Medical Policy

BlueCross BlueShield of Kansas
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Title: Hepatitis C Second Generation Antivirals – Through Preferred Pegylated Interferon (2014) (ledipasvir/sofosbuvir, paritaprevir/ritonavir/ombitasvir + dasabuvir, and Sovaldi [sofosbuvir])

- **Prime Therapeutics will review Prior Authorization requests.**

Prior Authorization Form:
http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth_6349KS_HepatitisC.pdf

For information concerning Prior Authorization Prescription Drugs:
http://www.bcbsks.com/CustomerService/PrescriptionDrugs/prior_authorization.htm

Link to Drug List (Formulary):
http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.htm

Professional
Original Effective Date: October 1, 2014
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Institutional
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Revision Date(s): October 1, 2014
Current Effective Date: October 1, 2014

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DESCRIPTION

The intent of the Hepatitis C second generation antiviral Prior Authorization (PA) program is to appropriately select patients for therapy according to the Food and Drug Administration (FDA) approved product labeling and/or clinical guidelines and/or clinical studies. The PA process will evaluate the use of these agents when there is supporting clinical evidence for their use. This criteria includes the use of sofosbuvir with our without simeprevir (Olysio). For the use of Olysio in combination with peginterferon and ribavirin, see Hepatitis C. criteria. Hepatocellular carcinoma patients will be allowed therapy with sofosbuvir plus ribavirin. Renewal requires HCV RNA laboratory values at treatment week 4.

Target Drugs

Ledipasvir/sofosbuvir
Paritaprevir/ritonavir/ombitasvir + dasabuvir
Sovaldi™ (sofosbuvir)

FDA Approved Indications and Dosage

Medication	Indications	Dose and Interval
(ledipasvir-sofosbuvir)	Treatment of chronic hepatitis C, genotype 1 infection	1 tablet orally once daily containing 90 mg of ledipasvir and 400 mg of sofosbuvir for up to 12 weeks
Olysio (simeprevir)	Treatment of chronic hepatitis C (CHC), genotype 1 infection as a component of a combination antiviral treatment regimen (pegylated interferon +/- ribavirin)^	150 mg capsule taken once daily with food for up to 48 weeks. Most patients will be on therapy for 12 to 24 weeks.
(paritaprevir/ritonavir/ombitasvir and dasabuvir)	Treatment of chronic hepatitis C, genotype 1 infection	1 tablet orally once daily containing 150 mg of paritaprevir, 100 mg of ritonavir, and 25 mg of ombitasvir PLUS 1 tablet orally twice daily of dasabuvir 250 mg ± ribavirin
Sovaldi (sofosbuvir)	HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection	400 mg tablet taken once daily with or without food for up to 48 weeks (hepatocellular carcinoma). Most patients will be on therapy for 12 to 24 weeks.

^Must NOT be used as monotherapy. Efficacy in combination with peginterferon alfa and ribavirin is substantially reduced in patients infected with HCV genotype 1a with an NS3 Q80K polymorphism at baseline compared to patients infected with hepatitis C virus (HCV) genotype 1a without the Q80K polymorphism. Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.

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POLICY

Prior Authorization Criteria for Approval

A. ledipasvir/sofosbuvir and paritaprevir/ritonavir/ombitasvir + dasabuvir will be approved when the following criteria are met:
   1. The patient has a diagnosis of chronic hepatitis C, genotype 1 (irrespective of subtype) confirmed by serological markers
      AND
   2. The patient has not been previously treated for chronic hepatitis C with another regimen containing any of the agents referenced above (individually or as part of any combination therapy)
      AND
   3. The agent is being prescribed by a specialist (i.e. Gastroenterologist, Hepatologist, or Infectious Disease) or in consultation with a specialist
      AND
   4. These agent will not be used in combination with other protease inhibitors used to treat chronic hepatitis C (i.e. boceprevir, simeprevir, or telaprevir)
      AND
   5. The patient does not have any FDA labeled contraindications to therapy with the requested agent
      AND
   6. The patient does not have hepatocellular carcinoma (see Sovaldi criteria for approval)
      AND
   7. The patient is not co-infected with chronic hepatitis B
      AND
   8. ONE of the following:
      a. The patient has a METAVIR score of ≥ 2
         OR
      b. The patient has a Ishak score ≥ 3
         OR
      c. The patient has a Fibroscan score of ≥ 7.65 kPa
         OR
      d. The patient has radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)
         OR
      e. The patient has type 2 or 3 mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis)
         OR
      f. The patient has proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis
         OR
      g. The patient is currently awaiting liver transplant
         OR

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h. The patient is post-liver transplant
OR
i. The patient is co-infected with HIV-1
AND

9. The dose is within the FDA labeled dose (90 mg of ledipasvir/400 mg of sofosbuvir or 150 mg of paritaprevir/100 mg ritonavir/25 mg ombitasvir plus 250 mg twice daily of dasabuvir)

Length of Approval: Up to 6 weeks.

B. **Initial Evaluation –Sovaldi® (sofosbuvir) ± Pegylated Interferon ± Olysio**

1. The patient is naïve to therapy with Sovaldi
AND
2. The agent is being prescribed by a specialist or in consultation with a specialist (i.e. Gastroenterologist, Hepatologist, Infectious Disease)
AND
3. The patient has a diagnosis of chronic hepatitis C infection confirmed by serological markers
AND
4. Sofosbuvir will be used in a combination antiviral treatment regimen supported by FDA approved labeling or the AASLD guidelines (listed in Rationale below)
   a. If genotype 1, treatment naïve requesting the combination of simeprevir and sofosbuvir, the patient has **BOTH** of the following:
      i. a METAVIR score of 3 or 4
      AND
      ii. Ineligible to receive peginterferon

AND

5. The patient does NOT have any FDA labeled contraindications to sofosbuvir or the other agents used in the combination therapy
AND
6. The patient will NOT be receiving Incivek (telaprevir) or Victrelis (boceprevir) concomitantly with sofosbuvir
AND
7. The patient is not coinfected with chronic hepatitis B
AND
8. If the patient has hepatocellular carcinoma the following are met:
   a. The patient has either a single tumor 5 cm or less in diameter OR The patient has up to 3 tumors with each being 3 cm or less in diameter
   AND
   b. The patient has NO extrahepatic manifestations of cancer or evidence of vascular invasion of tumor

AND

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9. The dosing of sofosbuvir is within the FDA labeled dosage (400 mg daily)
   AND
10. If the treatment regimen includes simeprevir, the dosing of simeprevir is within the FDA labeled dosage (150 mg daily)

Length of approval: As determined in Table 3 below based on regimen and genotype

C. ***Nonpreferred*** **peginterferon (TRIPLE THERAPY)** will be approved when the criteria for the preferred peginterferon listed above are met AND ONE of the following is met:
   1. The patient is currently being treated with the non-preferred agent
      OR
   2. The patient has a history of a trial of the preferred peginterferon
      OR
   3. The patient has an FDA labeled contraindication, documented intolerance, or hypersensitivity to the preferred peginterferon
      OR
   4. The prescriber has submitted documentation in support of the use of the non-preferred peginterferon, for the intended diagnosis

Length of approval: Up to 48 weeks based on regimen

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Table 1 AASLD Supported Sovaldi® Containing Antiviral Regimens

(Relapse to prior therapy should be treated the same as treatment naïve)

Genotype	Antiviral combination	SubGroup Designation[a] ([a]Patients are required to meet ALL subgroup requirements indicated by a ✓for the specified genotype and antiviral combination)			
		Naïve	Non-R	IFN eligible	IFN ineligible
1 (regardless of subtype)	Sovaldi + PEG + RBV	✓		✓	
	Sovaldi + Olysio ± RBV	✓			✓
	Sovaldi + RBV				
	Sovaldi + Olysio ± RBV		✓	One of the following: ✓	✓
	Sovaldi + PEG + RBV		✓	✓	
1a	Sovaldi + RBV		✓	One of the following: ✓	✓
	Sovaldi + PEG + RBV				
1b	Sovaldi + RBV		✓	One of the following: ✓	✓
	Sovaldi + PEG + RBV				
1 HIV Coinfect	Sovaldi + PEG + RBV	✓		✓	
	Sovaldi + RBV		✓		✓
	Sovaldi + Olysio ± RBV	✓	✓		✓
1 Post Transplant	Sovaldi + Olysio ± RBV	✓			
2*	Sovaldi + RBV	Any one of the following: ✓ ✓ ✓ ✓			
	Sovaldi + PEG + RBV		✓	One of the following: ✓	✓
2 Post Transplant	Sovaldi + RBV	✓			
3*	Sovaldi + RBV	Any one of the following ✓ ✓ ✓ ✓			
	Sovaldi + PEG + RBV	✓		✓	
			✓	One of the following: ✓	✓
4*	Sovaldi + RBV	One of the following: ✓ ✓			✓
	Sovaldi + PEG + RBV	One of the following: ✓ ✓		✓	
5* or 6*	Sovaldi + PEG + RBV	✓		✓	
	Sovaldi + RBV		✓		✓
hepato-cellular carcinoma or decompensated cirrhotics	Sovaldi + RBV	Any one of the following: ✓ ✓ ✓ ✓			

IFN = interferon, PEG = peginterferon, RBV = ribavirin, Non-R = non-responder

* Including HIV coinfected patients

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Table 2

IFN ineligible is defined as one or more of the following
▪ Intolerance* to IFN ▪ Autoimmune hepatitis and other autoimmune disorders ▪ Hypersensitivity to PEG or any of its components ▪ Decompensated hepatic disease ▪ Major uncontrolled depressive ▪ A baseline neutrophil count below 1500/µL, a baseline platelet count below 90,000/µL or baseline hemoglobin below 10 g/dL ▪ A history of preexisting cardiac disease

*Intolerance is defined by Prime as intolerance to the drug and/or excipients, not the route of administration including patients who have previously discontinued therapy with IFN due to adverse events (e.g. hypersensitivity, anaphylaxis, severe rash, severe anemia, etc.).

Table 3 Approval Duration

Genotype	Antiviral combination	Length of Approval
1	Sovaldi + PEG + RBV	12 weeks
	Sovaldi + Olysio ± RBV	12 weeks
	Sovaldi + RBV	24 weeks
	Sovaldi + Olysio ± RBV	12 weeks
	Sovaldi + PEG + RBV	12 weeks
1 Post Transplant	Sovaldi + Olysio ± RBV	12-24 weeks
1a	Sovaldi + RBV	24 weeks
	Sovaldi + PEG + RBV	Sovaldi 12 weeks PEG/RBV 24 weeks
1b	Sovaldi + RBV	24 weeks
	Sovaldi + PEG + RBV	Sovaldi 12 weeks PEG/RBV 12-24 weeks
1 – HIV Coinfect	Sovaldi + PEG + RBV	12 weeks
	Sovaldi + RBV	24 weeks
	Sovaldi + Olysio ± RBV	12 weeks
2	Sovaldi + RBV	12 weeks
	Sovaldi + PEG + RBV	12 weeks
2 Post Transplant	Sovaldi + RBV	24 weeks
3	Sovaldi + RBV	24 weeks
	Sovaldi + PEG + RBV	12 weeks
3 Post Transplant	Sovaldi + RBV	24 weeks
4	Sovaldi + RBV	24 weeks
	Sovaldi + PEG + RBV	12 weeks
5 or 6	Sovaldi + PEG + RBV	12 weeks
	Sovaldi + RBV	24 weeks
hepato-cellular carcinoma or decompensated cirrhotics	Sovaldi + RBV	48 weeks

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RATIONALE

Ledipasvir-sofosbuvir[1, 2, 3]

Safety and efficacy of this combination ± ribavirin was evaluated in 3 open label studies which included treatment naïve, previous failures, cirrhotic and non-cirrhotic genotype 1 patients. The ION studies (1, 2, and 3) all had a primary efficacy endpoint of a sustained virologic response (SVR) at 12 weeks after the end of therapy. ION-1 was conducted in previously untreated patients including those with compensated cirrhosis. Up to 20% of patients could be cirrhotic (defined as a Metavir stage of F4). ION-2 was conducted in patients who had not had a SVR after treatment with peginterferon + ribavirin with our without a protease inhibitor. In this study 52% of patients had received a prior treatment regimen with a protease inhibitor. ION-3 was evaluated in treatment naïve patients without cirrhosis. All three of these trials showed efficacy in these patient populations. SVR rates in these trials ranged from 93% to 100%.

Paritaprevir/ritonavir/ombitasvir and dasabuvir[13, 14, 15]

Safety and efficacy of this combination was evaluated in 4 pivotal trials including treatment naïve, previous failures, cirrhotics and non-cirrhotic genotype 1 patients. The studies (Sapphire I, Turquoise II, Pearl III and Pearl IV) all had a primary efficacy endpoint of a sustained virologic response (SVR) at 12 weeks after the end of therapy. Sapphire I was conducted in treatment naïve patients without cirrhosis. Turquoise-2 was conducted in treatment naïve and previously treated patients and included cirrhotic patients. Pearl III evaluated treatment naïve genotype 1b patients and Pearl IV evaluated treatment naïve genotype 1a patients. SVR rates in these trials ranged from 90% to 99%.

Sofosbuvir and Simeprevir Combination

The combination of these agents is being evaluated in an ongoing phase 2 clinical study of sofosbuvir plus simeprevir with or without RBV for 12 or 24 weeks. The study enrolled 2 cohorts: cohort 1 is comprised of prior null responders to PEG/RBV with Metavir fibrosis stage 0 or 2; Cohort 2 is treatment naïve or prior null responder patients with Metavir fibrosis stage 3 or 4. The 12-week SVR rates for cohort 1 for patients treated with RBV was 96% and 93% for those without RBV. The 24-week treatment group had SVR12 rates of 79.3% and 93% for patient with and without RBV use respectively. There were not any viral breakthroughs in cohort 1 but 3 patients had relapse after stopping therapy. Preliminary SVR4 rates for cohort 2 the 12 week regimen group were 100% in treatment naïve patients irrespective of ribavirin use and 100% and 93.3% in prior null responders treated with and without RBV respectively.[7]

The combination is well tolerated with approximately 2.4% of patients discontinuing due to adverse events. Sofosbuvir resistance-associated variants have not been detected.[7]

Based on feedback from clinical experts and taking into consideration the preliminary results from the second cohort in the COSMOS trial, the combination of simeprevir and sofosbuvir is being reserved for those patients with severe disease. The diagram below correlates METAVIR scores with fibrosis stages. METAVIR scores which describe liver damage are determined by liver biopsy. Liver biopsy is an invasive procedure and the current standard in viral hepatitis for staging the degree of injury and not for achieving a diagnosis.[11] Biopsy scoring systems for liver fibrosis including Metavir, Scheuer, Ishak and histological activity index give a number to a pattern of fibrosis. Fibroscan measures liver stiffness in kPa which correlates with increased fibrosis. Diagnosis of significant fibrosis (F>1) and cirrhosis measurements were 7.65 kPa and

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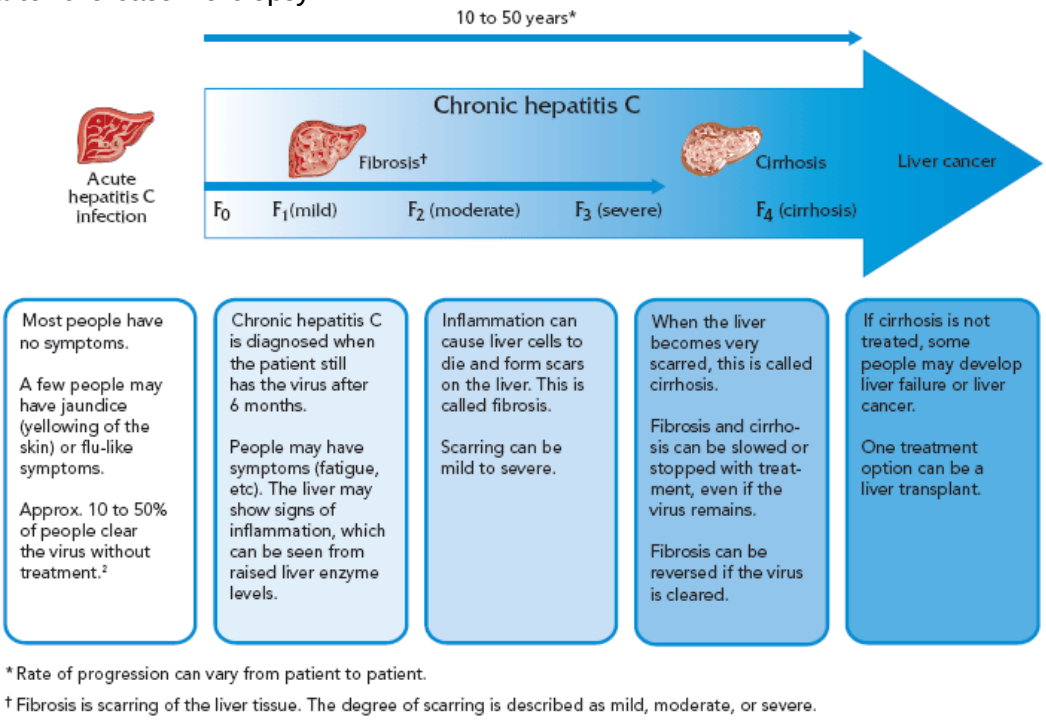
13.01 kPa, respectively.[11] Study data shows that Ishak fibrosis stages of ≥3 represent clinically progressive liver disease. Data from the HALT-C study showed that patients with Ishak fibrosis stage 2 had no clinical outcomes until nearly 5 years after randomization and closer to 6 years after the baseline biopsy.[12]



10

American Association for the Study of Liver Diseases (AASLD, 2013) guidelines recommend the following in treatment naïve patients (see guidelines for alternative regimen recommendations):[7]

1. Genotype 1 IFN eligible - sofosbuvir in combination with interferon (IFN) and ribavirin (RBV).
2. Genotype 1 IFN ineligible - sofosbuvir in combination with simeprevir with or without RBV irrespective of subtype.
3. Genotype 2 and 3 regardless of IFN eligibility - sofosbuvir in combination with RBV.
4. Genotype 4 IFN ineligible - sofosbuvir in combination with RBV.
5. Genotype 5 and 6 IFN eligible – sofosbuvir in combination with IFN and RBV.

AASLD guidelines recommend the following for previous failures of interferon (IFN) and ribavirin (RBV):[8]

1. Genotype 1 IFN/RBV only nonresponder patients – sofosbuvir in combination with simeprevir, with or without RBV irrespective of IFN eligibility or subtype
2. Genotype 1a IFN/RBV/DAA (telaprevir or boceprevir) failures – sofosbuvir for 12 weeks in combination with IFN and RBV for 24 weeks
3. Genotype 1b IFN/RBV/DAA (telaprevir or boceprevir) failures – sofosbuvir for 12 weeks in combination with IFN and RBV for 12-24 weeks
4. Genotype 2 IFN/RBV nonresponders – sofosbuvir plus RBV
5. Genotype 3 IFN/RBV nonresponders – sofosbuvir plus RBV
6. Genotype 4, 5 and 6 IFN/RBV nonresponders – sofosbuvir plus RBV

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AASLD guidelines recommend the following for special populations:[9]

1. HIV/HCV coinfected genotype 1 naïve and prior relapsers IFN eligible – sofosbuvir plus PEG and RBV for 12 weeks irrespective of subtype
    a. IFN ineligible – sofosbuvir plus RBV for 24 weeks
2. HIV/HCV coinfected genotype 1 naïve and prior relapsers IFN ineligible – sofosbuvir plus simeprevir ± RBV for 12 weeks
3. HIV/HCV coinfected genotype 1 treatment experienced with PEG/RBV nonresponse (irrespective of IFN eligibility) – sofosbuvir plus simeprevir ± RBV for 12 weeks
4. HIV/HCV coinfected genotype 1 previous DAA nonresponse – treat as monoinfected
5. HIV/HCV coinfected genotype 2 or 3 – use regimen for HCV monoinfected
    a. Genotype 2 – sofosbuvir + RBV for 12 in naïve and experienced
    b. Genotype 3 – sofosbuvir + RBV for 24 weeks
6. HIV/HCV coinfected genotypes 4, 5, or 6 – treat as monoinfected
7. Naïve patients with compensated cirrhosis (including those with hepatocellular carcinoma) treat same as those without cirrhosis
8. If treating decompensated cirrhosis patients – sofosbuvir + RBV for up to 48 weeks
9. Post liver transplant, genotype 1 – sofosbuvir + simeprevir ± RBV for 12 to 24 weeks
10. Post liver transplant genotypes 2 or 3 – sofosbuvir + RBV for 24 weeks

AASLD guidelines on when and in whom to treat:[4]

The goal of therapy is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by an SVR.

Treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C. **Based on available resources**, treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications are given high priority.

- **Highest Priority for Treatment Owing to Highest Risk for Severe Complications**
    - Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4)
        - Rating: Class I, Level A
    - Organ Transplant
        - Rating: Class I, Level B
    - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg. Vasculitis)
        - Rating: Class I, Level B
    - Proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis
        - Rating: Class IIa, Level B

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- **High Priority For Treatment Owing to High Risk for Complications**
  - Fibrosis (Metavir F2)
    - Rating: Class I, Level B
  - HIV-1 Co-infection
    - Rating: Class I, Level B
  - HBV Co-infection
    - Rating: Class IIa, Level C
  - Other coexistent liver disease (e.g., NASH)
    - Rating: Class IIa, Level C
  - Debilitating fatigue
    - Rating: Class IIa, Level B
  - Type 2 diabetes mellitus (insulin resistant)
    - Rating: Class IIa, Level B
  - Porphyria cutanea tarda
    - Rating: Class IIb, Level C

- **High HCV Transmission Risk – rating on all is: Class IIa, Level C**
  - MSM with high-risk sexual practices
  - Active injection drug users
  - Incarcerated persons
  - Persons on long-term hemodialysis

Evidence ratings refer to the strength and level of evidence with regard to benefits of treatment in these patient populations. Evidence ratings of Class 1, Level A and B are supported by this criteria until such time evidence based treatment guidelines are updated to reflect appropriate use of these agents.

Guidelines advise for patients with genotype 1a, detection of the Q80K polymorphism does not preclude treatment with simeprevir in combination with sofosbuvir because the SVR rate was higher in patients with genotype 1a/Q80K infection.[7] Guidelines define IFN ineligible as one or more of the following:

- Intolerance* to IFN
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to PEG or any of its components
- Decompensated hepatic disease
- Major uncontrolled depressive illnessA baseline neutrophil count below 1500/µL, a baseline platelet count below 90,000/µL or baseline hemoglobin below 10 g/dL
- A history of preexisting cardiac disease

  *Intolerance is defined by Prime as intolerance to the drug and/or excipients, not the route of administration including patients who have previously discontinued therapy with IFN due to adverse events (e.g. hypersensitivity, anaphylaxis, severe rash, severe anemia, etc.).

The guidelines address the use of simeprevir as it pertains to testing for the Q80K polymorphism. “For patients infected with genotype 1a HCV, baseline resistance testing for the Q80K polymorphism may be considered. However, in contrast to using simeprevir to treat a genotype 1a HCV patient with PEG/RBV when the mutation markedly alters the probability of an SVR, the finding of the Q80K polymorphism does not preclude treatment with simeprevir and sofosbuvir,

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because the SVR rate was high in patients with genotype 1a/Q80K infection (SVR12 rate for cohort 1 was 86% [24 of 28 patients]; SVR4 rate for cohort 2 was 90% [10 of 11 patients]). To date, virologic failure has not been observed in patients in either cohort infected with HCV genotype 1b and with HCV genotype 1a in the absence of the Q80K polymorphism. Thus Q80K testing can be considered but is not strongly recommended."[7]

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

There are no specific HCPCS codes for the drugs in this policy.

REVISIONS

10-01-2014	Policy added to the bcbsks.com web site on October 2, 2014. Policy was effective on October 1, 2014.

REFERENCES

1. Afdal N, Zeuzem S, Kwo P et al. Ledipasvir and Sofosbuvir for Untreated HCV Genotype 1 Infection. *New England Journal of Medicine* 2014;370:1889-98.
2. Afdal N, Reddy KR, Nelson DR et al. Ledipasvir and Sofosbuvir for Previously Treated HCV Genotype 1 Infection. *New England Journal of Medicine* 2014;370:1483-93.
3. Kowdley K, Gordon S, Reddy KR et al. Ledipasvir and Sofosbuvir for 8 or 12 Weeks for Chronic HCV without Cirrhosis. *New England Journal of Medicine* 2014;370:1879-88.
4. AASLD Treatment Guidelines. When and In Whome to Initiate HCV Therapy. Available at: http://www.hcvguidelines.org. Accessed 8/18/14.
5. (paritaprevir/ritonavir/ombitasvir and dasabuvir) prescribing information. Abbvie.
6. Ledipasvir-sofosbuvir prescribing information. Available at
7. AASLD Treatment Guidelines. Available at: http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection-patients-starting-treatment. Accessed 8/20/14.
8. AASLD Treatment Guidelines. Available at: http://www.hcvguidelines.org/full-report/retreatment-persons-whom-prior-therapy-has-failed. Accessed 8/20/14.
9. AASLD Treatment Guidelines. Available at: http://www.hcvguidelines.org/full-report/unique-patient-populations. Accessed 4/1/14.
10. Photo - epgonline.org. Hepatology. Accessed: February 2014.
11. Scott DR, Levy MT. Liver transient elastography (Fibroscan®): a place in the management algorithms of chronic viral hepatitis. *Antiviral Therapy* 2010;15:1-11 (doi: 10.3851/IMP1474).
12. Everhart JE, Wright EC, Goodman ZD et al. Prognostic Value of Ishak Fribrosis Stage: Findings from the HALT-C Trial. *Hepatology* 2010 February:51(2): doi: 10.1002/hep.23315.
13. Feld JJ, Kowdley KV, Coakley E, et al. Treatment of HCV with ABT-450/r-Ombitasvir and Dasabuvir with Ribavirin. *N Engl J Med* 2014;370:1594-603.
14. Poordad F, Hezode C, Trinh R, et al. ABT-450/r-Ombitasvir and Dasabuvir with Ribavirin for Hepatitis C with Cirrhosis. *N Engl J Med* 2014;370:1973-82.
15. Ferenci P, Bernstein D, Lalezari J et al. ABT-450/r-Ombitasvir and Dasabuvir with or without Ribavirin for HCV. *N Engl J Med* 2014;370:1983-92.

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