Treatment of HCV Genotype 1

Introduction

Background: In the United States, genotype 1 HCV is the most common infection, accounting for approximately 70 to 75% of all hepatitis C infections. Accordingly, treatment of genotype 1 has the most extensive data and highest clinical relevance for hepatitis C treatment issues in the United States. Genotype 1 infection has been historically difficult to treat, but multiple recent studies have shown SVR rates greater than 90% in these genotype 1 patients using well-tolerated, all-oral regimens consisting of new direct-acting antiviral agents. The use of these direct-acting antiviral agents has been complicated by the high price of therapy. For example, the cost of the preferred regimens in the 2014 AASLD/IDSA/IAS-USA Guidance for treatment of genotype 1 infection range from approximately $63,000 to $150,000 in patients without cirrhosis and $84,000 to $300,000 in those with cirrhosis (Figure 1). The following discussion regarding initial treatment and retreatment of patients with genotype 1a or 1b chronic hepatitis C assumes the patient and their clinician have already made the decision to initiate hepatitis C therapy.

Medications used to Treat Hepatitis C: The HCV Medications section on this web site provides detailed information for each of the FDA-approved medications listed in the treatment recommendations, including links to the full prescribing information and to patient assistance programs. Adherence with the treatment regimen is of paramount importance. Patients should receive detailed counseling regarding the importance of adherence prior to starting therapy as well as intensive monitoring and follow-up during therapy.

Genotype 1: Initial Treatment

Background: The treatment landscape for patients with genotype 1 chronic hepatitis C infection has rapidly changed in recent years. Historically, genotype 1 hepatitis C has been considered the most difficult to treat hepatitis C genotype. From 1998 to 2013, therapy evolved from interferon monotherapy, to peginterferon monotherapy, to peginterferon plus ribavirin, to triple therapy with peginterferon plus ribavirin plus a NS3A/4A protease inhibitor (boceprevir or telaprevir). In late 2013 and most of 2014, the standard of care for initial therapy of genotype 1 consisted of peginterferon plus ribavirin plus either sofosbuvir or simeprevir. Three new all-oral regimens were approved by the FDA in the second half of 2014 for the treatment of genotype 1 infection: (1) ledipasvir-sofosbuvir, (2) simeprevir plus sofosbuvir, and (3) ombitasvir, paritaprevir, ritonavir and dasabuvir. The current recommended therapy for genotype 1 infection consists of all-oral regimens that are safe, highly effective, and require relatively short duration in therapy.

Factors to Consider Prior to Choosing Treatment Regimen: For patients chronically infected with genotype 1 hepatitis C, three key factors should be considered when choosing the optimal treatment regimen: genotype 1 subtype (1a or 1b), prior treatment experience, and the presence or

absence of cirrhosis. If genotype 1 subtype is not known, the patient should be treated as genotype 1a. With most regimens, the baseline HCV RNA value does not influence the treatment choice or duration. With ledipasvir-sofosbuvir, however, a post-hoc analysis from the ION-3 trial in treatment-naive patients without cirrhosis noted that patients with a baseline HCV RNA level less than 6 million IU/ml had similar relapse rates with 8 or 12 weeks of therapy. The management of genotype 1 patients with decompensated cirrhosis, renal impairment, HIV coinfection, acute hepatitis C infection, or post-liver transplantation can impact choice of treatment regimens and duration of therapy and is not addressed in this lesson.

AASLD/IDSA/IAS-USA Guidance (see Initial Treatment of HCV Infection**):** The following is a summary of joint recommendations issued by the American Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America, in collaboration with the International Antiviral Society USA (IAS-USA). The AASLD/IDSA/IAS-USA recommendations summarized below are for patients with hepatitis C genotype 1a and 1b infection who will receive initial treatment. The recommended three regimens for genotype 1a or 1b are listed in alphabetical order and are considered to have similar efficacy. Ultimately, the choice of a particular regimen will be influenced by cost, insurance coverage, pill burden, potential drug interactions, use of ribavirin, relevant comorbid conditions, and the patient and provider preferences. Note that acid suppressing medications may significantly decrease the absorption of ledipasvir-sofosbuvir, thereby potentially causing lower drug levels.

Genotype 1 Chronic HCV: Initial Treatment
Treatment-Naive Patients with Genotype 1 Infection

Recommended regimen for Genotype 1a

Ledipasvir-Sofosbuvir
*Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) one tablet once daily x 12 weeks**

Rating: Class I, Level A
Note: *In the ION-3 trial, patients without cirrhosis and a baseline HCV RNA levels less than 6 million IU/ml had similar relapse rates when treated with 8 weeks versus 12 weeks. Decreasing the length of the regimen to 8 weeks should be done with caution.

Recommended regimen for Genotype 1a

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir
Fixed-dose combination of ombitasvir (12.5 mg)/paritaprevir (75 mg)/ritonavir (50 mg) two tablets once daily plus dasabuvir (250 mg) one tablet twice daily x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)

+

Ribavirin
1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)

Rating: Class I, Level A
Note: The ribavirin daily dose is given in two divided doses.

Recommended regimen for Genotype 1a

Sofosbuvir *400 mg once daily x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)*	+	**Simeprevir** *150 mg once daily x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)*	±	**Ribavirin** *1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)*

Rating: Class IIa, Level B
Note: The ribavirin daily dose is given in two divided doses.

Recommended regimen for Genotype 1b

Ledipasvir-Sofosbuvir
*Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) one tablet once daily x 12 weeks**

Rating: Class I, Level A
Note: *In the ION-3 trial, patients without cirrhosis and a baseline HCV RNA levels less than 6 million IU/ml had similar relapse rates when treated with 8 weeks versus 12 weeks. Decreasing the length of the regimen to 8 weeks should be done with caution.

Recommended regimen for Genotype 1b

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir *Fixed-dose combination of ombitasvir (12.5 mg)/paritaprevir (75 mg)/ritonavir (50 mg) two tablets once daily plus dasabuvir (250 mg) one tablet twice daily x 12 weeks*	±	**Ribavirin** *For patients with cirrhosis, the addition of ribavirin (1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 12 weeks is recommended*

Rating: Class I, Level A
Note: The ribavirin daily dose is given in two divided doses.

Recommended regimen for Genotype 1b

Sofosbuvir *400 mg once daily x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)*	+	**Simeprevir** *150 mg once daily x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis)*

Rating: Class II, Level B

Not recommended for Genotype 1a or 1b

- **Sofosbuvir 400 mg once daily plus weight-based Ribavirin (1000 mg/day if**

Genotype 1: Retreatment of Patients in whom Prior Therapy

Failed

Background: New interferon-free treatment options in 2014 have markedly improved the SVR12 response rates in patients with prior treatment experience, including those with a prior null response, with SVR12 rates greater than 90% (compared to historic SVR12 rates of 30 to 60% with triple therapy consisting of peginterferon, ribavirin, and either telaprevir or boceprevir). Prior failure with a regimen that included a NS3/4A protease inhibitor (boceprevir or telaprevir) does not impact subsequent therapy with sofosbuvir, ledipasvir, ombitasvir, or dasabuvir, but may potentially impact subsequent treatment with simeprevir or paritaprevir, the newer HCV protease inhibitors. Thus, use of a regimen that includes simeprevir or paritaprevir is not recommended for retreatment of patients who previously failed therapy that included boceprevir or telaprevir.

Factors to Consider Prior to Choosing Treatment Regimen: For patients with chronic hepatitis C genotype 1 infection who have treatment experience, the primary factors that determine the recommended regimen and duration of treatment are presence of cirrhosis, the prior regimen used when treatment failure occurred, and in some instances, genotype 1 subtype. If the genotype 1 subtype is not known, the patient should be treated as genotype 1a. Ultimately, the choice of a particular regimen will be influenced by cost, insurance coverage, pill burden, potential drug interactions, use of ribavirin, relevant comorbid conditions, and the patient and provider preferences. The retreatment of genotype 1 patients with decompensated cirrhosis, renal impairment, HIV coinfection, acute hepatitis C infection, or post-liver transplantation is not addressed here.

AASLD/IDSA/IAS-USA Guidance (see Retreatment of Persons in Whom Prior Therapy has Failed **):** The following is a summary of joint recommendations issued by the American Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America, in collaboration with the International Antiviral Society USA (IAS-USA). The recommendations listed below are for patients with hepatitis C genotype 1 infection who are treatment experienced and previously failed therapy. Note that acid suppressing medications may significantly decrese the absorption of ledipasvir-sofosbuvir, thereby potentially causing lower drug levels.

Genotype 1 Chronic HCV: Retreatment Prior Treatment Failure (received Peginterferon plus Ribavirin)

Recommended regimen for retreatment of Genotype 1a without cirrhosis

Ledipasvir-Sofosbuvir
Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 12 weeks

Rating: Class I, Level A

Recommended regimen for retreatment of Genotype 1a without cirrhosis

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir
Fixed-dose combination of ombitasvir (12.5 mg)/paritaprevir (75 mg)/ritonavir (50 mg) two tablets once daily plus

+

Ribavirin
1000 mg if <75 kg or 1200 mg if ≥75 kg x 12 weeks

dasabuvir (250 mg) one tablet twice daily x 12 weeks

Rating: Class I, Level A
Note: The ribavirin daily dose is given in two divided doses.

Recommended regimen for retreatment of Genotype 1a without cirrhosis

Sofosbuvir *400 mg once daily x 12 weeks* + **Simeprevir** *150 mg once daily x 12 weeks* ± **Ribavirin** *1000 mg if <75 kg or 1200 mg if ≥75 kg x 12 weeks*

Rating: Class IIa, Level B
Note: The ribavirin daily dose is given in two divided doses

Recommended regimen for retreatment of Genotype 1b without cirrhosis

Ledipasvir-Sofosbuvir
Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 12 weeks

Rating: Class I, Level A

Recommended regimen for retreatment of Genotype 1b without cirrhosis

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir
Fixed-dose combination of ombitasvir (12.5 mg)/paritaprevir (75 mg)/ritonavir (50 mg) two tablets once daily plus dasabuvir (250 mg) one tablet twice daily x 12 weeks

Rating: Class I, Level A

Recommended regimen for retreatment of Genotype 1b without cirrhosis

Sofosbuvir *400 mg once daily x 12 weeks* + **Simeprevir** *150 mg once daily x 12 weeks* ± **Ribavirin** *1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 12 weeks*

Rating: Class IIa, Level B
Note: The ribavirin daily dose is given in two divided doses

Recommended regimen for retreatment of Genotype 1a or 1b infection with compensated cirrhosis

Ledipasvir-Sofosbuvir
Fixed-dose combination of

ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 24 weeks

Rating: Class I, Level A

Recommended regimen for retreatment of Genotype 1a or 1b infection with compensated cirrhosis

Ledipasvir-Sofosbuvir *Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 12 weeks* + **Ribavirin** *1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 12 weeks*

Rating: Class I, Level B
Note: The ribavirin daily dose is given in two divided doses

Recommended regimen for retreatment of Genotype 1a or 1b infection with compensated cirrhosis

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir *Fixed-dose combination of ombitasvir (12.5 mg)/paritaprevir (75 mg)/ritonavir (50 mg) two tablets once daily plus dasabuvir (250 mg) one tablet twice daily x 24 weeks with genotype 1a and x 12 weeks for genotype 1b* + **Ribavirin** *1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 24 weeks with genotype 1a and x 12 weeks for genotype 1b*

Rating: Class I, Level A
Note: NOTE: 24 week course for genotype 1a and 12-week course for genotype 1b; the ribavirin daily dose is given in two divided doses

Recommended regimen for retreatment of Genotype 1a or 1b infection with compensated cirrhosis

Sofosbuvir *400 mg once daily x 24 weeks* + **Simeprevir** *150 mg once daily x 24 weeks* ± **Ribavirin** *1000 mg/day if <75 kg or 1200 mg/day if ≥75 kg x 24 weeks*

Rating: Class IIa, Level B

Adapted from AASLD, IDSA, IAS-USA. Recommendations for testing,managing, and treating hepatitis C.
http://www.HCVguidelines.org. Accessed January 5, 2015.

Genotype 1 Chronic HCV: Retreatment
Prior Treatment Failure (received Sofosbuvir-Containing Regimen)

Recommended regimens for patients without advanced fibrosis
Rating: Class IIb, Level C
Note: Based on the limited data available for effective therapy, patients without an urgent need for HCV treatment should defer antiviral therapy pending additional data or consider treatment within clinical trial settings.

Recommended regimen for patients with advanced fibrosis

Ledipasvir-Sofosbuvir *Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 24 weeks*	±	**Ribavirin** *1000 mg if <75 kg or 1200 mg if ≥75 kg x 24 weeks*

Rating: Class IIa, Level C
Note: The ribavirin daily dose is given in two divided doses.

Adapted from AASLD, IDSA, IAS-USA. Recommendations for testing,managing, and treating hepatitis C.
http://www.HCVguidelines.org. Accessed January 5, 2015.

Genotype 1 Chronic HCV: Retreatment
Prior Treatment Failure (received Peginterferon, Ribavirin, and HCV Protease Inhibitor)

Recommended regimen for patients without cirrhosis, regardless of genotype 1 subtype

Ledipasvir-Sofosbuvir
Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 12 weeks

Rating: Class I, Level A

Recommended regimen for patients with cirrhosis, regardless of genotype 1 subtype

Ledipasvir-Sofosbuvir
Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 24 weeks

Rating: Class I, Level A

Recommended regimen for patients with cirrhosis, regardless of genotype 1 subtype

Ledipasvir-Sofosbuvir *Fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) once daily x 12 weeks*	+	**Ribavirin** *1000 mg if <75 kg or 1200 mg if ≥75 kg x 12 weeks*

Rating: Class IIa, Level B
Note: The ribavirin daily dose is given in two divided doses.

Not recommended for patients who failed prior therapy that included an HCV protease inhibitor

• Any regimen containing peginterferon, including (a) peginterferon and ribavirin, (b) peginterferon and ribavirin plus either simeprevir, sofosbuvir, telaprevir, or boceprevir
Rating: Class IIb, Level A

• Monotherapy with peginterferon, ribavirin, or a direct acting antiviral agent
Rating: Class III, Level A

• Any interferon-free regimen containing an HCV protease inhibitor, including simeprevir or paritaprevir
Rating: Class IIb, Level A

Adapted from AASLD, IDSA, IAS-USA. Recommendations for testing,managing, and treating hepatitis C.
http://www.HCVguidelines.org. Accessed January 5, 2015.

Key Studies to Support Recommendations: The following key studies support the recommendations for retreatment of patients with chronic hepatitis C and genotype 1 infection who previously failed therapy. Click on the study name (blue) to see more details and summary PowerPoint slides.

- ION-2: In this phase 3 trial, 440 treatment-experienced patients with genotype 1 chronic hepatitis C infection, with or without cirrhosis, received a 12- or 24-week treatment with fixed-dose combination ledipasvir-sofosbuvir, with or without ribavirin. The SVR12 rate with 12 weeks of ledipasvir-sofosbuvir was 94% without ribavirin and 96% with ribavirin; with 24 weeks of therapy the SVR12 rates were 99%, with or without ribavirin. Patients with cirrhosis who received 12 weeks of therapy had lower SVR rates than patients without cirrhosis. In addition patients with cirrhosis had higher SVR rates with 24 weeks of ledipasvir-sofosbuvir than with 12 weeks (100% versus 86%).
- SAPPHIRE-II: In this phase 3 trial, investigators examined the safety and efficacy of ombitasvir-paritaprevir-ritonavir and dasabuvir plus ribavirin in patients with chronic hepatitis C infection, genotype 1, without cirrhosis, who had previously failed treatment with peginterferon and ribavirin. Among patients who received ombitasvir-paritaprevir-ritonavir

and dasabuvir plus ribavirin, 96.3% achieved an SVR12, with similar results observed with genotype 1a (96.0%) and 1b (96.7%).

- TURQUOISE-II: This phase 3 trial enrolled treatment-naive and treatment-experienced patients with chronic hepatitis C infection, genotype 1, and Child-Pugh class A cirrhosis. Patients received ombitasvir-paritaprevir-ritonavir and dasabuvir plus ribavirin regimen for 12 weeks (Group A) or 24 weeks (Group B). The overall SVR12 rates were 92% in Group A and 96% in Group B. For patients with genotype 1a, SVR12 rates were 89% and 94% for groups A and B respectively. For patients with genotype 1b, SVR12 rates were 99% in Group A and 100% in Group B. There was a clinically meaningful difference in the SVR12 between the 12-week and 24 week treatment groups in patients with Genotype 1a infection and prior null response (80% versus 92.9%), which suggests that patients in this subgroup will likely benefit from extending therapy to 24 weeks.
- COSMOS: In this open-label, phase 2a trial, investigators enrolled treatment-naive and prior null responders patients with genotype 1 to receive the combination of sofosbuvir plus simeprevir for 12 or 24 weeks, with or without ribavirin. All patients in cohort 1 were prior null responders to peginterferon and ribavirin and had Metavir fibrosis scores F0 to F2. Cohort 2 included null responders (54%) with and treatment-naive patients (46%) with Metavir fibrosis scores F3 to F24. The SVR rates ranged from 79 to 93%. and in Cohort 1 and 93 to 100% in Cohort 2.
- SIRIUS: In this phase 2, double-blind trial, treatment-experienced patients with genotype 1 HCV and compensated cirrhosis received either ledipasvir-sofosbuvir plus ribavirin for 12 weeks or ledipasvir-sofosbuvir without ribavirin for 24 weeks. All patients had previously sequentially failed dual therapy with peginterferon and ribavirin and triple therapy with peginterferon and ribavirin and a NS3/4A protease inhibitor. The SVR12 rates were very high in both groups: 96% in the 12-week group and 97% in the 24-week group. The study provides supportive data for the use of a 12-week course of ledipasvir-sofosbuvir plus ribavirin in patients with compensated cirrhosis, if they can tolerate ribavirin.
- NIAID Retreatment of Sofosbuvir Failures: In this small single-arm study by the NIAID, 14 patients with genotype 1 infection who had relapsed with prior therapy with 24 weeks of sofosbuvir and ribavirin in the SPARE study were subsequently treated with 12 weeks of ledipasvir-sofosbuvir and all 14 achieved an SVR12.
- Retreatment of Sofosbuvir Failures from Clinical Trials: This phase 2 trial enrolled patients with genotype 1 chronic HCV who failed a sofosbuvir-containing regimen while participating in a phase 2 or 3 Gilead-sponsored clinical trial. In the 12-week treatment arm, patients received retreatment with ledipasvir-sofosbuvir plus ribavirin. The study design permitted enrollment of patients with compensated cirrhosis. Preliminary results from this 12-week group showed an SVR12 rate of 98% (50 of 51). The other treatment arms, which involve 24 weeks of treatment of ledipasvir-sofosbuvir, with or without ribavirin, are currently ongoing.

Genotype 1: Future Treatment Options

Options for Treatment of HCV Genotype 1 in Future: Since genotype 1 remains the dominant genotype among persons infected with hepatitis C in the United States, development of new agents for treatment of genotype 1 will likely continue at a rapid pace. The following is a short list of investigational all-oral hepatitis C therapeutic regimens that are further along in development for the treatment of genotype 1 infection.

- **Daclatasvir plus Sofosbuvir**: Daclatasvir is an investigational NS5A replication complex inhibitor currently in phase 3 trials. A phase 2a trial that involved a once-daily regimen of daclatasvir combined with sofosbuvir, with or without ribavirin showed 100% SVR rates in patients with genotype 1 infection and thus has generated significant interest in this combination. Daclatasvir combined with the investigational NS3 protease inhibitor asunaprevir, with and without peginterferon and ribavirin, has also been studied in phase 2 trials and has shown moderately good SVR rates, but null responder patients with genotype

1a responded poorly. In a phase 3 trial (HALLMARK) in patients with genotype 1b, daclatasvir 60 mg once daily combined with asunaprevir 120 mg twice daily generated excellent SVR rates in both treatment-naive and treatment-experienced patients. On April 7, 2014, Bristol-Myers-Squibb announced submission of a new drug application to the U.S. FDA seeking approval for daclatasvir plus asunaprevir in patients with genotype 1b (and other genotypes), but on October 7, 2014 Bristol-Myers Squibb withdrew the FDA application for the dual regimen of daclatasvir and asunaprevir.

- **Grazoprevir (formerly MK-5172) and Elbasvir (formerly MK-8472)**: Grazoprevir is an investigational NS3/4A protease inhibitor that has been studied in combination with elbasvir, an investigational NS5A inhibitor. Both of these medications are dosed once-daily and are being studied as a coformulated product. The C-WORTHY study examined grazoprevir and elbasvir with or without ribavirin for 12 or 18 weeks in treatment-naïve cirrhotics and prior null responders with or without cirrhosis with genotype 1 infection. SVR12 rates were high among treatment-naïve cirrhotics (90-97%) and null responders (91-100%). Post-hoc analyses did not demonstrate a difference with the addition of ribavirin. The C-SWIFT study evaluated grazoprevir and elbasvir in fixed-dose combination with sofosbuvir for shorter durations of 4, 6 and 8 weeks in treatment-naïve genotype 1 patients with reasonably high SVR4/8 rates noted in preliminary results in the 6- and 8-week arms (80-95%) but lower SVR4/8 rate (39%) in the 4-week arm.

Summary Points

- New directing-acting interferon-free regimens are now the standard of care for the treatment of chronic hepatitis C genotype 1 infection.
- For initial therapy of treatment-naive patients with genotype 1 infection, three regimens with similar efficacy are recommended in the AASLD/IDSA/IAS-USA guidance: (a) ledipasvir-sofosbuvir, (b) ombitasvir-paritaprevir-ritonavir and dasabuvir, with or without ribavirin, or (c) sofosbuvir plus simeprevir with or without ribavirin.
- For initial therapy, the addition of ribavirin to (a) ombitasvir-paritaprevir-ritonavir and dasabuvir or (b) sofosbuvir plus simeprevir depends on the genotype 1 subtype. If the genotype 1 subtype is not known, the patient should be treated as genotype 1a.
- For retreatment of patients with genotype 1 who previously failed therapy with peginterferon and ribavirin, the AASLD/IDSA/IAS-USA recommends one of following regimens that have similar efficacy: (a) ledipasvir-sofosbuvir, (b) ombitasvir-paritaprevir-ritonavir and dasabuvir plus ribavirin, or (c) sofosbuvir plus simeprevir with or without ribavirin.
- In treatment-experienced patients, the duration of therapy with ledipasvir-sofosbuvir is 12 weeks without cirrhosis; those with cirrhosis can receive either ledipasvir-sofosbuvir for 24 weeks or ledipasvir-sofosbuvir plus ribavirin for 12 weeks.
- In treatment-naive and treatment-experienced patients with genotype 1 infection, the new benchmark for sustained virologic response rates is 90% or greater.
- The major barrier to treatment with all new therapies is the extremely high cost of a treatment course.

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Figures

Figure 1 Cost of Medication Regimens Used to Treat Genotype 1 Chronic HCV

This figure shows the approximate cost of different regimens used for treatment-naive and/or treatment-experienced patients with genotype 1 chronic HCV. Cost estimates based on available wholesale acquisition cost data.

Estimated Medication Cost for Treatment of Genotype 1 Chronic HCV	
Regimen and Duration	**Regimen Cost**
Ledipasvir-Sofosbuvir x 8 weeks	$63,000
Ledipasvir-Sofosbuvir x 12 weeks	$94,500
Ledipasvir-Sofosbuvir x 24 weeks	$189,000
Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir +/- Ribavirin x 12 weeks	$84,00
Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir +/- Ribavirin x 24 weeks	$168,000
Sofosbuvir + Simeprevir +/- Ribavirin x 12 weeks	$150,000
Sofosbuvir + Simeprevir +/- Ribavirin x 24 weeks	$300,000