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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Hepatitis C

   AND ONE of the following:
   a. Required documented viral load (HCV RNA) at least 6 months prior to request for treatment
   b. Patient has a poor prognosis and treatment cannot be delayed
   c. Past history of hepatitis C infection is evident or suspected

   AND ALL of the following:
   a. Presence of viral load (HCV RNA) in the serum prior to treatment
   b. If the patient has a history of hepatitis B (HBV) infection
      i. Prescriber agrees to monitor for HBV reactivation

AND the following for each listed medication**:**

<u>Epclusa</u>

1. 3 years of age and older
2. Genotype 1, 2, 3, 4, 5, or 6

AND ONE of the following:

1. Treatment naïve
   a. With or without cirrhosis
      i. If decompensated cirrhosis must be used in combination with ribavirin, <u>unless ribavirin ineligible</u>
2. Treatment experienced with peginterferon alfa/ribavirin with or without an HCV

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir)
   a. With or without cirrhosis
      i. If decompensated cirrhosis must be used in combination with ribavirin, unless ribavirin ineligible
3. Treatment experienced with sofosbuvir or an NS5A inhibitor (9) (see Appendix 1)
   a. Decompensated cirrhosis
4. Post liver transplant (10)
   a. Treatment naïve or treatment experienced
   b. With or without cirrhosis
      i. If decompensated cirrhosis must be used in combination with ribavirin
5. Post kidney transplant (11)
   a. **NO** decompensated cirrhosis

AND ALL of the following **if combined with ribavirin therapy**:

1. **NO** significant or unstable cardiac disease
2. Females of reproductive potential **only**: pregnancy will be excluded before start of treatment, and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose
3. Males with female partners of reproductive potential **only**: pregnancy will be excluded before start of treatment and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose

Harvoni

1. 3 years of age and older

AND ONE of the following:

1. Genotype 1 with **ONE** of the following:
   a. Treatment naïve **without** cirrhosis
      i. If pretreatment HCV RNA is less than 6 million IU/mL, prescriber must agree to draw week 4 HCV RNA level
   b. Treatment naïve **with** cirrhosis
      i. Compensated or decompensated cirrhosis
      ii. If decompensated cirrhosis, must be used in combination with ribavirin
   c. Treatment experienced with peginterferon +/- ribavirin with or without an

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)
   i. With or without cirrhosis
   ii. If decompensated cirrhosis, must be used in combination with ribavirin

2. Genotype 4, 5 or 6 :
   a. Treatment naïve or treatment experienced with peginterferon +/- ribavirin with or without an NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)
   b. **NO** decompensated cirrhosis
3. Post liver transplant (10)
   a. Genotype 1, 4, 5 or 6
   b. Treatment naïve or experienced
   c. With or without cirrhosis
      i. If decompensated cirrhosis must be used in combination with ribavirin
4. Post kidney transplant (11)
   a. Genotype 1, 4, 5 or 6
   b. Treatment naïve or experienced
   c. **NO** decompensated cirrhosis

AND ALL of the following **if combined with ribavirin therapy**:

1. **NO** significant or unstable cardiac disease
2. Females of reproductive potential **only**: pregnancy will be excluded before start of treatment, and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose
3. Males with female partners of reproductive potential **only**: pregnancy will be excluded before start of treatment and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose

Mavyret

1. 3 years of age and older
2. **NO** moderate or severe hepatic impairment (Child-Pugh Class B or C)
3. **NO** decompensated cirrhosis

AND ONE of the following:

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

1. Treatment naïve
    a. Genotype 1, 2, 3, 4, 5, 6 or unknown
2. Treatment experienced and **ONE** of the following:
    a. Previously treated with peginterferon, ribavirin and an NS5A inhibitor, without prior treatment with an NS3/4A protease inhibitor (see Appendix 1)
        i. Genotype 1
    b. Previously treated with peginterferon, ribavirin and an NS3/4A protease inhibitor, without prior treatment with an NS5A inhibitor (see Appendix 1)
        i. Genotype 1
    c. Previously treated with peginterferon and ribavirin with or without sofosbuvir, without prior treatment with an NS3/4A protease inhibitor or NS5A inhibitor (see Appendix 1)
        i. Genotype 1, 2, 3, 4, 5 or 6
3. Post kidney/liver transplant
    a. Genotype 1, 2, 3, 4, 5 or 6

Sovaldi

AND ONE of the following:

1. Genotype 1 or 4
    a. 18 years of age and older
    b. Treatment naïve
    c. **NO** decompensated cirrhosis
    d. Used in combination with peginterferon and ribavirin
        i. **Genotype 1**: Sovaldi can be used alone if ineligible for interferon-based regimen
2. Genotype 2 or 3
    a. 3 years of age and older
    b. Treatment naive or treatment experienced with peginterferon +/- ribavirin
    c. **NO** decompensated cirrhosis
    d. Used in combination with ribavirin
3. Hepatocellular carcinoma
    a. 18 years of age and older
    b. Genotype 1, 2, 3 or 4

HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

c. Awaiting liver transplantation
d. Used in combination with ribavirin

AND ALL of the following **<u>if combined with ribavirin therapy</u>**:

1. **NO** significant or unstable cardiac disease
2. Females of reproductive potential **only**: pregnancy will be excluded before start of treatment, and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose
3. Males with female partners of reproductive potential **only**: pregnancy will be excluded before start of treatment and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose

<u>Vosevi</u>

1. 18 years of age and older
2. Genotype 1, 2, 3, 4, 5 or 6
3. **NO** decompensated cirrhosis

AND ONE of the following:

1. Treatment experienced with **ONE** of the following:
   a. Previously treated with an NS5A inhibitor (see Appendix 1)
   b. Previously treated with a sofosbuvir-based regimen[9]
      i. **Genotype 3:** if compensated cirrhosis, must be used in combination with ribavirin <u>unless ribavirin ineligible</u>
2. Post liver/kidney transplant [10,11]
   a. Previously treated with a Direct Acting Antiviral (DAA) (see Appendix 1)

AND ALL of the following **<u>if combined with ribavirin therapy</u>**:

1. **NO** significant or unstable cardiac disease
2. Females of reproductive potential **only**: pregnancy will be excluded before start of treatment, and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose
3. Males with female partners of reproductive potential **only**: pregnancy will be excluded before start of treatment and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

Zepatier

1. 12 years of age and older **OR** weighing at least 30 kg
2. **NO** moderate or severe hepatic impairment (Child-Pugh Class B or C)
3. **NO** liver transplant or waiting for a liver transplant
4. **NO** decompensated cirrhosis
5. Patient **MUST** have a contraindication to at least **TWO** of the preferred products (Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi)

AND ONE of the following:

1. Treatment naïve:
   a. Genotype 1a, 1b or 4
      i. **Genotype 1a**: must be tested for NS5A resistance-associated polymorphisms. If positive, must be used in combination with ribavirin

2. Treatment experienced with peginterferon and ribavirin
   a. Genotype 1a, 1b or 4
      i. **Genotype 1a**: must be tested for NS5A resistance-associated polymorphisms. If positive, must be used in combination with ribavirin
      ii. **Genotype 4**: must be used in combination with ribavirin
3. Treatment experienced with peginterferon, ribavirin and an NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)
   a. Genotype 1a or 1b
   b. Must be used in combination with ribavirin

AND ALL of the following **if combined with ribavirin therapy**:

1. **NO** significant or unstable cardiac disease
2. Females of reproductive potential **only**: pregnancy will be excluded before start of treatment, and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose
3. Males with female partners of reproductive potential **only**: pregnancy will be excluded before start of treatment and patient will be advised to use effective contraception during treatment with ribavirin and for 6 months after the final dose

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

Prior - Approval Limits

EPCLUSA Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen and Duration**
1, 2, 3, 4, 5, 6	Treatment naïve **or** Treatment experienced with **Peg-INF/RBV** +/- **NS3/4A PI** **NO** decompensated cirrhosis	Epclusa 12 weeks
	Treatment naïve **or** Treatment experienced with **Peg-INF/RBV** +/- **NS3/4A PI** **Decompensated** cirrhosis	Epclusa + RBV 12 weeks **or** Epclusa 24 weeks, ***if RBV ineligible***[12]
	Treatment experienced with **sofosbuvir** or **NS5A inhibitor** [9] **Decompensated** cirrhosis	Epclusa + RBV 24 weeks
	Post kidney[11] transplant **NO** decompensated cirrhosis	Epclusa 12 weeks
	Post liver [10] transplant **NO** decompensated cirrhosis	Epclusa 12 weeks
	Post liver[10] transplant Treatment naïve **Decompensated** cirrhosis	Epclusa + RBV 12 weeks
	Post liver[10] transplant Treatment experienced **Decompensated** cirrhosis	Epclusa + RBV 24 weeks

EPCLUSA Dosing		
Age/Weight	**EPCLUSA Strength**	**Quantity per day**
Age 18+	400 mg/100 mg tablet	1/day
Age 3-17 and weight 30kg or greater	400 mg/100 mg tablet **or** 200 mg/50 mg tablet 200 mg/50 mg packet of pellets	1/day **or** 2/day **or** 2/day
Age 3-17 and weight 17kg to < 30kg	200 mg/50 mg tablet **or**	1/day **or**

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

	200 mg/50 mg packet of pellets	1/day
Age 3-17 and weight <17kg	150 mg/37.5 mg packet of pellets	1/day

HARVONI Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen and Duration**
1	Treatment naïve **NO** cirrhosis *Pretreatment HCV RNA < than 6 million IU/ML*	Harvoni 8 weeks, ***Must repeat viral load testing at week 4***
	Treatment naïve **NO** cirrhosis *Pretreatment HCV RNA > than 6 million IU/ML*	Harvoni 12 weeks
	Treatment naïve **Compensated** cirrhosis	Harvoni 12 weeks
	Treatment naïve **or** Treatment experienced with **Peg-INF** +/- **RBV** and +/- **NS3/4A PI** **Decompensated** cirrhosis	Harvoni + RBV 12 weeks
	Treatment experienced with **Peg-INF** +/- **RBV** and +/- **NS3/4A PI** **NO** cirrhosis	Harvoni 12 weeks
	Treatment experienced with **Peg-INF** +/- **RBV** and +/- **NS3/4A PI** **Compensated** cirrhosis	Harvoni 24 weeks **or** Harvoni + RBV 12 weeks ***if RBV eligible***
4, 5, 6	Treatment naïve **or** Treatment experienced with **Peg-INF** +/- **RBV** and +/- **NS3/4A PI** **NO** decompensated cirrhosis	Harvoni 12 weeks
1, 4, 5, 6 *Liver transplant* *(10)*	Treatment naïve/experienced Liver transplant **NO** decompensated cirrhosis	Harvoni 12 weeks
	Treatment naïve Liver transplant **Decompensated** cirrhosis	Harvoni + RBV 12 weeks
	Treatment experienced	Harvoni + RBV 24

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

	Liver transplant **Decompensated** cirrhosis	weeks
1, 4, 5, 6 *Kidney transplant* (11)	Treatment naïve/experienced Kidney transplant **NO** decompensated cirrhosis	Harvoni 12 weeks

HARVONI Dosing		
Age/Weight	**Strength**	**Quantity per day**
18 years old +	90/400 mg tablet	1/day
Age 3-17 and weight 35kg or greater	90/400 mg tablet **or** 45/200 mg packet of pellets	1/day **or** 2/day
Age 3-17 and weight 17kg to <35kg	45/200 mg packet of pellets	1/day
Age 3-17 and <17kg	33.75/150 mg packet of pellets	1/day

MAVYRET Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen and Duration**
1, 2, 3, 4, 5, 6 or unknown	Treatment naïve **NO** decompensated cirrhosis	Mavyret 8 weeks
1**	Treatment experienced with **Peg-INF/RBV + NS5A inhibitor** **NO** prior treatment with an **NS3/4A PI** **NO** decompensated cirrhosis	Mavyret 16 weeks**
1	Treatment experienced with **Peg-INF/RBV + NS3/4A PI** **NO** prior treatment with an **NS5A inhibitor** **NO** decompensated cirrhosis	Mavyret 12 weeks
1, 2, 4, 5, 6	Treatment experienced with **Peg-INF/RBV** +/- **sofosbuvir** **NO** prior treatment with **NS3/4A PI** or **NS5A inhibitor** **NO** cirrhosis	Mavyret 8 weeks
	Treatment experienced with **Peg-INF/RBV** +/- **sofosbuvir**	Mavyret 12 weeks

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

	NO prior treatment with **NS3/4A PI** or **NS5A inhibitor** **Compensated** cirrhosis	
3**	Treatment experienced with **Peg-INF/RBV** +/- **sofosbuvir** **NO** prior treatment with **NS3/4A PI or NS5A inhibitor** **NO** decompensated cirrhosis	Mavyret 16 weeks**
1, 2, 3, 4, 5, 6 Liver / Kidney Transplant	Liver / kidney transplant recipients **NO** decompensated cirrhosis	Mavyret 12 weeks **or** Mavyret 16 weeks, ***if genotype 1 or 3 treatment experienced***** ** ***Genotype 1*** *(NS5A inhibitor experienced without prior treatment with an NS3/4A protease inhibitor)* ****Genotype 3*** (Peg-INF/RBV +/- sofosbuvir experienced, without prior treatment with NS3/4A PI or NS5A inhibitor)

MAVYRET Dosing		
Age/Weight	**Strength**	**Quantity per Day**
Age 12+	100 mg/40 mg tablet	3/day
Age 3-12 and weight 45kg or greater***	100 mg/40 mg tablet or 50 mg/20 mg packet of pellets	3/day **or** 6/day
Age 3-12 and weight 30kg to <45kg	50 mg/20 mg packet of pellets	5/day

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Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

Age 3-12 and weight 20kg to <30kg	50 mg/20 mg packet of pellets	4/day
Age 3-12 and <20kg	50 mg/20 mg packet of pellets	3/day
***Pediatric patients weighing 45 kg and greater who are unable to swallow tablets may take **six** 50 mg/20 mg packets of oral pellets once daily. Dosing with oral pellets has not been studied for pediatric patients weighing greater than 45 kg.		

SOVALDI Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen and Duration**
1 Age 18+ only	Treatment naïve	Sovaldi + Peg-INF + RBV 12 weeks **or** Sovaldi + RBV 24 weeks, ***if interferon ineligible***
2 Age 3+	Treatment naïve **or** Treatment experienced with **Peg-INF +/- RBV**	Sovaldi + RBV 12 weeks
3 Age 3+	Treatment naïve **or** Treatment experienced with **Peg-INF +/- RBV**	Sovaldi + RBV 24 weeks
4 Age 18+ only	Treatment naïve	Sovaldi + Peg-INF + RBV 12 weeks
1, 2, 3, 4 Age 18+ only	Hepatocellular carcinoma Awaiting liver transplantation	Sovaldi + RBV up to 48 weeks

SOVALDI Dosing		
Age/Weight	**Strength**	**Quantity per Day**
Age 18+	400 mg tablet	1/day
Age 3-17 and weight at least 35 kg	400 mg tablet **or** 200 mg tablet **or** 200 mg pellets	1/day **or** 2/day **or** 2/day
Age 3-17 and weight 17 to <35kg	200 mg tablet **or** 200 mg pellets	1/day **or** 1/day
Age 3-17 and weight <17 kg	150 mg pellets	1/day

VOSEVI Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen**

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

		and Duration
1, 2, 3, 4, 5, 6	Treatment experienced with an **NS5A inhibitor** **NO** decompensated cirrhosis	Vosevi 12 weeks
1, 2, 3, 4, 5, 6 (9)	Treatment experienced with **sofosbuvir** **NO** decompensated cirrhosis	Vosevi 12 weeks
3 (9)	Treatment experienced with **sofosbuvir** **Compensated** cirrhosis	Vosevi 12 weeks + RBV, ***If RBV eligible***
1, 2, 3, 4, 5, 6 Liver / Kidney transplant (10,11)	Treatment experienced with a **DAA** Liver / kidney transplant **NO** decompensated cirrhosis	Vosevi 12 weeks +/- RBV

VOSEVI Dosing	
Strength	**Quantity per day**
400 mg/100 mg/100 mg tablet	1/day

ZEPATIER Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen and Duration**
1**a**	Treatment naïve **NEGATIVE** for NS5A polymorphism	Zepatier 12 weeks
	Treatment naïve **POSITIVE** for NS5A polymorphism	Zepatier + RBV 16 weeks
	Treatment experienced with **Peg-INF/RBV** **NO** decompensated cirrhosis **NEGATIVE** for NS5A polymorphism	Zepatier 12 weeks
	Treatment experienced with **Peg-INF/RBV** **POSITIVE** for NS5A polymorphism	Zepatier + RBV 16 weeks
	Treatment experienced with **Peg-INF/RBV + NS3/4A PI** The optimal Zepatier based treatment regimen and duration of therapy for Peg-INF/RBV + NS3/4A PI experienced, genotype 1a, positive for NS5A polymorphism has not been established. NS5A polymorphism testing is not needed for this patient population.	Zepatier + RBV 12 weeks

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

1**b**	Treatment naïve	Zepatier 12 weeks
	Treatment experienced with **Peg-INF/RBV**	Zepatier 12 weeks
	Treatment experienced with **Peg-INF/RBV + NS3/4A PI**	Zepatier + RBV 12 weeks
4	Treatment naïve	Zepatier 12 weeks
	Treatment experienced with **Peg-INF/RBV**	Zepatier + RBV 16 weeks

ZEPATIER Dosing	
Strength	**Quantity per day**
50 mg/100 mg tablet	1/day

Prior – Approval *Renewal* Requirements

Harvoni Only

Age 3 years of age and older

Diagnosis

Patient must have the following:

1. Hepatitis C
    a. Genotype 1
    b. Continuation of therapy for treatment-naïve patients, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:
        i. Evaluation of patient at 4 weeks to determine that the viral load was not met within the 8 weeks of treatment has been performed

Prior - Approval *Renewal* Limits

Harvoni Only

HARVONI Treatment Duration		
HCV Genotype	**Patient Population**	**Treatment Regimen and Duration**
1	Treatment naïve **NO** cirrhosis	Harvoni 4 weeks **(1 renewal only)**

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

	Pretreatment HCV RNA < 6 million IU/ML	

HARVONI Dosing		
Age/Weight	**Strength**	**Quantity per Day**
Age 18+	90/400 mg tablet	1/day
Age 3-17 and weight 35kg or greater	90/400 mg tablet 45/200 mg packet of pellets	1/day **or** 2/day
Age 3-17 and weight 17kg to <35kg	45/200 mg packet of pellets	1/day
Age 3-17 and weight <17kg	33.75/150 mg packet of pellets	1/day

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HEPATITIS C AGENTS

Epclusa (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Sovaldi** (sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Preferred hepatitis C products: Epclusa, Harvoni, Mavyret, Sovaldi and Vosevi

Appendix 1

Direct Acting Antivirals (DAAs)		
NS3/4A Protease Inhibitors	**NS5A Inhibitors**	**NS5B Polymerase Inhibitors**
boceprevir (Victrelis)	daclatasvir (Daklinsa)	dasabuvir non-nuclear analog *(component of Viekira Pak)*
glecaprevir *(component of Mavyret)*	elbasvir *(component of Zepatier)*	sofosbuvir (Sovaldi) nuclear analog *(component of Epclusa, Harvoni, Vosevi)*
grazoprevir *(component of Zepatier)*	ledipasvir *(component of Harvoni)*	
paritaprevir *(component of Viekira Pak and Technivie)*	ombitasvir *(component of Viekira Pak and Technivie)*	
simeprevir (Olysio)	pibrentasvir (component of Mavyret)	
telaprevir (Incivek)	velpatasvir *(component of Epclusa and Vosevi)*	
voxilaprevir *(component of Vosevi)*		