Madrigal patient SUPPORT

Prior Authorization Checklist

A guide to completing prior authorizations (PAs) or renewals for Rezdiffra™ (resmetirom)

Your patient's insurer may require a prior authorization (PA) as part of a claim submission.

PAs can be submitted through CoverMyMeds (CMM) or directly to the patient's payer. PAs should be initiated with the insurer before the prescription is sent to the specialty pharmacy to ensure timely processing.

Be sure to review the insurer's website for PA guidelines, including forms and contacts, required clinical data and supporting documents, renewal criteria, deadlines, and the insurer's preferred submission method, such as electronic portal or fax.

INDICATION

Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

This indication is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: Avoid use in patients with decompensated cirrhosis.

Please see the Important Safety Information on the next page.

Rezdiffra™ resmetirom tablets

Please see the full Prescribing Information for Rezdiffra or visit MadrigalPharma.com/Rezdiffra-USPI.

Age, diagnosis, dosing

- ☐ Patient's age
- ☐ MASH, stage (F2 or F3), noncirrhotic state
- ☐ Date of initial diagnosis
- ☐ Rx details
- ☐ NDC

Chart notes

- ☐ Relevant health conditions or symptoms, including but not limited to metabolic risk factors such as diabetes; obesity; hypertriglyceridemia; hypertension, and medications used to treat these conditions
- ☐ Date and results of diagnostic and prognostic tests to assess fibrosis, including but not limited to imaging such as elastography and MRE, and blood tests such as FIB-4 and ELF. Note that ELF cannot be listed as the only non-invasive test (NIT).
- ☐ ICD-10-CM Code (K75.81, consistent with F2 or F3)

FOR PA RENEWALS ONLY

- ☐ Demonstration of clinical benefit, including lab results and/or imaging reports
  - Improvement or stabilization of fibrosis stage
  - Resolution or no worsening of steatohepatitis
  - Reduction in ALT levels
  - Imaging exhibiting a reduction in liver fat content
- ☐ Duration of therapy compliance
  - Proof of completion of at least one year of therapy with evidence of continued benefit

Conjoint prescription with diet and exercise

- ☐ Documentation of conjoint prescription with diet and exercise
- ☐ Include if patient follows or fails to follow a diet and exercise program
- ☐ Attestation of reduced or no alcohol consumption

FOR PA RENEWALS ONLY

- ☐ Lifestyle adherence
  - Proof of continued participation in a provider-supervised lifestyle, diet, or exercise program

Use of this checklist does not guarantee that the insurance company will provide coverage for Rezdiffra and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider.

Prescriber(s)

- ☐ Prescribing specialist (your name)
- ☐ Name of additional prescriber if the prescription is in conjunction with a specialist (e.g., gastroenterologist, hepatologist, or endocrinologist) or in consultation with a gastroenterologist or hepatologist

FOR PA RENEWALS ONLY

- ☐ Confirmation of ongoing management by a specialist

Explanation of medical necessity

FOR PA SUBMISSIONS AND RENEWALS

- ☐ Letter of Medical Necessity explaining why the patient's diagnosis, severity of condition, and impact of disease warrant treatment with Rezdiffra

Previous management of MASH if applicable

- ☐ Documentation of previous management if applicable

Rezdiffra Prescribing Information (PI)

- ☐ MadrigalPharma.com/Rezdiffra-USPI

Common reasons for PA denials

- Incorrect diagnostic code
- Off-label diagnosis or fibrosis stage (e.g., F0, F1, F4)
- Lack of documentation (e.g., fibrosis stage, lifestyle counseling)
- Insufficient information beyond the diagnostic code
- Lack of formulary coverage/plan exclusion

If the PA is denied, our team can help support your office through the appeals process.

Questions? We are here to help.

1-877-219-7770, Monday – Friday, 8 AM – 8 PM ET
MadrigalPatientSupport.com

Madrigal patient SUPPORT

Your support team for every step

Remember you can get ongoing support from our dedicated Case Managers and Access Reimbursement Managers (ARMs).

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INDICATION AND IMPORTANT SAFETY INFORMATION

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WARNINGS AND PRECAUTIONS

Hepatotoxicity

Hepatotoxicity has been observed with the use of Rezdiffra. One patient developed substantial elevations of liver biochemistries that resolved when treatment was interrupted. *Please see full Prescribing Information for more details on this specific case of Hepatotoxicity [see Warnings and Precautions (5.1)].*

Monitor for elevations in liver tests, liver-related adverse reactions, and symptoms/signs of hepatotoxicity (eg, fatigue, nausea, vomiting, right upper quadrant pain or tenderness, jaundice, fever, rash, and/or eosinophilia [>5%]). If hepatotoxicity is suspected, discontinue Rezdiffra and monitor. If laboratory values return to baseline, weigh the potential risks against the benefits of restarting Rezdiffra. If laboratory values do not return to baseline, consider drug-induced autoimmune-like hepatitis (DI-ALH) or autoimmune liver disease in the evaluation of elevations in liver tests.

Gallbladder-Related Adverse Reactions

Cholelithiasis, acute cholecystitis, and obstructive pancreatitis (gallstone) were observed more often in Rezdiffra-treated patients than in placebo-treated patients. The exposure-adjusted incidence rates (EAIRs) for these events were less than 1 per 100 person-years (PY) for all treatment arms. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated. If an acute gallbladder event is suspected, interrupt treatment until the event is resolved.

Drug Interaction with Certain Statins

An increase in exposure of atorvastatin, pravastatin, rosuvastatin and simvastatin was observed when concomitantly administered with Rezdiffra, which may increase the risk of adverse reactions related to these drugs.

Dosage adjustment for certain statins is recommended. Monitor for statin-related adverse reactions including, but not limited to, elevation of liver tests, myopathy, and rhabdomyolysis. *Please see the upcoming* Drug Interactions *section of the Important Safety Information for more details.*

ADVERSE REACTIONS

The most common adverse reactions with Rezdiffra (reported in ≥ 5% of patients and higher compared to placebo) are diarrhea, nausea, pruritus, vomiting, constipation, abdominal pain, and dizziness. Diarrhea and nausea were the most common causes of treatment discontinuation.

DRUG INTERACTIONS

Clinically Significant Interactions Affecting Rezdiffra

- Concomitant use with strong CYP2C8 inhibitors (eg, gemfibrozil) is not recommended. Reduce dosage if used concomitantly with a moderate CYP2C8 inhibitor (eg, clopidogrel).
- Concomitant use with OATP1B1 or OATP1B3 inhibitors (eg, cyclosporine) is not recommended.

Clinically Significant Interactions Affecting Other Drugs

- **Statins:** Limit daily rosuvastatin and simvastatin dosage to 20 mg. Limit pravastatin and atorvastatin dosage to 40 mg.
- **CYP2C8 Substrates:** Monitor patients more frequently for substrate-related adverse reactions if Rezdiffra is co-administered with CYP2C8 substrates where minimal concentration changes may lead to serious adverse reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on Rezdiffra use in pregnant women. Report pregnancies to Madrigal Pharmaceuticals, Inc.'s Adverse Event reporting line at 1-800-905-0324 and https://www.madrigalpharma.com/contact/.

Lactation

There is no information regarding the presence of Rezdiffra in human or animal milk, the effects on the breast-fed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Rezdiffra and any potential adverse effects on the breastfed infant from Rezdiffra or from the underlying maternal condition.

Geriatric Use

Numerically higher incidence of adverse reactions have been observed in patients ≥65 years of age compared to younger adult patients.

Renal Impairment

Rezdiffra has not been studied in patients with severe renal impairment.

Hepatic Impairment

Avoid use in patients with decompensated cirrhosis (consistent with moderate to severe hepatic impairment). Moderate or severe hepatic impairment (Child-Pugh Class B or C) may increase the risk of adverse reactions.

The safety and effectiveness have not been established in patients with cirrhosis.

Please see the full Prescribing Information for Rezdiffra or visit MadrigalPharma.com/Rezdiffra-USPI.

Rezdiffra™ resmetirom tablets
60 mg · 80 mg · 100 mg

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