Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Rezdiffra (resmetirom)**

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Rezdiffra (resmetirom) is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction-associated steatohepatitis (MASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

This indication is approved under accelerated approval based on improvement of NASH/MASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Rezdiffra (resmetirom) when **ALL** the following criteria are met:

Initial Authorization

1. Documentation of BOTH of the following as confirmed by liver biopsy or elastography:
    a. Documented diagnosis of noncirrhotic, non-alcoholic steatohepatitis (or metabolic dysfunction-associated steatohepatitis) (NASH/MASH)
    b. Fibrosis stage 2 or 3

AND

2. Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

3. Alcohol consumption of no more than 20 g per day for women and no more than 30 g per day for men

AND

4. Prescribed by or in consultation with a gastroenterologist or hepatologist

Reauthorization Criteria

1. Patient demonstrates positive response to therapy (e.g., NASH resolution, fibrosis stage improvement, etc.) or no worsening of fibrosis

AND

2. Documentation by the prescribing physician that the patient is adherent to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

3. Alcohol consumption of no more than 20 g per day for women and no more than 30 g per day for men

Limitations

1. Initial coverage of Rezdiffra will be authorized for 12 months. Reauthorization of Rezdiffra will be provided for 12-month intervals.
2. Members new to the plan stable on Rezdiffra should be reviewed against Reauthorization Criteria.

3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Rezdiffra [package insert], West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; December 2025.
2. Institute for Clinical and Economic Review (ICER). Resmetirom and obeticholic acid for non-alcoholic steatohepatitis (NASH) (final evidence report). May 25, 2023. https://icer.org/wp-content/uploads/2022/10/NASH-Final-Report_For-Publication_053023.pdf.
3. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology*. 2023(a);77(5):1797-1835. doi: 10.1097/HEP.0000000000000323.
4. Rinella ME, Lazarus JV, Ratziu V, et al for the NAFLD Nomenclature consensus group. A multisociety Delphi consensus statement on new fatty liver disease nomenclature. *J Hepatol*. 2023(b);79(6):1542-1556. doi: 10.1016/j.jhep.2023.06.003.
5. Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology clinical practice guideline for the diagnosis and management of nonalcoholic fatty liver disease in primary care and endocrinology clinical settings co-sponsored by the American Association for the Study of Liver Diseases (AASLD). Endocr Pract. 2022;28(5):528-562. doi: 10.1016/j.eprac.2022.03.010.
6. European Association for the Study of the Liver (EASL), European Association for the Study of Diabetes (EASD), European Association for the Study of Obesity (EASO). EASL-EASD-EASO Clinical Practice Guidelines for the management of non-alcoholic fatty liver disease. J Hepatol 2016; 64:1388.

Approval And Revision History

July 9, 2024: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 8, 2025: No changes
- July 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.