

# Prior Authorization Criteria

#### REZDIFFRA™ (resmetirom) PA CRITERIA:

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 metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

Prior authorization is required for REZDIFFRA<sup>TM</sup> (*resmetirom*). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

### **Initial Authorization: 12 months**

- 1. Age of the patient is within the age range as recommended by the FDA label; AND
- 2. Patient has a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) that has been confirmed by clinical presentation along with laboratory findings and/or imaging and/or biopsy results; **AND**
- 3. Patient does NOT have decompensated cirrhosis; AND
- 4. Prescribed by or in consultation with a gastroenterologist or hepatologist; AND
- 5. Prescriber attests that REZDIFFRA ™ will be used in conjunction WITH diet and exercise and WITHOUT excessive alcohol consumption; **AND**
- 6. Prescribed dosage does NOT exceed one REZDIFFRA™ tablet by mouth once daily.

#### **Re-Authorization: 12 months**

- 1. Patient continues to meet initial authorization requirements; **AND**
- 2. Documentation of positive clinical response to therapy (e.g., improvement or stabilization of fibrosis); **AND**
- 3. Prescribed dosage does NOT exceed one REZDIFFRA TM tablet by mouth once daily.

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## **REZDIFFRATM Dosing:**

- The recommended dosage of REZDIFFRA™ is based on actual body weight. For patients weighing:
  - < 100 kilograms, the recommended dose is 80 mg orally once daily</li>
  - $\circ$   $\geq$  100 kilograms, the recommended dose is 100 mg orally once daily
- If REZDIFFRA<sup>TM</sup> is used concomitantly with a moderate CYP2C8 inhibitor, reduce the dosage as outlined below.
  - For actual body weight < 100 kilograms, reduce the dosage of REZDIFFRA™ to 60 mg orally once daily.
  - For actual body weight  $\geq$  100 kilograms, reduce the dosage of REZDIFFRA<sup>TM</sup> to 80 mg orally once daily.

#### Formulation:

• Available as 60 mg, 80 mg, and 100 mg oral tablets

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