



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1443-1
Program	Prior Authorization/Notification
Medication	Rezdiffra™ (resmetirom)
P&T Approval Date	4/2024
Effective Date	6/1/2024

1. Background:

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) 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 and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations of Use:

Avoid use of Rezdiffra in patients with decompensated cirrhosis.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Rezdiffra** will be approved based on **both** of the following criteria:

- a. Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]

-AND-

- b. Moderate to advanced liver fibrosis (i.e., fibrosis stage F2 or F3)

Authorization will be issued for 12 months

B. Reauthorization

1. **Rezdiffra** will be approved based on the following criterion:

- a. Documentation of positive clinical response to Rezdiffra therapy

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-



10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits, Medical Necessity and/or Step Therapy may be in place.

4. References:

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

Program	Prior Authorization/Notification – Rezdifra (resmetirom)
Change Control	
4/2024	New program.