PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**PEGASYS**
(generic)	**(peginterferon alfa-2a)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 556-A***

FDA-APPROVED INDICATIONS[1]

Chronic Hepatitis C

Adult Patients:

Pegasys, as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs.

Chronic Hepatitis B

Pegasys is indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Pegasys is indicated for the treatment of HBeAG-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine.

Compendial Uses[2]

1. Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, primary myelofibrosis and post-polycythemia vera or post-essential thrombocythemia myelofibrosis)
2. Systemic mastocytosis

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of chronic hepatitis C virus (HCV) infection that has been confirmed by the presence of hepatitis C virus ribonucleic acid (HCV RNA) in the serum? [If no, skip to question 8.]	Yes	No
2	Is the requested drug being prescribed as monotherapy or as dual therapy with ribavirin? [If no, skip to question 4.]	Yes	No
3	Has the patient received a total 48 weeks of treatment? [No further questions.]	Yes	No
4	Is the requested drug being prescribed as part of a three-drug regimen that includes Sovaldi and ribavirin? [If no, skip to question 6.]	Yes	No
5	Has the patient received a total 12 weeks of treatment? [No further questions.]	Yes	No
6	Is the requested drug being prescribed as part of a three-drug regimen that includes Olysio and ribavirin? [If no, no further questions.]	Yes	No
7	Has the patient received a total 48 weeks of treatment? [No further questions.]	Yes	No

8	Does the patient have a diagnosis of chronic hepatitis B virus infection? [If yes, no further questions.]	Yes	No
9	Does the patient have a diagnosis of myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, primary myelofibrosis and post-polycythemia vera or post-essential thrombocythemia myelofibrosis)? [If yes, no further questions.]	Yes	No
10	Does the patient have a diagnosis of systemic mastocytosis?	Yes	No

Guidelines for Approval					
Duration of Approval	**Total 48 weeks of treatment**	**Duration of Approval**	**Total 12 weeks of treatment**	**Duration of Approval**	**Total 48 weeks of treatment**
Set 1: Hep C, monotherapy or combination with ribavirin		**Set 2:** Hep C, PEG + RBV + Sovaldi		**Set 3:** Hep C, PEG + RBV + Olysio	
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	2	1	2
2		4	5	6	4
					7
Duration of Approval	**48 weeks**	**Duration of Approval**	**12 months**	**Duration of Approval**	**12 months**
Set 4: Hep B		**Set 5:** Myeloproliferative neoplasm		**Set 6:** Systemic mastocytosis	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
8	1	9	1	10	1
			8		8
					9

Mapping Instructions		
	Yes	**No**
1.	Go to 2	Go to 8
2.	Go to 3	Go to 4
3.	Deny	Approve, total 48 weeks of treatment
4.	Go to 5	Go to 6
5.	Deny	Approve, total 12 weeks of treatment
6.	Go to 7	Deny
7.	Deny	Approve, total 48 weeks of treatment
8.	Approve, 48 weeks	Go to 9
9.	Approve, 12 months	Go to 10
10.	Approve, 12 months	Deny

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. Pegasys [package insert]. South San Francisco, CA: Genentech, Inc; October 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 19, 2019.
3. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; November 2017.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2018.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made May 24, 2018. Accessed March 19, 2019.
6. Terrault NA, Bzowej NH, Chang KM, et al. AASLD guidelines for treatment of chronic hepatitis B. *Hepatology*. 2016;63(1):261-283.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Myeloproliferative Neoplasms (Version 2.2019). http://www.nccn.org. Accessed March 19, 2019.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Systemic Mastocytosis (Version 2.2019). http://www.nccn.org. Accessed March 19, 2019.

DOCUMENT HISTORY

Written by:	UM Development (LS)
Revised:	07/1998, 04/1999, 03/2001, 08/2001 JG 02/2002, 11/2002, 01/2004; TM 11/2004, 03/2005, 05/2005; NB 07/2006(3); MG 07/2007, 08/2008; GY 11/2009; AC 09/2010, 05/2011, 09/2011 (changed initial duration of approval for triple therapy), 10/2011 (CMS), KH 12/2011; AC 09/2012 (CMS); HY 01/2013; AS/HY 12/2013, 02/2014; HY 09/2014 (CMS), DK/HY 01/2015, 08/2015 (CMS), 10/2015 (aligning with Pegintron criteria based on CMS review), KW 01/2016, 07/2016 (CMS); JP 10/2016, 07/2017 (CMS), IP 10/2017 (CMS), 07/2018 (CMS), PK 02/2019 (no change), KF 03/2019 (annual review), JL 06/2019 (CMS), KF 04/2020 (CMS)
Reviewed:	CRC 8/1998, 4/1999, 04/2001, 08/20/2001. 02/2002; 12/2002; 01/2004; CDPR/MM 03/2005, 06/2005, 07/2006; WLF 07/2007, 08/2008; KP 11/2009, 05/2011, 09/2011, 01/2012, 01/2013, 12/2013, 02/2014, SES 01/2015, WLF 07/2015, ADA 11/2015, 09/2016, 10/2016, 09/2017, 11/2017, AN 04/2018, EPA 04/2019
External Review:	05/2002; 02/2003; 02/2004; 11/2005; 12/2006; 11/2007; 12/2008; 12/2009, 05/2011, 02/2012, 03/2013, 01/2014, 03/2014, 02/2015, 08/2015, 12/2015, 11/2016, 12/2016, 12/2017, 05/2018, 04/2019