Drug Coverage Policy

Effective Date……6/15/2025
Coverage Policy Number……IP0642
Policy Title……Rezdiffra

Hepatology – Rezdiffra

- Rezdiffra™ (resmetirom tablets - Madrigal Pharmaceuticals)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Rezdiffra, a thyroid hormone receptor-beta (THR-β) agonist, is indicated in combination with diet and exercise for the treatment of **non-cirrhotic non-alcoholic steatohepatitis (NASH)** with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.[1]
Limitations of Use: Avoid use in patients with decompensated cirrhosis.

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 trial.[1]

Disease Overview

Metabolic dysfunction-associated steatotic liver disease (MASLD) is the most common liver disease in the US.[11] MASLD is defined as the presence of hepatic steatosis with at least one cardiometabolic risk (i.e., obesity, prediabetes/diabetes, hypertension, elevated triglycerides, and/or low high-density lipoprotein cholesterol) in the absence of other identifiable causes of liver disease or hepatic steatosis. Metabolic dysfunction-associated steatohepatitis (MASH), a subtype of MASLD, is the progressive form of the disease. Previously, these conditions were known as non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), respectively, until the terminology was updated in 2023. MASH is characterized by the presence of ≥ 5% hepatic steatosis with hepatocellular damage and inflammation in the absence of a readily identified alternative cause of steatosis (e.g., medications, starvation, monogenic disorders) in individuals who drink little or no alcohol (defined as < 20 g/day for women and < 30 g/day for men).[2] Once MASH progresses to clinically meaningful fibrosis (stages F2 and F3), the risk of adverse clinical outcomes increases. In the US, it is estimated that more than one-third of adults have MASLD[11]; 1.5% to 6.5% of adults have MASH.[3] The estimated prevalence of high-risk MASH (defined as non-alcoholic fatty liver disease activity score [NAS] ≥ 4 and fibrosis stage ≥ 2 [F2]) in the US is 5.8%. The risk of MASH is two- to three-fold higher in individuals with obesity (25% to 30%) and/or type 2 diabetes (30% to 40%).[4] In the US, MASH is among the top causes of hepatocellular carcinoma and the second most common indication for liver transplantation after hepatitis C.

Clinical Efficacy

The efficacy of Rezdiffra was evaluated in one ongoing, Phase III, randomized, double-blind, placebo-controlled, multicenter, pivotal study in adults with biopsy-confirmed NASH (MAESTRO-NASH) with fibrosis (F1B, F2, or F3) [n = 966].[5] The dual primary endpoints at Week 52 were 1) NASH resolution (achievement of a hepatocellular ballooning score = 0, inflammation score = 0 or 1, and ≥ 2 point reduction in non-alcoholic fatty liver disease activity score [NAS]) with no worsening of fibrosis, and 2) ≥ 1 stage improvement in fibrosis with no worsening of NAS. The key secondary endpoint was the percent reduction in low-density lipoprotein cholesterol (LDL-C) at Week 24. Patients who reached the Week 52 analysis were eligible to continue to the open-label extension with a primary endpoint of a composite of all-cause mortality, liver transplant, and significant hepatic events (including hepatic decompensation events [ascites, encephalopathy, or variceal hemorrhage], histological progression to cirrhosis, and a confirmed increase of modified end-stage liver disease [MELD] score from < 12 to ≥ 15). Eligible patients were ≥ 18 years of age, had at least three of five metabolic risk factors according to the International Diabetes Foundation criteria for metabolic syndrome[9] (central obesity, elevated triglycerides [≥ 150 mg/dL], reduced high-density lipoprotein cholesterol [< 50 mg/dL in females or < 40 mg/dL in males], elevated blood pressure [≥ 130/85 mmHg], elevated fasting plasma glucose [≥ 100 mg/dL]), and had undergone prescreening vibration-controlled transient elastography (VCTE; FibroScan) within the past 3 months that showed a controlled attenuation parameter of ≥ 280 dB/meter and a liver stiffness measurement of ≥ 8.5 kPa (alternately, a liver biopsy that was performed within 6 months before randomization could be confirmed to be eligible as a baseline biopsy by the central pathologist of the trial). Additional key inclusion criteria were histologic evidence of NASH and an NAS of ≥ 4 (on a scale of 0 to 8 with higher scores indicating more severe disease), with a score of ≥ 1 for each component (steatosis [on a scale of 0 to 3], lobular inflammation [on a scale from 0 to 3], and hepatocellular ballooning [on a scale from 0 to 2]). Key exclusion criteria were alcohol consumption of > 20 g/day for women and > 30 g/day for men for a period of ≥ 3 consecutive months within 1 year of screening and causes of chronic liver disease other than non-cirrhotic NASH.

The mean age was 57 years, the mean body mass index was 35.7 kg/m^2, 67% of patients had type 2 diabetes, 78% of patients had hypertension, and 71% of patients had dyslipidemia (approximately 50% of patients were taking a statin).[5] Glucagon-like receptor-1 agonist use was reported in approximately 15% of patients. Most patients had a fibrosis stage of F3 (62%), 33% of patients had F2, and 5% of patients had F1B. All patients underwent lifestyle modification consisting of diet and exercise.

At Week 52, NASH resolution associated with a ≥ 2 point reduction in NAS without worsening of fibrosis stage was reported for 29.9% and 25.9% of patients in the Rezdiffra 100 mg and 80 mg groups, respectively vs. 9.7% of patients in the placebo group (P < 0.0001 for Rezdiffra doses vs. placebo).[5] The proportion of patients with ≥ 1 stage fibrosis improvement with no worsening in NAS at Week 52 was 25.9% and 24.2% for Rezdiffra 100 mg and 80 mg, respectively vs. 14.2% for placebo (P < 0.0001 for Rezdiffra doses vs. placebo). At Week 24, LDL-C was reduced by -16.3% and -13.6% with Rezdiffra 100 mg and 80 mg, respectively, vs. +0.7% with placebo (P = 0.0001 Rezdiffra doses vs. placebo) [key secondary endpoint]. Fewer patients treated with Rezdiffra vs. placebo with F1B or F2 at baseline progressed to ≥ F3 (18% to 19% vs. 34%, respectively) and more patients treated with Rezdiffra vs. placebo with F1B or F2 at baseline had an improved fibrosis stage (31% to 33% vs. 15%, respectively). A similar proportion of patients treated with Rezdiffra and placebo with F1B or F2 at baseline had no change (stable) in fibrosis stage at Week 52 (48% to 51% vs. 51%, respectively).

Guidelines

An update to the American Association for the Study of Liver Diseases (AASLD) Practice Guidance on the Clinical Management of NAFLD was published in October 2024 to address the approval of Rezdiffra.[10] It is recognized that although MASH can only be definitively diagnosed by histologic exam (biopsy), in practice, patient selection is based on evidence of steatosis and fibrosis as determined by non-invasive liver disease assessments (NILDAs) in patients with cardiometabolic risk factors without other causes of steatosis, notably, alcohol consumption of > 20 g/day for women and > 30 g/day in men. There are no FDA-approved NILDAs to diagnose MASH with stage F2 to F3 fibrosis or to monitor the response to pharmacotherapy. In general imaging-based NILDAs such as liver stiffness measurement (LSM) by VCTE or magnetic resonance elastography (MRE) have better accuracy in assessing fibrosis vs. blood-based tests. In general, magnetic resonance spectroscopy and magnetic resonance imaging proton fat density fat fraction (MRI-PDFF) are considered the most accurate quantitative measures of hepatic steatosis, followed by VCTE-controlled attenuation parameter score and gray scale ultrasound. However, for the purpose of selecting patients for treatment with Rezdiffra, non-quantitative imaging evidence of hepatic steatosis (e.g., ultrasonographic evidence) in individuals with at least one cardiometabolic risk factor and F2 or F3 fibrosis may be sufficient. Liver biopsy is not typically recommended for fibrosis staging in current clinical practice; however, histologic exam remains the gold standard to quantify fibrosis if performed previously (historical biopsy obtained reasonably recently, e.g., within 3 years). Since NILDAs are more readily available than liver biopsy, it is recommended that more current data (e.g., within 6 to 12 months) be utilized to determine patients who are appropriate candidates for treatment with Rezdiffra. Regardless of treatment, the management of MASLD should include comprehensive lifestyle modification (e.g., nutrition, exercise, and behavior modification) and optimal control of comorbid metabolic conditions. Further, given the comorbidity profile of individuals with MASLD, cardiovascular risk management is an important aspect of medical management.

When selecting appropriate patients for treatment, Rezdiffra can be considered in adults with MASH and moderate to advanced liver fibrosis (consistent with F2 or F3 fibrosis).[10] The diagnosis should be assessed by one of the following: 1) NILDA, preferably imaging-based test results, consistent with MASH with stage F2 or F3 fibrosis; or 2) Historical liver biopsy demonstrating MASH with stage F2 or F3 fibrosis (and without evidence of concomitant, histologically active autoimmune liver

disease). Rezdiffra is not recommended in patients with the following: compensated or decompensated cirrhosis, concomitant uncontrolled active liver diseases (e.g., autoimmune hepatitis, primary biliary cholangitis), or alcohol consumption > 20 grams/day (women) or > 30 grams/day (men), or symptomatic gallstone-related conditions (e.g., acute cholecystitis). While some values for NILDAs (VCTE and MRE) are cited within the update, for choosing patients appropriate for treatment with Rezdiffra, they are not completely aligned with the MAESTRO-NASH trials, and the AASLD notes that clinicians may consider expanded non-invasive criteria in making treatment decisions.

The updated guidance also addresses efficacy and futility of Rezdiffra treatment based on the Week 52 data with Rezdiffra from MAESTRO-NASH.[10] However, it is recognized that these recommendations may change when longer-term data before available. The decision to continue treatment beyond 12 months should be based on evidence of improvement, worsening, or treatment failure, or disease stabilization. Although the guidance provides recommendations for continuing/re-evaluating treatment with Rezdiffra based on LSM values for VCTE or MRE, reliable evidence to correlate LSM data with histologic changes in liver fibrosis is lacking. Continuation of Rezdiffra in patients with significant fibrosis improvement is recommended. In patients with evidence of worsening of liver disease at Month 12, discontinuation of Rezdiffra should be considered. Worsening liver disease can be identified by clinical data suggestive of worsening liver disease including consistent increase in alanine aminotransferase or fibrosis progression as assessed by NILDA. In patients without clear evidence of liver disease improvement or worsening, the decision to continue therapy (pending longer-term data) should be based on holistic patient assessment considering baseline fibrosis status and potential benefit of slowing or stabilizing liver fibrosis even if no regression is noted; individual comorbidity profile associated with progressive liver disease; concomitant therapy including adherence and response to lifestyle interventions; changes in liver biochemical and NILDA parameters; and adverse effects (if any) during treatment with Rezdiffra.

Other available guidelines do not address Rezdiffra. The AASLD (2023), American Association of Clinical Endocrinology (2022), and American Gastroenterological Association (AGA) [2021] provide guidelines and/or guidance on the overall management of NAFLD and NASH.[4,6,7] The goal of liver-directed treatment is to reverse steatohepatitis and fibrosis, or to at least halt the progression of fibrosis.[7] Importantly, the presence of steatosis serves largely as a biomarker or risk factor of steatohepatitis with fibrosis; however, the presence of steatosis does not necessarily imply severe disease. In general, in patients with NASH with ≥ F2 fibrosis, agents approved for other indications that have shown benefit for NASH in clinical trials should be considered under specific circumstances (e.g., diabetes, obesity).[4,6,7] A healthy diet and regular exercise are the foundation of treatment. Weight loss of ≥ 10% is generally required to improve NASH fibrosis. Management of comorbid conditions (e.g., cardiovascular disease, obesity, diabetes) should be done in-line with the standard of care and encourage use of agents that have shown benefit in NASH (e.g., liraglutide, semaglutide, pioglitazone, vitamin E).

According to the AASLD, targeted screening of populations at increased risk for advanced liver disease is advised to identify and manage those with clinically significant fibrosis (stage ≥ F2).[2] The primary goal in the specialty care setting (gastroenterology, hepatology) is the identification of patients with "at-risk" NASH or advanced fibrosis. Such patients require further assessment and may benefit from targeted interventions. The AGA recommends that at-risk patients be screened for alcohol use and have liver tests as well as a complete blood count as part of the initial screening process.[7] Results from standard laboratory tests can allow calculation of simple fibrosis scores using non-invasive tests for fibrosis (e.g., Fibrosis-4 [FIB-4] or NAS). Patients with a FIB-4 of ≥ 1.3 to ≤ 2.67 are considered to be at indeterminate risk and should undergo an LSM, ultrasound is acceptable if VCTE (Fibroscan) is unavailable. Other methods such as bidimensional shear wave elastography or point shear wave elastography can also be used to measure LSM. If the LSM by VCTE is ≥ 8 kPa

to ≤ 12 kPa, patients are considered to be at indeterminate risk, and referral to a hepatologist for liver biopsy or MRE or monitoring with re-evaluation in 2 to 3 years is recommended. Of note, an LSM of ≥ 8.0 equates to clinically significant fibrosis (≥ F2); an LSM < 8.0 is considered low risk for clinically significant fibrosis and can be managed with repeat surveillance testing in 2 to 3 years. Patients with a FIB-4 > 2.67 are considered high risk and should be referred to a hepatologist. Additionally, patients with a LSM > 12 kPa or a liver biopsy showing F2 to F4 fibrosis are also considered high risk.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for prescription benefit coverage of Rezdiffra. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a male, regardless of the individual's gender identity or gender expression; females are defined as individuals with the biological traits of a female, regardless of the individual's gender identity or gender expression. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rezdiffra as well as the monitoring required for adverse events and long-term efficacy, approval requires Rezdiffra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required for use of Rezdiffra as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information.

Rezdiffra is considered medically necessary when the following is met:

FDA-Approved Indication

1. **Metabolic-Dysfunction Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH), with Moderate to Advanced Liver Fibrosis.** Approve for 1 year if the patient meets the ONE of the following (A or B):
   - **A)** Initial Therapy: Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Prior to treatment with Rezdiffra, the diagnosis of MASH/NASH is confirmed by ONE of the following (a or b):
       - **a)** Patient has had a liver biopsy AND meets BOTH of the following [(1) and (2)]:
         - **(1)** Liver biopsy has been performed within the 3 years preceding treatment with Rezdiffra **[documentation required]**; AND
         - **(2)** Liver biopsy shows non-alcoholic fatty liver disease activity score of ≥ 4 with a score of ≥ 1 in ALL of the following ([i], [ii], and [iii]) **[documentation required]**:
           - **(i)** Steatosis; AND
           - **(ii)** Ballooning; AND
           - **(iii)** Lobular inflammation; OR
       - **b)** Patient has had ONE of the following imaging exams performed within the 6 months preceding treatment with Rezdiffra [(1), (2), or (3)] **[documentation required]**:
         - **(1)** Elastography; OR

Note: Examples of elastography include, but are not imputed to vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography.

(2) Computed tomography; OR

(3) Magnetic resonance imaging; OR

iii. Patient meets ONE of the following prior to treatment with Rezdiffra (a or b) **[documentation required]**:

a) Patient has stage F2 fibrosis; OR

b) Patient has stage F3 fibrosis; AND

iv. According to the prescriber, the patient has THREE or more of the following metabolic risk factors that are managed according to standard of care (a, b, c, d, e):

a) Central obesity;

b) Hypertriglyceridemia;

c) Reduced high-density lipoprotein cholesterol;

d) Hypertension;

e) Elevated fasting plasma glucose indicative of diabetes or pre-diabetes; AND

v. According to the prescriber, patient meets ONE of the following (a or b):

a) Female* patient: Alcohol consumption is < 20 grams/day; OR
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.

b) Male* patient: Alcohol consumption < 30 grams/day; AND
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.

vi. The medication will be used in combination with appropriate diet and exercise therapy; AND

vii. The medication is prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist.

B) Patient is Currently Receiving Rezdiffra: Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
Note: A patient who has received < 1 year of therapy or who is restarting therapy should be considered under criterion A (Initial Therapy).

i. Patient has completed ≥ 1 year of therapy with Rezdiffra AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH; AND
Note: This applies to a patient starting their second (or more) year of therapy with Rezdiffra (i.e., the patient has already completed 1 year or more of therapy with Rezdiffra).

ii. According to the prescriber, patient has not progressed to stage F4 (cirrhosis); AND

iii. According to the prescriber, metabolic risk factors are managed according to standard of care; AND

iv. According to the prescriber, patient meets ONE of the following (a or b):

a) Female* patient: Alcohol consumption is < 20 grams/day; OR
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.

b) Male* patient: Alcohol consumption < 30 grams/day; AND
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.

v. The medication will be used in in combination with to appropriate diet and exercise therapy; AND

vi. The medication is prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist.

*Refer to the Policy Statement

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Rezdiffra for any other use is considered not medically necessary , including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Metabolic-Dysfunction Associated Steatotic Liver Disease (MASLD)/Non-Alcoholic Fatty Liver Disease (NAFLD).** Resmetirom is indicated in patients with non-cirrhotic NASH with moderate to advanced liver fibrosis.[1] NAFLD and NASH include the presence of steatosis; however, NASH additionally involves inflammation and injury to liver cells.[2]

2. **Metabolic-Dysfunction Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH) with Cirrhosis.** Resmetirom is indicated in patients with non-cirrhotic NASH with moderate to advanced liver fibrosis.[1] The safety and effectiveness of Rezdiffra have not been established in patients with NASH cirrhosis. MEASTRO-NASH-OUTCOMES is an ongoing trial to assess the efficacy of Rezdiffra in adults with NASH with well-compensated cirrhosis (Child-Pugh A) [n = 700].[8] Results are anticipated in 2025.

References

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9. International diabetes foundation. The IDF consensus worldwide definition of the metabolic syndrome. Available at: https://idf.org/media/uploads/2023/05/attachments-30.pdf. Accessed on: March 20, 2024.
10. Chen VL, Morgan TR, Rotman Y, et al. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. *Hepatology.* 2025;81(1):312-320.
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Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	08/15/2024
Selected Revision	For Metabolic-Dysfunction Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH), with Moderate to Advanced Liver Fibrosis, for Initial Therapy, the timeframe requirement for a patient with a liver biopsy was changed to be within the 3 years preceding treatment with Rezdiffra, previously within the past 6 months preceding treatment with Rezdiffra. For a Patient Currently Receiving Rezdiffra, the criteria that the patient has completed ≥ 1 year and < 2 years of therapy with Rezdiffra and has derived benefit from treatment with Rezdiffra as demonstrated by one of the following, according to the prescriber: 1) MASH/NASH resolution AND no worsening of fibrosis; OR No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage, was removed. A patient who has completed ≥ 1 year of therapy with Rezdiffra is now reviewed under the same criterion that was previously applied for a patient who has completed ≥ 2 years of therapy. As revised, a patient who has completed ≥ 1 year of therapy with Rezdiffra AND according to the prescriber has not had worsening of fibrosis or MASH/NASH may be approved if other criteria are met.	3/15/2025
Annual Revision	**Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH), with Moderate to Advanced Liver Fibrosis.**	6/15/2025

	Initial Therapy. The criterion that the liver biopsy shows non-alcoholic fatty liver disease activity score of ≥ 4 with a score of > 1 in ALL of the following [documentation required]: Steatosis, ballooning, and lobular inflammation; was modified such that a score of ≥ 1 is required in ALL of the following [documentation required]: Steatosis, ballooning, and lobular inflammation. The timeframe within the criterion for an imaging exam was changed from within the 3 months preceding treatment with Rezdiffra to within the 6 months preceding treatment with Rezdiffra.	

The policy effective date is in force until updated or retired.