

Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Resmetirom (Rezdiffra)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as 18 month treatment duration on maintenance dose
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **Resmetirom (Rezdiffra)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **Resmetirom (Rezdiffra)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Hepatology Provider
- Patient has a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH)
- Patient is 18 years or older
- Patient has fibrosis stage F2 or F3 as determined by transient elastography (FibroScan), ultrasound elastography, magnetic resonance elastography (MRE), or liver biopsy within one year
- Patient has at least one of the following:
 - Body mass index (BMI) < 27 kg/m²
 - Failed an adequate trial[^] of semaglutide or has an allergy or intolerance* to semaglutide
 - Unable to use semaglutide due to safety or personal reasons AND has failed adequate trial[^] of formal weight loss program
 - Disease refractory to weight loss of 7-10%
- Patient does not have any of the following:
 - Active hyperthyroidism
 - Untreated clinical hypothyroidism defined by TSH > 7 IU/L with symptoms or > 10 IU/L without symptoms
 - HbA1c ≥ 9%
 - Regular use of drugs associated with metabolic dysfunction-associated steatotic liver disease (MASLD)
 - ALT/AST > 5 times upper limit of normal (ULN) that is likely from other etiology of chronic liver disease
 - Significant alcohol consumption defined as ≥ 7 drinks per week for females and ≥ 14 drinks for males
 - Active, serious medical disease with a likely life expectancy <2 years

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- Currently pregnant or breastfeeding or planning to become pregnant

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **Resmetirom (Rezdiffra)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescribed by Hepatology Provider
- Patient has a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH)
- Patient is 18 years or older
- Patient has fibrosis stage F2 or F3 as determined by transient elastography (FibroScan), ultrasound elastography, magnetic resonance elastography (MRE), or liver biopsy within one year
- Patient has at least one of the following:
 - Body mass index (BMI) < 27 kg/m²
 - Failed an adequate trial[^] of semaglutide or has an allergy or intolerance* to semaglutide
 - Unable to use semaglutide due to safety or personal reasons AND has failed adequate trial[^] of formal weight loss program
 - Disease refractory to weight loss of 7-10%
- Patient does not have any of the following:
 - Active hyperthyroidism
 - Untreated clinical hypothyroidism defined by TSH > 7 IU/L with symptoms or > 10 IU/L without symptoms
 - HbA1c ≥ 9%
 - Moderate to severe hepatic impairment (Child-Pugh Class B or C)
 - Regular use of drugs associated with metabolic dysfunction-associated steatotic liver disease (MASLD)
 - ALT/AST > 5 times upper limit of normal (ULN) that is likely from other etiology of chronic liver disease
 - Significant alcohol consumption defined as ≥ 7 drinks per week for females and ≥ 14 drinks for males
 - Active, serious medical disease with a likely life expectancy <2 years
 - Currently pregnant or breastfeeding or planning to become pregnant

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Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **Resmetirom (Rezdiffra)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Hepatology Provider
- Patient does not have any of the following:
 - Fibrosis stage F4 or liver cirrhosis
 - Progression of liver disease (i.e. increased fibrosis stage from baseline)
 - HbA1c $\geq 9\%$
 - Regular use of drugs associated with metabolic dysfunction-associated steatotic liver disease (MASLD)
 - Non-adherence to medication, recommended diet and lifestyle measures, abstinence of alcohol or follow-up labs and assessments
 - Active, serious medical disease with a likely life expectancy < 2 years
 - Currently pregnant or breastfeeding or planning to become pregnant