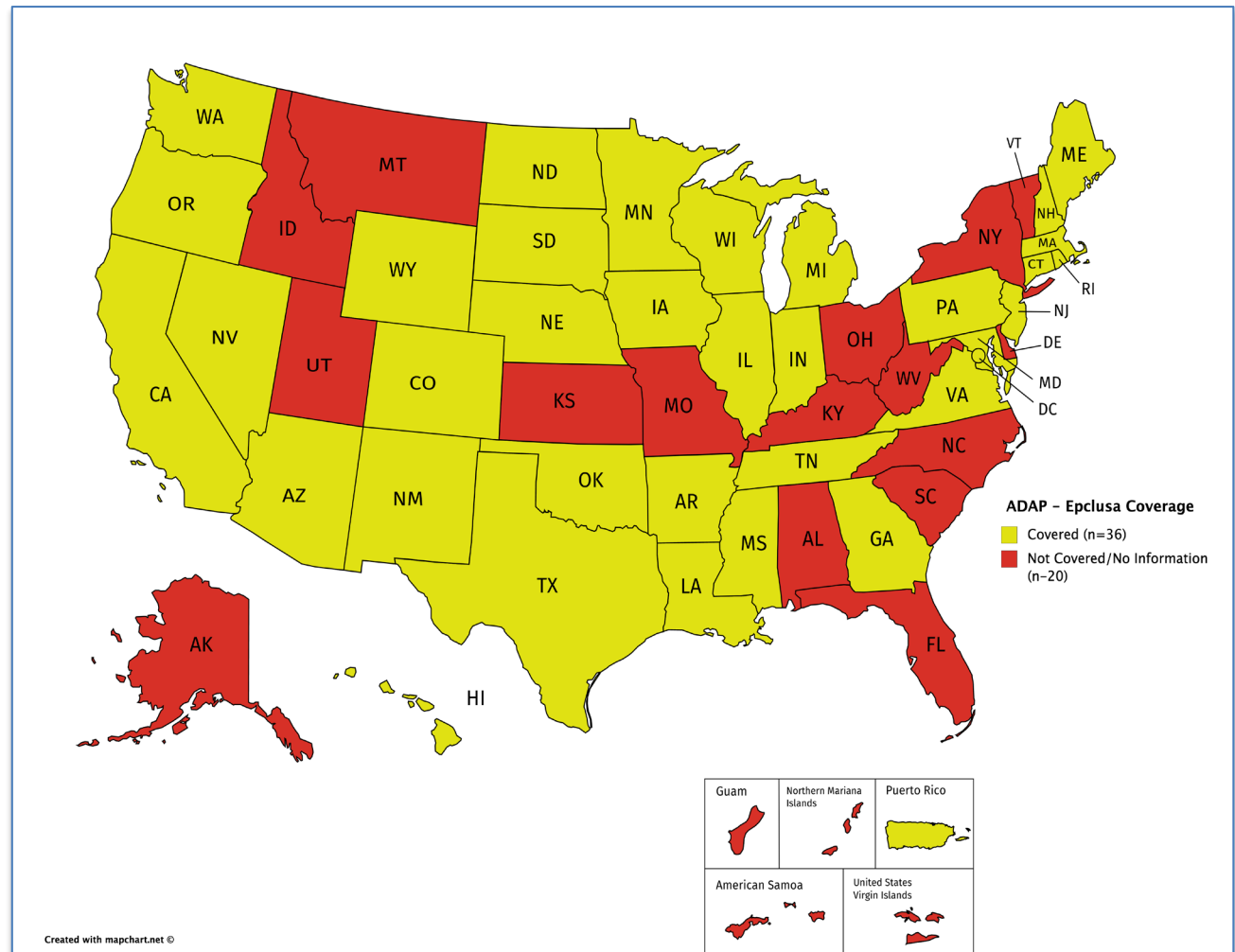
ADAP – Epclusa Coverage
Covered (n=36)
Not Covered/No Information (n–20)

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Vosevi Coverage Map
April 2020

Figure 9.

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

ADAP – Vosevi Coverage
Covered (n=26)
Not Covered/No Information (n–31)

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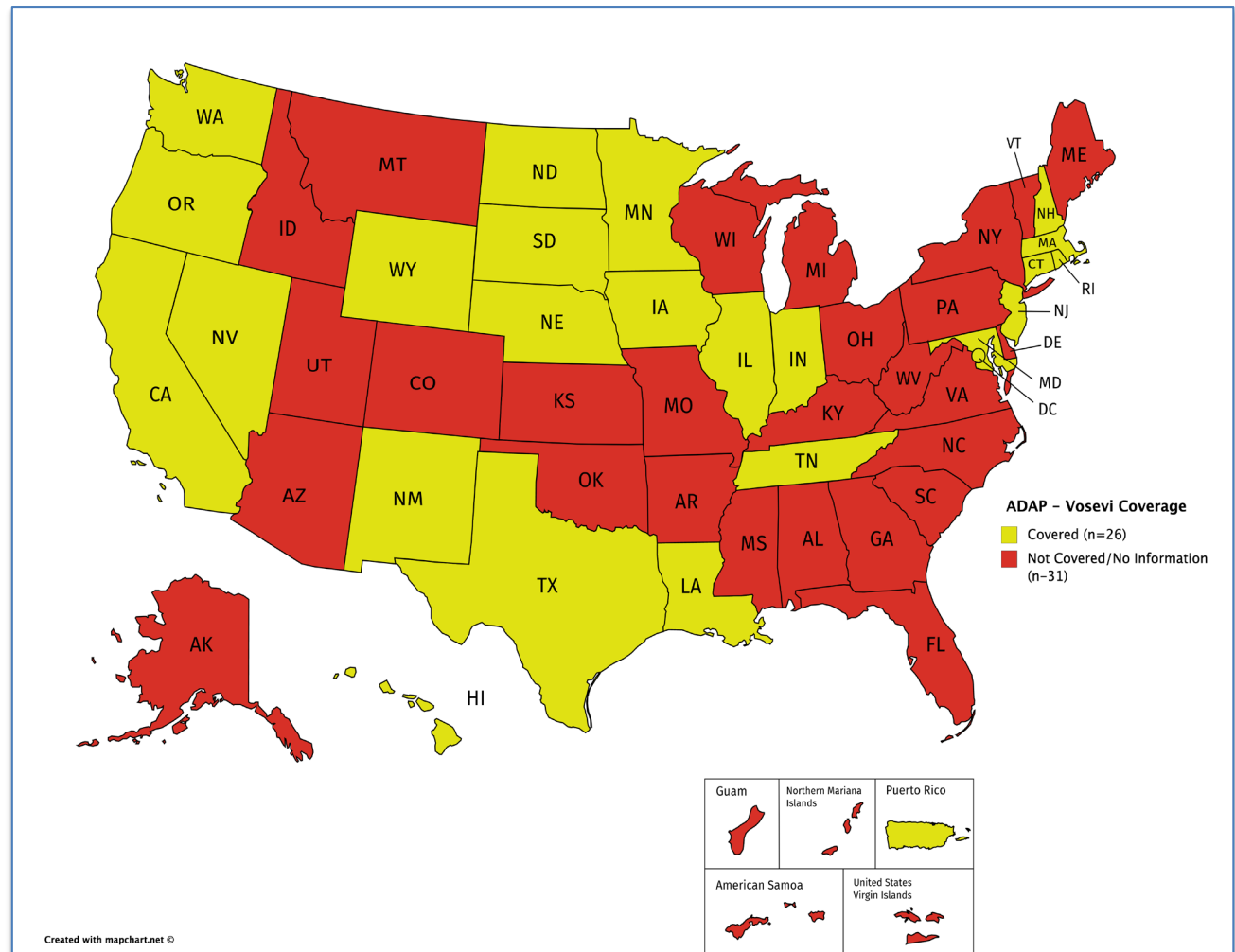
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Mavyret Coverage Map
April 2020

Figure 10.

Mavyret Coverage Map Key:
   Lime Green: Coverage
   Red: No Coverage
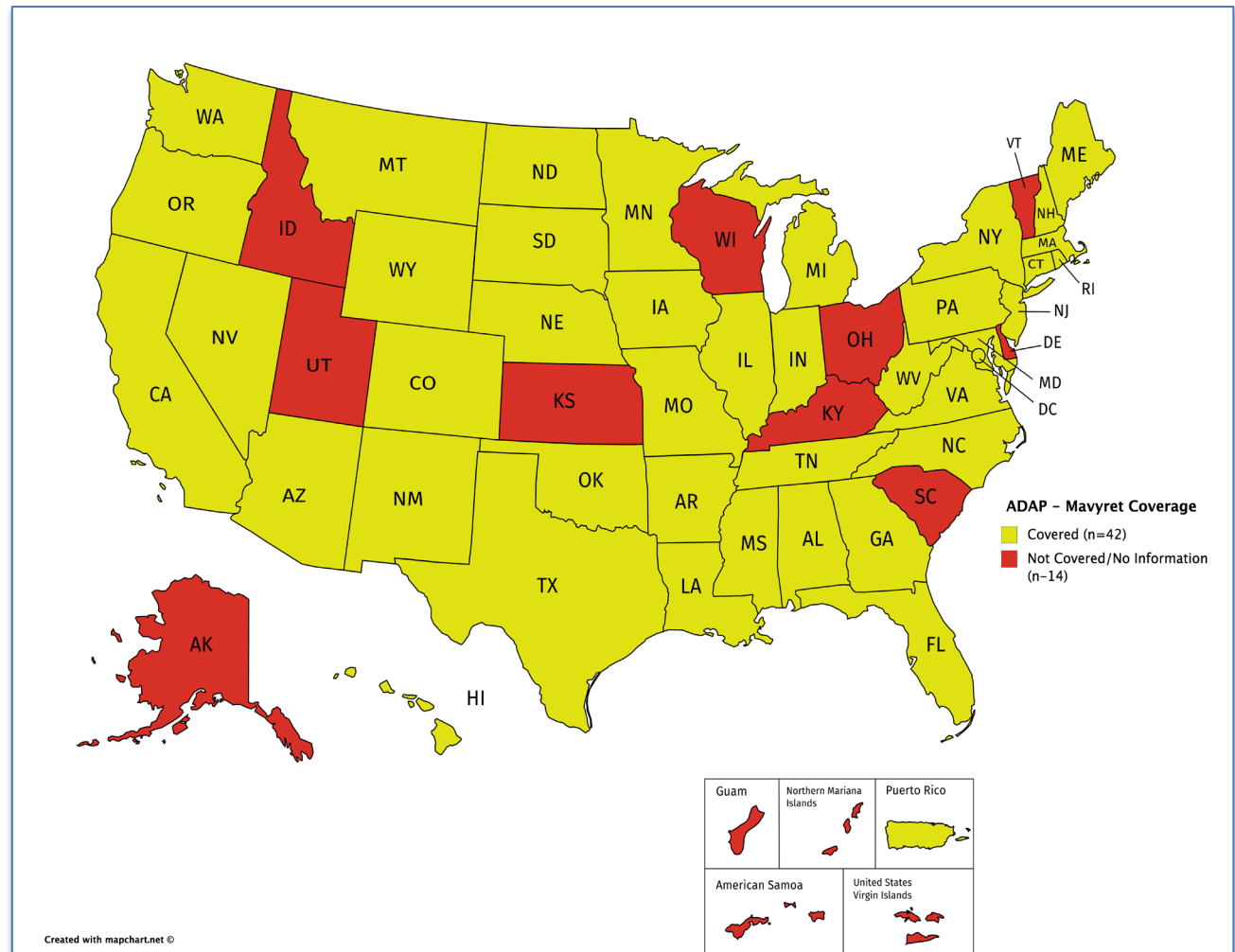
ADAP – Mavyret Coverage
Covered (n=42)
Not Covered/No Information (n–14)

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AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Harvoni *Generic* Coverage Map
April 2020

Figure 11.

Harvoni *Generic* Coverage Map Key:
 Lime Green: Coverage
 Red: No Coverage
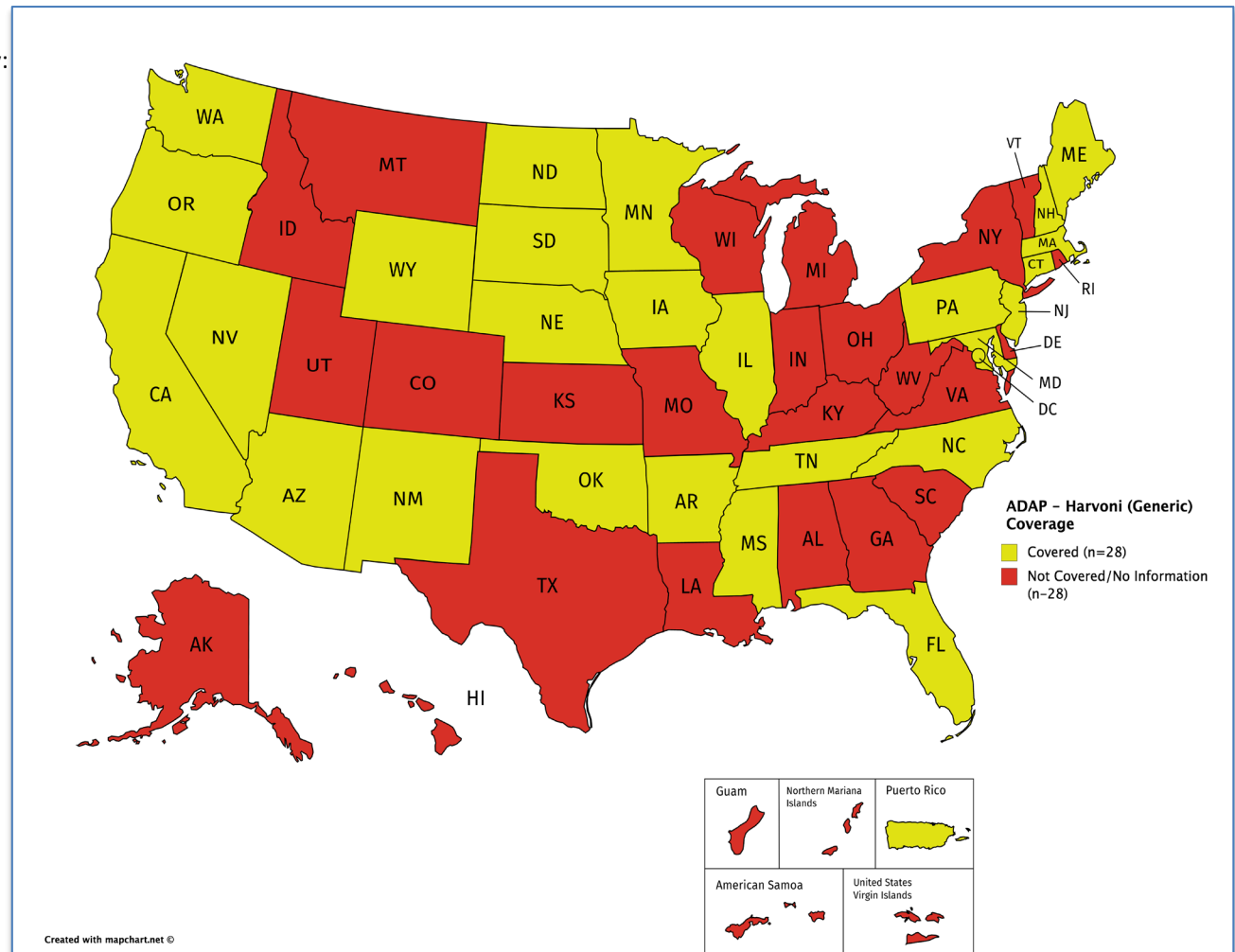
ADAP – Harvoni (Generic) Coverage
 Covered (n=28)
 Not Covered/No Information (n–28)

AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

Epclusa *Generic* Coverage Map
April 2020

Figure 12.

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

ADAP – Epclusa (Generic) Coverage

Covered (n=27)

Not Covered/No Information (n–29)
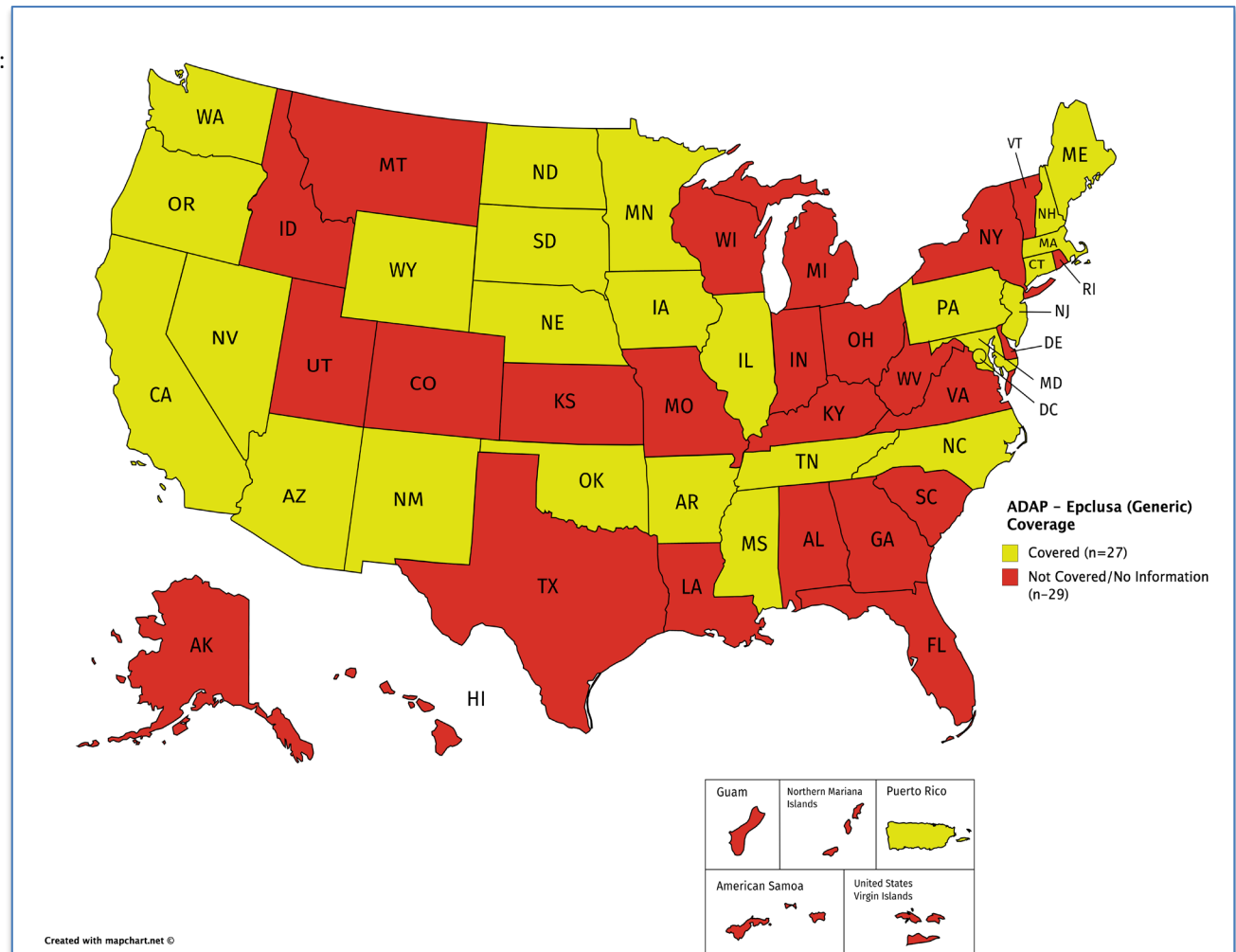
AIDS Drug Assistance Programs (ADAPs) & HCV Treatments

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 April 15, 2020.

April 2020 Updates:
• Both Daklinza and Viekira Pak have been discontinued. They will be removed from both the formulary chart and map sections

April 2020 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, Sovaldi, Ribavirin, Zepatier, 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

Medicaid Programs & HCV Treatments

Figure 13. – Figure 24.

Medicaid Programs & HCV Treatments

Figure 13. (* Indicates "Preferred Drug")

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni Generic	Epclusa Generic	X
Alabama	Y	N	Y*	N	N	Y*	Y*	N	Y*	Y*	Y*	X
Alaska	Y	Y	Y	Y	Y	Y	Y	Y	Y*	Y	Y	X
Arizona	Y	N	N	N	N	N	N	N	Y*	N	Y*	X
Arkansas	Y	Y	Y	Y	Y	Y*	Y*	Y	Y*	N	N	X
California	Y	Y*	Y*	Y*	N	Y*	Y*	N	Y*	Y*	Y*	X
Colorado	Y	Y	Y*	Y	N	Y	Y*	Y	Y*	Y	Y	X
Connecticut	Y	N	N	N	N	N	Y*	Y*	Y*	N	N	X
Delaware	Y	Y	N	Y	Y	Y	N	Y	Y*	Y	Y*	X
Florida	Y	N	N	N	N	N	N	Y*	Y*	N	Y*	X
Georgia	Y	Y	Y	N	Y	Y	Y*	Y*	Y*	N	N	X
Hawaii	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y	X
Idaho	Y	Y	Y	Y	Y	Y	Y*	Y*	Y*	Y	Y	X
Illinois	Y	Y	Y	Y	N	Y	Y	Y	Y*	Y	Y*	X
Indiana	Y	Y	Y	Y	Y	Y*	Y*	Y	Y*	Y	Y	X
Iowa	Y	Y	Y	N	Y	Y	Y	Y	Y*	Y	Y*	X
Kansas	Y	Y	Y	Y	Y	Y	Y	Y	Y*	N	N	X
Kentucky	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	X
Louisiana	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y*	X
Maine	Y	Y	Y	Y	Y	Y	Y*	Y	Y*	N	N	X

Co-Infection Watch

Medicaid Programs & HCV Treatments

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

State	Basic	Sovaldi	Harvoni	Viekira Pak	Daklinza	Zepatier	Epclusa	Vosevi	Mavyret	Harvoni *Generic*	Epclusa *Generic*	X
Maryland	Y	Y	N	Y	Y	Y*	N	Y*	Y*	Y*	Y*	X
Massachusetts	Y	Y	Y	Y	Y	Y	Y	Y	Y*	Y*	Y*	X
Michigan	Y	Y	Y	Y	Y	Y*	Y*	Y*	Y*	Y	Y	X
Minnesota	Y	Y	Y	Y	Y	Y	Y	Y*	Y*	Y	Y	X
Mississippi	Y	Y	Y	Y	Y	Y	Y	Y	Y*	Y	Y*	X
Missouri	Y	Y	Y	Y	Y	Y	Y*	Y*	Y*	Y	Y	X
Montana	Y	Y	Y	N	Y	Y	Y	Y	Y*	Y	Y	X
Nebraska	Y	Y	Y	Y	Y	Y	N	Y*	Y*	Y*	Y	X
Nevada	Y	Y*	Y*	Y	Y	Y*	Y*	Y	Y*	Y*	Y*	X
New Hampshire	Y	Y	Y*	N	N	Y	Y*	Y*	Y*	Y*	Y*	X
New Jersey	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	X
New Mexico	Y	N	N	N	N	N	N	N	Y	Y	Y	X
New York	Y	Y	Y	Y	Y	Y	Y	Y*	Y*	Y	Y*	X
North Carolina	Y	Y	Y	Y	Y	Y	Y	Y*	Y*	Y	Y*	X
North Dakota	Y	Y	Y	Y	N	Y	Y*	Y	Y*	Y	Y	X
Ohio	Y	Y	N	N	Y	Y	N	Y	Y*	Y	Y*	X
Oklahoma	Y	Y*	Y*	Y	Y*	Y*	Y*	Y*	Y*	Y*	Y*	X
Oregon	Y	N	N	N	N	N	Y*	Y*	Y*	N	Y*	X
Pennsylvania	Y	Y	Y*	Y	Y	Y*	Y=	Y	Y*	Y	Y*	X

Co-Infection Watch

Medicaid Programs & HCV Treatments

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

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

Medicaid Programs & HCV Treatments

There are currently **51** Medicaid programs that cover some form of HCV-related drug therapies as part of their Preferred Drug Lists. To learn more about Medicaid or their Preferred Drug Lists, please visit http://medicaiddirectors.org.

Figure 14.

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

Medicaid – HCV Drug Coverage

■ At Least One Non–DAA or DAA HCV Drug Covered (n=51)

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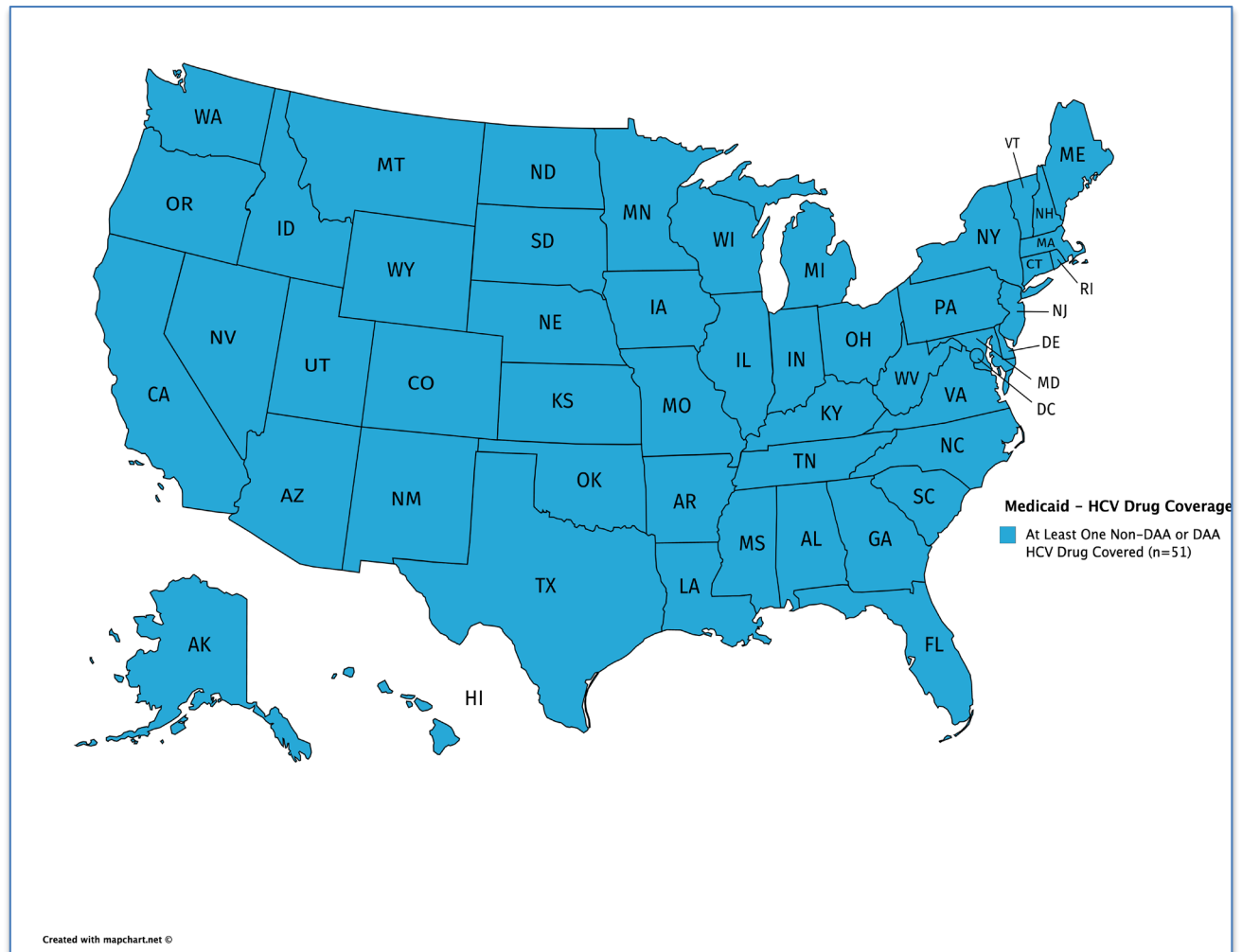
Medicaid Programs & HCV Treatments

Sovaldi Coverage Map
April 2020

Figure 15.

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

Medicaid – Sovaldi Coverage
- Covered (n=44)
- Not Covered (n=7)

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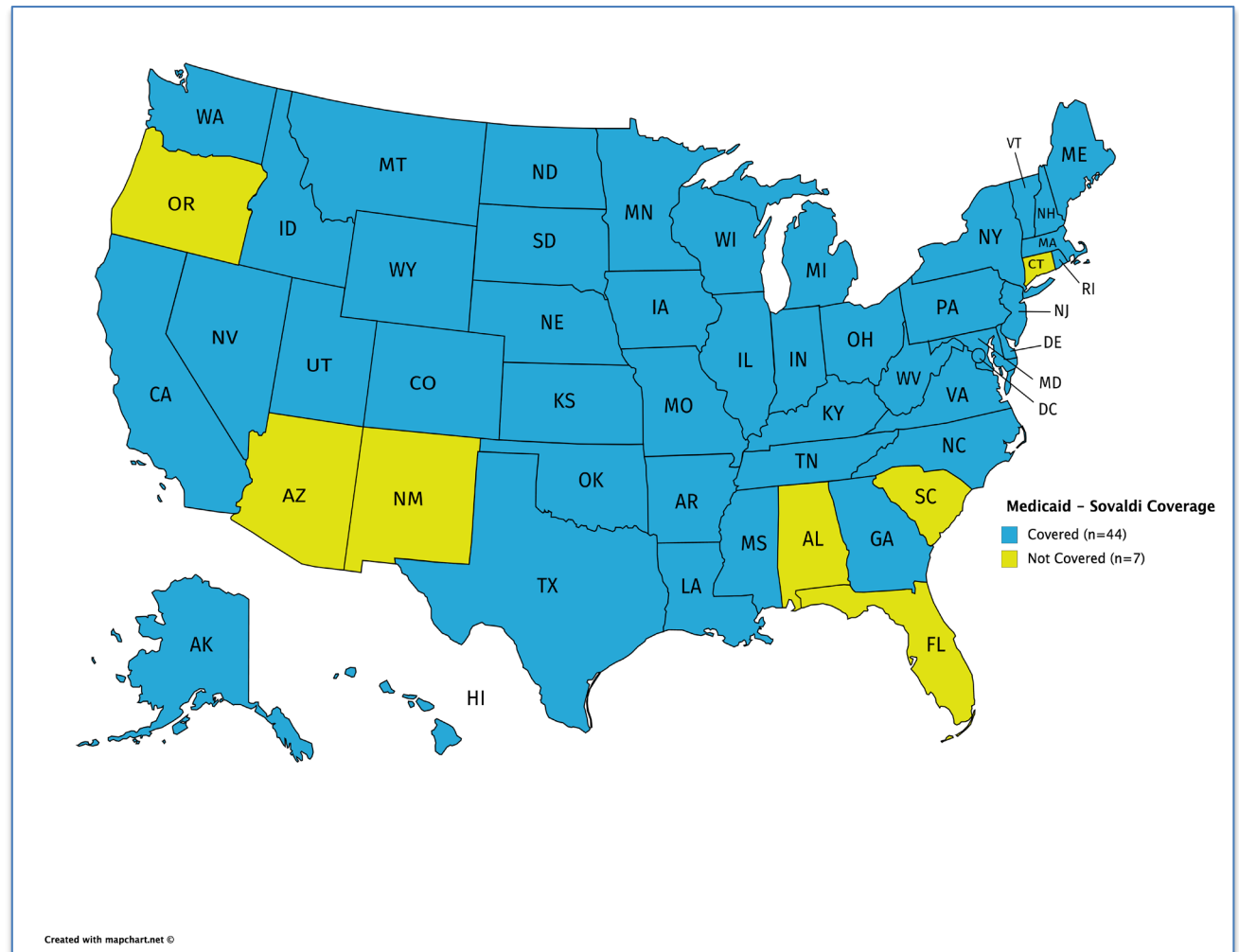
Medicaid Programs & HCV Treatments

Harvoni Coverage Map
April 2020

Figure 16.

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

Medicaid – Harvoni Coverage
Covered (n=42)
Not Covered (n=9)

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Co-Infection Watch

Medicaid Programs & HCV Treatments
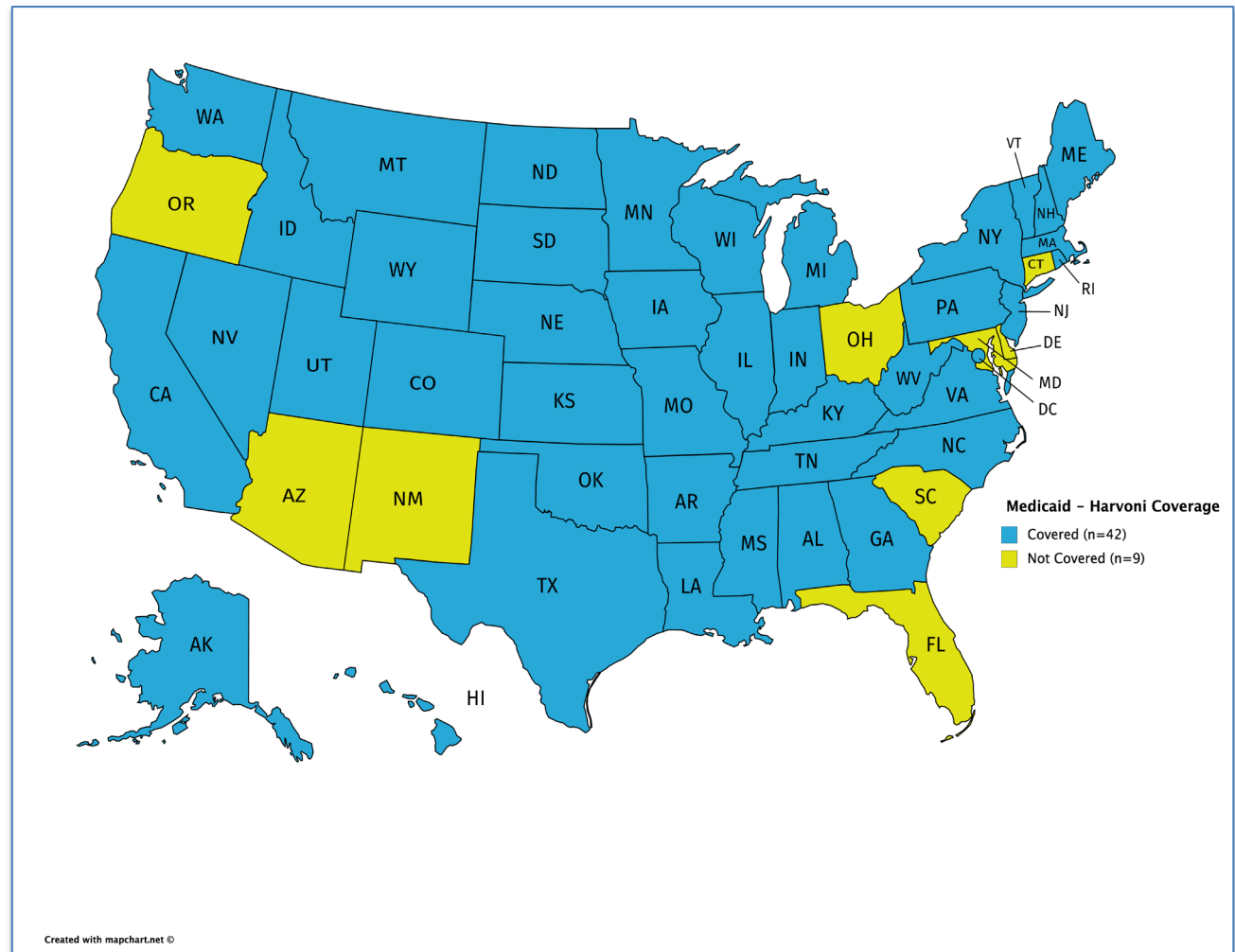
Viekira Pak Coverage Map
April 2020

Figure 17.

Viekira Pak Coverage Map Key:
  Light Blue: Covered
  Yellow: Not Covered

Medicaid – Viekira Pak Coverage
- Covered (n=37)
- Not Covered (n=14)

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Medicaid Programs & HCV Treatments
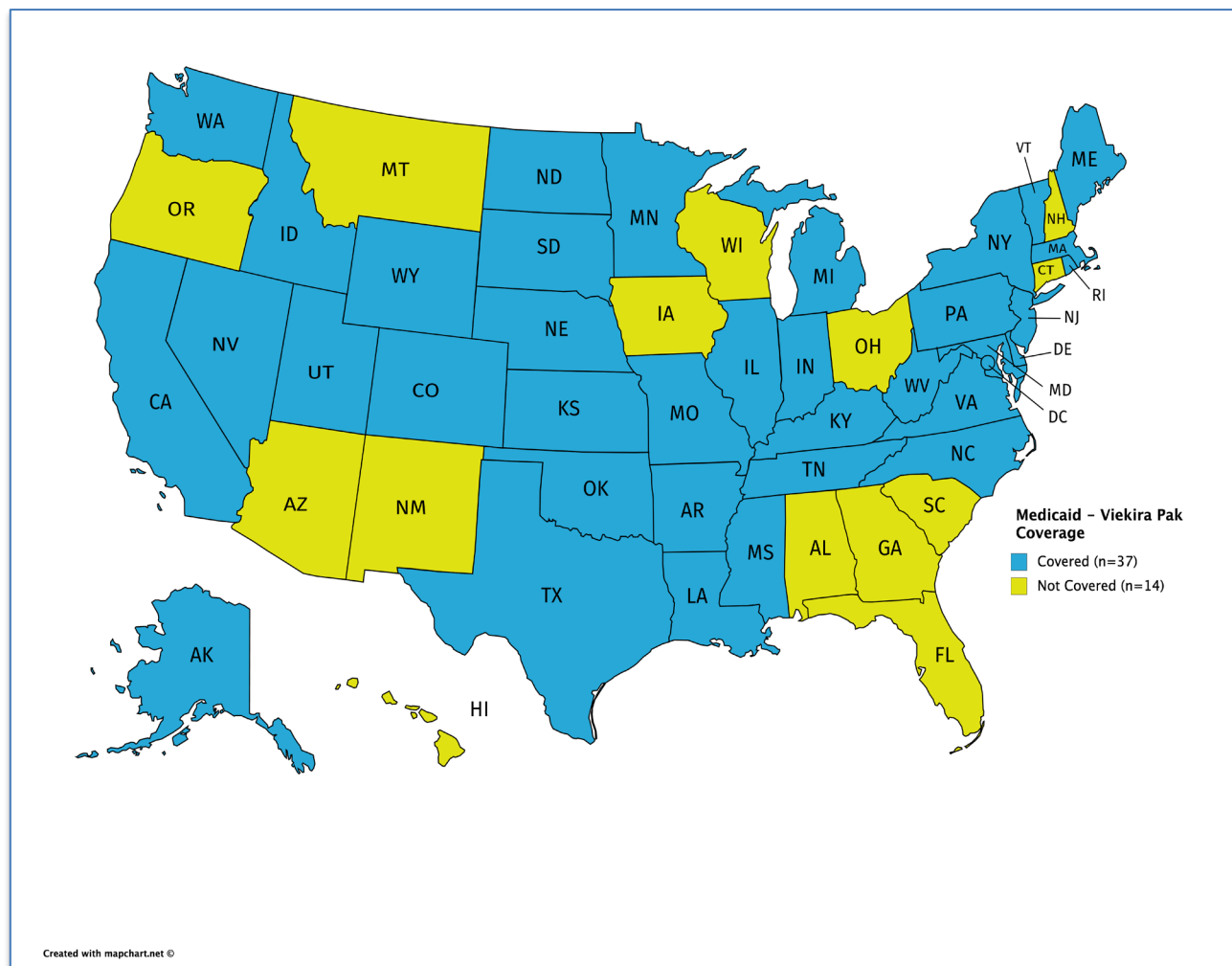
Daklinza Coverage Map
April 2020

Figure 18.

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

Medicaid – Daklinza Coverage
Covered (n=37)
Not Covered (n=14)

Created with mapchart.net ©

Medicaid Programs & HCV Treatments
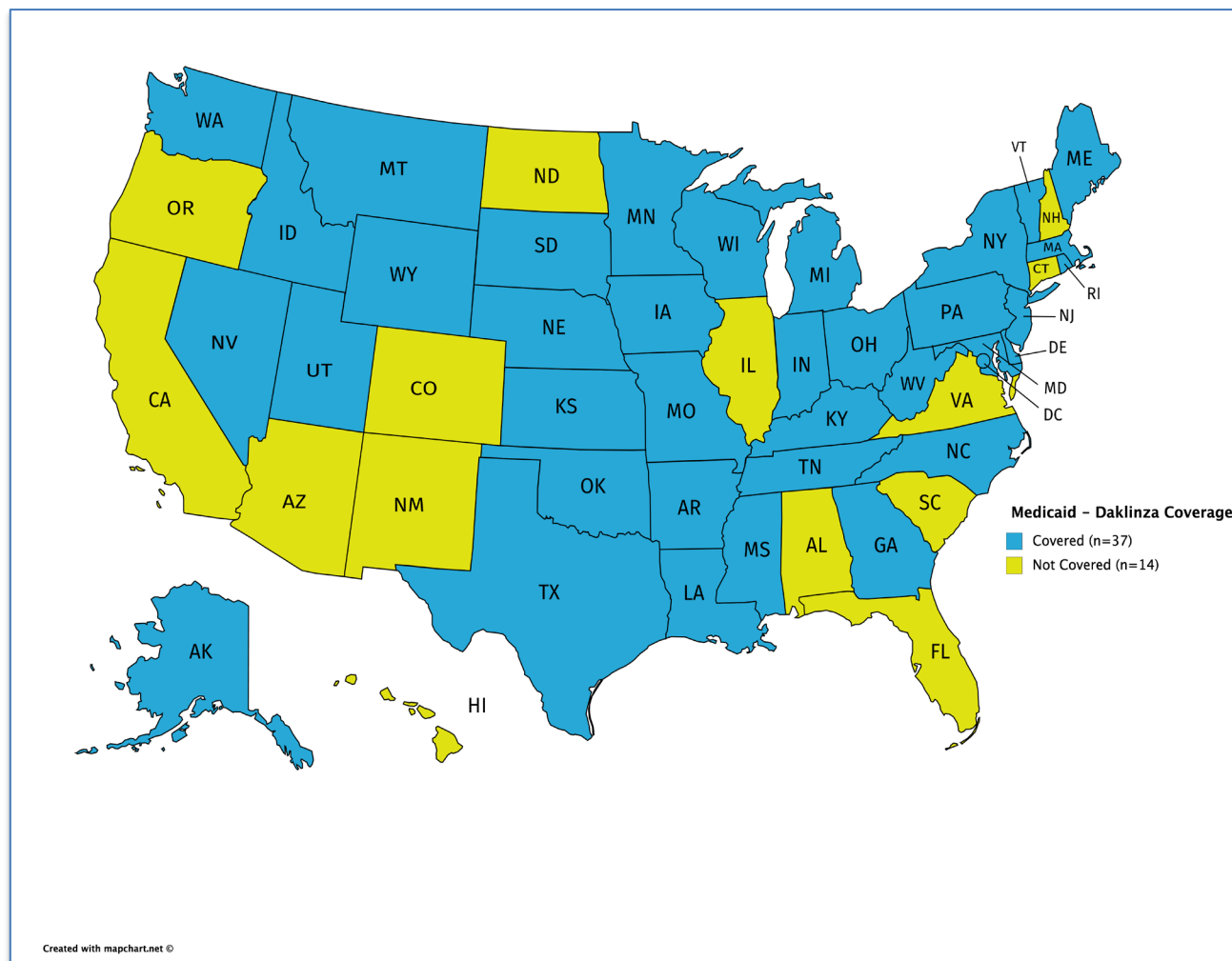
Zepatier Coverage Map
April 2020

Figure 19.

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

Medicaid – Zepatier Coverage
■ Covered (n=45)
■ Not Covered (n=6)

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Co-Infection Watch
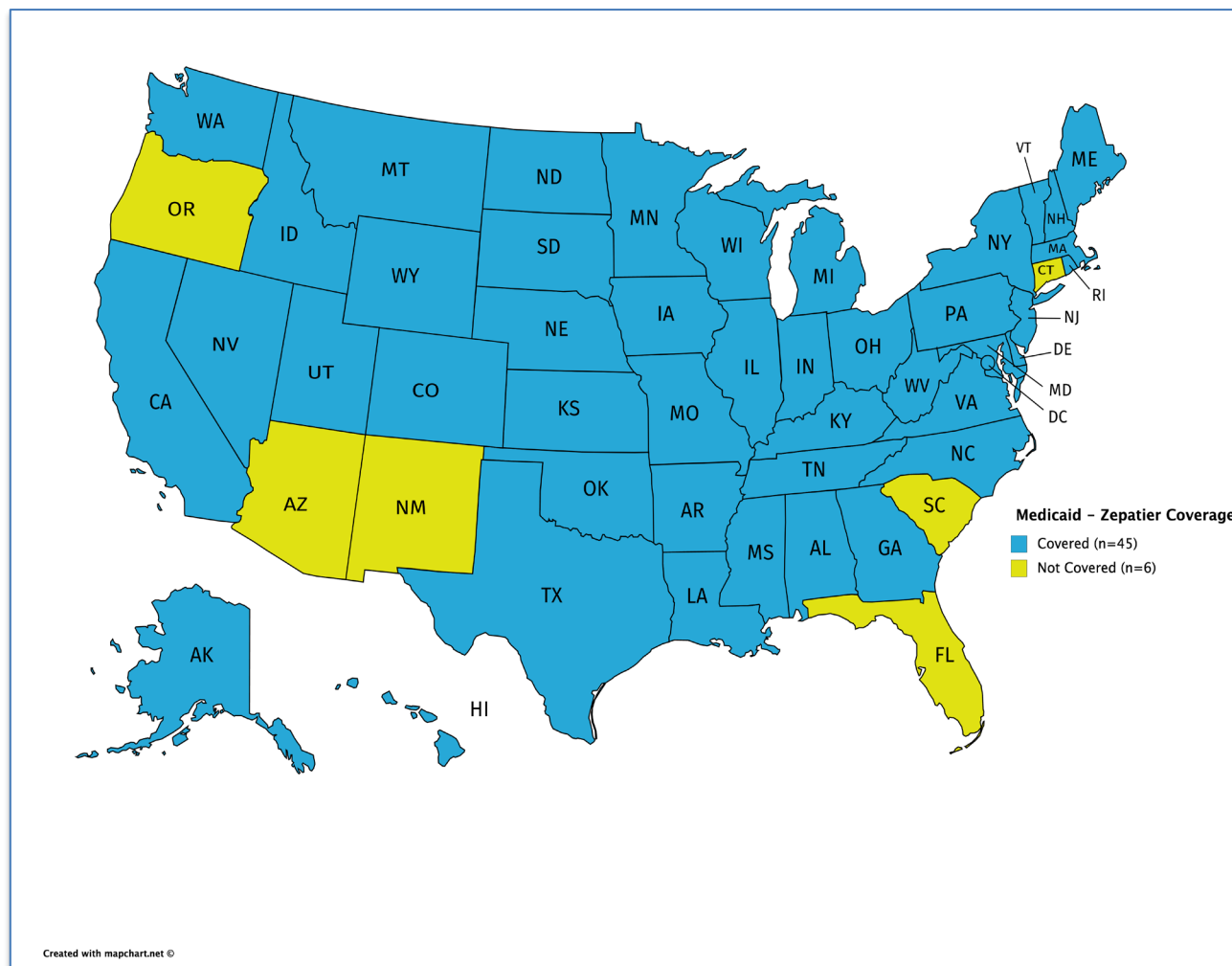
Medicaid Programs & HCV Treatments

Epclusa Coverage Map
April 2020

Figure 20.

Epclusa Coverage Map Key:
  Light Blue: Covered
  Yellow: Not Covered
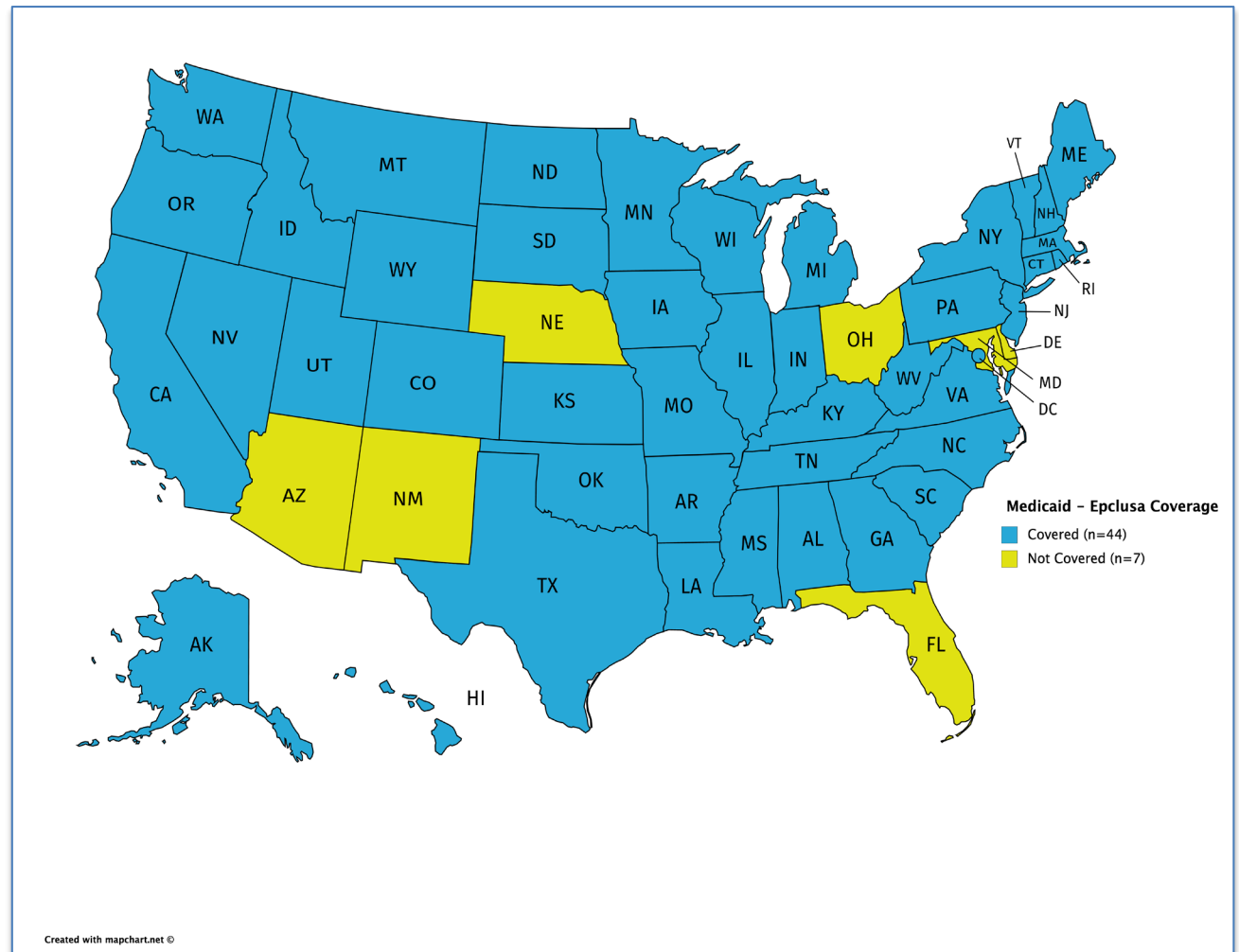
Medicaid Programs & HCV Treatments

Vosevi Coverage Map
April 2020

Figure 21.

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

Medicaid – Vosevi Coverage
■ Covered (n=47)
■ Not Covered (n=4)

Created with mapchart.net ©
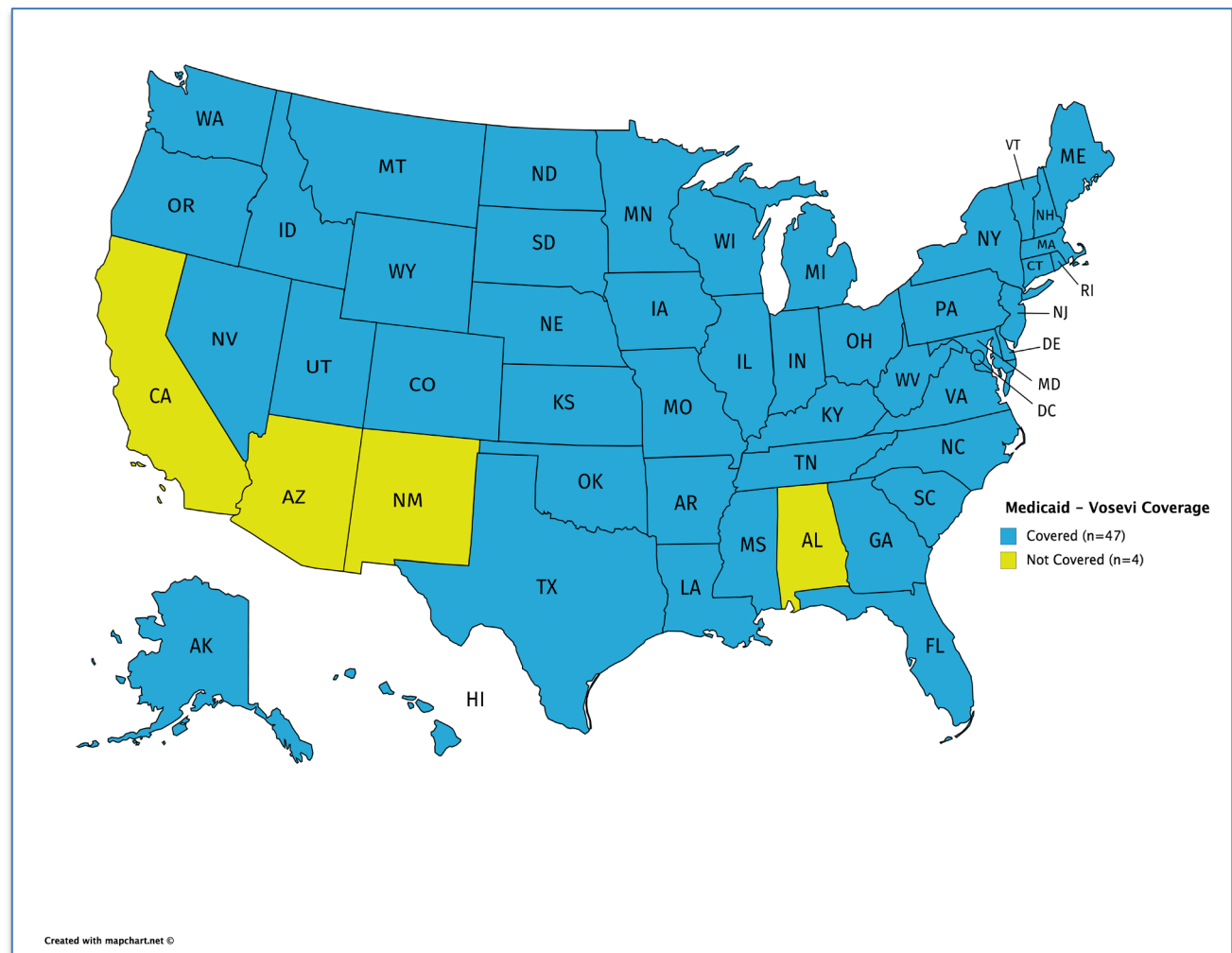
Medicaid Programs & HCV Treatments

Mavyret Coverage Map
April 2020

Figure 22.

Mavyret Coverage Map Key:
  Light Blue: Covered
  Yellow: Not Covered
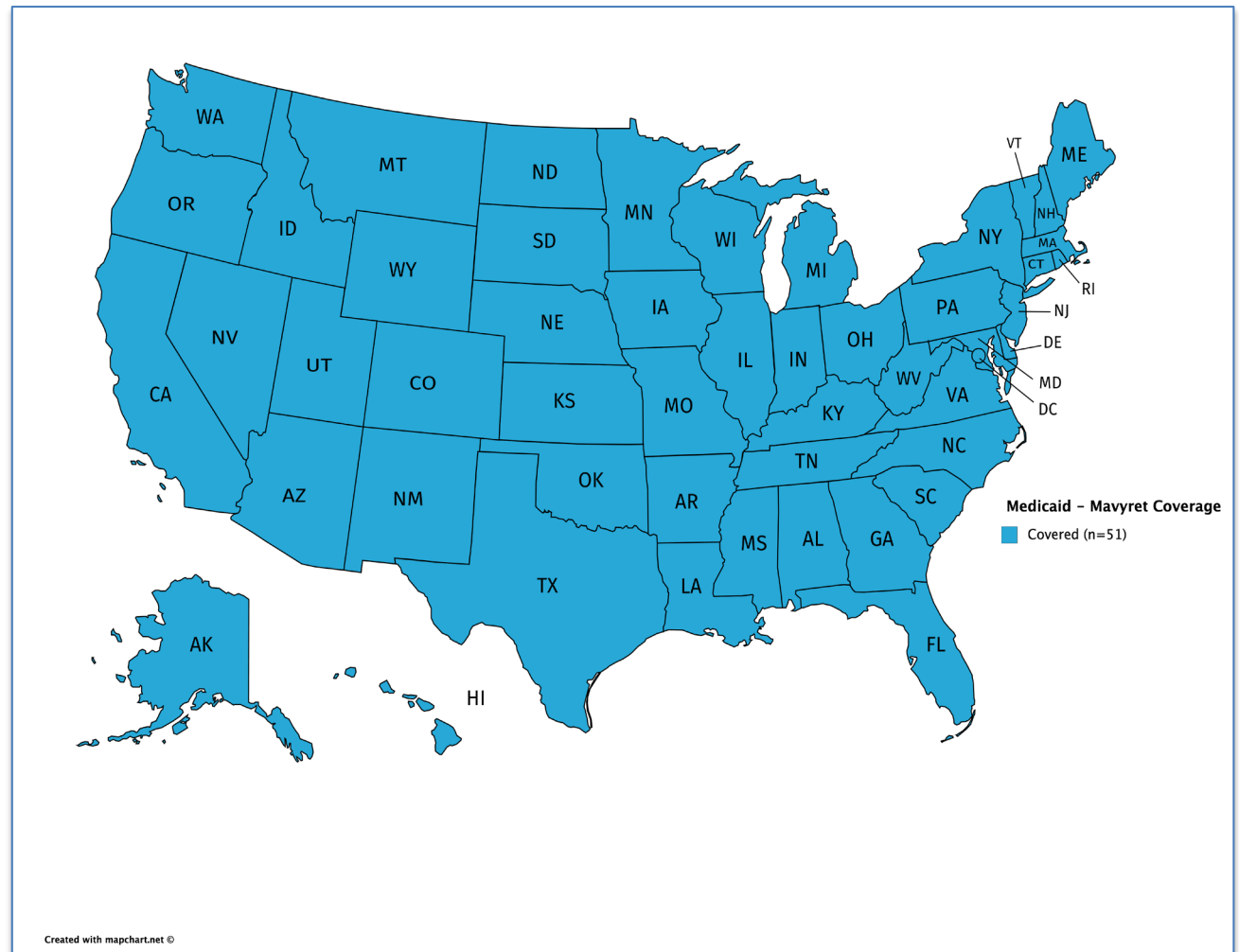
Medicaid Programs & HCV Treatments

Harvoni *Generic* Coverage Map
April 2020

Figure 23.

Harvoni *Generic* Map Key:
  Light Blue: Covered
  Yellow: Not Covered

Medicaid – Harvoni (Generic) Coverage
- Covered (n=40)
- Not Covered (n=11)
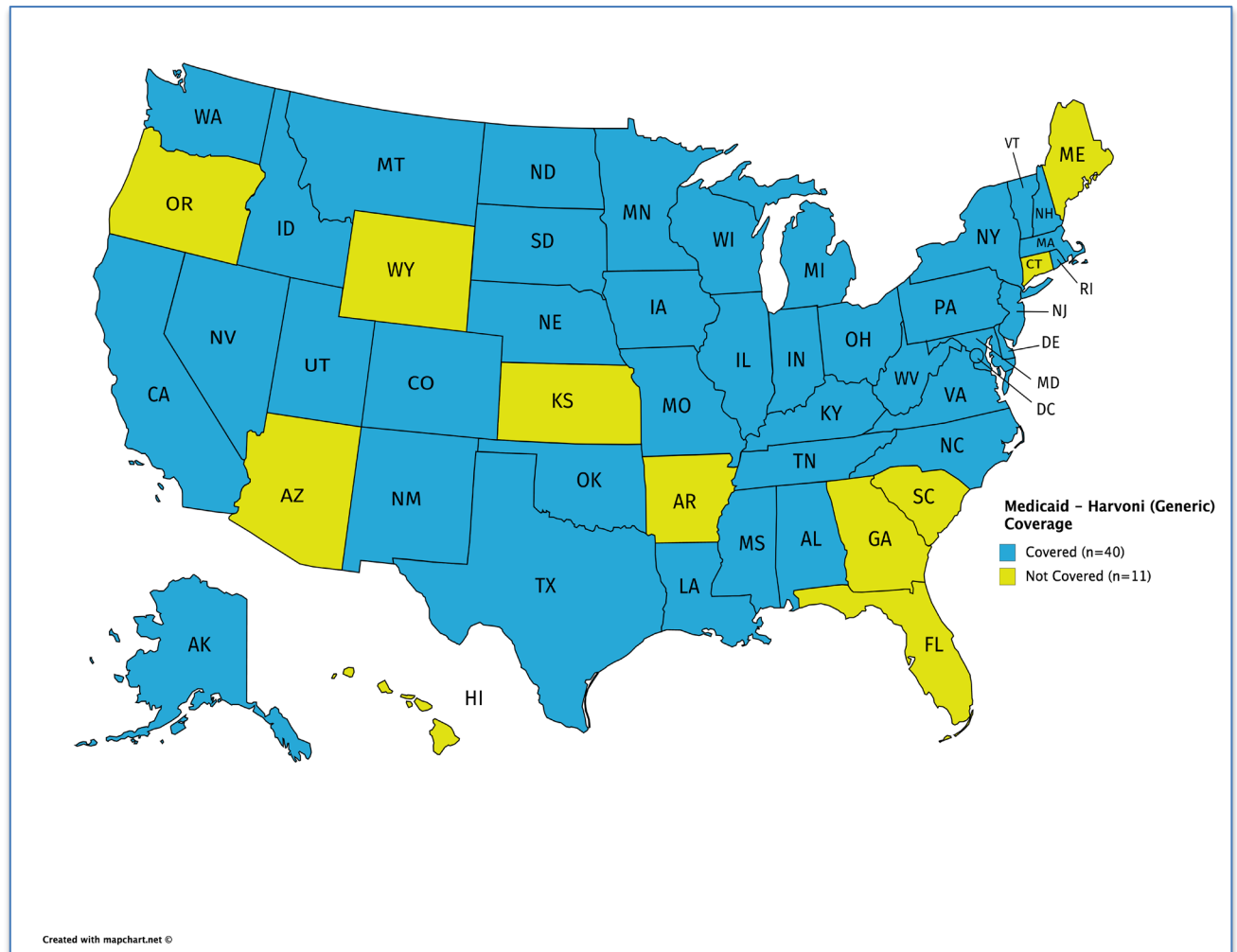
Medicaid Programs & HCV Treatments

Epclusa *Generic* Coverage Map
April 2020

Figure 24.

Epclusa *Generic* Coverage Map Key:

  Light Blue: Covered

  Yellow: Not Covered

Medicaid – Epclusa (Generic) Coverage

Covered (n=44)
Not Covered (n=7)

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Co-Infection Watch
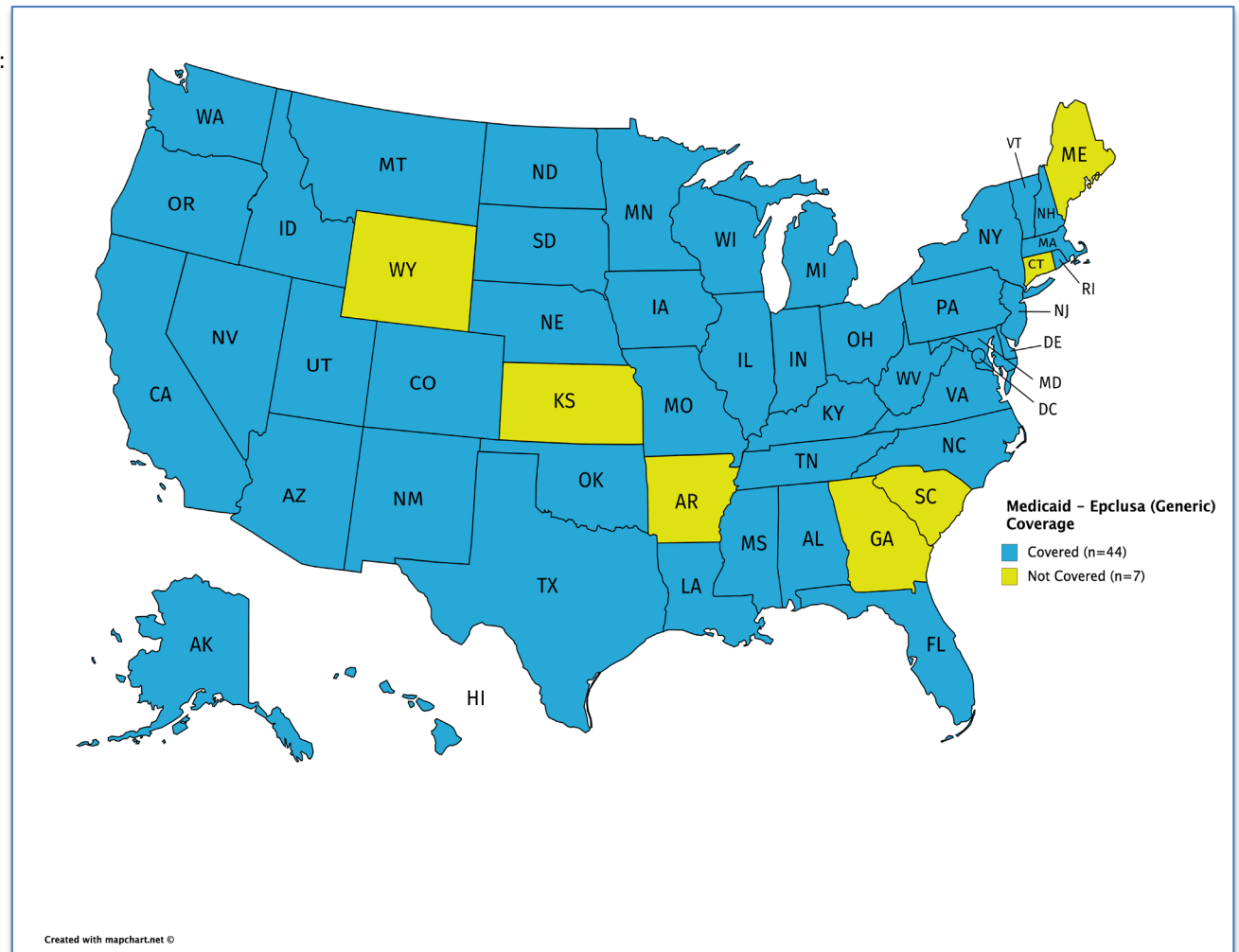
Medicaid Programs & HCV Treatments

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

April 2020 Updates:
- Both Daklinza and Viekira Pak have been discontinued. They will be removed from both the formulary chart and map sections
- Ohio has removed drug and alcohol abstinence requirements from its Prior Authorization criteria for Hepatitis C treatment

April 2020 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; (3) **Western Sky Community Care**
  –Ohio – Ohio has a Unified Medicaid Formulary that applies to all MCOs
- No data is has been made available by the Medicaid programs in the U.S. Territories

* Medicaid coverage excludes patients from most drug manufacturer patient assistance programs (PAPs)

Veterans Affairs
& HCV Treatments

Co-Infection Watch

Veterans Affairs & HCV Treatments

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

Abbreviations:

CTP – Child-Turcotte-Pugh (score used to assess severity of cirrhosis)

IU/mL – International Units Per Milliliter

PEG-IFN/IFN – Peginterferon/Interferon

RAS – Resistance-associated substitutions

RBV – Ribavirin

Genotype 1:

- Treatment-naïve without or with cirrhosis (CTP A):
    - Zepatier: 1 tablet orally daily for 12 weeks if GT1a without baseline NS5A RAS or GT1b
    - Mavyret: 3 tablets orally daily with food
- If non-cirrhotic: 8 weeks
- If cirrhotic: 12 weeks
    - Harvoni: 1 tablet orally daily
- If HCV-monoinfected, non-cirrhotic, and baseline HCV RNA <6 million IU/mL: 8 weeks
- If cirrhotic, baseline HCV RNA ≥6 million IU/mL or HIV/HCV 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)

Veterans Affairs & HCV Treatments

Genotype 1 (Cont.):

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

Co-Infection Watch

Veterans Affairs & HCV Treatments

Genotype 2:

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

Genotype 3:

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

Veterans Affairs & HCV Treatments

Genotype 3 (Cont.):

- Treatment-experienced (NS5A-experienced) without or with cirrhosis (CTP A)
    - Vosevi: 1 tablet orally daily with food for 12 weeks
- If CTP A, consider adding RBV (no supporting data)
- Treatment-naïve or treatment-experienced with decompensated cirrhosis (CTP B or 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)

Veterans Affairs & HCV Treatments

Genotype 4 (Cont.):

- Treatment-experienced (Sovaldi-experienced and NS5A-naïve) without or with cirrhosis (CTP A)
  - Mavyret: 3 tablets orally daily with food for 12 weeks
  - Epclusa: 1 tablet orally daily + RBV for 12 weeks; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
- Treatment-experienced (NS5A-experienced) without or with cirrhosis (CTP A)
  - Vosevi: 1 tablet orally daily with food for 12 weeks
- Treatment-experienced with decompensated cirrhosis (CTP B or CTP C)
  - Epclusa: 1 tablet orally daily + RBV; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)
    - » If NS5A-naïve: 12 weeks
    - » If NS5A-experienced: 24 weeks; NOT FDA approved for 24 weeks

Patient Assistance Programs (PAPs)

Patient Assistance Programs (PAPs)

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

Support Path (Gilead Sciences):

- Financial Assistance
    – Provides Co-Pay Coupons for 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

Patient Assistance Programs (PAPs)

NeedyMeds:

- NeedyMeds Drug Discount Card
  - Designed to lower cost of prescription medications by up to 80% at participating pharmacies
  - NeedyMeds DOES NOT keep a list of prescription medications covered
  - No eligibility requirements
  - Patients CANNOT be enrolled in any insurance
  - CANNOT be used in combination with government healthcare programs, but CAN be used IN PLACE of program
  - CANNOT be combined with other offers
- Website: http://ow.ly/fEJo309cJ7Z

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 Assistance Programs (PAPs)

Patient Access Network (PAN) Foundation:

- Status: Closed
- Co-Pay Assistance with a maximum award of $7,200
    - Patients may apply for a second grant during their eligibility period subject to availability of funding
- Eligibility Requirements:
    - Must be being treated for HCV
    - Have insurance that covers HCV prescribed medication
    - 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/

Harm Reduction Programs

Figure 25. – Figure 34.

Harm Reduction Programs

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

- **Syringe Exchange:**

Syringe Services Programs (SSPs) 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.

Harm Reduction Programs

- **ID Required for Purchase of Opioid Prescription:**

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

- **Prescriber Education Required/Recommended**:

States that require/do not require that prescribing physicians undergo special training related to safer prescribing and utilization practices.

- **Medicaid Lock-In Program:**

Lock-In Programs are laws requiring that patients either receive prescriptions from only one physician and/or fill prescriptions from only one pharmacy.

Harm Reduction Programs

Figure 27.

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

Harm Reduction Programs

Figure 27.

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

Harm Reduction Programs

Figure 27.

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

Harm Reduction Programs

Syringe Exchange Coverage Map
April 2020

Figure 28.

Syringe Exchange Map Key:

Purple: Syringe Exchange(s)

Red: No Syringe Exchange(s)

Syringe Services Programs (SSPs)

- At Least One SSP Operating (Regardless of Legal Status) (n=47)
- No SSP Operating (n=12)

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Co-Infection Watch
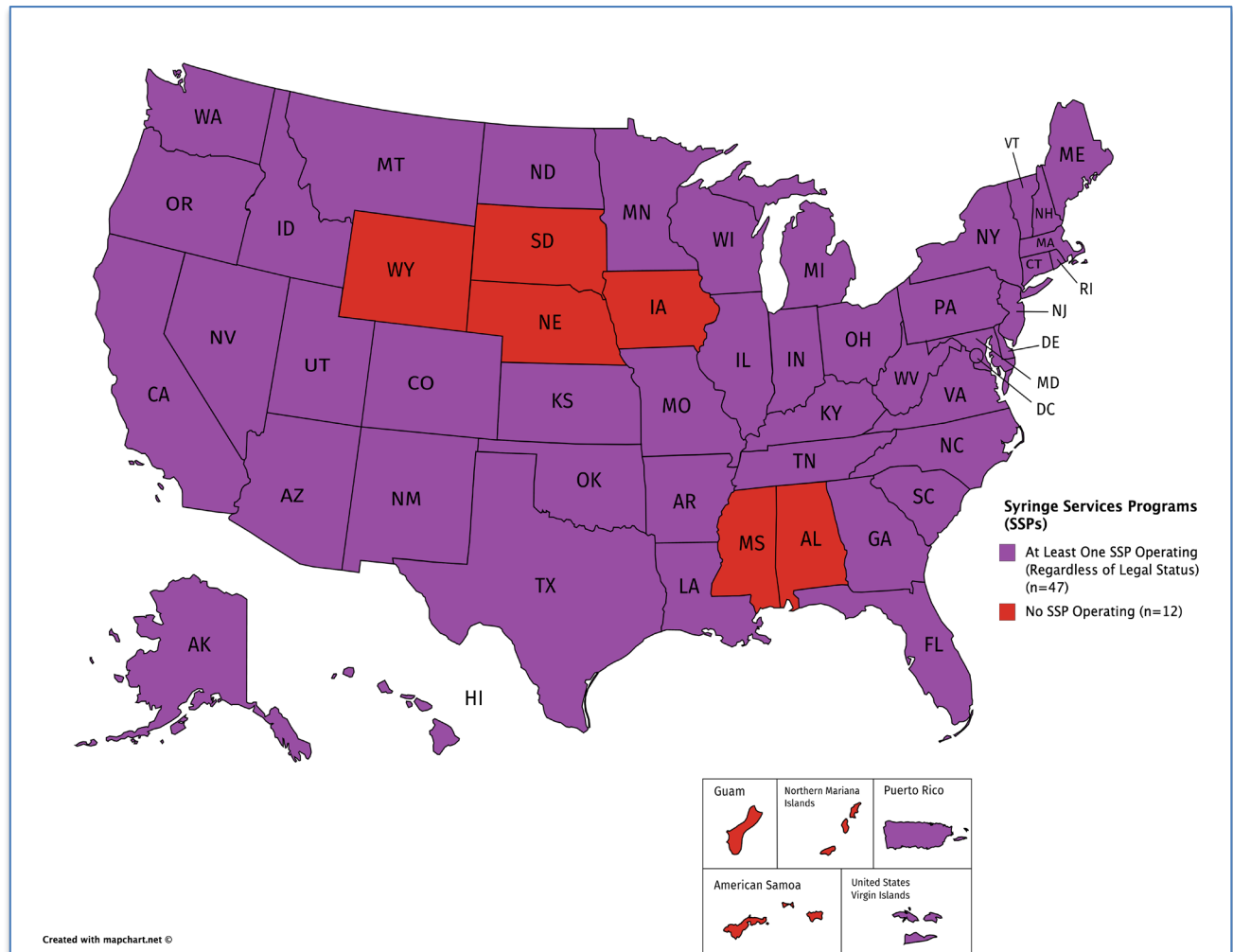
Harm Reduction Programs

Expanded Naloxone Coverage Map
April 2020

Figure 29.

Expanded Naloxone Map Key:

Purple: Expanded Naloxone

Red: Restricted Naloxone

Expanded Naloxone Access

Naloxone Access Expanded (n=51)

No Information (n=8)

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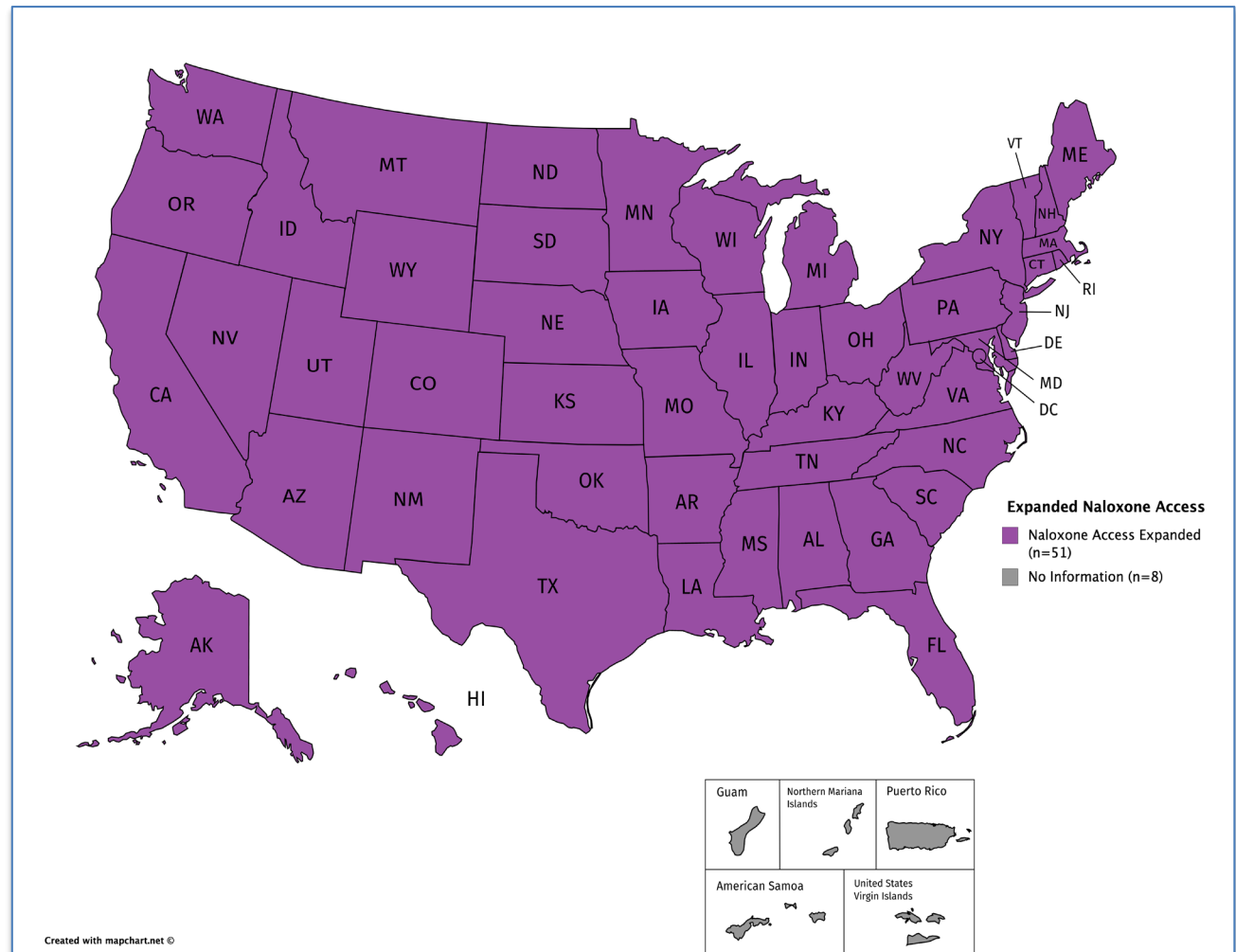
Harm Reduction Programs

Good Samaritan Laws Coverage Map
April 2020

Figure 30.

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

Good Samaritan Protections

Good Samaritan Protections In Place (n=51)

No Information (n=8)

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Co-Infection Watch
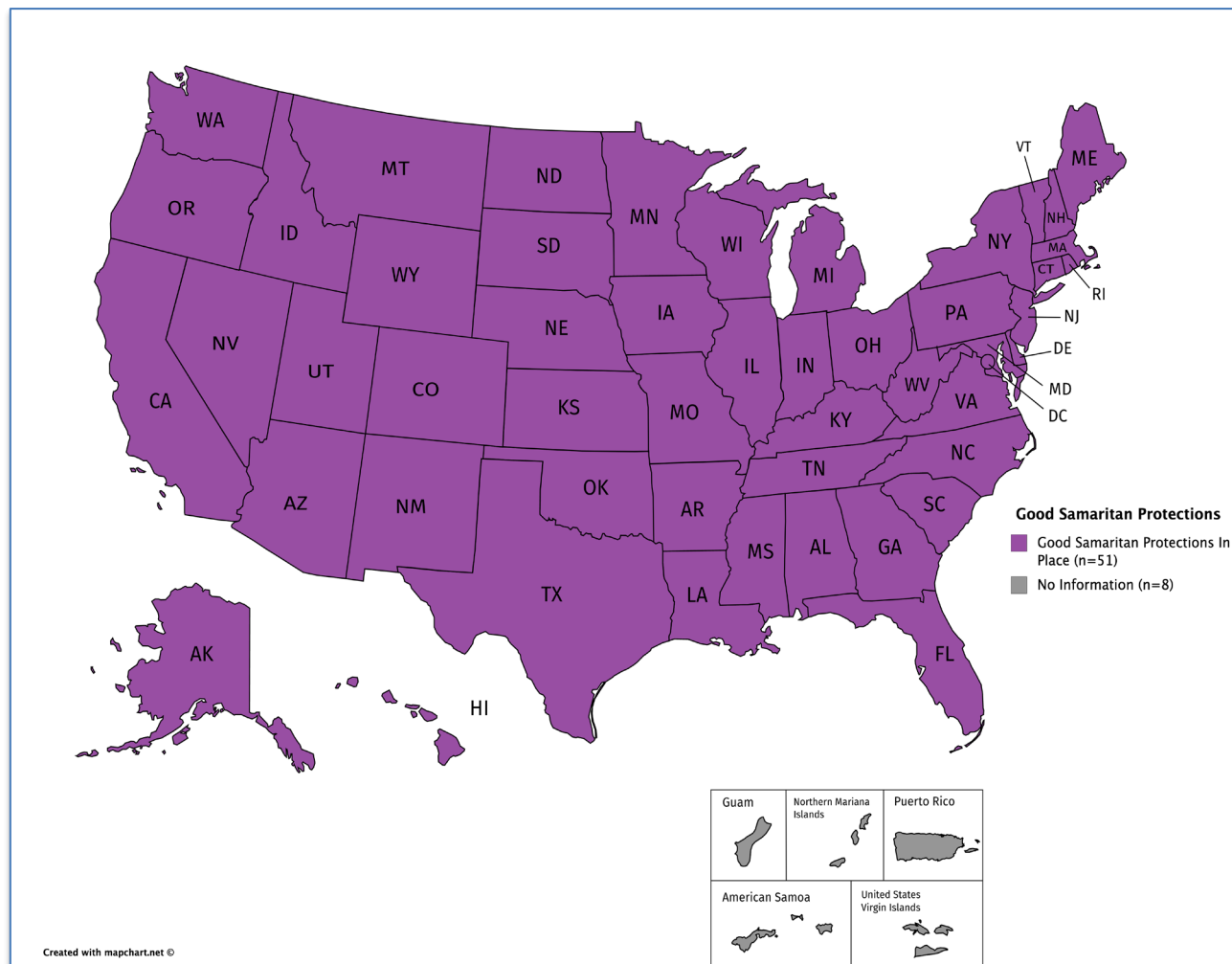
Harm Reduction Programs

Prescription Drug Monitoring Programs (PDMPs) Coverage Map
April 2020

Figure 31.

PDMPs Map Key:
   Purple: Mandatory PDMPs
   Red: No Mandatory PDMPs

Mandatory Prescription Drug Monitoring Program Reporting

- Yes (n=38)
- No (n=14)
- No Information (n=7)
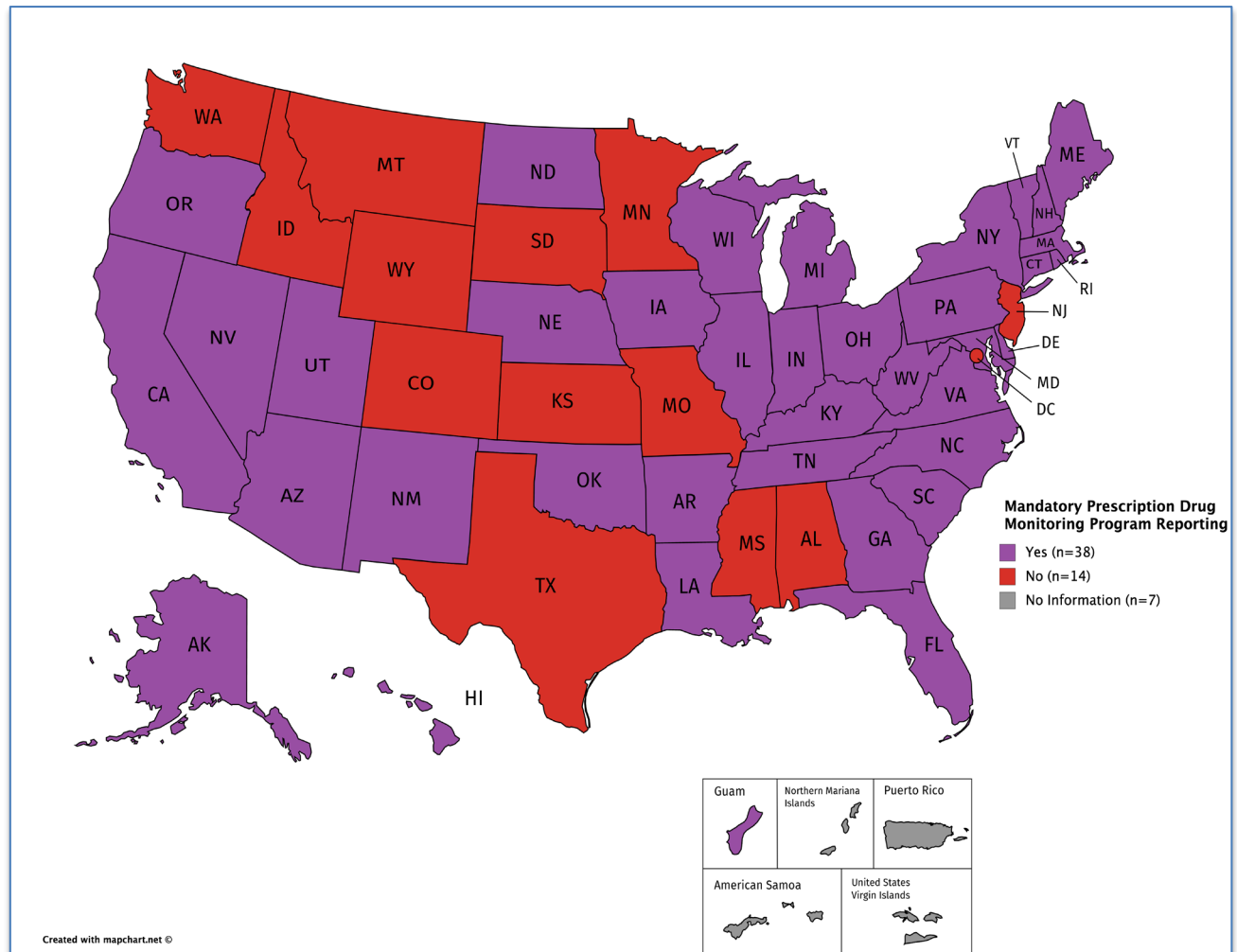
Harm Reduction Programs

Doctor Shopping Laws Coverage Map
April 2020

Figure 32.

Doctor Shopping Laws Map Key:
  Purple: Doctor Shopping Laws
  Red: No Doctor Shopping Laws

Opioid–Specific Doctor Shopping Laws
- Yes (n=40)
- No (n=19)
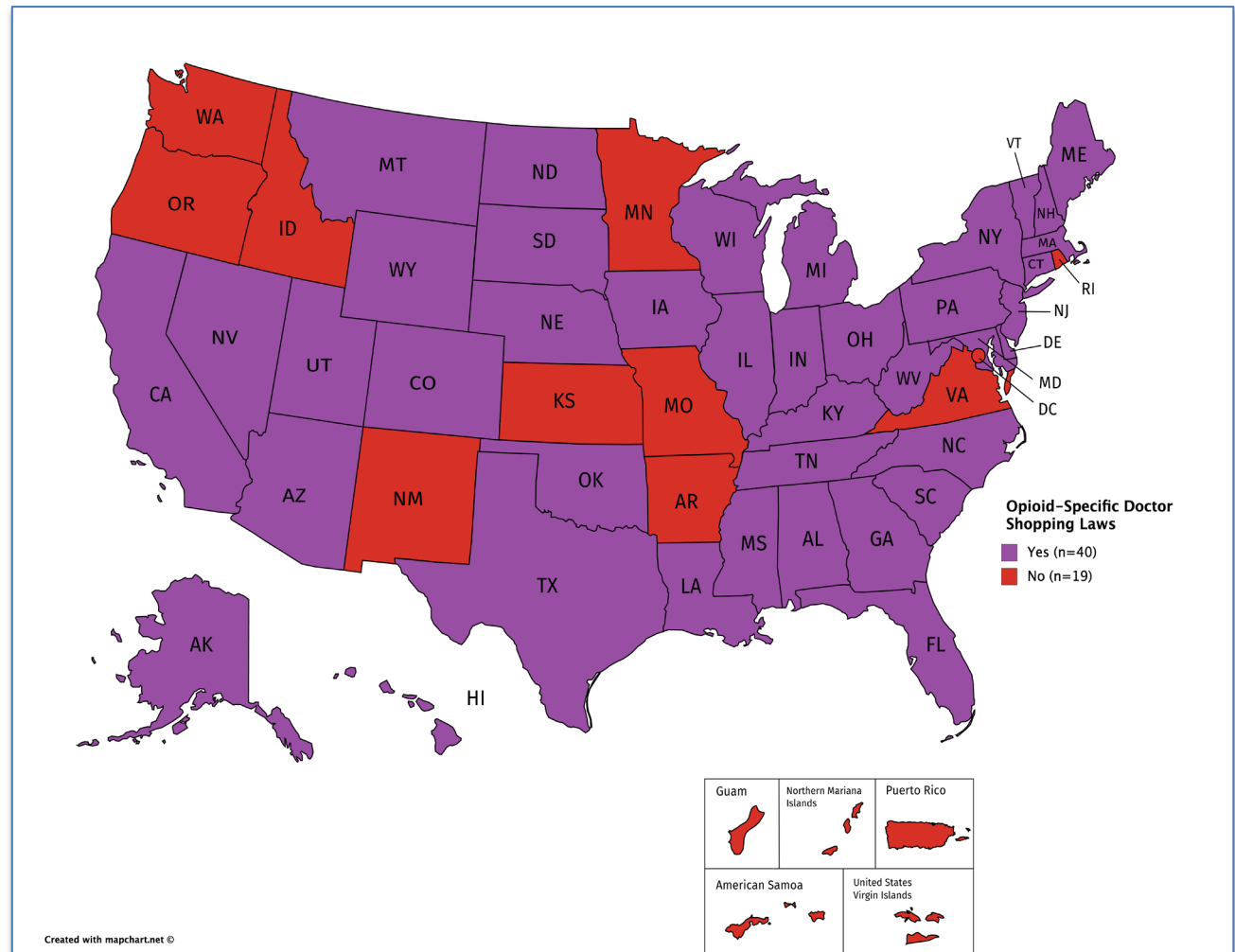
Harm Reduction Programs

Physical Exam Required Coverage Map
April 2020

Figure 33.

Physical Exam Required Map Key:

Purple: Physical Exam Required

Red: No Physical Exam Required

Physical Exam Requirement for Opioid Prescription

- Yes (n=40)
- No (n=19)
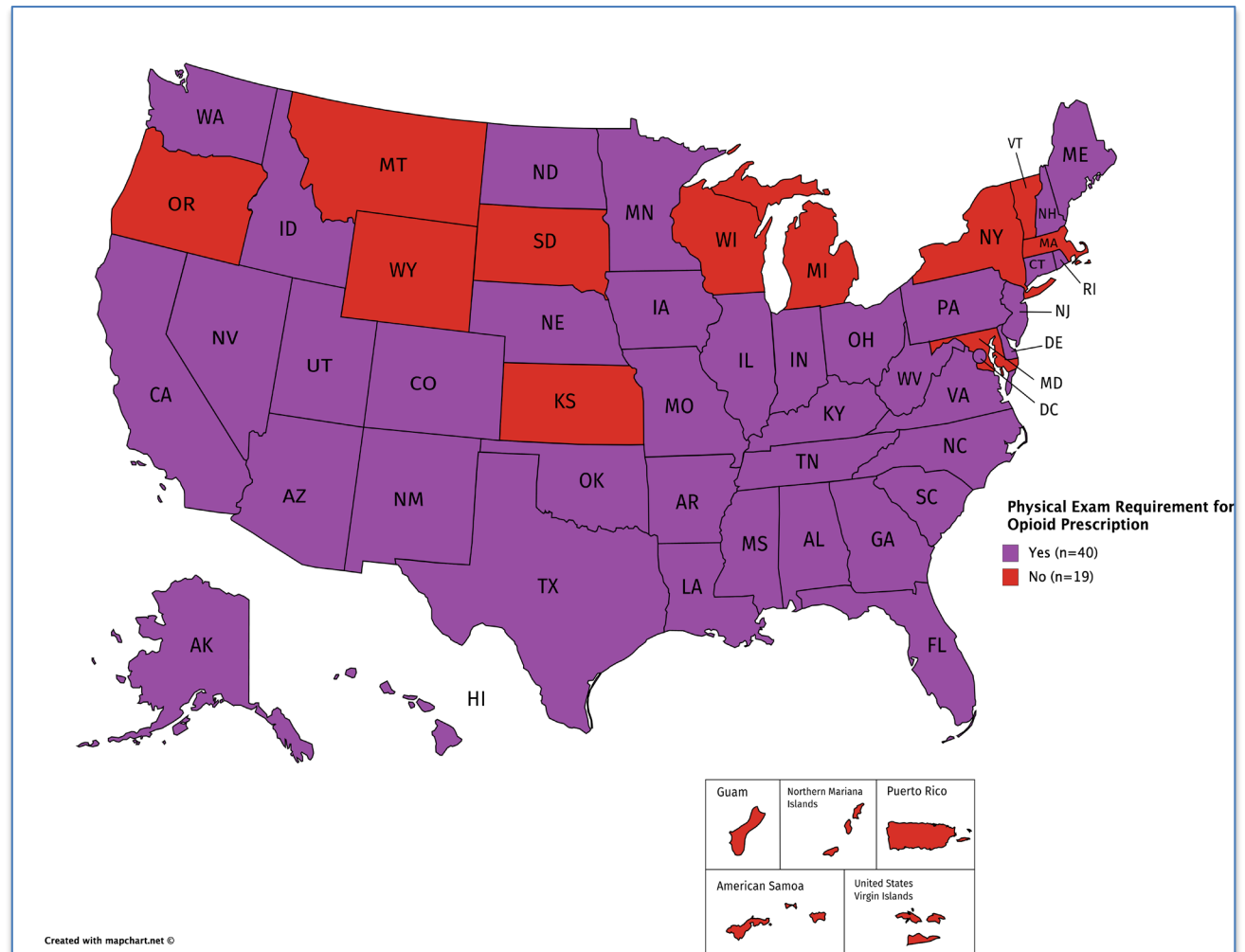
Harm Reduction Programs

I.D. Required Coverage Map
April 2020

Figure 34.

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

Identification Required for Opioid Purchase
- Yes (n=27)
- No (n=24)
- No Information (n=8)
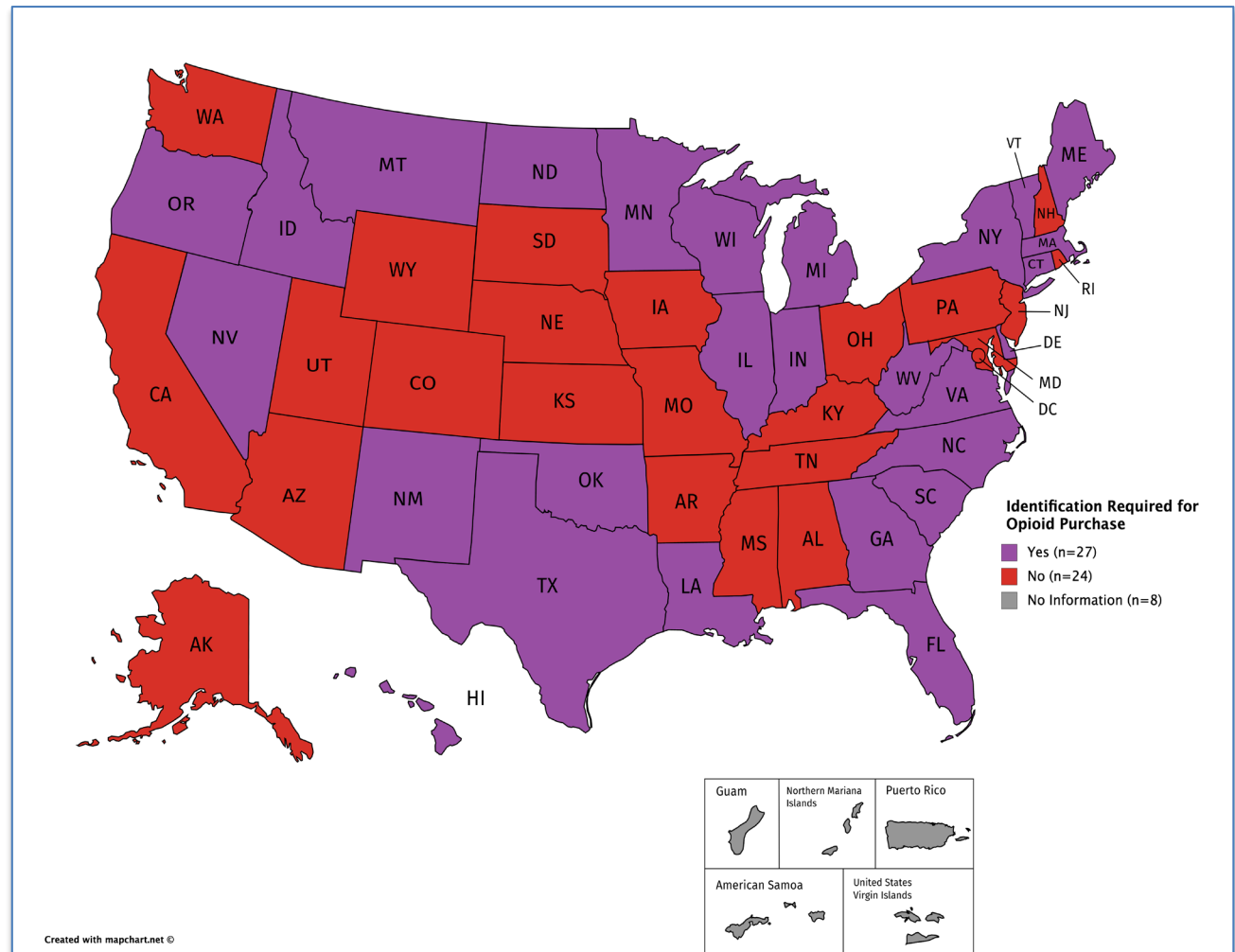
Harm Reduction Programs

Prescriber Education Required Coverage Map
April 2020

Figure 35.

Prescriber Ed Required Map Key:

Purple: Prescriber Ed Required
Red: No Prescriber Ed Required

Opioid-Specific Prescriber
Education Requirement

- Yes (n=45)
- No (n=6)
- No Information (n=8)

Harm Reduction Programs
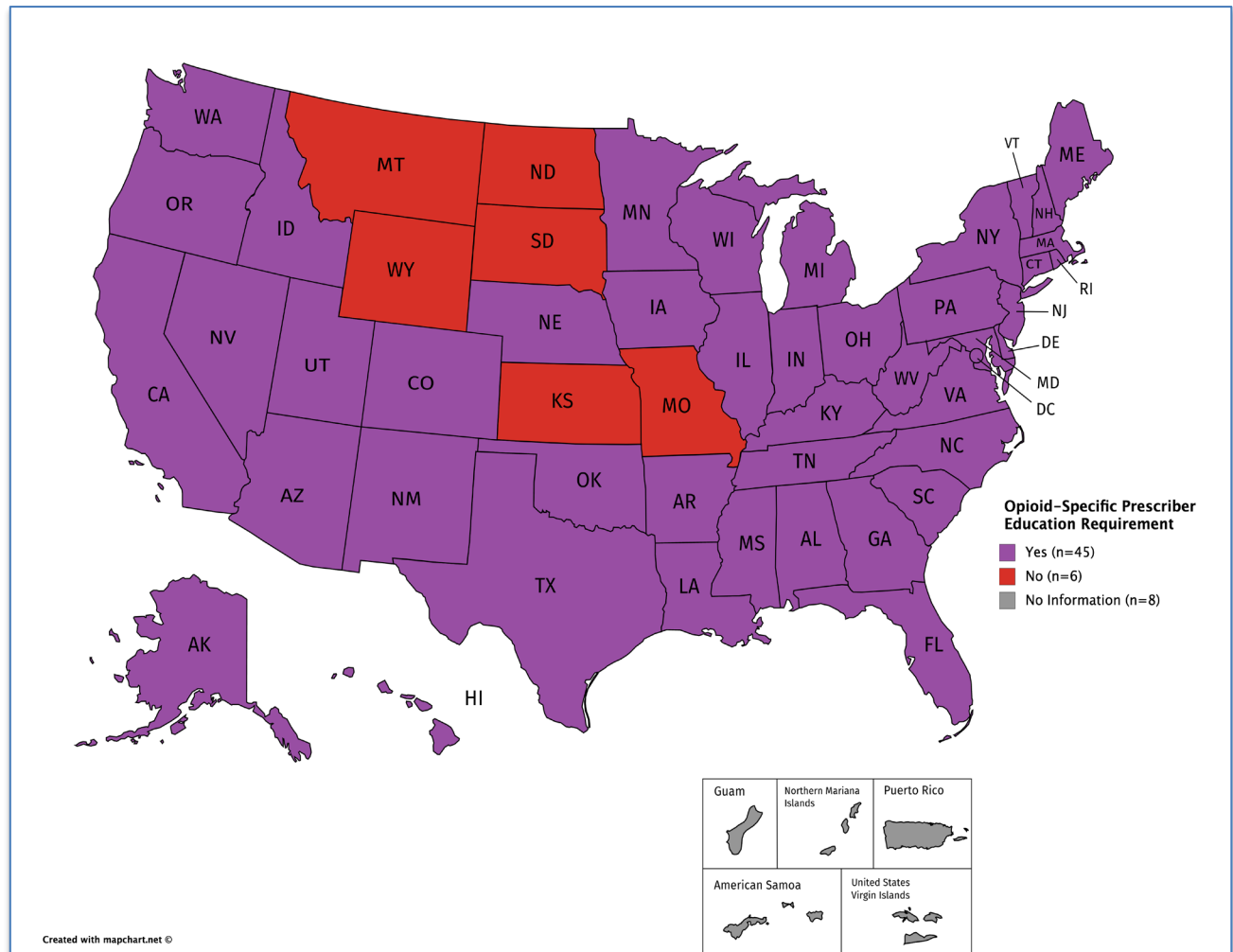
Lock-In Program Coverage Map
April 2020

Figure 36.

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

Medicaid Pharmacy Lock–In Regulation in Place
- Yes (n=44)
- No (n=7)
- No Information (n=8)

Created with mapchart.net ©
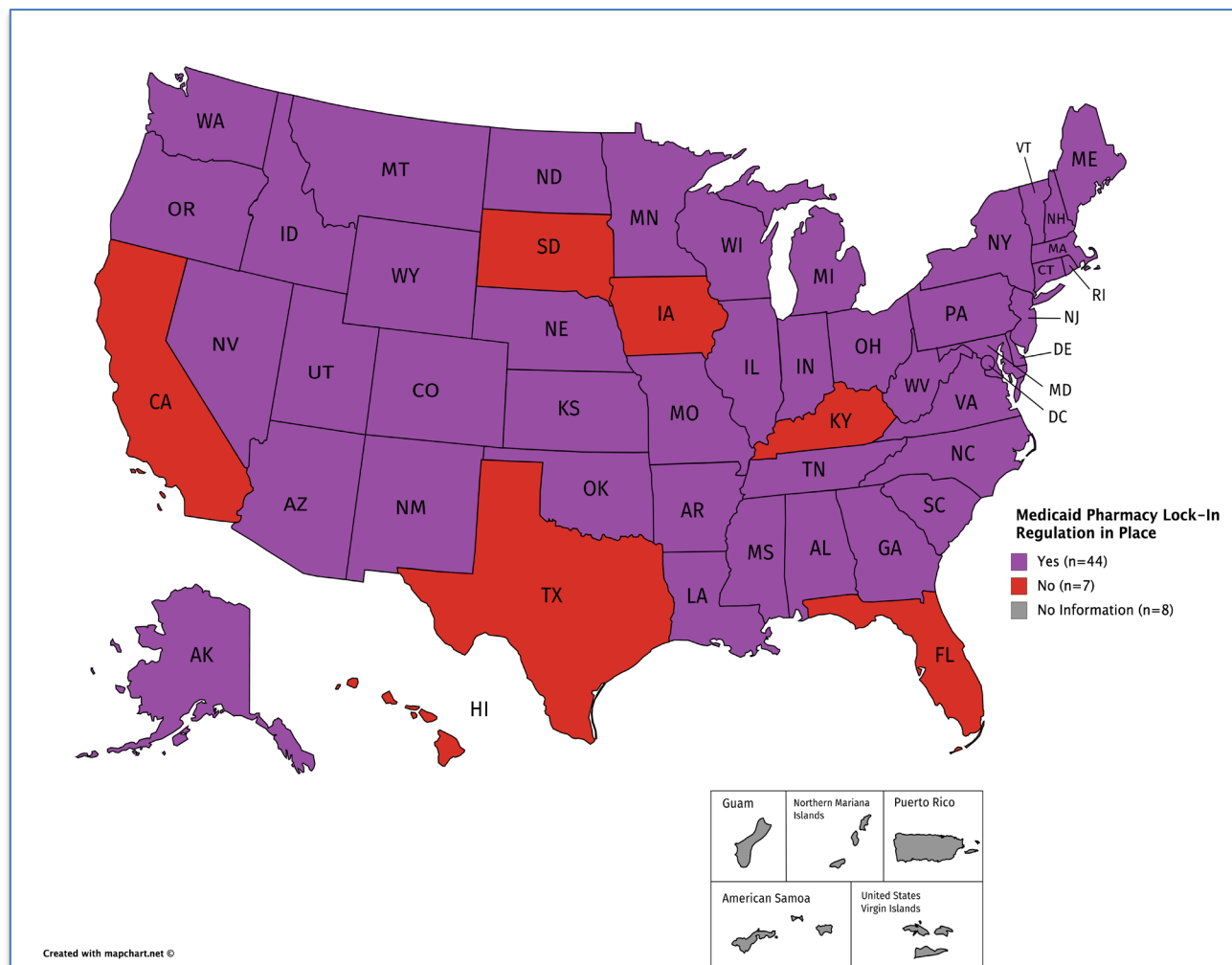
Harm Reduction Programs

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

April 2020 Updates:
- No Updates

April 2020 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

Regional Districts 4 – 6

Co-Infection Watch

Regional Trends Con't.

District 04 - West-North Central (IA, KS, MN, MO, NE, ND, SD)

HIV – New Diagnoses (2018 Preliminary National Rate – 11.4):
- This district has a low burden of HIV, with all six states in District 04 having rates of new HIV diagnoses well below the national rate of 11.4 (per 100,000)
- Missouri has the highest rate of new HIV diagnoses in District 04, with a rate of 7.3 and is ranked 26th in the nation for new HIV diagnoses
- Only two states – Kansas and Minnesota – saw an increase in new HIV diagnoses from 2017 to 2018 (KS – 4.1 to 5.3; MN – 4.9 to 5.0).

HBV (2017 National Rate – 1.1):
- This district has a low burden of HBV, with no states in District 01 having a rate of new HBV diagnoses above the 2017 national rate of 1.1 (per 100,000)
- Kansas has the highest rate of new HBV diagnoses in District 01 0.8.
- Only North Dakota and Minnesota saw a decrease in new HBV diagnoses from 2016 to 2017. Every other state either stayed the same or increased by 0.1. ND had a rate of 0.0, with 0 new reported HBV diagnoses

HCV – New Diagnoses (2017 National Rate – 1.0):
- This district has a relatively low burden of HCV, with only two states in District 04 – Minnesota and South Dakota – having rates of new HCV diagnoses at or above the national rate of 1.0 (MN – 1.0; SD – 2.2)
- South Dakota has the highest rate of new HCV infections, with a rate of 2.2, and ranks 5th in the nation for new diagnoses
- The majority of states in District 04 have rates of new HCV diagnoses well below the 2017 national rate of 1.1

Regional Trends Con't.

District 05 – South Atlantic (DE, FL, GA, MD, NC, SC, VA, WV, DC)

HIV – New Diagnoses (2018 Preliminary National Rate – 11.4):
- This district has a very high burden of HIV, with six states in District 05 having rates of new HIV diagnoses above the national rate of 11.4 (NC – 11.6; SC – 14.1; MD – 16.2; FL – 22.1; GA – 24.3; DC – 29.6)
- Five states in District 05 rank within the Top 10 states with the highest rates of new HIV infections (DC – 1st; GA – 2nd; FL – 3rd; MD – 6th; SC – 9th)
- DC saw a precipitous drop in it rates of new HIV infections from 2016 to 2018, from 50.3 in 2016 to 44.1 in 2017 to 29.6 in 2018

HBV – New Diagnoses (2017 National Rate – 1.1):
- This district has a relatively high burden of HBV, with three states in District 02 having rates of new HBV diagnoses well above the 2017 national rate of 1.1 (NC – 1.8; FL – 2.8; WV – 11.7)
- West Virginia has the highest rate of new HBV diagnoses in both District 02 and the nation, with 38% of new HBV infections in 2016 reporting Injection Drug Use as a risk factor. WV's rate is roughly double the next highest rate of new HBV infections (Maine – 5.8)
- Florida and North Carolina both rank within the ten highest rates of new HBV infections in the nation (FL – 5th; NC – 8th)

HCV – New Diagnoses (2017 National Rate – 1.0):
- This district has a relatively high burden of HCV, with four states in District 05 having rates of new HCV diagnoses at or above the national rate of 1.0
- West Virginia has the highest rate of new HCV diagnoses in both District 05 and the nation, with a rate of 5.8. 42% of new HCV diagnoses reported IDU as a risk factor
- Florida has the 8th-highest rate of new HCV diagnoses in the nation, with a rate of 1.7 (tied with Pennsylvania). While IDU is a factor in FL's new HCV diagnoses, many new diagnoses occur in the Birth Cohort (people born between 1945-1965)
- DC does not track HCV

Co-Infection Watch

Regional Trends Con't.

District 06 – East-South Central (AL, KY, MS, TN)

HIV – New Diagnoses (2018 Preliminary National Rate – 11.4):
- This district has a high burden of HIV, with three states in District 06 having rates of new HIV diagnoses around or above the national rate of 11.4 (TN – 11.3; AL – 11.8; MS – 16.0)
- Mississippi has the highest rate of new HIV diagnoses in District 06 with a rate of 16.0 and is ranked 7th in the nation for new HIV diagnoses
- Mississippi and Tennessee both saw increases in their rates of new HIV infections from 2017 to 2018 (TN – 10.9 to 11.3; MS – 14.3 to 16.0)

HBV – New Diagnoses (2017 National Rate – 1.1):
- This district has a very high burden of HBV, with all four states in District 03 having rates of new HBV diagnoses above the 2017 national rate of 1.1 (MS – 1.5; AL – 1.7; TN – 3.2; KY – 5.3)
- Kentucky and Tennessee have the third- and fourth-highest rates, respectively, of new HBV infections in the nation. Both of these states report that these rates are likely due to IDU
- Alabama has the 9th-highest rate of new HBV diagnoses in the nation
- All four states saw increases in new HBV diagnoses from 2016 to 2017

HCV – New Diagnoses (2017 National Rate – 1.0):
- This district has a high burden of HCV, with two states in District 06 having rates of new HCV diagnoses above the national rate of 1.0 (KY – 1.9; TN – 2.1)
- Both Kentucky and Tennessee have both seen two consecutive years of decreases in new HCV diagnoses (KY – 2.7 à 2.3 à 1.9; TN – 2.6 à 2.3 à 2.1). Despite these decreases, Tennessee and Kentucky rank 6th and 7th in the nation for new HCV diagnoses, largely as a result of IDU
- Alabama has the lowest rate of new HCV diagnoses in District 06, with a rate of 0.3, down from 0.7 in 2016. This decrease may be a result of decreased testing due to an increase in the uninsured rate
- Mississippi does not track HCV

Latest News

Latest News

- **90% of Injection Drug Users Miss Opportunities for HIV or HCV Testing**

Using data from more than 840,000 health care encounters, researchers estimated that around 90% of people who inject drugs missed opportunities for HIV or hepatitis C virus testing during a recent 8-year period — especially rural males seeking care for skin infections or endocarditis.

Bull-Otterson and colleagues used a nationwide health insurance database to assess the prevalence of testing for HIV and HCV infection among patients with claims filed between 2010 and 2017 who had at least one diagnosis, procedure or medication dispensed that was indicative of injection drug use. The researchers then estimated the percentage of PWID tested for HIV or HCV and assessed demographic and clinical factors associated with testing.

Overall, they found that approximately 90% of 844,242 PWID missed opportunities for testing — 71,938 (8.5%) were tested for HIV and 65,188 (7.7%) for HCV (Stulpin, 2020).

- **DDIs affect around 40% of HCV patients taking DAAs**

Drug-drug interactions, or DDIs, affect about 40% of patients with hepatitis C virus being treated with direct-acting antivirals, or DAAs, according to a study published in Open Forum Infectious Diseases. Researchers said lower DDI potential among modern DAA regimens is counteracted by changing patient characteristics.

The frequency of patients with real-world DDIs was highest in period B at 49.6%, with frequencies of 37.1% and 38.8% for periods A and C, respectively. Although DAAs in period C showed a lower DDI risk profile, real-world DDIs were still comparable to period A due to changing HCV patient characteristics, the researchers said. For example, the percentage of patients with HCV aged 75 years or older was 3.1%, 9.8% and 5.6% in periods A, B and C respectively. Additionally, the percentage of polypharmacy patients with HCV using eight or more drugs in their outpatient medication was 11.1%, 15.2% and 17.2% for periods A, B and C, respectively (Dreisbach, 2020).

Latest News Con't.

- **Effect of HCV Clearance on Cardiovascular Risks in People With HIV**

Among patients coinfected with HIV and hepatitis C virus (HCV), eradication of HCV had no effect on markers of preclinical atherosclerosis and biomarkers of inflammation and endothelial dysfunction, according to data published in the Journal of Acquired Immunodeficiency Syndrome. However, associations with a clinically relevant rise in serum low-density lipoprotein cholesterol (LDL-C) were revealed.

The link between HCV infection and cardiovascular events has been tenuous and controversial. Several studies, including meta-analyses, have concluded that HCV infection is associated with an increased cardiovascular disease and related mortality, and stroke; however, several other studies found no association between HCV and coronary artery disease.

Anti-HCV therapies consisted of pegylated interferon and ribavirin plus 1 direct-acting antiviral (DAA) in 55.2% of patients, pegylated interferon and ribavirin in 33.8%, and all-oral DAA in 11.0% of patients.

Sustained viral response (SVR) was achieved in 62% of patients. There were median increases in LDL-C in patients with and without SVR: 14 mg/dl and 0 mg/dl (P =.024), respectively. In 26.9% of patients with SVR, increases in cardiovascular risk categories, including the Framingham risk score, were observed (P =.005 vs baseline) compared with 8.1% of patients without SVR (P =.433). This resulted in a significant interaction between SVR and cardiovascular risk over time (P <.001), but no significant effect of SVR was found for pulse wave velocity (P =.446), carotid intima-media thickness (P =.320), or biomarkers of inflammation and endothelial dysfunction (van Paridon, 2020).

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.

Marcus also serves as the West Virginia Policy Coordinator for the Community Education Group. He is also a Guest Blog Contributor for the ADAP Advocacy Association.

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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