Pharmacy Medical Necessity Guidelines:
Rezdiffra (resmetirom)

Effective: July 14, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

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.

COVERAGE GUIDELINES

The plan may authorize coverage of **Rezdiffra (resmetirom)** when **ALL** of 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.

CODES

None

REFERENCES

1. Rezdiffra [package insert], West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; March 2024.
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 HISTORY

July 9, 2024: Reviewed by the Pharmacy & Therapeutics Committee
July 8, 2025: No Changes
July 14, 2026: No changes.

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.

Provider Services