HIGHMARK HEALTH OPTIONS

Updated: 05/2024
DMMA Approved: 05/2024

Request for Prior Authorization for Rezdiffra (resmetirom)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Rezdiffra (resmetirom) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Rezdiffra (resmetirom) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) and all of the following criteria is met:

- Documentation of a confirmed diagnosis of NASH by **one** of the following:
  - Liver biopsy within the past 2 years confirming steatosis AND ALL of the following:
    - NAFLD Activity Score (NAS) of at least 4
    - A score of at least 1 in each NAS component [i.e., steatosis (scored 0 to 3), ballooning degeneration (scored 0 to 2), lobular inflammation (scored 0 to 3)]
    - Moderate to advanced liver fibrosis (stages F2 to F3 fibrosis)
  - Vibration-controlled transient elastography (VCTE; e.g FibroScan) with kPa greater than or equal to 8.5 AND controlled attenuation parameter (CAP) greater than or equal to 280 dB.m-1
  - **ONE** of the following historical biochemical tests for fibrosis:
    - PRO-C3 >14 ng/mL
    - Enhanced Liver Fibrosis (ELF) greater than or equal to 9
  - The member has an MRI-PDFF greater than or equal to 8% liver fat included MRE
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- Member must not have any of the following exclusions:
  - Thyroid diseases including:
    - Active hyperthyroidism
    - Untreated clinical hypothyroidism defined by thyroid stimulating hormone (TSH) >7 IU/L with symptoms of hypothyroidism or >10 IU/L without symptoms
  - Recent significant weight gain or loss
  - HbA1c ≥ 9.0%

  - Presence of cirrhosis on liver biopsy defined as stage 4 fibrosis
  - Diagnosis of hepatocellular carcinoma (HCC)
  - MELD score ≥12, unless due to therapeutic anti coagulation
  - Decompensated cirrhosis Chronic liver diseases other than NASH
  - History of bariatric surgery (within the past 5 years)
  - Active autoimmune disease
  - Serum ALT > 250 U/L
  - Active, serious medical disease with a likely life expectancy less than 2 years
  - History of significant alcohol consumption for a period of more than 3 consecutive months within 1 year prior to starting requested therapy
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be prescribed by or in consultation with a liver specialist physician such as a hepatologist or gastroenterologist
- The prescriber must monitor for elevations in liver tests and development of liver related adverse reactions.
- The member must discontinue use of any medication that may affect NAS or fibrosis stage or regular use of drugs historically associated with NAFLD
- Documentation the member has received lifestyle counseling on nutrition and exercise and will continue to use in conjunction with the requested medication
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
- The member has received a clinical benefit demonstrated by either:
  - the resolution of steatohepatitis and no worsening of liver fibrosis or
  - at least one stage improvement in liver fibrosis and no worsening of steatohepatitis
- The member has documentation of an annual evaluation, including laboratory values since starting treatment, by a hepatologist or gastroenterologist
- Documentation the member continues to diet and exercise in conjunction with the requested medication
- The member continues to not use any medication that may affect NAS or fibrosis stage or regular use of drugs historically associated with NAFLD

- The member does not have any exclusions as listed in the initial review criteria
- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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REZDIFFRA (RESMETIROM)
PRIOR AUTHORIZATION FORM- PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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 (Complete for ALL requests)

Diagnosis: ☐ Noncirrhotic nonalcoholic steatohepatitis (NASH) ☐ Other: _____

How was the diagnosis confirmed (please submit chart documentation)?
☐ Liver biopsy with the past 2 years
☐ NAFLD Activity Score (NAS) of at least 4
☐ A score of at least 1 in each NAS component [i.e., steatosis (scored 0 to 3), ballooning degeneration (scored 0 to 2), lobular inflammation (scored 0 to 3)]
☐ Moderate to advanced liver fibrosis (stages F2 to F3 fibrosis)
☐ Vibration-controlled transient elastography (VCTE; e.g FibroScan) with kPa greater than or equal to 8.5 AND controlled attenuation parameter (CAP) greater than or equal to 280 dB.m-1
One of the following biochemical tests for fibrosis:
☐ PRO-C3 >14 ng/mL
☐ Enhanced Liver Fibrosis (ELF) greater than or equal to 9

☐ The member has an MRI-PDFF greater than or equal to 8% liver fat included MRE

Does the member have any of the following (check all that apply):
☐ Thyroid diseases including active hyperthyroidism or untreated clinical hypothyroidism defined by thyroid stimulating hormone (TSH) >7 IU/L with symptoms of hypothyroidism or >10 IU/L without symptoms
☐ Recent significant weight gain or loss
☐ HbA1c ≥ 9.0%
☐ Presence of cirrhosis on liver biopsy defined as stage 4 fibrosis
☐ Diagnosis of hepatocellular carcinoma (HCC)
☐ MELD score ≥12, unless due to therapeutic anti coagulation
☐ Decompensated cirrhosis Chronic liver diseases other than NASH
☐ History of bariatric surgery (within the past 5 years)

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REZDIFFRA (RESMETIROM)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)- continued

☐ Active autoimmune disease
☐ Serum ALT > 250 U/L
☐ Active, serious medical disease with a likely life expectancy less than 2 years
☐ History of significant alcohol consumption for a period of more than 3 consecutive months within 1 year prior to starting requested therapy

Will the member be monitored for elevations in liver tests and development of liver related adverse reactions: ☐ Yes ☐ No
Has the member discontinued any medication that may affect NAS or fibrosis stage or regular use of drugs historically associated with NAFLD? ☐ Yes ☐ No
Is there documentation the member has received lifestyle counseling on nutrition and exercise and will continue to use in conjunction with the requested medication? ☐ Yes ☐ No

REAUTHORIZATION

Has the member received a clinical benefit demonstrated by either resolution of steatohepatitis and no worsening of liver fibrosis or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis? ☐ Yes ☐ No
Is there documentation of an annual evaluation, including laboratory values since starting treatment, by a hepatologist or gastroenterologist? ☐ Yes ☐ No
Is there documentation the member continues to diet and exercise in conjunction with the requested medication? ☐ Yes ☐ No
Does the member continue to not use any medication that may affect NAS or fibrosis stage or regular use of drugs historically associated with NAFLD? ☐ Yes ☐ No
Does the member have any exclusions to the requested medication? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date