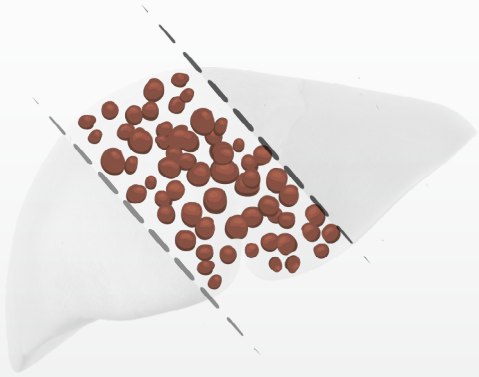
Treatment of MASH

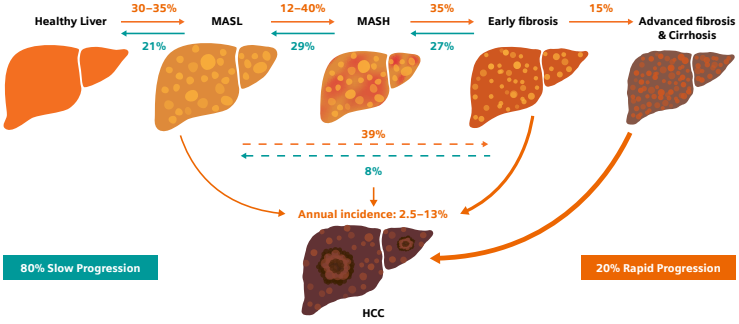
Importance and utility of the Enhanced Liver Fibrosis (ELF) test



The Enhanced Liver Fibrosis (ELF) test is the only non-invasive blood test measuring direct markers of fibrosis included in the prescribing information for the first FDA approved MASH therapy Rezdiffra (resmetirom)*

Background

Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) is formerly known as non-alcoholic fatty liver disease (NAFLD). MASLD is estimated to affect approximately 30 percent of the global population[1] and comprises different conditions, including metabolic dysfunction-associated steatohepatitis (MASH).[2]



Adapted from Lekakis V, Papatheodoridis GV. Natural history of metabolic dysfunction-associated steatotic liver disease.[2]

MASH is a more serious condition that can lead to cirrhosis and liver cancer but until recently there was no FDA-approved therapy to treat this condition.

Characteristic		Overall n=888
Fibrosis stage, n (%)	F2	328 (37)
	F3	560 (63)
Type 2 Diabetes, n (%)		608 (68)
Hypertension, n (%)		700 (79)
Dyslipidemia, n (%)		633 (71)
Statin use, n (%)		434 (49)
Thyroxine use, n (%)		124 (14)
Vibration-controlled Transient Elastography (VCTE) (kPa), Median (Q1, Q3)[a,b]		12 (10, 15)
Controlled attenuation parameter (CAP) (Db/M), Median (Q1, Q3)[a]		349 (320, 378)
Fibrosis Index Based on 4 Factors (FIB-4), Median (Q1, Q3)[a]		1.3 (1, 1.8)
Enhanced Liver Fibrosis (ELF), Median (Q1, Q3)[a]		**9.7 (9.2, 10.4)**

a Less than 5% missingness in these variables is omitted.
b kPa = kilopascal; Db/M = decibels per meter.

Table extracted from Rezdiffra's prescribing information shows baseline characteristics and ELF median value in patients with noncirrhotic NASH with stage 2 to stage 3 fibrosis included in the MAESTRO-NASH trial (NCT03900429).

Rezdiffra (resmetirom) the first FDA-approved therapy for NASH

In one of 2024's most anticipated decisions, and following the successful outcomes of the Phase 3 MAESTRO-NASH trial, the FDA has approved Madrigal Pharmaceuticals' Rezdiffra (resmetirom) the first-ever therapy for NASH (non-alcoholic steatohepatitis),[3] now known as metabolic dysfunction-associated steatohepatitis (MASH).

**For the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis (i.e. stages F2 to F3 fibrosis) and is to be administered in conjunction with diet and exercise.[4]*

Only for distribution in United States.

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AID IN THERAPY ASSESSMENT

NITs (Non-Invasive Tests) that are **easily accessible** and **widely available**, such as ELF, will likely **drive adoption and use of new medication such as resmetirom**. Along with clinical assessments, the ELF test may aid in stratification based on risk levels for patients who would benefit from specific pharmaceutical therapy such as resmetirom. It could also inform treatment decisions, such as more aggressive lifestyle modification or therapies.

About MASLD, MASH and Rezdiffra (Resmetirom)

- Formerly known as non-alcoholic fatty liver disease (NAFLD) MASLD is estimated to affect approximately 30 percent of the global population. It is the most common cause of chronic liver diseases and the second most common indication for all liver transplants in United States.[1]
- Despite its prevalence, MASLD is a silent and largely undiagnosed condition.[5]
- Multiple studies have indicated the central role of fibrosis as the causative factor for disease progression.[6]
- The drug is now approved for use in the United States (under the brand name, Rezdiffra) since March 2024 and is currently under regulatory review in the EU for the treatment of MASH/ NASH. Therefore, availability is still pending EMA authorization.
- Madrigal Pharmaceuticals included the ELF test in five studies with resmetirom 80 mg (three studies) and with resmetirom 100 mg (two studies). Changes from baseline in the ELF test were compared to placebo treatment and were similar with both doses of resmetirom and the ELF test helped provide a comprehensive assessment of liver health.[7]

About the ELF Test

The ELF test is a blood test that includes three direct markers of liver fibrosis: hyaluronic acid (HA), amino-terminal propeptide of type III procollagen (PIIINP) and tissue inhibitor of metalloproteinase 1 (TIMP-1). In the United States, ELF is indicated to aid prognostic evaluation of disease progression (to cirrhosis and liver-related clinical events) in NASH (MASH) patients with advanced liver fibrosis.

References

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Talk to your Siemens Healthineers representative to learn more about the ELF test and don't miss the opportunity to demonstrate the vital role and value of your clinical laboratory in MASLD patient management. Also discover the complete menu of solutions and tests that our company offers to manage chronic liver diseases.

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