CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Pegasys (peginterferon alfa-2a)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 4 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Pegasys (peginterferon alfa-2a) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEPATITIS B

For **initial** authorization:

1. Member is an adult with chronic Hepatitis B (CHB) and compensated liver disease (Child-Pugh A score less than or equal to 6) or a child (3 years of age or older) with non-cirrhotic CHB; AND
2. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist, a physician assistant or a nurse practitioner working with the above specialists; AND
3. Member has two elevated ALT lab values within the past 12 months (> 60 IU/L for men, > 38 IU/L for women) and HBV DNA levels > 20,000 IU/ml; AND
4. Member has tried and failed course of treatment with tenofovir (for ≥12 years of age) or entecavir (for ≥2 years of age); AND
5. Member does **not** have any of the following;
   a) Acute autoimmune hepatitis;
   b) HIV;
   c) Hepatic decompensation.
6. **Dosage allowed:** Adults: 180 mcg (1.0 mL) once weekly by subcutaneous administration in the abdomen or thigh; pediatrics: BSA x 180 mcg/1.732 m^2 subcutaneously once weekly.

Note: Serial monitoring of HBV-DNA levels along with ALT level should be used in determining the need for a treatment.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

HEPATITIS C

For **initial** authorization:
1. Member is 5-17 years of age previously untreated with interferon alfa; AND
2. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist, a physician assistant or a nurse practitioner working with the above specialists.
3. **Dosage allowed:** Pediatrics: BSA x 180 mcg/1.732 m^2 subcutaneously once weekly.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

MYELOPROLIFERATIVE NEOPLASMS (MYELOFIBROSIS (MF), POLYCYTHEMIA VERA (PV), AND ESSENTIAL THROMBOCYTHEMIA (ET))

For **initial** authorization:
1. Member has diagnosis of Myeloproliferative Neoplasms (or one of the following: myelofibrosis (MF), polycythemia vera (PV), or essential thrombocythemia (ET)); AND
2. Medication must be prescribed by oncologist or hematologist; AND
3. Member has tried and failed course of treatment with at least **two** of the following:
   a) Low-dose aspirin (81-100 mg);
   b) Phlebotomy (to maintain a hematocrit level of <45%) and/or hydroxyurea;
   c) Anagrelide.
4. **Dosage allowed:** 180 mcg (1.0 mL) once weekly by subcutaneous administration in the abdomen or thigh.

Note: Pegasys will be considered for younger members, pregnant members, or members who defer hydroxyurea.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Pegasys (peginterferon alfa-2a) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute hepatitis B
- Bechet's disease
- Chronic uveitis

DATE	ACTION/DESCRIPTION
03/21/20018	New policy for Pegasys created. Coverage for adults for Hepatitis C was removed since no longer recommended by AASLD guidelines and since other more effective treatments are currently available. NCCN recommendations of off-label use added. CHB criteria revised.

References:

1. Pegasys [package insert]. South San Francisco, CA: Genentech USA, Inc.; October, 2017.
2. Terrault NA, Bzowej NH, Chang KM, et al. "AASLD guidelines for treatment of chronic hepatitis B." *American Association for the Study of Liver Diseases*. Published: December 21, 2015. Accessed March 21, 2018.
3. Vannucchi AM. How I treat polycythemia vera. *Blood*, 124(22), 3212-3220. Accessed March 19, 2018. https://doi.org/10.1182/blood-2014-07-551929.
4. Quinta´s-Cardama A, Kantarjian H, Manshouri T, et al. "Pegylated Interferon Alfa-2a Yields High Rates of Hematologic and Molecular Response in Patients With Advanced Essential Thrombocythemia and Polycythemia." *VeraJ Clin Oncol*, 27:5418-5424. Published: November 10, 2009. Accessed: March 21, 2018. http://ascopubs.org/doi/pdfdirect/10.1200/JCO.2009.23.6075.
5. Mascarenhas JO, Prchal JT, Rambaldi A, et al. "Interim Analysis of the Myeloproliferative Disorders Research Consortium (MPD-RC) 112 Global Phase III Trial of Front Line Pegylated Interferon Alpha-2a Vs. Hydroxyurea in High Risk Polycythemia Vera and Essential Thrombocythemia." *Blood,* 128(22), 479. Accessed March 19, 2018. Retrieved from http://www.bloodjournal.org/content/128/22/479.
6. Mesa RA, Jamieson C, Bhatia R, et al. "NCCN Guidelines Insights: Myeloproliferative Neoplasms, Version 2.2018." *J Natl Compr Canc Netw* 2017;15:1193-1207. Published: 2017. Accessed: http://www.jnccn.org/content/15/10/1193.long.
7. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Published: September 21, 2017. Accessed: March 21, 2018.
8. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. PRACTICE GUIDANCE | HEPATOLOGY, VOL. 67, NO. 4, 2018.

Effective date: 10/26/2018
Revised date: 03/21/2018