

## PHARMACY POLICY STATEMENT

### Georgia 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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<sup>2</sup> 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<sup>2</sup> 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