HIGHMARK WHOLECARE

Updated: 05/2024
PARP Approved: 05/2024

Prior Authorization Criteria

Noncirrhotic metabolic dysfunction– associated steatohepatitis (MASH) Agents

All requests for Noncirrhotic metabolic dysfunction– associated steatohepatitis (MASH) Agents require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Noncirrhotic metabolic dysfunction– associated steatohepatitis (MASH) Agents include: Rezdiffra (resmetirom).

Coverage may be provided with a diagnosis of noncirrhotic metabolic dysfunction– associated steatohepatitis (MASH) and all of the following criteria is met:

- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Documentation the member has received lifestyle counseling on nutrition and exercise and will continue to use in conjunction with the requested medication
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Documentation of a confirmed diagnosis of MASH with fibrosis stage 2 or 3 confirmed by **one** of the following within the last 6 months:
    - Liver biopsy 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)]
    - One of the following assessments:
        - Serum-based assessment (e.g., fibrosis-4 [FIB-4], NAFLD fibrosis score [NFS], enhanced liver fibrosis test [ELF]);
        - imaging-based assessment (e.g., FibroScan, magnetic resonance-based elastography [MRE], magnetic resonance imaging–proton density fat fraction [MRI-PDFF]);
        - FAST score, as measured by FibroScan and serum aspartate aminotransferase (AST);
        - MAST score, as measured by MRI-PDFF, MRE, and serum AST;
        - MEFIB score, as measured by FIB-4 and MRE
- 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
  - Hepatic decompensation
  - 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 member must discontinue use of any medication that may affect NAS or fibrosis stage or regular use of drugs historically associated with NAFLD
- Member has at least 2 metabolic risk factors (e.g., obesity, type 2 diabetes, dyslipidemia, hypertension)
- **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.

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.

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NONCIRRHOTIC METABOLIC DYSFUNCTION-ASSOCIATED STEATOHEPATITIS (MASH) AGENTS 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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
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:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, 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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

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