PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**RIBAVIRIN**
BRAND NAME (generic)	**COPEGUS (ribavirin tablet)** **MODERIBA (ribavirin tablet)** **REBETOL (ribavirin capsule and oral solution)** **RIBASPHERE (ribavirin capsules)** **ribavirin, oral**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 558-A***

FDA-APPROVED INDICATIONS[1-4]

Copegus
Copegus in combination with Pegasys (peginterferon alfa-2a) is indicated for the treatment of patients 5 years of age and older with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

Moderiba
Moderiba in combination with peginterferon alfa-2a is indicated for the treatment of patients 5 years of age and older with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

Rebetol
Rebetol in combination with interferon alfa-2b (pegylated and nonpegylated) is indicated for the treatment of chronic hepatitis C in patients 3 years of age or older with compensated liver disease.

Ribasphere/RibaPak
Ribasphere in combination with peginterferon alfa-2a is indicated for the treatment of patients 5 years of age and older with CHC virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

CRITERIA FOR APPROVAL

1	Prior to initiating therapy, has hepatitis C virus (HCV) infection been confirmed by the presence of HCV RNA in serum? [If no, no further questions.]	Yes	No
2	Will ribavirin be discontinued if any other component of the hepatitis C treatment regimen is discontinued? [If no, no further questions.]	Yes	No

3	Is ribavirin being prescribed as part of a three-drug regimen that includes pegylated interferon and Sovaldi? [If no, skip to question 5.]	Yes	No
4	Has the patient received greater than or equal to 12 weeks of treatment? [No further questions.]	Yes	No
5	Is ribavirin being prescribed as part of a two-drug regimen that includes Sovaldi? [If no, skip to question 7.]	Yes	No
6	Has the patient received greater than or equal to 48 weeks of treatment? [No further questions.]	Yes	No
7	Is ribavirin being prescribed as part of a three-drug regimen that includes Olysio and pegylated interferon? [If no, skip to question 9.]	Yes	No
8	Has the patient received greater than or equal to 48 weeks of treatment? [No further questions.]	Yes	No
9	Is ribavirin being prescribed in combination with Viekira Pak/Viekira XR? [If no, skip to question 11.]	Yes	No
10	Has the patient received greater than or equal to 24 weeks of treatment? [No further questions.]	Yes	No
11	Is ribavirin being prescribed in combination with Technivie? [If no, skip to question 13.]	Yes	No
12	Has the patient received greater than or equal to 12 weeks of treatment? [No further questions.]	Yes	No
13	Is ribavirin being prescribed in combination with Harvoni? [If no, skip to question 15.]	Yes	No
14	Has the patient received greater than or equal to 24 weeks of treatment? [No further questions.]	Yes	No
15	Is ribavirin being prescribed as part of a three-drug regimen that includes Sovaldi and Olysio? [If no, skip to question 17.]	Yes	No
16	Has the patient received greater than or equal to 12 weeks of treatment? [No further questions.]	Yes	No
17	Is ribavirin being prescribed as part of a dual therapy regimen with pegylated interferon (Pegasys) or non- pegylated interferon? [If no, skip to question 19.]	Yes	No
18	Has the patient received greater than or equal to 48 weeks of treatment? [No further questions.]	Yes	No
19	Is ribavirin being prescribed as part of a three-drug regimen with Sovaldi and Daklinza? [If no, skip to question 21.]	Yes	No
20	Has the patient received greater than or equal to 24 weeks of treatment?	Yes	No

[No further questions.]

21	Is ribavirin being prescribed in combination with Zepatier? [If no, skip to question 23.]	Yes	No
22	Has the patient received greater than or equal to 16 weeks of treatment? [No further questions.]	Yes	No
23	Is ribavirin being prescribed in combination with Epclusa? [If no, skip to question 25.]	Yes	No
24	Has the patient received greater than or equal to 24 weeks of treatment? [No further questions.]	Yes	No
25	Is ribavirin being prescribed in combination with Vosevi? [If no, no further questions.]	Yes	No
26	Has the patient received greater than or equal to 12 weeks of treatment?	Yes	No

Guidelines for Approval							
Duration of Approval	**Total 12 weeks of treatment**	**Duration of Approval**	**Total 48 weeks of treatment**	**Duration of Approval**	**Total 48 weeks of treatment**	**Duration of Approval**	**Total 24 weeks of treatment**
Set 1: PEG + RBV + Sovaldi		**Set 2:** Sovaldi + RBV		**Set 3:** PEG + RBV + Olysio		**Set 4:** Viekira Pak/Viekira XR + RBV	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	4	1	3	1	3	1	3
2		2	6	2	5	2	5
3		5		7	8	9	7
							10
Duration of Approval	**Total 12 weeks of treatment**	**Duration of Approval**	**Total 24 weeks of treatment**	**Duration of Approval**	**Total 12 weeks of treatment**	**Duration of Approval**	**Total 48 weeks of treatment**
Set 5: Technivie + RBV		**Set 6:** Harvoni + RBV		**Set 7:** Sovaldi + Olysio + RBV		**Set 8:** IFN + RBV	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	3	1	3	1	3	1	3
2	5	2	5	2	5	2	5
11	7	13	7	15	7	17	7
	9		9		9		9
	12		11		11		11
			14		13		13
					16		15
							18

Duration of Approval	Total 24 weeks of treatment	Duration of Approval	Total 16 weeks of treatment	Duration of Approval	Total 24 weeks of treatment	Duration of Approval	Total 12 weeks of treatment
Set 9: Daklinza + Sovaldi + RBV		**Set 10:** Zepatier + RBV		**Set 11:** Epclusa + RBV		**Set 12:** Vosevi + RBV	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	3	1	3	1	3	1	3
2	5	2	5	2	5	2	5
19	7	21	7	23	7	25	7
	9		9		9		9
	11		11		11		11
	13		13		13		13
	15		15		15		15
	17		17		17		17
	20		19		19		19
			22		21		21
					24		23
							26

Internal Use Only – Mapping Instructions		
	Yes	**No**
1	Go to 2	Deny
2	Go to 3	Deny
3	Go to 4	Go to 5
4	Deny	Approve, Total 12 weeks of treatment.
5	Go to 6	Go to 7
6	Deny	Approve, Total 48 weeks of treatment
7	Go to 8	Go to 9
8	Deny	Approve, Total 48 weeks of treatment
9	Go to 10	Go to 11
10	Deny	Approve, Total 24 weeks of treatment
11	Go to 12	Go to 13
12	Deny	Approve, Total 12 weeks of treatment
13	Go to 14	Go to 15
14	Deny	Approve, Total 24 weeks of treatment
15	Go to 16	Go to 17
16	Deny	Approve, Total 12 weeks of treatment
17	Go to 18	Go to 19
18	Deny	Approve, Total 48 weeks of treatment
19	Go to 20	Go to 21
20	Deny	Approve, Total 24 weeks of treatment
21	Go to 22	Go to 23
22	Deny	Approve, Total 16 weeks of treatment
23	Go to 24	Go to 25
24	Deny	Approve, Total 24 weeks of treatment
25	Go to 26	Deny
26	Deny	Approve, Total 12 weeks of treatment

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Copegus [package insert]. South San Francisco, CA: Genentech USA, Inc.; August 2015.
2. Moderiba [package insert]. North Chicago, IL: AbbVie Inc.; February 2015.
3. Rebetol [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2016.
4. Ribasphere/Ribapak [package insert]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; August 2014.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made September 21, 2017. Accessed September 22, 2017.
6. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; November 2017.
7. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
8. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; November 2017.
9. Technivie [package insert]. North Chicago, IL: AbbVie Inc.; November 2017.
10. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2017.
11. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
12. Viekira XR [package insert]. North Chicago, IL: AbbVie Inc.; November 2017.

DOCUMENT HISTORY

Written by:	JA/CW08/2001
Revised:	MG 12/2002, 10/2003, 05/2004 (Ribasphere added); JG 06/2005; NB 07/2006; Specialty Clinical Development (MG) 08/2007, 08/2008; TG 06/2009; GY 11/2009; AC 09/2010, 05/2011, 09/2011 (changed initial duration of approval for Incivek and Victrelis combination therapy), 10/2011 (CMS); KH 12/2011; AC 09/2012 (CMS); HY 09/2013 (CMS); AS/HY 12/2013, 02/2014; HY 09/2014 (CMS), DK 12/2014 (added Viekira), 01/2015 (added Harvoni), 03/2015, KW 07/2015 (added Technivie), DK 08/2015 (CMS), 10/2015 (CMS issues), KW 01/2016 (added Daklinza+Sovaldi), 02/2016 (added Zepatier), 07/2016 (added Epclusa) (CMS), 10/2016 (added Viekira XR, guideline update); JP 10/2016, 07/2017 (CMS), IP 01/2018 (guideline update)
Reviewed:	CRC 08/22/2001, 12/2002; 10/2003 CDPR/MM 06/2004; 07/2005, 07/2006; WLF 08/2007, 08/2008, 06/2009; KP 11/2009, 05/2011, 09/2011, 01/2012, 01/2013, 12/2013, 02/2014, MM 12/2014, SES 01/2015 (Harvoni), LCB 07/2015, DHR 09/2015, ADA 02/2016, 07/2016, 09/2016, 10/2016
External Review:	02/2003; 10/2003; 10/2004; 11/2005; 12/2006; 11/2007; 12/2008; 12/2009, 05/2011, 02/2012; 03/2013, 01/2014, 03/2014, 12/2014, 01/2015, 08/2015, 02/2016, 07/2016, 11/2016