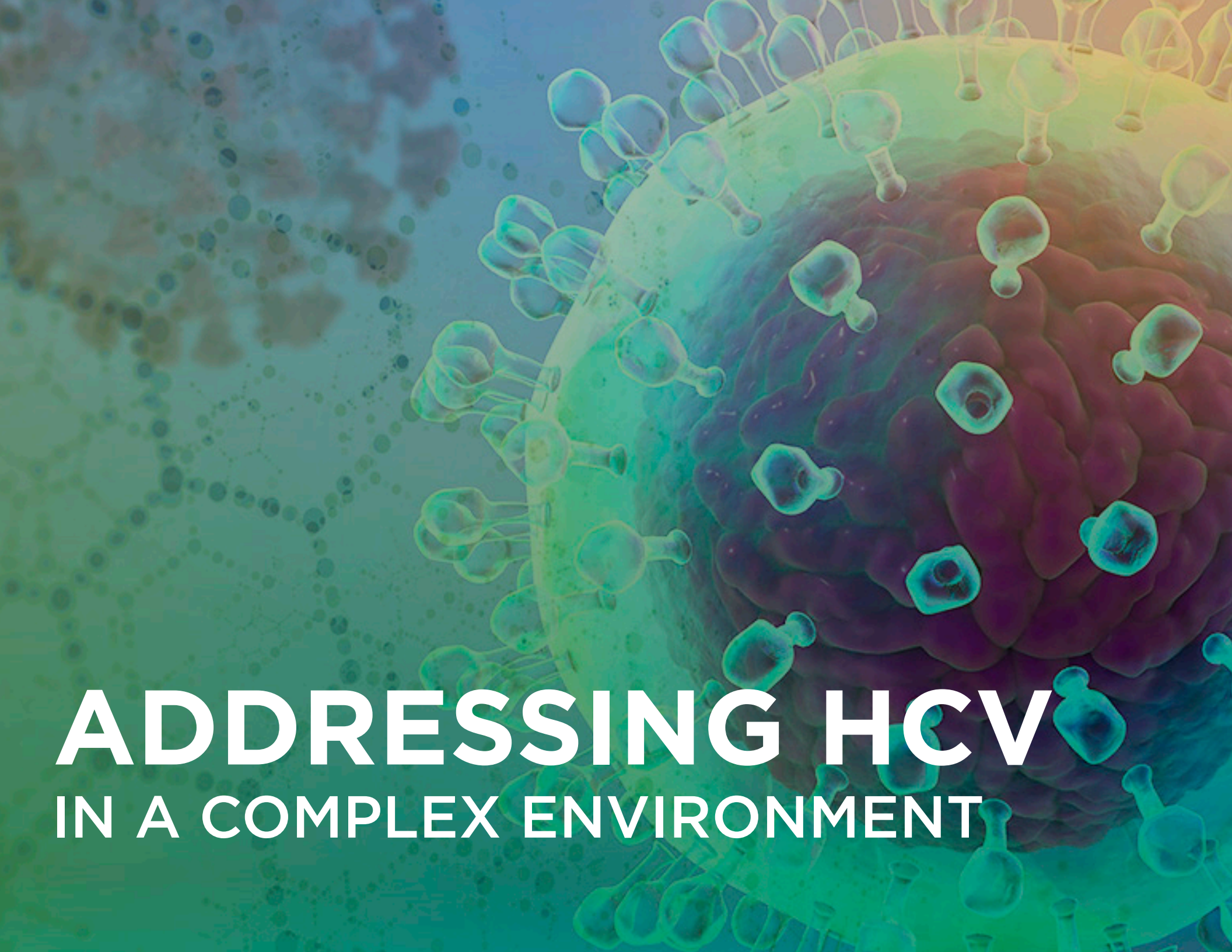


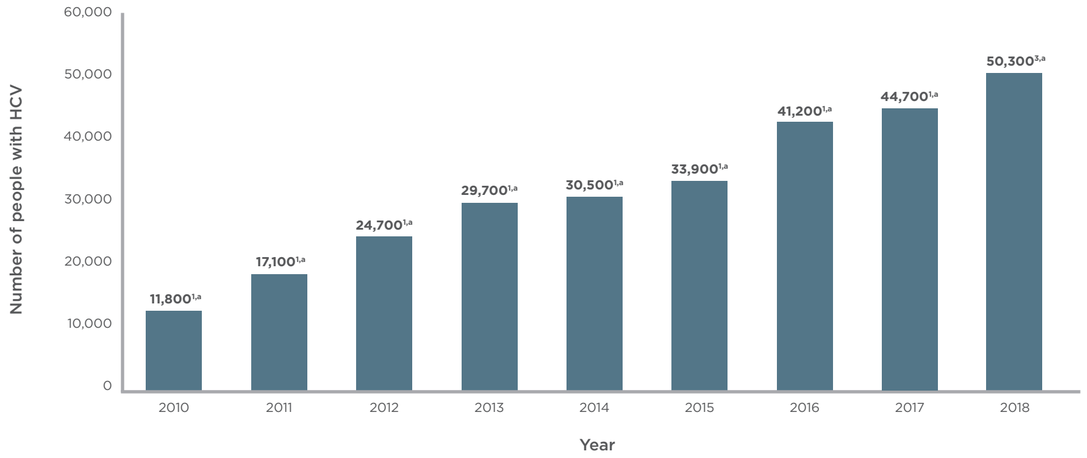
ADDRESSING HCV
IN A COMPLEX ENVIRONMENT

THE HCV EPIDEMIC IN THE UNITED STATES IS CORRELATED WITH A RISE IN INJECTION DRUG USE

New cases of acute HCV have increased rapidly in the United States since 2010[1]

- The number of people living with chronic HCV in the United States was approximately **2.7 million** in 2018,[2] with injection drug use the most common risk factor for new infections[1]

The Incidence of New HCV Infections in the United States Climbed by 426% Between 2010 and 2018[1,3]

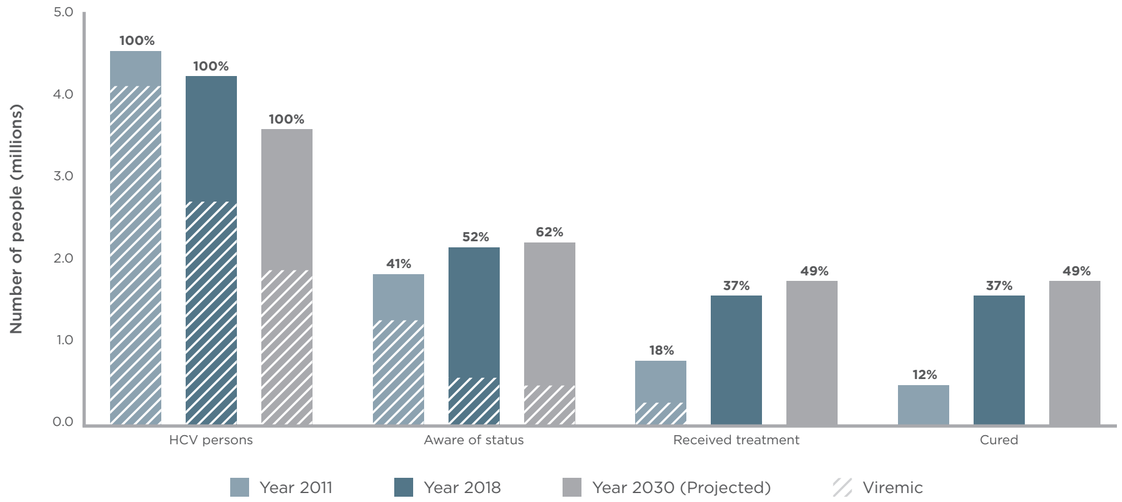


CDC=Centers for Disease Control and Prevention; HCV=hepatitis C virus.

[a]Estimated actual new cases based on CDC projections.[1,3]

Despite the availability of curative[a] treatments, many patients with chronic HCV are not being diagnosed or treated[2]

Changing Cascade of HCV Care in the Era of DAAs, 2011-2030[2,b]



DAA=direct-acting antiviral; WHO=World Health Organization.

[a]Cure, or sustained virologic response (SVR12), is defined as undetectable levels of HCV RNA in the blood at 12 weeks after completion of therapy.[4]

[b]Cascade of HCV care for Years 2011 (ie, the year of the launch of first-generation DAAs), 2018, and 2030 (the WHO target year for HCV elimination). The steps of the HCV care cascade were defined as: (a) HCV persons alive: number of people alive who currently have HCV (ie, viremic) or ever had HCV (ie, cured); (b) Aware of status: number of people alive who have been diagnosed with HCV; (c) Received treatment: number of people alive who ever received anti-viral treatment; and (d) Cured: number of people alive who achieved SVR after treatment.

SCREENING AND TREATMENT OF HCV ARE BECOMING INCREASINGLY COST EFFECTIVE[5,6]

The CDC considers universal HCV screening critical and cost effective[5]

In response to sub-optimal HCV screening rates and a recent analysis of the cost-effectiveness of HCV screening, the CDC has expanded its recommendation from risk-based to universal screening of adults for HCV[5]

2020 CDC Recommendations[5]:

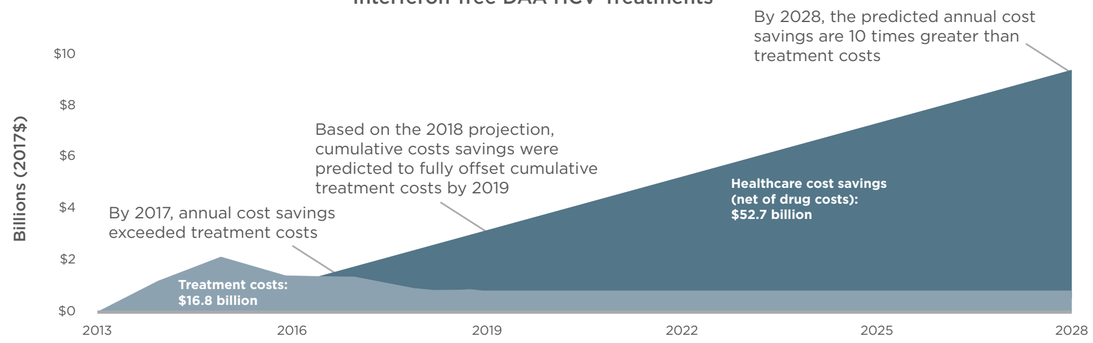
HCV screening of **all adults aged ≥18 years** once in their lifetimes, and screening of **all pregnant women (regardless of age)** during each pregnancy[a]

CDC recommends that **people with risk factors**, including people who have ongoing injection drug use, be tested regularly

[a]The recommendations include an exception for settings where the prevalence of HCV infection is demonstrated to be <0.1%; however, few settings are known to exist with an HCV prevalence below this threshold.

Cumulative net Medicaid cost savings due to DAA treatment of HCV are estimated to reach ~$4.1 billion in 2020[6]

Projected Cumulative Medicaid Treatment Costs vs Cost Savings With Interferon-free DAA HCV Treatments[6,a,b]



Based on a burden-of-illness analysis of Medicaid claims data from 2012, and real-world drug utilization and cost data from 2013-2018[6]:

- Total cumulative treatment costs since 2013 were projected to be fully offset by total cumulative healthcare expenditure reductions **by the end of 2019**
- The cumulative net total healthcare savings from DAAs is projected to reach **$7.7 billion in 2021** and **$12 billion in 2022**

[a]The impact of DAA utilization on overall healthcare costs in Medicaid from 2013 through 2022 was projected by combining the results from an observational retrospective analysis of 2012 Medicaid Analytic eXtract files obtained from Centers for Medicare & Medicaid Services in 16 states, including over 5 million Medicaid enrollees, with DAA costs and utilization data from the Medicaid State Drug Utilization files from the 4th quarter of 2013 though the 2nd quarter of 2018. Healthcare costs included inpatient hospitalizations, hospital days, emergency department visits, physician's office/clinic visits, and prescription drug fills. Projected costs for the remainder of 2018 through 2028 assumed that DAA prices and utilization rates will not change from the levels exhibited in the first half of 2018. All costs were inflated to 2017 dollars using the Consumer Price Index for Medical Care.

[b]Figure recreated from Partnership for Health Analytic Research, LLC. Cumulative net savings from chronic hepatitis C cures are expected to reach $53 billion by 2028. https://www.pharllc.com/wp-content/uploads/2019/07/Burden-of-Illness-of-Chronic-Hepatitis-C.pdf.

INCREASED DIAGNOSIS AND TREATMENT IN THE UNITED STATES ARE CRITICAL FOR MEETING WHO 2030 ELIMINATION GOALS

The United States is not on track to meet WHO HCV elimination goals

According to WHO, the elimination of HCV as a public health threat will require by 2030[7]:

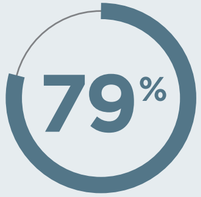
of HCV cases diagnosed

of diagnosed people with HCV treated

=72% of overall HCV cases treated

However, the projected US diagnosis and treatment rates in 2030 are[2]:

of HCV cases diagnosed



of diagnosed people with HCV treated

=49% of overall HCV cases treated

WHO recommends the use of pangenotypic DAA regimens for the treatment of persons with chronic HCV infection aged ≥18 years[7]

Pangenotypic (GT 1-6) regimens

Obviate the need for genotyping

High SVR12 rates

Treatment with DAAs leads to high SVR rates

Safety profile

Well tolerated with minor side effects

Drug interaction considerations

Limited with other medications

GT=genotype; SVR12=sustained virologic response at 12 weeks after the end of treatment.

EPCLUSA: A CONSISTENT TREATMENT OPTION FOR A BROAD RANGE OF PATIENTS WITH CHRONIC HCV

EPCLUSA®
sofosbuvir/velpatasvir
400 mg/100 mg tablets

EPCLUSA is indicated for the treatment of adults with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis and in combination with ribavirin for those with decompensated cirrhosis.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV COINFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with EPCLUSA. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals (DAAs) and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Cases have been reported in patients who are HBsAg positive, in patients with serologic evidence of resolved HBV, and also in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV reactivation associated with treatment with HCV DAAs may be increased in patients taking these other agents. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

IMPORTANT SAFETY INFORMATION (CONT'D)

CONTRAINDICATIONS

- If EPCLUSA is used in combination with ribavirin (RBV), all contraindications, warnings and precautions, in particular pregnancy avoidance, and adverse reactions to RBV also apply. Refer to RBV prescribing information.

WARNINGS AND PRECAUTIONS

- **Serious Symptomatic Bradycardia When Coadministered with Amiodarone:** Amiodarone is not recommended for use with EPCLUSA due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. A fatal cardiac arrest was reported in a patient taking amiodarone who was coadministered a sofosbuvir-containing regimen. In patients without alternative viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.
- **Risk of Reduced Therapeutic Effect Due to Concomitant Use of EPCLUSA with P-gp Inducers and/or Moderate to Strong Inducers of CYP2B6, CYP2C8 or CYP3A4:** Rifampin, St. John's wort, and carbamazepine are not recommended for use with EPCLUSA as they may significantly decrease sofosbuvir and/or velpatasvir plasma concentrations.

ADVERSE REACTIONS

- The most common adverse reactions (≥10%, all grades) with EPCLUSA were headache and fatigue; and when used with RBV in decompensated cirrhotics were fatigue, anemia, nausea, headache, insomnia, and diarrhea.

DRUG INTERACTIONS

- Coadministration of EPCLUSA is not recommended with topotecan due to increased concentrations of topotecan.
- Coadministration of EPCLUSA is not recommended with proton-pump inhibitors, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir.

Consult the full Prescribing Information for EPCLUSA for more information on potentially significant drug interactions, including clinical comments.

EPCLUSA CAN BE USED TO TREAT HCV IN AN ENVIRONMENT COMPLICATED BY COVID-19 AND THE OPIOID EPIDEMIC

EPCLUSA is a once-daily, protease inhibitor (PI)-free, single-tablet regimen of sofosbuvir/velpatasvir for adults without cirrhosis (NC) or with compensated cirrhosis (CC)[8]

Pill not actual size.

SOFOSBUVIR (400 MG)	A nucleotide analog NS5B polymerase inhibitor
VELPATASVIR (100 MG)	An HCV NS5A inhibitor

1 PILL/DAY

One pill, once a day for 12 weeks for NC/CC patients

12 WEEKS

EPCLUSA is used in combination with ribavirin for 12 weeks with food in patients with decompensated cirrhosis

No food requirement for NC/CC patients

PI FREE

No dose adjustment of EPCLUSA required regardless of level of hepatic impairment[a]

One duration, one pill, once a day[8]:
EPCLUSA dosing provides simplicity for patients and predictability for payers

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

[a]Clinical and hepatic laboratory monitoring (including direct bilirubin), as clinically indicated, is recommended for patients with decompensated cirrhosis receiving treatment with EPCLUSA and ribavirin.

MANY OF THE ATTRIBUTES OF EPCLUSA ALIGN WITH THOSE INCLUDED IN THE WHO GUIDELINES[7,8]

EPCLUSA® sofosbuvir/velpatasvir 400 mg/100 mg tablets

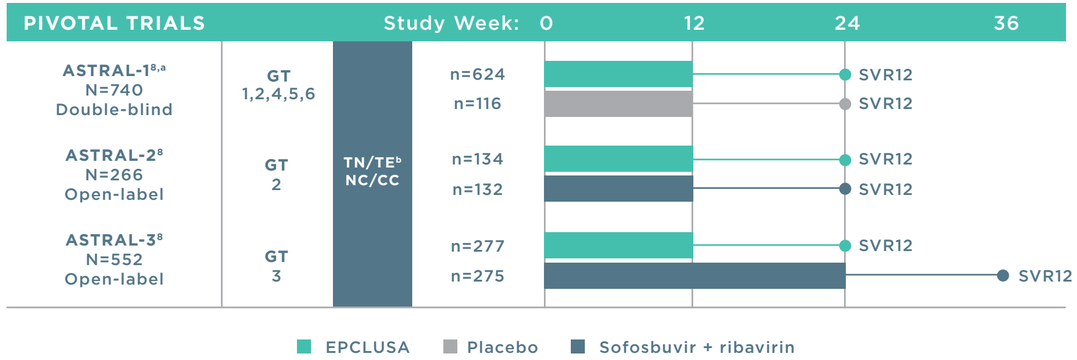
EPCLUSA is a pangenotypic (GT 1-6), panfibrotic regimen[8]

PANGENOTYPIC (GT 1-6)

PANFIBROTIC (F0-F4)

MANY OF THE ATTRIBUTES OF **EPCLUSA** ALIGN WITH THOSE INCLUDED IN THE WHO GUIDELINES[7,8] (CONT'D)

EPCLUSA Was Evaluated in Treatment-naïve (TN) and Treatment-experienced (TE) Subjects With HCV Without Cirrhosis and With Compensated Cirrhosis[8-11]



- The Phase 3 clinical trials were developed to evaluate the safety and efficacy of EPCLUSA[8-10]
- SVR12 (cure) was the primary endpoint for all pivotal clinical trials of EPCLUSA[8]
  - SVR12 was defined as HCV RNA <15 IU/mL at 12 weeks after the end of treatment.[8] Achieving SVR12 is considered a virologic cure[11]

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

[a]All subjects with GT 5 HCV infection were enrolled in the EPCLUSA group.
[b]Prior regimens contained pegylated interferon alfa + ribavirin with or without an HCV NS3/4A PI (boceprevir, simeprevir, or telaprevir).

EPCLUSA®
sofosbuvir/velpatasvir
400 mg/100 mg tablets

EPCLUSA has a high SVR12 rate[8]

98%

OVERALL CURE RATE IN HCV GT 1-6, TN AND TE[a] SUBJECTS WITHOUT CIRRHOSIS OR WITH CC[8] (N=1015/1035; ASTRAL-1, -2, & -3)

GT 1	GT 2
98% (n=323/328) ASTRAL-1	**99%** (n=237/238) ASTRAL-1 & -2
GT 3	**GT 4–6**
95% (n=264/277) ASTRAL-3	**99%** (n=191/192) ASTRAL-1

See trial safety data on **page 13**

[a]Prior regimens contained pegylated interferon alfa + ribavirin with or without an HCV NS3/4A PI (boceprevir, simeprevir, or telaprevir).[8]

MANY OF THE ATTRIBUTES OF **EPCLUSA** ALIGN WITH THOSE INCLUDED IN THE WHO GUIDELINES[7,8] (CONT'D)

EPCLUSA has an established safety profile[8]

Adverse Reactions (All Grades) Reported in ≥5% of Subjects in ASTRAL-1[8,a]

ADVERSE REACTIONS	12 WEEKS (N=624)
HEADACHE	22%
FATIGUE	15%
NAUSEA	9%
ASTHENIA	5%
INSOMNIA	5%

- The majority of adverse reactions were of mild severity (Grade 1, 79%)[8]

- The adverse reactions observed in subjects treated with EPCLUSA in ASTRAL-2 and ASTRAL-3 were consistent with those observed in ASTRAL-1[8]
- Irritability was also observed in ≥5% of subjects treated with EPCLUSA in ASTRAL-3[8]

0.2% **Discontinuations due to adverse reactions[8]** (ASTRAL-1, -2, and -3)

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

[a]Includes subjects who received EPCLUSA alone for 12 weeks.

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400 mg/100 mg tablets

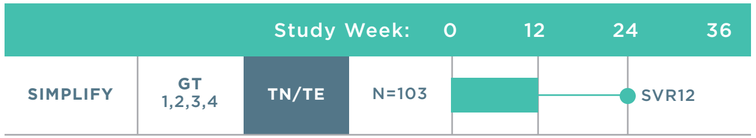
Drug interaction considerations for EPCLUSA[8]

- Coadministration of EPCLUSA is not recommended with topotecan due to increased concentrations of topotecan
- Coadministration of EPCLUSA is not recommended with proton-pump inhibitors, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir
- P-gp inducers and/or moderate to strong cytochrome P (CYP) inducers (eg, rifampin, St. John's wort, carbamazepine) may decrease concentrations of sofosbuvir and/or velpatasvir. Use of EPCLUSA with P-gp inducers and/or moderate to strong CYP inducers is not recommended
- Clearance of HCV infection with DAAs may lead to changes in hepatic function, which may impact safe and effective use of concomitant medications. Frequent monitoring of relevant laboratory parameters (international normalized ratio or blood glucose) and dose adjustments of certain concomitant medications may be necessary
- EPCLUSA has potentially significant drug interactions with some drugs within the following classes that may require alteration in dose or regimen: acid-reducing agents, antiarrhythmics, anticancers, anticonvulsants, antimycobacterials, HIV antiretrovirals, herbal supplements, and HMG-CoA reductase inhibitors

Consult the full Prescribing Information for EPCLUSA for more information on potentially significant drug interactions, including clinical comments.

EPCLUSA'S EFFICACY AND SAFETY WERE DEMONSTRATED IN A UNIQUE, PROSPECTIVE STUDY FOCUSED SOLELY ON PEOPLE WHO INJECT DRUGS[11]

The Phase 4 SIMPLIFY clinical trial evaluated the efficacy and safety of EPCLUSA for 12 weeks in adults with HCV and recent injection drug use (within the past 6 months) and naïve to NS5A-based HCV therapy



International, multicenter, single-arm, open-label Phase 4 trial

- SVR12 was the primary endpoint in SIMPLIFY and was defined as HCV RNA <12 IU/mL at 12 weeks after the end of treatment[11]
- **Patients were instructed to use EPCLUSA for 12 weeks as recommended in the EPCLUSA Prescribing Information and given weekly electronic blister packs[11]**
- Patients with HIV and/or decompensated liver disease were excluded[11]
- **This study is not presented in the Prescribing Information for EPCLUSA**
- **Active injection drug users (within 12 months)[a] were excluded from the ASTRAL pivotal trials[12]**
- Funding for the SIMPLIFY study was provided by Gilead

At baseline[11]:

74% had injected drugs in the past 30 days

26% had injected drugs at least daily in the past 30 days

60% had used alcohol in the past 30 days

59% were receiving opioid substitution therapy

23% had unstable housing

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

[a]Or those with a positive urine drug test at screening.[12]

Adverse Reactions (All Grades) Reported in ≥5% of Subjects in SIMPLIFY[11]

	EPCLUSA
ADVERSE REACTIONS	**12 WEEKS (N=103)**
FATIGUE	22%
HEADACHE	18%
NAUSEA	14%
INSOMNIA	9%
ARTHRALGIA	6%
DIZZINESS	5%
NASOPHARYNGITIS	5%

OVERALL CURE RATE (intent-to-treat) (n=97/103, SIMPLIFY); GT 1-4 NC/CC adult patients[11]

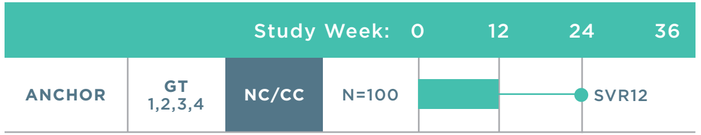
- The majority of subjects reported experiencing a mild or moderate (Grades 1-2) adverse reaction up to 28 days following the last dose[11]
- Seven (7%) patients had at least 1 serious adverse reaction; one (1%) was considered treatment-related[11]

Discontinuations due to adverse reactions[11] (n=1/103)

- Adherence (≥90%) was a secondary endpoint and was assessed by dividing the number of total doses received by total expected number of doses.
- **Study Limitations:** Weekly clinic visits and weekly electronic blister packs, which patients were incentivized to return, may have led to improved adherence, which may not be generalizable to the larger HCV population. The study population was recruited from hospital-based and community-based clinics/centers; it may not be generalizable to all populations of people with injection drug use[11]

EPCLUSA WAS STUDIED IN PEOPLE WITH ONGOING INJECTION DRUG USE IN THE PROSPECTIVE, REAL-WORLD ANCHOR STUDY[13]

ANCHOR evaluated the efficacy of EPCLUSA for 12 weeks in adults with opioid use disorder and reported ongoing injection drug use (within 3 months of screening visit) treated at a harm-reduction center in Washington, DC (N=100)



Prospective, open-label, observational, single-site trial

- SVR12 was the primary endpoint in ANCHOR and was defined as an undetectable HCV RNA at 12 weeks after treatment completion[13]
- **Patients were instructed to use EPCLUSA for 12 weeks as recommended in the EPCLUSA Prescribing Information[13]**
- Participants were offered optional buprenorphine initiation
- **This study is not presented in the Prescribing Information for EPCLUSA**
- **Active injection drug users (within 12 months)[a] were excluded from the ASTRAL pivotal trials[12]**
- Funding for the ANCHOR study was provided by Gilead

At baseline[13]:

59% had daily or more frequent injection drug use

40% had hazardous alcohol use

33% were receiving opioid agonist therapy (OAT)

51% had unstable housing

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

[a]Or those with a positive urine drug test at screening.[12]

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400 mg/100 mg tablets

88% **OVERALL CURE RATE (per-protocol) (n=82/93, ANCHOR); GT 1-4 adult patients[13]**

For the total patient population, the cure rate was (82/100)[13]: **82%**

80% cure rate in adults with hazardous alcohol use[13]

88% cure rate in adults with baseline OAT[13]

75% cure rate in adults with unstable housing[13]

- Adherence was assessed by monthly pill count, HCV viral load, number of bottles completed, interruptions on treatment (≥3 days with resumption), and date of last pill taken relative to planned end-of-treatment date. Imperfect daily adherence was defined as finishing treatment >7 days after the anticipated treatment end date
- Real-world data are observational in nature and are not based on controlled clinical studies. Results from these studies may differ from those observed in clinical practice[13]
- **Study Limitations:** OAT status groups were non-randomized and self-selected. Factors associated with non-uptake or discontinuation of OAT may have been the same factors that led to HCV treatment failure or loss to follow-up. Results may not be generalizable to the larger HCV population[13]

EPCLUSA provided a consistent cure in people who inject drugs with varied adherence[13]

ADDRESSING THE HCV EPIDEMIC DURING THE COVID-19 PANDEMIC WITH **EPCLUSA**

EPCLUSA can be used to treat appropriate patients with HCV during this time using telehealth

According to the 2020 AASLD statement on clinical best practices during the COVID-19 pandemic, treatment for HCV can continue in those already on treatment, and there is no contraindication to initiating treatment of HCV in patients without COVID-19 as clinically warranted[14]

- However, initiating treatment of HCV in a patient with COVID-19 is not routinely warranted

Telemedicine can be used for treating patients with HCV

- For stable outpatients with liver disease, AASLD advises treaters to utilize phone visits or telemedicine as appropriate and available to replace in-person visits during the COVID-19 pandemic[14]
- The short duration of therapy and few serious adverse events associated with DAA therapy makes it well suited for telemedicine[15]

The 2019 AASLD/IDSA simplified HCV treatment guidance for treatment-naïve patients without cirrhosis[16]:

- Includes telehealth as an option for patient support, assessment of symptoms, and/or new medications
- Does not require on-treatment laboratory monitoring for patients not on diabetes medication or warfarin
- Does not require liver-related follow-up for patients who achieve SVR
- Includes EPCLUSA for 12 weeks

Please click to see the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING on hepatitis B virus reactivation**.

AASLD=American Association for the Study of Liver Diseases; IDSA=Infectious Diseases Society of America.

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The 2019 AASLD/IDSA simplified HCV treatment guidance for treatment-naïve patients without cirrhosis includes EPCLUSA for 12 weeks[16]

ELIGIBLE

Patients with chronic HCV who do not have cirrhosis and have not previously received HCV treatment

PRE-TREATMENT ASSESSMENT

Cirrhosis Assessment
- Biopsy not required
- Cutoffs suggesting cirrhosis
  - FIB-4 >3.25
  - APRI >2.0
  - Platelets <150,000/mm^3
  - FibroScan® >12.5 kPa

Medication Reconciliation
- Current Rx and OTC medications, and herbal/dietary supplements

DDI Assessment

Education
- Treatment administration, adherence, avoidance of alcohol, and reinfection prevention

Pre-treatment Lab Testing

Within 6 months
- CBC
- Hepatic function panel
- eGFR

Prior to starting antiviral therapy
- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- HBsAg

Before initiating treatment
- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age

NOT ELIGIBLE

Patients who have any of the following characteristics:
- Prior HCV treatment
- Cirrhosis
- Prior liver transplant
- HIV-positive or HBsAg-positive
- End-stage renal disease (ie, eGFR <30 mL/min/1.73 m^2)
- Currently pregnant

TREATMENT WITH ELIGIBLE REGIMENS, WHICH INCLUDES EPCLUSA FOR 12 WEEKS

Information about post-treatment assessment of cure and follow-up care can be found at https://www.hcvguidelines.org

ON-TREATMENT MONITORING

- In patients not taking warfarin or diabetes medication, no on-treatment laboratory monitoring is required
- An in-person or telehealth visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications

APRI=aspartate aminotransferase to platelet ratio index; CBC=complete blood count; DDI=drug–drug interaction; eGFR=estimated glomerular filtration rate; FIB-4=Fibrosis-4; HBsAg=hepatitis B surface antigen; OTC=over-the-counter; Rx=prescription.

TREAT CHRONIC HCV IN THE MIDST OF THE CHALLENGES ASSOCIATED WITH THE COVID-19 AND OPIOID EPIDEMICS

- New cases of HCV have increased rapidly in the United States since 2010, and are mostly associated with injection drug use[1]
- The United States is not on track to meet WHO targets for addressing the HCV epidemic[2,7] despite the availability of cost-effective, curative treatments[6]
- HCV treatment can proceed in many patients during the COVID-19 pandemic, using telemedicine to replace in-person visits[14]

See inside brochure for information about a treatment option

References

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