I. Medication Description

Interferons are a family of proteins that have complex antiviral, antineoplastic (anticancer), and immunomodulating activities, which may enhance or suppress the immune system. Interferons are often referred to as biologic response modifiers. They are used in the treatment of various neoplasms and viral infections. Pegylated interferons are modified by polyethylene glycol, resulting in a longer half-life (and duration of action) than non-pegylated interferons. The longer duration of action prevents viral replication between doses. Pegylated interferons can be dosed once weekly for the treatment of hepatitis B and hepatitis C.

II. Position Statement

- Coverage is determined through a prior authorization process with supporting clinical documentation for every request.
- Pegasys is the plan-preferred pegylated interferon for the treatment of chronic hepatitis C infection.

III. Policy

- Coverage of the requested medication(s) is provided when the following criteria are met:
  - Member is at least
    - 5 years of age (for Moderiba and Pegasys)
    - 2 years of age (for Peg-Intron)
    - 3 years of age (for Intron-A, ribavirin) AND
  - Medication is prescribed by a:
    - Hepatologist, gastroenterologist, infectious disease specialist, transplant physician, healthcare practitioner under the direct supervision of one of the preceding listed specialists, or a healthcare practitioner experienced and trained in the treatment of HCV infection prescriber working in collaboration with one of these specialists, or a prescriber who has clinical experience with the management and treatment of HCV infection (defined as the management AND treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months) OR
    - Healthcare professional in partnership (defined as consultation, preceptorship, or via telemedicine) with an experienced HCV provider who meets the above criteria AND
  - A diagnosis of chronic hepatitis C has been established and baseline viral load reported AND
  - The medication(s) requested is being used in a regimen that is recommended by current treatment guidelines and/or supported by available clinical trials AND
If non-preferred medication (Peg-Intron) is requested, it is documented that the plan-preferred medication (Pegasys) is medically inappropriate due to intolerance or inefficacy associated with past usage OR the following criteria are met:

- When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
- At least one of the following is met:
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
  - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).
  - The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

If used in combination with a direct-acting antiviral (DAA) medication, one must refer to the specific DAA policy for complete coverage criteria.

IV. Quantity Limitations

According to current treatment guidelines, prescribing information, and available clinical trials.

V. Coverage Duration

According to current treatment guidelines and available clinical trials. Other corporate Drug Therapy Guidelines may apply.

VI. Coverage Renewal Criteria

According to current treatment guidelines and available clinical trials. Other corporate Drug Therapy Guidelines may apply.
VII. Billing/Coding Information

n/a

VIII. Summary of Policy Changes

- 6/1/11:
  - Acknowledgement of other covered diagnoses
  - biopsy, CBC and LFTs required for initial coverage
- 9/1/11: Reference to Victrelis and Incivek policy added
- 9/15/12: Requirement for liver biopsy removed from coverage criteria
- 9/15/13: No policy changes made
- 10/1/13: Exclusive/Exchange coverage added to policy
- 6/15/14: Policy changed to reflect 2014 AASLD/IDSA/IAS-USA chronic hepatitis C treatment guidelines
- 12/1/14: Updated to include reference to individual DAA policy should a DAA be part of the requested treatment regimen
- 7/1/15: Formulary distinctions made
- 9/15/15: Age limits changed from 2 to 3 for Intron-A and ribavirin
- 4/22/16: Specialist qualifications clarified
- 7/19/16: No policy changes
- 5/1/17: Step therapy criteria added
- 6/21/17: Infergen removed as product is off-market; Moderiba added to policy

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.