

Federal Employee Program.

REZDIFFRA (resmetirom)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Rezdiffra (resmetirom) is a partial agonist of the thyroid hormone receptor-beta (THR- β) which is the major form of THR in the liver. Stimulation of THR- β in the liver reduces intrahepatic triglycerides (1).

Regulatory Status

FDA-approved indication: Rezdiffra is a thyroid hormone receptor-beta (THR-β) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) (1).

Limitations of Use: Avoid use of Rezdiffra in patients with decompensated cirrhosis (1).

Rezdiffra may cause hepatotoxicity and gallbladder-related adverse reactions. Patients should be monitored for elevations in liver tests and for the development of liver-related adverse reactions. If hepatotoxicity is suspected, Rezdiffra should be discontinued and the patient should be monitored. Gallbladder diagnostic studies and appropriate clinical follow-up is indicated if cholelithiasis is suspected. If an acute gallbladder event is suspected, interrupt Rezdiffra treatment until the event is resolved (1).

The safety and effectiveness of Rezdiffra in pediatric patients less than 18 years of age have not been established (1).

Summary

Rezdiffra is a thyroid hormone receptor-beta agonist indicated for the treatment of noncirrhotic nonalcoholic steatohepatitis with moderate to advanced liver fibrosis. Rezdiffra may cause hepatotoxicity and gallbladder-related adverse reactions. The safety and effectiveness of Rezdiffra in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rezdiffra while maintaining optimal therapeutic outcomes.



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References

1. Rezdiffra [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; March 2024.