HARVONI®
ledipasvir/sofosbuvir
90 mg/400 mg tablets

CONNECTING CHRONIC HCV PATIENTS
TO A ONCE-DAILY, SINGLE-TABLET REGIMEN

HARVONI is indicated with or without ribavirin for the
treatment of patients with chronic hepatitis C virus (HCV)
genotype 1, 4, 5, or 6 infection

This educational program and speaker are sponsored by
Gilead Sciences, Inc.

Shobha Joshi, MD
Director, Hepatology Research
Transplant Hepatologist
Ochsner Clinic Foundation
TODAY’S AGENDA

- HCV Overview
- HARVONI Overview
- Your Role in HCV
HCV OVERVIEW
HCV DISCOVERY

- An RNA virus that used to be known as non-A, non-B hepatitis until it was formally identified in 1988\(^1\)

- No vaccine available

- HCV infection is the most common chronic bloodborne infection in the United States\(^1\)

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CHRONIC HEPATITIS C IS A PROGRESSIVE DISEASE

Chronic HCV frequently has few or no symptoms and can progress without signs for decades.¹

Most chronic HCV patients are asymptomatic until serious liver complications arise.²

Approximately 3.5 million people in the United States have chronic HCV infection\(^1\)

1.3% of the US general population\(^2\)

Seroprevalence is higher among these cohorts\(^2\):

- Baby boomers (persons born between 1945 and 1965) (3.5%)
- Non-Hispanic blacks (2.2%)
- Males (1.9%)

**Distribution of HCV Genotypes (GTs) in the United States\(^3\)**

- 75.5% GT 1
- 22.8% GT 4, 5, 6
- 1.7% Other GTs

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THE GAP IN HCV DIAGNOSIS AND TREATMENT

HCV Treatment Cascade Based on Analyses Published January 2003 to July 2013\(^1\)

- **Infected**: 3,500,000
- **Diagnosed\(^a\)**: 1,750,000 (50% of infected)
- **Cured\(^b\)**: 315,000 (9% of diagnosed)

\(^a\)HCV detected=positive HCV RNA and HCV antibody tests.
\(^b\)Achieved sustained virologic response (SVR).

WHY IS HCV CURABLE?

• Unlike some other viruses, HCV RNA is only present in the cytoplasm (not in the nucleus) of the host cell\(^1\)

• Without the stable, genetic-material reservoir of the nucleus created by other viruses, the possibility exists for HCV cure by treatment\(^1\)

cccDNA=covalently closed circular DNA; HBV=hepatitis B virus; HIV=human immunodeficiency virus.

DEFINING HCV CURE

• The goal of HCV therapy is to achieve cure. Cure, also known as SVR, is defined as undetectable levels of HCV in the blood at 12 or more weeks after therapy is complete, which is also referred to as SVR12\textsuperscript{1,2}

• In some instances, HCV treatment does not result in cure
  • Virus does not reach undetectable levels (non-responder)
  • Virus does not stay undetectable after therapy completion (relapser)


SELECT HISTORY OF TREATMENT FOR HCV GT 1

- Pegylated interferon (Peg-IFN) alfa with ribavirin (RBV) was approved in 2001 with a treatment duration of 48 weeks for chronic HCV GT 1 and cure (SVR) rates between 40% and 50%.

- Starting in 2011, direct-acting antivirals (DAAs) were approved for use in combination therapy with Peg-IFN and RBV, and produced higher cure rates in GT 1 patients.

- HARVONI was approved in 2014 as a once-daily, single-tablet regimen without IFN or RBV for the treatment of patients with chronic HCV GT 1.

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HARVONI IS INDICATED WITH OR WITHOUT RBV FOR THE TREATMENT OF CHRONIC HCV GT 1, 4, 5, OR 6 INFECTION

- A complete once-daily, single-tablet regimen
- IFN-free
- RBV-free for most patients

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

• If HARVONI is used in combination with 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

Risk of Serious Symptomatic Bradycardia When Coadministered with Amiodarone:

• Amiodarone is not recommended for use with HARVONI 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. 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 of HARVONI Due to P-gp Inducers:

• Rifampin and St. John’s wort are not recommended for use with HARVONI as they may significantly decrease ledipasvir and sofosbuvir plasma concentrations

Related Products Not Recommended:

• HARVONI is not recommended for use with other products containing sofosbuvir
HARVONI is a once-daily, single-tablet regimen of ledipasvir and sofosbuvir, which are DAAs against HCV.¹

**Sofosbuvir**
An inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication

**Ledipasvir**
An inhibitor of the HCV NS5A protein, which is required for viral replication

¹. HARVONI US full Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2016.
RECOMMENDED TREATMENT DURATION FOR HCV PATIENTS WITH GT 1

<table>
<thead>
<tr>
<th>HARVONI TABLET DAILY</th>
<th>NO FOOD REQUIREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Can be considered in treatment-naïve patients without cirrhosis and with pre-treatment HCV RNA &lt;6 million IU/mL</strong></td>
<td>8 weeks</td>
</tr>
<tr>
<td><strong>Treatment-naïve patients with or without cirrhosis</strong></td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Treatment-experienced patients without cirrhosis</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Treatment-experienced patients with cirrhosis</strong></td>
<td>24 weeks</td>
</tr>
</tbody>
</table>

- The dosing information listed here does not include GT 1 patients with decompensated cirrhosis (Child-Pugh B or C) or liver transplant recipients

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**a** Cirrhosis=compensated cirrhosis (Child-Pugh A).

**b** Treatment-experienced=patients who have failed a Peg-IFN alfa + RBV–based regimen with or without an HCV PI.

HARVONI + RBV for 12 weeks can be considered in treatment-experienced GT 1 patients with cirrhosis who are eligible for RBV. The daily dosage of RBV is weight-based (1000 mg for patients <75 kg and 1200 mg for those ≥75 kg) administered orally in 2 divided doses with food. Refer to the RBV prescribing information.

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## CLINICAL STUDY DESIGNS OVERVIEW

**HARVONI ± RBV Was Studied in 3 Pivotal Open-Label Studies With 1952 GT 1 Subjects With or Without Compensated Cirrhosis**

<table>
<thead>
<tr>
<th>Study</th>
<th>Subject Type</th>
<th>N</th>
<th>Treatment Arms and Fixed Durations</th>
</tr>
</thead>
<tbody>
<tr>
<td>ION-1</td>
<td>Treatment-Naïve</td>
<td>865</td>
<td>Evaluated 12 and 24 weeks of treatment with HARVONI with or without RBV</td>
</tr>
<tr>
<td></td>
<td>With or without compensated cirrhosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ION-3</td>
<td>Treatment-Naïve</td>
<td>647</td>
<td>Evaluated 8 weeks of treatment with HARVONI with or without RBV and 12 weeks of treatment with HARVONI</td>
</tr>
<tr>
<td></td>
<td>Without cirrhosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ION-2</td>
<td>Treatment-Experienced</td>
<td>440</td>
<td>Evaluated 12 and 24 weeks of treatment with HARVONI with or without RBV</td>
</tr>
<tr>
<td></td>
<td>With or without compensated cirrhosis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- In all studies, SVR12 was the primary endpoint, defined as HCV RNA <25 IU/mL at 12 weeks after the cessation of treatment. Achieving SVR12 is considered a virologic cure. Relapse was a secondary endpoint

- Response-guided therapy was not utilized in these studies

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*RBV 1000 mg-1200 mg/day.

bSubjects had relapse or non-response to prior Peg-IFN + RBV with or without an HCV PI.

### HARVONI STUDIES INCLUDED A BROAD RANGE OF SUBJECTS WITH GT 1\(^{1-4}\)

<table>
<thead>
<tr>
<th>Subject Characteristics</th>
<th>Details</th>
</tr>
</thead>
</table>
| Subjects with cirrhosis\(^{a,2,3}\)                          | 224 subjects had compensated cirrhosis\(^{2,3}\)  
|                                                               | 16% of subjects in ION-1 and 20% of subjects in ION-2\(^{2,3}\) |
| No upper limit of age\(^{2-4}\)                              | 117 subjects were older than 65 years\(^{1}\)  
|                                                               | Oldest subject was aged 80 years\(^{2}\) |
| No upper limit of body mass index (BMI)\(^{2-4}\)            | 497 subjects had BMI >30\(^{5-7}\)  
|                                                               | 56 kg/m\(^2\) was the highest BMI\(^{4}\) |
| Inclusion of subjects with prior HCV PI experience            | 231 subjects previously failed an HCV PI–based regimen\(^{3}\) |
| Race/ethnicity                                                | 16% subjects were Black\(^{2-4}\)  
|                                                               | 9% subjects were Hispanic or Latino\(^{2-4}\)  
|                                                               | 82% subjects were White\(^{2-4}\) |

- HARVONI clinical studies did not exclude subjects taking diabetes medications or subjects who were stable on an anticoagulant regimen\(^{8-10}\)

\(^{a}\) Cirrhosis was defined as any one of the following: liver biopsy showing cirrhosis (eg, METAVIR score=4 or Ishak score ≥5); FibroScan\(^{®}\) (in countries where locally approved) showing cirrhosis or results >12.5 kPa; FibroTest\(^{®}\) score >0.75 AND aspartate aminotransferase (AST): platelet ratio index >2 during screening.\(^{8-10}\)

HARVONI CURED NEARLY ALL TREATMENT-NAÏVE, TREATMENT-EXPERIENCED, AND CIRRHOTIC HCV GT 1 SUBJECTS<sup>1</sup>

97% OVERALL CURE RATE ACROSS ION-1, ION-2, AND ION-3 HARVONI PHASE 3 STUDIES<sup>1-4</sup>
(n=1042/1079)

- HARVONI alone delivered overall cure rates of 94%-99% in HARVONI Phase 3 clinical studies<sup>1</sup>
  - RBV was not shown to increase response rates observed with HARVONI
- High cure rates were observed in a broad range of subjects, including those with cirrhosis, previous HCV treatment experience, advanced age, and high BMI<sup>1-4</sup>

HARVONI WAS HIGHLY EFFECTIVE FOR A VARIETY OF CHRONIC HCV GT 1 SUBJECTS¹

SVR12 RATES BY SUBJECT TYPE ACROSS HARVONI ION-1, ION-2, AND ION-3 PHASE 3 CLINICAL STUDIES²,¹

<table>
<thead>
<tr>
<th></th>
<th>8 Weeks</th>
<th>12 Weeks</th>
<th>24 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-Naïve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without cirrhosis and with pretreatment HCV RNA &lt;6 million IU/mL (ION-3)</td>
<td>97%</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>Without cirrhosis (ION-3)</td>
<td>119</td>
<td>176</td>
<td>83</td>
</tr>
<tr>
<td>Without cirrhosis (ION-1)</td>
<td>208</td>
<td>177</td>
<td>87</td>
</tr>
<tr>
<td>With cirrhosis (ION-1)</td>
<td>223</td>
<td>32</td>
<td>22</td>
</tr>
<tr>
<td>Treatment-Experienced</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without cirrhosis (ION-2)</td>
<td>96%</td>
<td>94%</td>
<td>95%</td>
</tr>
<tr>
<td>With cirrhosis (ION-2)</td>
<td>123</td>
<td>34</td>
<td>22</td>
</tr>
</tbody>
</table>

¹SVR12 was the primary endpoint and was defined as HCV RNA <25 IU/mL at 12 weeks after the end of treatment.¹ Achieving SVR is considered a virologic cure.² Relapse was a secondary endpoint.¹

HARVONI WAS SAFE WITH LOW RATES OF ADVERSE EVENTS IN ION-1, ION-2, AND ION-3


Important Safety Information: Adverse Reactions

- Most common (≥10%, all grades) adverse reactions were fatigue, headache and asthenia
THE MAJORITY OF ADVERSE REACTIONS WITH HARVONI ALONE OCCURRED AT A SEVERITY OF MILD TO MODERATE IN ION-1, ION-2, AND ION-3

### Adverse Reactions (All Grades) Reported in ≥5% of Subjects Receiving 8, 12, or 24 Weeks of Treatment With HARVONI

<table>
<thead>
<tr>
<th></th>
<th>HARVONI 8 Weeks N=215</th>
<th>HARVONI 12 Weeks N=539</th>
<th>HARVONI 24 Weeks N=326</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>16%</td>
<td>13%</td>
<td>18%</td>
</tr>
<tr>
<td>Headache</td>
<td>11%</td>
<td>14%</td>
<td>17%</td>
</tr>
<tr>
<td>Nausea</td>
<td>6%</td>
<td>7%</td>
<td>9%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4%</td>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>3%</td>
<td>5%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Direct comparison across studies should not be made due to differing study designs.

- Based on pooled data from 3 HARVONI Phase 3 clinical studies in GT 1 subjects with compensated liver disease with or without cirrhosis
- The majority of the adverse reactions presented in the table occurred at a severity of grade 1 (mild, transient, and did not require treatment modification)

DRUG INTERACTIONS

- In addition to rifampin and St. John’s wort, coadministration of HARVONI is also not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such coadministration is expected to decrease the concentration of ledipasvir and sofosbuvir, reducing the therapeutic effect of HARVONI.

- Coadministration of HARVONI is not recommended with simeprevir due to increased concentrations of ledipasvir and simeprevir. Coadministration is also not recommended with rosvastatin or co-formulated elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate due to increased concentrations of rosvastatin and tenofovir, respectively.

Consult the full Prescribing Information for HARVONI for more information on potentially significant drug interactions, including clinical comments.
HARVONI MAY BE COADMINISTERED WITH ACID-REDUCING AGENTS¹

Ledipasvir solubility decreases as pH increases. Drugs that increase gastric pH are expected to decrease the concentration of ledipasvir.

<table>
<thead>
<tr>
<th>What if my patient is taking an antacid?²</th>
<th>It is recommended to separate antacid and HARVONI administration by 4 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>What if my patient is taking an H₂-receptor antagonist?²</td>
<td>H₂-receptor antagonists may be administered simultaneously with or 12 hours apart from HARVONI at a dose that does not exceed doses comparable to famotidine 40 mg twice daily</td>
</tr>
<tr>
<td>What if my patient is taking a proton-pump inhibitor?³</td>
<td>Proton-pump inhibitor doses comparable to omeprazole 20 mg or lower can be administered simultaneously with HARVONI under fasted conditions</td>
</tr>
</tbody>
</table>

²Eg, aluminum and magnesium hydroxide.
³Eg, famotidine.
²Eg, omeprazole.

HARVONI DRUG INTERACTIONS WITH THE ANTIARRHYTHMIC MEDICATIONS DIGOXIN OR AMIODARONE

What if my patient is taking digoxin?

Monitor patients during HARVONI treatment
• Coadministration may increase digoxin levels

What if my patient is taking amiodarone?

Coadministration is not recommended
• May result in serious symptomatic bradycardia

For patients without alternative, viable treatment options who will be coadministered HARVONI with amiodarone:
• Counsel patients about the risk of serious symptomatic bradycardia
• Cardiac monitoring in an in-patient setting for the first 48 hours of coadministration is recommended
• After 48 hours of in-patient monitoring, outpatient or self-monitoring of the heart rate should occur on a daily basis through at least the first 2 weeks of treatment


PLEASE SEE FULL PRESCRIBING INFORMATION AVAILABLE WITH THIS PRESENTATION.
**POTENTIALLY SIGNIFICANT DRUG INTERACTIONS WITH HIV ANTIRETROVIRALS**

- **Tenofovir disoproxil fumarate (DF) + HIV PI/ritonavir or cobicistat**
  - Consider alternative HCV or antiretroviral therapy
  - If coadministration is necessary, monitor for tenofovir-associated adverse reactions

- **Regimens containing tenofovir DF without HIV PI/ritonavir or cobicistat**
  - Monitor patients for tenofovir-associated adverse reactions

- Tenofovir concentrations are increased when HARVONI is coadministered with tenofovir DF–containing HIV antiretroviral regimens. Refer to the tenofovir DF (VIREAD®) or emtricitabine/tenofovir DF (TRUVADA®) prescribing information for recommendations on renal monitoring.

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*a* The safety of increased tenofovir concentrations in the setting of HARVONI and an HIV PI/ritonavir or cobicistat has not been established.

*b* Regimens include: atazanavir/ritonavir or cobicistat + TRUVADA, darunavir/ritonavir or cobicistat + TRUVADA, lopinavir/ritonavir (Kaletra®) + TRUVADA.

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1. **HARVONI US full Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2016.**
Based on drug interaction studies, no clinically significant drug interactions are expected for the following agents:

- **Antiretrovirals**: abacavir, atazanavir/ritonavir, darunavir/ritonavir, dolutegravir, efavirenz, emtricitabine, lamivudine, raltegravir, rilpivirine, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide
- **Immunosuppressants**: cyclosporine, tacrolimus
- **Opioids**: methadone
- **Oral contraceptives**: including ethinyl estradiol
- **Statins**: pravastatin
- **Calcium-channel blockers**: verapamil

HARVONI is not metabolized by the CYP450 pathway.

# HARVONI CONSIDERATIONS IN SPECIFIC POPULATIONS

<table>
<thead>
<tr>
<th>No dose adjustments required</th>
<th>Geriatric patients(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients with mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C)</td>
</tr>
<tr>
<td></td>
<td>Patients with mild or moderate renal impairment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety and efficacy of HARVONI have not been established</th>
<th>Pediatric patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients with severe renal impairment (estimated Glomerular Filtration Rate &lt;30 mL/min/1.73m(^2)) or end-stage renal disease requiring hemodialysis</td>
</tr>
</tbody>
</table>

\(^{a}\)Clinical studies included 225 subjects aged 65 years and older. Safety and effectiveness were similar between subjects over 65 years and younger subjects across treatment groups, but greater sensitivity of some older individuals cannot be ruled out.

YOU’RE TAKING ACTION.
PATIENTS ARE CONNECTING.

#1 PRESCRIBED TREATMENT FOR HCV GT 1 IN THE UNITED STATES\textsuperscript{a,1}

MORE THAN 200,000 PATIENTS HAVE BEEN PRESCRIBED HARVONI IN THE UNITED STATES\textsuperscript{b,1}

\textsuperscript{a}IMS Weekly NPA Market Dynamics from week ending 10/24/14–8/14/15.

\textsuperscript{b}This information is derived from IMS NPA Market Dynamics, IMS NPA Monthly data, IntegriChain DNA National, and 867 data; data reflect estimated patient starts October 2014 to September 2015.

1. Data on file, Gilead Sciences, Inc.

Patients shown are hypothetical.
YOUR ROLE IN HCV
CHANGE IN HCV CAN START WITH YOU

Screen for HCV Antibodies
• A simple blood test will reveal if your patient has been exposed to HCV

Diagnose with an HCV RNA Test
• If the screening test is positive, the RNA test can detect the presence of HCV RNA to confirm a chronic infection

Connect to an HCV Specialist
• Refer all chronically infected patients to an HCV specialist for treatment evaluation, regardless of presence of symptoms or disease severity

Counsel your patients along the way.
Educate them about HCV, how it can be cured, and available treatment options.
CURRENT SCREENING GUIDELINES TO HELP IDENTIFY PATIENTS

• Screening based on risk factors alone was not optimal
  • Many patients have no known exposure risk
  • Baby boomers (born between 1945 and 1965) account for 75% of all HCV patients

• The CDC, USPSTF, and AASLD issued updated guidelines to include the one-time screening of all baby boomers

• This age cohort should be screened regardless of symptoms or other risk factors

• Along with baby boomers, other high-risk groups to screen include people who currently inject or ever injected drugs, those who received a tattoo in an unregulated setting, and those who had a blood transfusion before 1992

AASLD=American Association for the Study of Liver Diseases; CDC=US Centers for Disease Control and Prevention; USPSTF=US Preventive Services Task Force.

Screening Process

- Counsel your patients on who should be screened
- Explain why they should be screened
- Discuss that there are viable treatment options

Order a Simple Blood Test That Can Reveal the Presence of HCV Antibodies

If the result is negative:
It is unlikely your patient has been exposed to HCV.

If the result is positive:
Your patient has been exposed to HCV; the diagnosis will need to be confirmed with an HCV RNA test.
A Second Blood Test for HCV RNA Is Needed to Verify a Chronic Infection

• Explain the need to confirm possible infection and steps to take following a positive antibody test

• Order an HCV RNA test to detect HCV RNA in the blood

• Discuss the importance of treatment evaluation if the RNA test shows chronic infection

If no HCV RNA is detected:
Your patient has been exposed to HCV but is not chronically infected. About 20%-50% of patients clear the virus spontaneously within the first 6 months.1

If the result is positive:
Your patient is chronically infected and should be referred to an HCV specialist for treatment evaluation.

Many labs perform automatic reflex HCV RNA tests on samples that test positive for HCV antibodies.

Look for “Reflex” or “w/Reflex” in the test name.

After their diagnosis is confirmed, your chronic HCV patients should be promptly referred to an HCV specialist regardless of viral load or liver enzyme levels.

Viral load or liver function tests may not be a reliable indicator of liver damage.¹

Most chronic HCV patients are asymptomatic until serious liver complications arise.²

Explain what to expect when meeting with an HCV specialist

Emphasize the importance of keeping the appointment


“[Clinicians] should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR, preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications.”

– AASLD/IDSA Guidance³
REFERRAL BEST PRACTICES TO CONSIDER

- Explain to your patient what a diagnosis of HCV means and that *HCV is curable*

- Tell your patient that there are IFN-free treatment options that offer simple dosing

- Consider ordering a blood test to determine the HCV GT, which will help the specialist determine an appropriate treatment option

- Assist with scheduling the specialist appointment; call to check that your patient followed through

- After the specialist appointment, stay in touch with your patient and the specialist
Getting Started
Support Path helps patients access therapy and get off to an efficient start
• Benefits investigation and prior authorization support
• Co-pay and other financial assistance
• Specialty pharmacy finder

Help Along the Way
Support Path is ready to assist patients along the way toward treatment completion
• Educational resources, support for adherence, and progress tracking
• A 24/7 help line with nurses on call can provide answers and assistance
• Ongoing support for access and reimbursement, including help with refill authorization

Support Path makes it easy to connect to these services when you need them
• Visit MySupportPath.com
• Call 1-855-7-MYPATH (1-855-769-7284)
HYPOTHETICAL CASE STUDY

GREGORY: A BABY BOOMER

Patient characteristics

<table>
<thead>
<tr>
<th>Age</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race/ethnicity</td>
<td>Caucasian</td>
</tr>
<tr>
<td>BMI</td>
<td>31 kg/m²</td>
</tr>
</tbody>
</table>

- Gregory’s physician identified him as being at risk for HCV infection on the basis of his age group: baby boomer (born between 1945 and 1965)
- Gregory did not reveal any other known risk factors to his physician
- Laboratory tests showed that Gregory’s alanine aminotransferase (ALT) and AST levels were in the normal range
GREGORY: SCREENING, DIAGNOSIS, AND CONNECTION

Screening
- Gregory was counseled on the need for screening, and he agreed to be screened
  - Gregory tested positive for HCV antibodies

Diagnosis
- An HCV RNA test confirmed chronic infection
  - A GT test was also ordered, which showed GT 1 infection
  - The physician explained that Gregory may be eligible for treatment with HARVONI

Connection
- The physician selected an HCV specialist and had her staff call to make the appointment for Gregory
  - Gregory visited the specialist, who evaluated him for treatment and prescribed HARVONI
  - The specialist provided Gregory with information to connect to HARVONI’s Support Path
HCV Is Underdiagnosed and Undertreated

HCV Is Curable

Take Action Now: Screen, Diagnose, and Connect

- Cure, also known as SVR, is defined as undetectable levels of HCV in the blood at 12 or more weeks after therapy is complete, which is also referred to as SVR12\(^1,2\)

To learn more and enroll for updates, go to BeTheConnection.HARVONI.com