CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Rezdiffra (resmetirom)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Rezdiffra is a thyroid hormone receptor-beta (THR-beta) agonist indicated, in conjunction with diet and exercise, for the treatment of noncirrhotic non-alcoholic steatohepatitis (NASH) in adults with moderate to advanced liver fibrosis, in conjunction with diet and exercise. NASH is a progressive liver disease characterized by the accumulation of lipids in the liver. In NASH, THR-beta function in the liver is impaired causing a reduction in mitochondrial function and beta-oxidation of fatty acids, leading to fibrosis. Once NASH progresses to fibrosis, the risk of adverse clinical outcomes increases. Through THR-beta agonism, Rezdiffra, is able to decrease intra-hepatic lipids through increased mitochondrial beta-oxidation and improving hepatocyte mitochondrial function. Efficacy was demonstrated in the MAESTRO-NASH clinical trial. It is a daily oral tablet dosed based on actual body weight.
NASH is also known as metabolic dysfunction-associated steatohepatitis (MASH).

Rezdiffra (resmetirom) will be considered for coverage when the following criteria are met:

Noncirrhotic Non-Alcoholic Steatohepatitis (NASH)/ Metabolic Dysfunction-Associated Steatohepatitis (MASH)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist or hepatologist; AND
3. Member has a diagnosis of NASH with fibrosis stage 2 or 3 confirmed by one of the following:
   a) Liver biopsy
   b) FIB-4 >2.67
   c) FIB-4 >1.3 AND at least ONE of the following: VTCE 8.5-20 kPa or ELF 9-11.3; AND
4. Member has at least 2 metabolic risk factors (e.g., obesity, type 2 diabetes, dyslipidemia, hypertension); AND
5. Attestation that Rezdiffra will be used in conjunction with diet and exercise; AND
6. Member does NOT have any of the following:
   a) History of significant alcohol consumption (i.e., more than 20 g per day for women and more than 30 g per day for men) for a period of more than 3 consecutive months within the past year
   b) Decompensated cirrhosis
   c) Thyroid disease.
7. **Dosage allowed/Quantity limit:**
   a. 80mg by mouth daily if member weighs <100kg. (30 tablets per 30 days)
   b. 100mg by mouth once daily if member weighs ≥100kg. (30 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must show fibrosis improvement or stabilization: AND
2. Provider attestation that the member has continued to abstain from alcohol consumption.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rezdiffra (resmetirom) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/17/2024	New policy for Rezdiffra created.

References:

1. Rezdiffra [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; March 2024.
2. Harrison SA, Bedossa P, Guy CD, et al. A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis. *N Engl J Med.* 2024; 390:497-509. Doi: 10.1056/NEJMoa2309000
3. Rinella M, Neuschwander-Tetri B, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology*. 2023; 77(5):p 1797-1835. doi: 10.1097/HEP.0000000000000323
4. Nalbantoglu IL, Brunt EM. Role of liver biopsy in nonalcoholic fatty liver disease. *World J Gastroenterol*. 2014; 20(27):9026-37. doi: 10.3748/wjg.v20.i27.9026

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