

ALASKA MEDICAID
Prior Authorization Criteria

**Rezdiffra™
(resmetirom)**

FDA INDICATIONS AND USAGE¹

Rezdiffra 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

APPROVAL CRITERIA^{1,2,3,4}

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a gastroenterologist or hepatologist **AND**;
3. Patient has a diagnosis noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis **AND**;
4. Patient has liver fibrosis stage F2 or F3, confirmed by liver biopsy within the previous 12 months or **two or more** of the following:
 - a. Magnetic resonance elastography (MRE) score >2.6
 - b. Vibration-controlled transient elastography (VCTE) score >8.1
 - c. Enhanced liver fibrosis (ELF) score >7.7 **AND**;
5. Patient Fibrosis 4 index (FIB-4) score ≥ 1.3 **AND**;
6. Patient currently has three or more metabolic risk factors (e.g. hypertension, obesity, diabetes mellitus II, etc.) **AND**;
7. Submitted chart notes confirm Rezdiffra™ is being used as an adjunct to lifestyle modification including increased physical activity and reduced calorie diet

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Patient has a diagnosis of other liver disease, including decompensated cirrhosis, hepatocellular carcinoma, hepatitis, etc.

CAUTIONS¹

- Rezdiffra™ may increase the incidence of cholelithiasis and cholecystitis.
- Patients receiving Rezdiffra™ should be monitored for signs and symptoms of hepatotoxicity
- The most common adverse reactions observed with Rezdiffra™ include diarrhea, pruritus, nausea and abdominal pain

ALASKA MEDICAID
Prior Authorization Criteria

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization: up to 12 months

QUANTITY LIMIT

- 30 tablets per 30 days
- Not to exceed 100mg per day

REFERENCES / FOOTNOTES:

1. Rezdiffra (resmetirom) [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals; December 2025
2. Harrison SA, Taub R, Neff GW, et al. Resmetirom for nonalcoholic fatty liver disease: a randomized, double-blind, placebo-controlled phase 3 trial. *Nat Med.* 2023;29:2919-2928.
3. 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.
4. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD practice guideline on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology.* 2023;77(5):1797-1835.