AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Rezdiffra™ (resmetirom)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosing: <100 kg: 80 mg once daily. ≥100 kg: 100 mg once daily. Coadministration with moderate CYP2C8 inhibitors: Reduce dose to 80 mg daily for patients weighing ≥100 kg, or reduce dose to 60 mg daily for patients weighing <100 kg

Quantity Limits: One tablet daily (all strengths – 60, 80 & 100 mg)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Member is 18 years of age or older
- ❑ Medication is prescribed by or in consultation with a hepatologist or gastroenterologist
- ❑ Member has a diagnosis of nonalcoholic steatohepatitis or metabolic dysfunction–associated steatohepatitis (NASH/MASH)

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- ❑ Provider must submit **ONE** of the following
  - ❑ Biopsy results (completed within the last 6 months) documenting **BOTH** of the following:
    - ❑ Liver fibrosis stage F2 or F3
    - ❑ Non-alcoholic fatty liver disease activity score (NAS) of ≥ 4 with a score of > 1 in all the following: steatosis, ballooning, and lobular inflammation
  - ❑ Liver fibrosis stage F2 or F3 as determined by an elastography test, such as vibration-controlled transient elastography (i.e., FibroScan), magnetic resonance elastography (MRE), shear wave elastography; etc. **(must submit current test results)**
- ❑ In cases of indeterminate fibrosis stage (i.e., inconsistency between fibrosis stage and clinical presentation), a liver biopsy will be required to be submitted
- ❑ Member has three or more of the following metabolic risk factors that are managed according to standard of care **(verified by medical chart notes, lab test results and/or pharmacy claims)**:
  - ❑ Central obesity
  - ❑ Hypertriglyceridemia
  - ❑ Reduced high-density lipoprotein cholesterol
  - ❑ Hypertension
  - ❑ Elevated fasting plasma glucose indicative of diabetes or pre-diabetes
- ❑ Current liver function (CMP) and CBC test results must be submitted
- ❑ Other causes of liver disease or hepatic steatosis have been ruled out (i.e., alcoholic steatohepatitis, acute fatty liver, autoimmune hepatitis, Hepatitis A, B or C, hemochromatosis, drug-induced liver disease)
- ❑ Member has adopted liver-protective lifestyle interventions such as optimizing weight loss, dietary changes, and exercise and is compliant with treatment for comorbidities (i.e. hyperlipidemia, hypertension, diabetes; etc.)
- ❑ Member does **NOT** have significant alcohol consumption (alcohol consumption of more than 20 g per day for women and more than 30 g per day for men)
- ❑ Member does **NOT** have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma **(must submit documentation)**
- ❑ Member has had an unsuccessful 6-month trial of Wegovy and documentation of insufficient clinical response (i.e. lack of MASH/NASH resolution, no improvement in fibrosis score; etc.) must be submitted

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet **ALL** initial authorization criteria

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- ❑ Member has experienced **ONE** of the following as determined by an elastography test, such as vibration-controlled transient elastography (e.g., FibroScan), magnetic resonance elastography (MRE), shear wave elastography or biopsy:
  - ❑ MASH/NASH resolution **AND** no worsening of fibrosis
  - ❑ No worsening of MASH/NASH **AND** improvement in fibrosis by ≥ 1 stage

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*