Prescriber Criteria Form

Mavyret 2024 PA Fax 2243-A v2 010124.docx Mavyret (glecaprevir and pibrentasvir) Coverage Determination

This fax machine is located in a secure location as required by HIPAA regulations. Complete/review information, sign and date. Fax signed forms to CVS Caremark at **1-855-633-7673**. Please contact CVS Caremark at **1-866-785-5714** with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of Mavyret (glecaprevir and pibrentasvir).

Drug Name: Mavyret (glecaprevir and pibrentasvir)

Patient Name:			
Patient ID:			
Patient DOB:	Patient Phone:		
Prescriber Name:	·		
Prescriber Address:			
City:	State:	Zip:	
Prescriber Phone:	Prescriber Fax:	·	
Diagnosis:	ICD Code(s):		

1	Does the patient have a diagnosis of hepatitis C virus (HCV) infection? [If yes, then skip to question 6.]	Yes	No
2	Does the patient have decompensated cirrhosis or moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C)? (Note: The requested drug is not indicated in patients with moderate or severe hepatic impairment [Child Turcotte Pugh [CTP] class B or C]). [If yes, then no further questions.]	Yes	No
3	Is the request for a patient who has received a liver transplant from a hepatitis C virus (HCV)-viremic donor and the requested drug is being prescribed for use alone (i.e., without any other antiviral for hepatitis C)? [If yes, then skip to question 47.]	Yes	No
4	Is the request for a patient who has received a non-liver organ transplant from a hepatitis C virus (HCV)-viremic donor and the requested drug is being prescribed for use alone (i.e., without any other antiviral for hepatitis C)? [If no, then no further questions.]	Yes	No
5	Will the treatment with the requested drug be initiated within 7 days of transplant? [If yes, then skip to question 46.] [If no, then skip to question 47.]	Yes	No

6	Prior to initiating therapy, has hepatitis C virus (HCV) infection been confirmed by the presence of hepatitis C virus ribonucleic acid (HCV RNA) in serum? [If no, then no further questions.]	Yes	No
7	Does the patient have decompensated cirrhosis or moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C)? (Note: The requested drug is not indicated in patients with moderate or severe hepatic impairment [Child Turcotte Pugh [CTP] class B or C]). [If yes, then no further questions.]	Yes	No
8	Is the requested drug being prescribed for use alone (i.e., without any other antiviral for hepatitis C)? [If no, then skip to question 38.]	Yes	No
9	Is the request for a patient with recurrent hepatitis C virus (HCV) infection post liver transplantation or a patient who is a kidney transplant recipient? [If no, then skip to question 15.]	Yes	No
10	Does the patient have genotype 2, 4, 5, or 6 infection? [If yes, then skip to question 47.]	Yes	No
11	Does the patient have genotype 1 infection? [If no, then skip to question 13.]	Yes	No
12	Does the patient meet both of the following: A) the patient has failed prior treatment with a nonstructural protein 5A (NS5A) inhibitor, excluding glecaprevir/pibrentasvir (Mavyret), for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], elbasvir and grazoprevir [Zepatier]), B) the patient has not received prior treatment with a regimen containing a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], boceprevir [Victrelis], sofosbuvir, velpatasvir, and voxilaprevir [Vosevi], elbasvir and grazoprevir [Zepatier])? [If yes, then skip to question 48.] [If no, then skip to question 47.]	Yes	No
13	Does the patient have genotype 3 infection? [If no, then no further questions.]	Yes	No
14	Does the patient meet both of the following: A) the patient has failed prior treatment with a regimen containing pegylated interferon (PEG-INF), ribavirin and/or sofosbuvir [Sovaldi] (for example, Sovaldi and ribavirin, PEG-INF and ribavirin), B) the patient has not received prior treatment with a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], boceprevir [Victrelis], sofosbuvir, velpatasvir, and voxilaprevir [Vosevi], elbasvir and grazoprevir [Zepatier]) or a nonstructural protein 5A (NS5A) inhibitor (for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], elbasvir and grazoprevir [Zepatier])? [If yes, then skip to question 48.] [If no, then skip to question 47.]	Yes	No
15	Is the patient's genotype unknown or undetermined? [If no, then skip to question 19.]	Yes	No

16	Is the request for a treatment-naïve patient without cirrhosis? [If no, then no further questions.]	Yes	No
17	Does the patient have all of the following: A) human immunodeficiency virus (HIV) positive, B) currently taking a tenofovir disoproxil fumarate (TDF)-containing regimen, C) an eGFR less than 60 milliliters per minute (mL/min)? [If yes, then no further questions.]	Yes	No
18	Does the patient have any of the following: A) hepatitis B surface antigen (HBsAg) positive, B) currently pregnant, C) known or suspected hepatocellular carcinoma, D) prior liver transplantation? [If yes, then no further questions.] [If no, then skip to question 46.]	Yes	No
19	Does the patient have genotype 1, 2, 3, 4, 5, or 6 infection? [If no, then no further questions.]	Yes	No
20	Is the request for a treatment-naïve patient? [If no, then skip to question 25.]	Yes	No
21	Is the patient co-infected with human immunodeficiency virus (HIV)? [If no, then skip to question 46.]	Yes	No
22	Does the patient have compensated cirrhosis (Child Turcotte Pugh [CTP] class A)? [If no, then skip to question 24.]	Yes	No
23	Does the patient have genotype 4 infection? [If yes, then skip to question 47.] [If no, then no further questions.]	Yes	No
24	Does the patient have genotype 5 or 6 infection? [If yes, then skip to question 47.] [If no, then skip to question 46.]	Yes	No
25	Does the patient meet all of the following: A) pediatric patient, B) the patient has had prior exposure to a nonstructural protein 5A (NS5A) inhibitor, excluding glecaprevir/pibrentasvir (Mavyret), (for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], elbasvir and grazoprevir [Zepatier]), C) the patient has not received prior treatment with a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], boceprevir [Victrelis], sofosbuvir, velpatasvir, and voxilaprevir [Vosevi], elbasvir and grazoprevir [Zepatier])? [If yes, then skip to question 48.]	Yes	No
26	Does the patient meet all of the following: A) pediatric patient, B) the patient has had prior exposure to a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], boceprevir [Victrelis], sofosbuvir, velpatasvir, and voxilaprevir [Vosevi], elbasvir and grazoprevir [Zepatier]), C) the patient has not received prior treatment with a nonstructural protein 5A (NS5A) inhibitor (for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], elbasvir and grazoprevir [Zepatier])? [If yes, then skip to question 47.]	Yes	No

27	Does the patient meet both of the following: A) the patient has failed prior treatment with a regimen containing pegylated interferon (PEG-INF) with or without ribavirin, B) the patient has not received prior treatment with a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], boceprevir [Victrelis], sofosbuvir, velpatasvir, and voxilaprevir [Vosevi], elbasvir and grazoprevir [Zepatier]) or a nonstructural protein 5A (NS5A) inhibitor (for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], elbasvir and grazoprevir [Zepatier])? [If no, then skip to question 30.]	Yes	No
28	Does the patient have genotype 3 infection? [If yes, then skip to question 48.]	Yes	No
29	Does the patient have compensated cirrhosis (Child Turcotte Pugh [CTP] class A)? [If yes, then skip to question 47.] [If no, then skip to question 46.]	Yes	No
30	Does the patient meet both of the following: A) the patient has failed prior treatment with a nonstructural protein 5A (NS5A) inhibitor, excluding glecaprevir/pibrentasvir (Mavyret), (for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], ledipasvir and sofosbuvir [Harvoni]), B) the patient has not received prior treatment with a regimen containing a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], boceprevir [Victrelis], sofosbuvir, velpatasvir, and voxilaprevir [Vosevi], elbasvir and grazoprevir [Zepatier])? [If no, then skip to question 32.]	Yes	No
31	Does the patient have genotype 1 infection? [If yes, then skip to question 48.] [If no, then no further questions.]	Yes	No
32	Does the patient meet both of the following: A) the patient has failed prior treatment with a regimen containing a nonstructural protein 3/4A (NS3/4A) protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek], or boceprevir [Victrelis] in combination with ribavirin and peginterferon alfa, simeprevir [Olysio] with sofosbuvir [Sovaldi]), B) the patient has not received prior treatment with a regimen containing a nonstructural protein 5A (NS5A) inhibitor (for example, daclatasvir [Daklinza], sofosbuvir and velpatasvir [Epclusa], ledipasvir and sofosbuvir [Harvoni])? [If no, then skip to question 34.]	Yes	No
33	Does the patient have genotype 1 infection? [If yes, then skip to question 47.] [If no, then no further questions.]	Yes	No
34	Does the patient meet both of the following: A) the patient failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon, sofosbuvir and ledipasvir, sofosbuvir and velpatasvir), B) the patient has not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir)? [If no, then no further questions.]	Yes	No

35	Does the patient have genotype 1,2,4,5, or 6 infection?	Yes	No
	[If yes, then skip to question 48.]		
36	Does the patient have genotype 3 infection?	Yes	No
	[If no, then no further questions.]		
37	Has the patient had prior sofosbuvir/NS5A inhibitor experience (e.g.,	Yes	No
	sofosbuvir/ledipasvir, sofosbuvir/velpatasvir)?		
	[If yes, then no further questions.]		
	[If no, then skip to question 48.]		
38	Is the requested drug being requested for use in combination with sofosbuvir (Sovaldi)	Yes	No
	and ribavirin?		
	[If no, then no further questions.]		
39	Does the patient have genotype 1, 2, 3, 4, 5, or 6 infection?	Yes	No
	[If no, then no further questions.]		
40	Has the patient failed 16 weeks of therapy with sofosbuvir (Sovaldi) and	Yes	No
	glecaprevir/pibrentasvir (Mavyret)?		
	[If no, then skip to question 42.]		
41	Has the patient received greater than or equal to 24 weeks of treatment with the	Yes	No
	requested drug?		
	[No further questions.]		
42	Has the patient failed prior treatment with glecaprevir/pibrentasvir (Mavyret)?	Yes	No
	[If yes, then skip to question 48.]		
43	Has the patient failed prior treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi)?	Yes	No
	[If no, then no further questions.]		
44	Does the patient have genotype 3 infection?	Yes	No
	[If no, then skip to question 48.]		
45	Does the patient have compensated cirrhosis (Child Turcotte Pugh [CTP] class A)?	Yes	No
	[If yes, then skip to question 49.]		
	[If no, then skip to question 48.]		
46	Has the patient received greater than or equal to 8 weeks of treatment with the requested	Yes	No
	drug?		
	[No further questions.]		
47	Has the patient received greater than or equal to 12 weeks of treatment with the	Yes	No
	requested drug?		
	[No further questions.]		
48	Has the patient received greater than or equal to 16 weeks of treatment with the	Yes	No
	requested drug?		
	[No further questions.]		

49	Has the patient received greater than or equal to 24 weeks of treatment with the	Yes	No
	requested drug?		

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Comments.						

By signing this form, I attest that the information provided is accurate and true as of this date and that the documentation supporting this information is available for review if requested by the health plan.

Prescriber	(or	Authorized)	Signature:	
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Date:_____