Gateway Health
Prior Authorization Criteria
Hepatitis B Medications

All requests for Hepatitis B Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Hepatitis B Medications Prior Authorization Criteria:

The following Hepatitis B Medications are formulary:

- Pegasys (Peginterferon alfa-2a)
- Lamivudine (does not require prior authorization)
- Adefovir Dipivoxil
- Entecavir
- Viread

All other Hepatitis B Medications are considered non-formulary and require documentation of failure with Entecavir in addition to meeting the criteria outlined below.

For all requests for Hepatitis B Medications all of the following criteria must be met:

- Must be prescribed by an infectious disease physician, a gastroenterologist, a hepatologist, or a transplant physician
- Must submit documentation of baseline evaluation and results from the following tests:
  - Hepatitis B virus (HBV) DNA viral load
  - HBeAg
  - Anti-HBe
  - HBsAg
  - Anti-HBs
  - Anti-HBc (if requiring immunosuppressive or cytotoxic therapy only)
  - Liver function tests
  - Liver biopsy (if available)
- Must be receiving anti-retroviral therapy if the member has HIV coinfection or the medical record documents the rationale for the beneficiary not being treated.
- Must have documentation of results of Hepatitis B Virus Drug Resistance panel if member has received previous anti-viral drug treatment for Hepatitis B
  - Requests for Entecavir require the submission of the provider's clinical rationale to support their use over Viread when there is a history of Lamivudine resistance. This does not apply if the member would meet Pegasys exclusion criteria listed in the below section.

Coverage may be provided with a diagnosis of Chronic Hepatitis B and the following criteria is met:

- Member is HBsAg-positive for at least 6 months
- Must meet at least one of the following criteria:
  - Compensated or decompensated cirrhosis
  - Presence of extrahepatic manifestations

- HBV DNA > 2,000 IU/mL and at least moderate fibrosis or necroinflammation on liver biopsy
- HBV DNA > 2,000 IU/mL and family history of cirrhosis or hepatocellular carcinoma
- HBV DNA > 2,000 IU/mL and age greater than 40 years old
- If HBeAG positive, HBV DNA >20,000 IU/mL and one of the following:
  - ALT ≥ 2 times ULN
  - At least moderate fibrosis or necroinflammation on liver biopsy
- If HBeAg negative, HBV DNA > 2,000 IU/mL and one of the following:
  - ALT ≥ 2 times ULN
  - ALT > ULN on two separate laboratory tests at least three months apart

- Requests for Pegasys must **NOT** meet any of the following exclusion criteria:
  - Member is below 3 years of age
  - Member has decompensated cirrhosis
  - Member has autoimmune illness
  - Member has a history of suicidal tendency or uncontrolled psychiatric illness
  - Member is cirrhotic and between 3 years and 18 years of age
  - Member requires immunosuppressive or cytotoxic therapy
- Requests for Lamivudine and Adefovir Dipivoxil require the submission of the provider's clinical rationale to support their use over Pegasys, Viread, or Entecavir due to inferior anti-viral activity and high rates of resistance.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Requests for Pegasys may only be approved up to a total treatment duration of 48 weeks
  - Members with cirrhosis are eligible indefinitely
  - Members with HBeAg-positive chronic hepatitis B are eligible indefinitely until member meets all of the following:
    - Loss of HBeAg documented by undetectable HBeAg and development of hepatitis B e antibodies confirmed on two tests at least two months apart
    - Member has completed an additional 12 months of treatment after loss of HBeAg
  - Members with HBeAg-negative chronic hepatitis B are eligible indefinitely until member has documentation of confirmed HBsAg loss on two tests at least six months apart
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for members who have had a liver transplant for Hepatitis B OR for solid organ transplant recipients who have received organs from Hepatitis B positive donors and the following criteria is met:

- Requests for Lamivudine and Adefovir Dipivoxil require the submission of the provider's clinical rationale to support their use over Viread or Entecavir due to inferior anti-viral activity and high rates of resistance.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Members are eligible indefinitely

- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Hepatitis B members requiring immunosuppressive or cytotoxic therapy and the following criteria is met:

- Must meet one of the following criteria:
    - Member has HBsAg-positive documentation
    - Member has HBsAg-negative and anti-HBc positive documentation in addition to one of the following:
        - Undergoing stem cell transplantation
        - Receiving B-cell depleting agents such as rituximab and ofatumumab
        - Receiving anthracycline derivatives such as doxorubicin and epirubicin
        - Receiving corticosteroid therapy for ≥ 4 weeks
- Requests for Lamivudine and Adefovir Dipivoxil require the submission of the provider's clinical rationale to support their use over Viread or Entecavir due to inferior anti-viral activity and high rates of resistance.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Members with HBsAg-positive hepatitis B receiving immunosuppressive or cytotoxic therapy are eligible up to 12 months after cessation of the immunosuppressive or cytotoxic treatment
        - Member is authorized up to 18 months after cessation of rituximab-based regimens
    - Members with HBsAg-negative and anti-HBc positive hepatitis B receiving immunosuppressive or cytotoxic therapy are eligible up to 18 months after cessation of the immunosuppressive or cytotoxic treatment
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Updated: 04/2019
PARP Approved: 04/2019

Hepatitis B Medications
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: ____________pounds or ___________kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:___________________________

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY

Diagnosis: ____
If member has previously been treated, please provide results of Hepatitis B Virus Drug Resistance panel

Does the member have a HIV coinfection? ☐ Yes ☐ No
If Yes, is the member receiving anti-retroviral therapy? ☐ Yes ☐ No (If No, please provide documentation of rationale)

Please check any of the applicable boxes and provide documentation:
☐ Member has cirrhosis (please specify if compensated or decompensated): ________________________________
☐ Member has extrahepatic manifestations
☐ Member has at least moderate fibrosis or necroinflammation on liver biopsy
☐ Member has a family history of cirrhosis or hepatocellular carcinoma
☐ Member has had a liver transplant for Hepatitis B or received organs from Hepatitis B positive donors
☐ Member requires immunosuppressive or cytotoxic therapy (please provide regimen and duration)

Requests for Pegasys only:
Please check any of the applicable boxes:
☐ Member has an autoimmune illness
☐ Member has a history of suicidal tendency or uncontrolled psychiatric illness

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

Gateway Health

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MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____________pounds or ____________kg

LABORATORY VALUES (or attach documentation)

Lab	Initial (Pre-Treatment) Value	Reference Range	Date	Post-Therapy Value (Reauthorization only)	Reference Range	Date
Hepatitis B Virus DNA viral load						
HBeAg						
Anti-HBe						
HBsAg						
Anti-HBs						
Anti-HBc						
Aspartate Transaminase (AST)						
Alanine Transaminase (ALT)						

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date