Navigating MASLD: Clinical Updates for Frontline Providers

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Disclosure

Advisory Board: Madrigal

Consultant: Alpha Insights; Antheneum Partners; Gerson Lehrman Group; Slingshot Insights

Research Grant: Akero; Madrigal; W.L. Gore & Associates

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When You Identify Hepatic Steatosis in a Patient with Metabolic Risk Factors, What Is Your *Usual Next Step?*

A. Reassure if ALT/AST are normal
B. Order ultrasound and follow clinically
C. Calculate FIB-4
D. Refer directly to GI/hepatology
E. Screen for viral hepatitis

What Should You Usually Emphasize to Patients with MASLD as Their *Greatest Long-term Health Risk*?

A. Progression to cirrhosis
B. Hepatocellular carcinoma
C. Liver Transplantation
D. Cardiovascular disease
E. Diabetes mellitus

Which Patient with MASLD Should Be Referred to GI/Hepatology for *Consideration of Liver-directed MASH Therapy*?

A. Steatosis on imaging with normal labs
B. Low-risk FIB-4 (score <1.3)
C. Compensated cirrhosis
D. Confirmed stage 2 or 3 (F2-F3) fibrosis
E. Decompensated cirrhosis

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Describe the diagnosis, staging, and natural history of MASLD/MASH

Understand treatment goals and potential therapeutic modalities in MASLD/MASH

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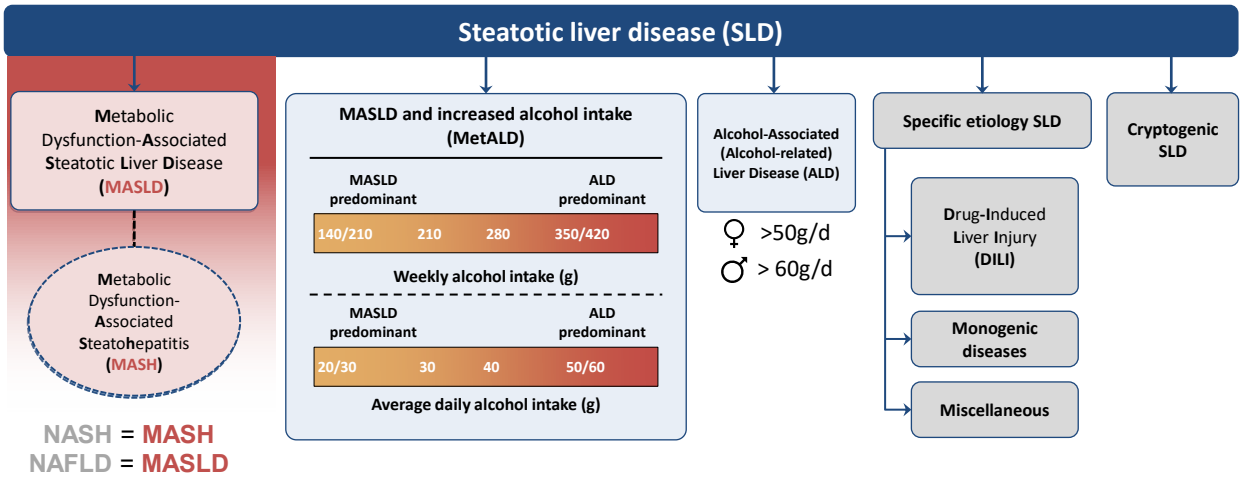
New Nomenclature: Steatotic Liver Disease and Beyond



Rinella ME et al. *Hepatology.* 2023;78:1966-1986.

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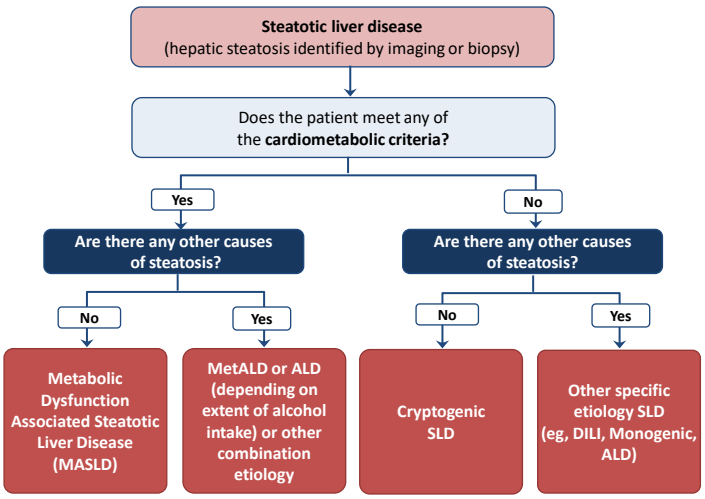
Categorizing Steatotic Liver Disease



Adult cardiometabolic criteria

At least 1 out of 5:

- ❑ BMI ≥25 kg/m^2 [23 Asia] **WC>94 cm (M) / >80 cm (F) OR** ethnicity-adjusted equivalent
- ❑ Fasting serum glucose ≥ 5.6 mmol/L (100 mg/dL) **OR** 2-hour post-load glucose levels ≥ 7.8 mmol/L (≥140 mg/dL) **OR** HbA1c ≥5.7% (39 mmol/L) **OR** type 2 diabetes **OR** treatment for T2DM
- ❑ Blood pressure ≥130/85 mmHg **OR** specific antihypertensive drug treatment
- ❑ Plasma triglycerides ≥1.70 mmol/L (150 mg/dL) **OR** lipid lowering treatment
- ❑ Plasma HDL-cholesterol ≤1.0 mmol/L (40 mg/dL) (M) and ≤1.3 mmol/L (50 mg/dL) (F) **OR** lipid lowering treatment

ALD, alcohol-related liver disease; BMI, body mass index; DILI, drug-induced liver injury; SLD, steatotic liver disease; T2DM, type 2 diabetes mellitus; WC, waist circumference.
Rinella ME et al. *Hepatology.* 2023;78:1966-1986.

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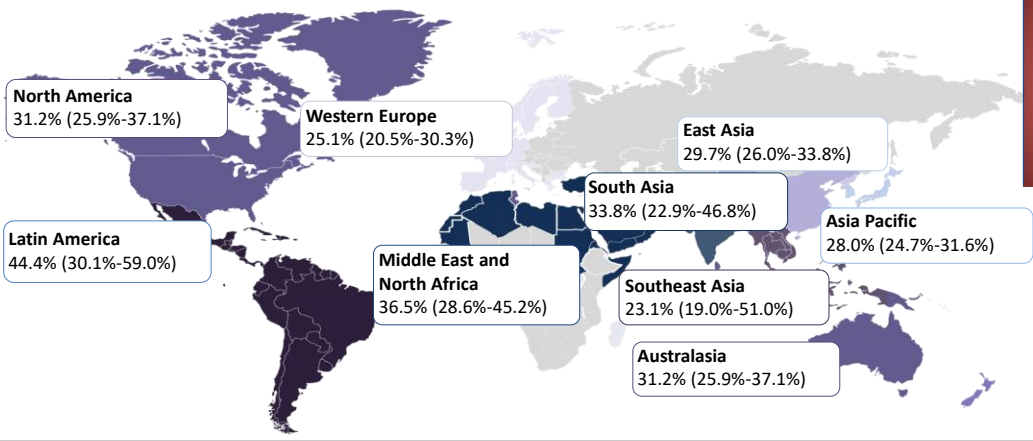
MASLD Is a Crisis in the US and Worldwide

Prevalence (95% CI) of MASLD by global regions data, 1990-2019



30.0%
(27.8-32.3%)
POOLED PREVALENCE OF MASLD

Younossi Z et al. *Hepatology*. 2023;77:1335-1347.

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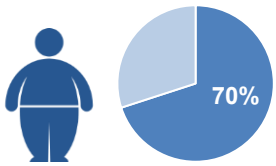
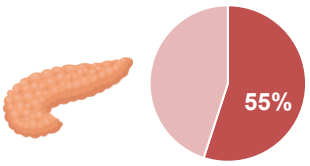
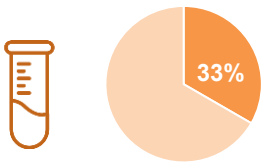
MASLD Prevalence in General Practice



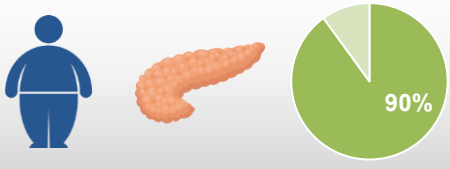
Obesity



DM2



Abnl ALT



Obesity + DM2

Obesity + DM2 + Abnl ALT

Younossi et al, Hepatology, 2019
Nabi et al, Gastroenterology, 2020
Noureddin et al, Hepatol Commun, 2022
Quek et al, Lancet Gastro Hep, 2023

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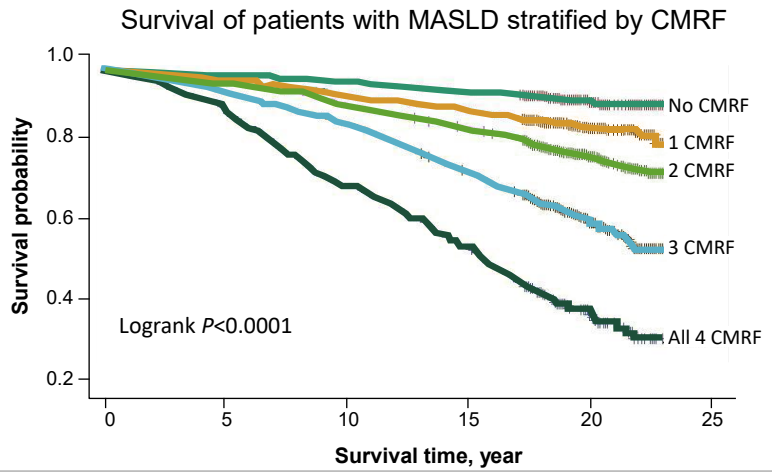
Clinical Predictors of Outcomes in MASLD: Impact of Cardiometabolic Risk



Increasing number of cardiometabolic risk factors (CMRF) are associated with mortality

Golabi P et al. *Medicine.* 2018;97(13):e0214.

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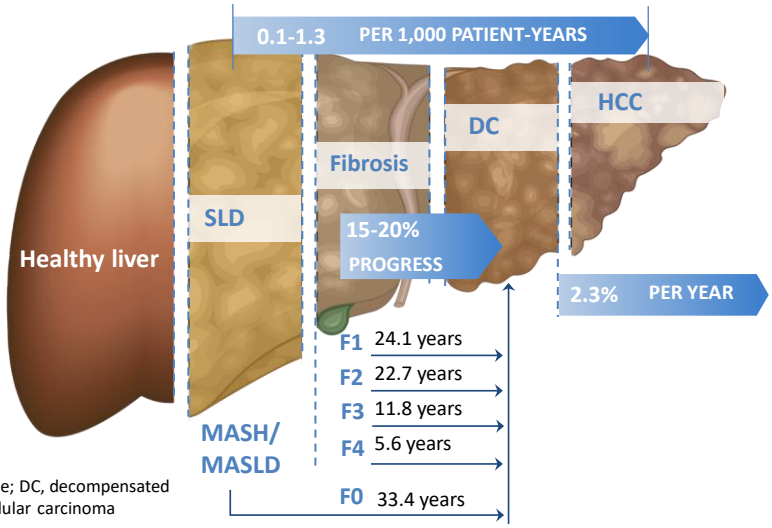
Natural History of MASLD and MASH



SLD, steatotic liver disease; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma

1. Younossi Z et al. *EMJ Hepatol*. 2022; 2. Sayiner M et al. *Clin Liver Dis*. 2016;20(2):205-214; 3. Younossi ZM et al. *Hepatology*. 2016; 64(5):1577-1586; 4. Lequoy M et al. *Horm Mol Biol Clin Investig*. 2020;29;41(1); 5. Younossi Z et al. *Hepatology*. 2018; 6. Younossi Z J. *Hepatology*. 2019.

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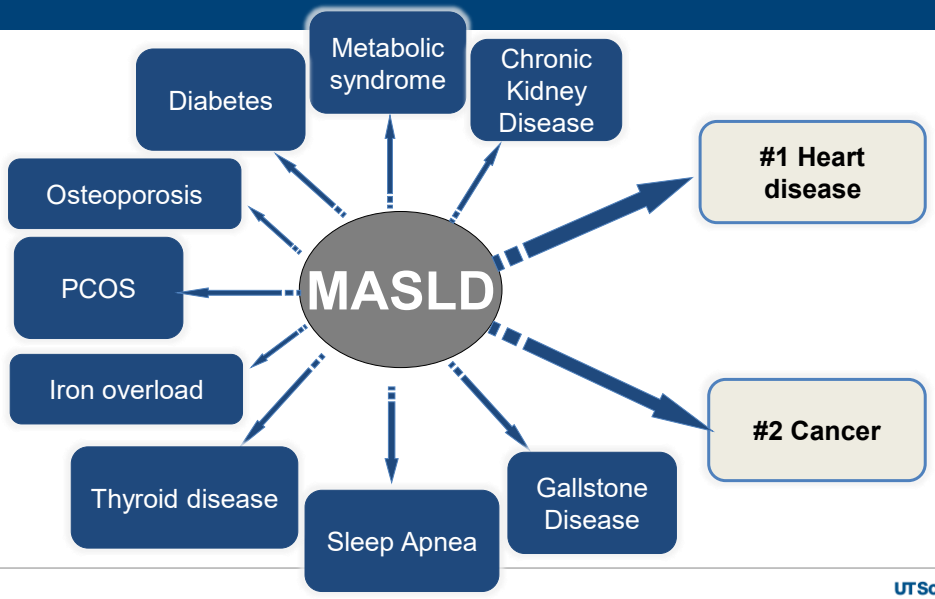
MASLD Affects More Than Just the Liver



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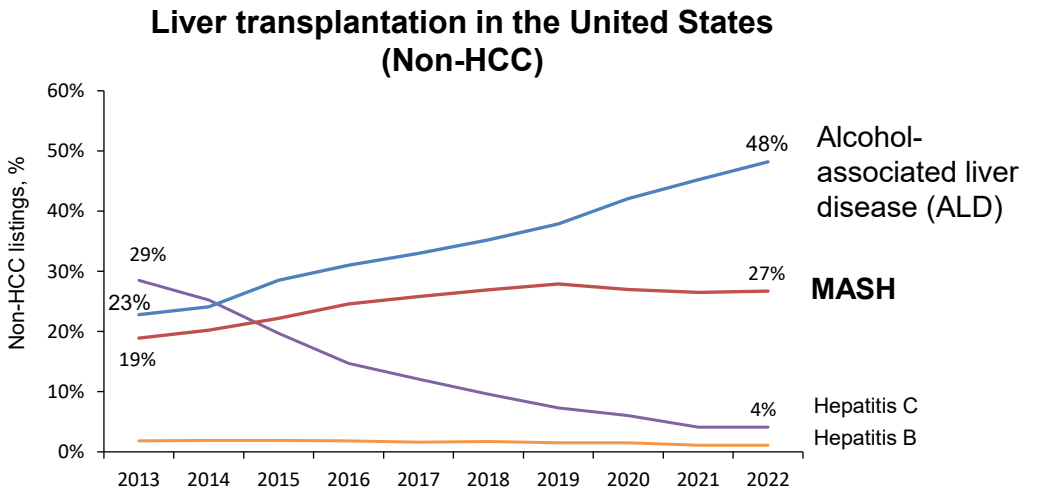
Consequences of MASH: Liver Transplantation



Younossi ZM. *Hepatol Commun*. 2023 22;8(1):e0352.

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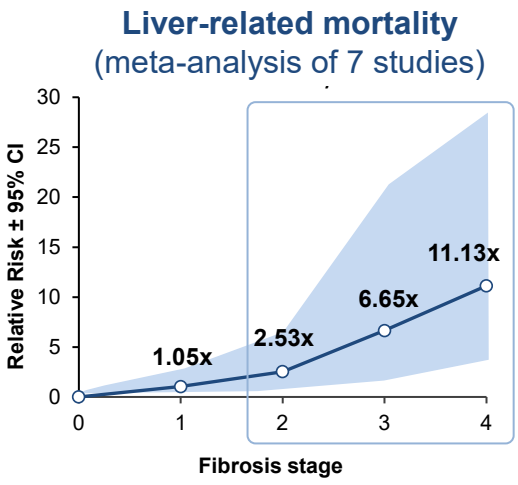
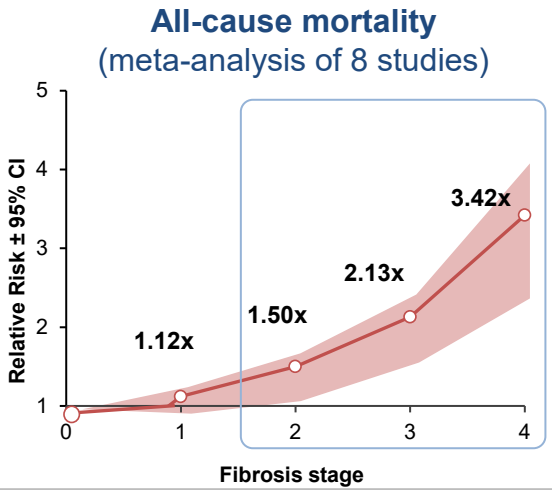
Fibrosis Stage Predicts Liver Outcomes and Mortality





Taylor RS et al. *Gastroenterology*. 2020;158:1611-25.

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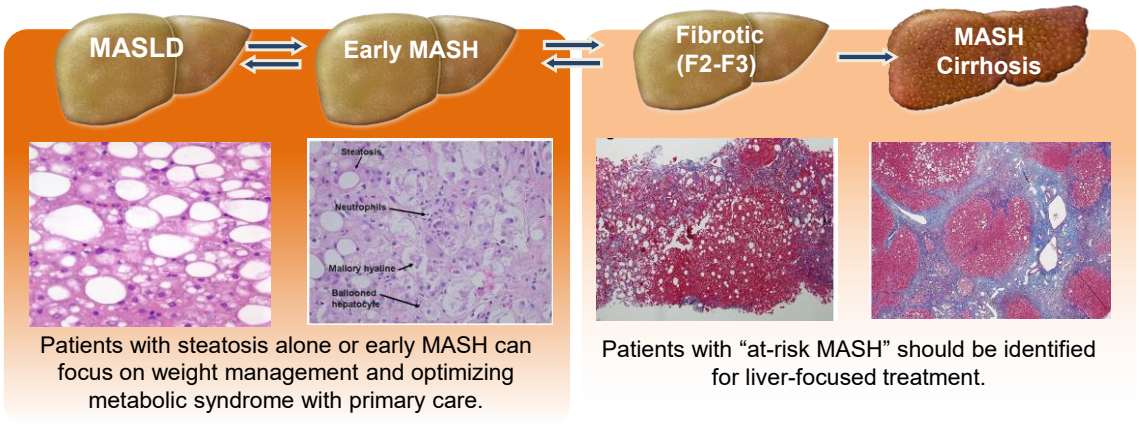
Disease Staging

Historically, MASH has been diagnosed by liver biopsy. **Currently, non-invasive tests (NITs) can distinguish between lower risk patients and patients with "at-risk MASH" with reasonable reliability.**



Patients with steatosis alone or early MASH can focus on weight management and optimizing metabolic syndrome with primary care.

Patients with "at-risk MASH" should be identified for liver-focused treatment.

Provided by Mazen Noureddin, MD, MHSc Reproduced for educational purposes only.

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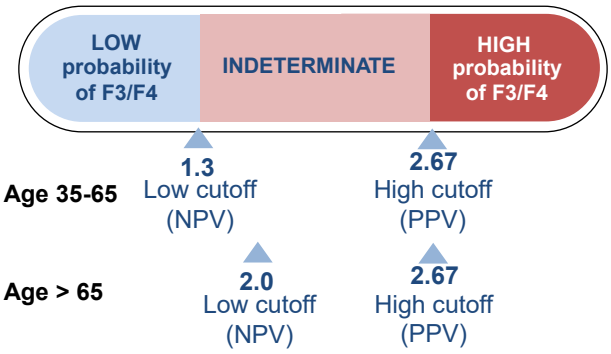
NIT Staging: Fibrosis-4 (FIB-4) Score

FIB-4 for MASLD/MASH screening



$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet count } (10^9/\text{L}) \times \sqrt{\text{ALT (U/L)}}}$$

1. Sterling et al. *Hepatology*. 2006. **2.** Eddowes et al. *Gastroenterology*. 2019. **3.** Vali Y et al. *J Hepatology*. 2020;73(2):252-262.
4. Day J et al. *J Appl Lab Med*. 2019;3(5):815-826. **5.** Newsome et al; *Lancet Gastro Hep*. 2020.

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NIT Staging: Enhanced Liver Fibrosis (ELF) Score

1. Lichtinghagen R et al. *J Hepatol*. 2013;59:236–42. **2.** Fagan KJ et al. *Liver Int*. 2015;35:1673–81. **3.** Vali Y et al. *J Hepatology*. 2020;73(2):252-262. **4.** Day J et al. *J Appl Lab Med*. 2019;3(5):815-826.

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NIT Staging: Elastography

Provides Two Values

1. **Stiffness Score (kPa)***
   Estimates fibrosis
   Reported in kilopascals (kPa)
2. **CAP Score**
   Estimates fat quantity
   Only good if >30% liver has fat

	Transient Elastography (kPa)	3D S-WAVE Ultrasound Elastography (kPa)
Advantages	• Can be performed in clinic with real-time results	• Can be performed in clinic with real-time results
Disadvantages	• Increased failure rate with obesity • Expensive device • Cutoff values with XL probe are slightly different from M probe	• More time consuming than TE (although time can be reduced significantly with training) • Limited availability

Fibroscan (VCTE) kPa ≠ shear wave kPa; CAP, controlled attenuation parameter.

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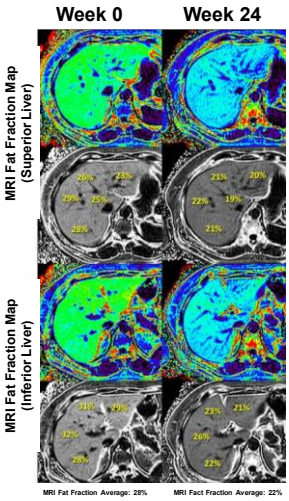
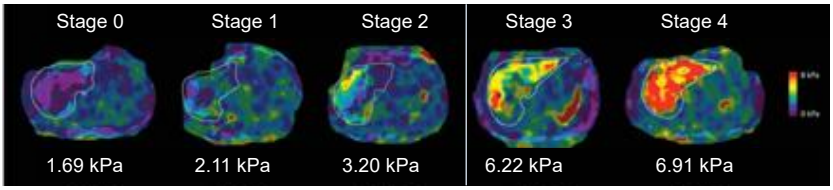
NIT for MASLD Staging: MRI-PDFF and MRE



Modified phase-contrast pulse sequence to visualize rapidly propagating mechanical shear waves (~60 Hz)



Cutoff for Detecting Advanced Fibrosis	Sensitivity (95%CI)	Specificity (95%CI)	PPV (95%CI)	NPV (95%CI)
MRE stiffness ≥3.64 kPa	0.86 (0.65-0.97)	0.91 (0.83-0.96)	0.68 (0.48-0.84)	0.97 (0.91-0.99)

Noureddin. *Hepatology.* 2013, Loomba. *Hepatology.* 2015, Loomba *Hepatology*. 2014; Patel et al. *Ther Adv Gastroenterol.* 2016; Han, Noureddin. *Liver Int.* 2020.

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Practice-Based Guidance for MASLD Risk Stratification

Step 1: Identify patients at risk

2 or more metabolic risk factors | Type 2 diabetes | Steatosis on imaging or elevated LFTs

Step 2: History and laboratory tests
Assess alcohol intake and metabolic risk factors, obtain CBC and LFTs

	Step 3: Non-invasive testing (NIT) for significant fibrosis (FIB4 is calculated based on age, AST, ALT & platelet count)		
Age < 35	FIB4 may not be accurate; consider referral to GI/hepatology and/or alternative fibrosis assessment (see Step 4)		
Age 35-64	FIB-4 < 1.3	FIB-4 1.3 to 2.67	FIB-4 > 2.67
Age ≥ 65	FIB-4 < 2.0	FIB-4 2.0 to 2.67	FIB-4 > 2.67

INDETERMINATE RISK

Step 4: Liver Stiffness Measurement* or ELF Score

LSM < 8 kPa	LSM 8 to 12 kPa	LSM > 12 kPa
ELF < 7.7	ELF ≥ 7.7 to < 9.8	ELF ≥ 9.8***

LOW RISK
Repeat NIT in 1-3 years based on metabolic risk**

INDETERMINATE RISK

HIGH RISK

Refer to GI/hepatology

*VCTE (preferred) or ultrasound elastography (sheer wave or ARFI) based on availability

**1-2 years if T2DM or 2 or more met risk factors; 2-3 years if no T2DM and <2 met risk factors

***ELF ≥ 11.3 is consistent with cirrhosis
ELF ≥ 13 is associated with rapid decompensation and requires urgent referral

Adapted from Kanwal et al. *Gastroenterology* Nov 2021 and Rinella et al. *Hepatology* 2023

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First Step in MASLD/MASH Management:
Lifestyle Modifications

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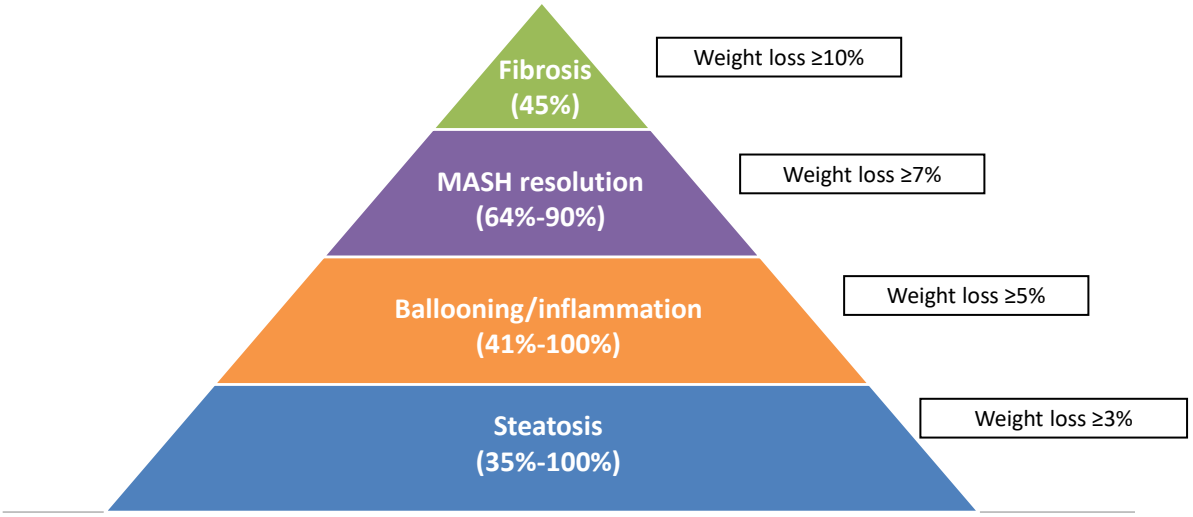
MASLD Management: Address Weight



Hannah. Clin Liver Dis. 2016:20;339.

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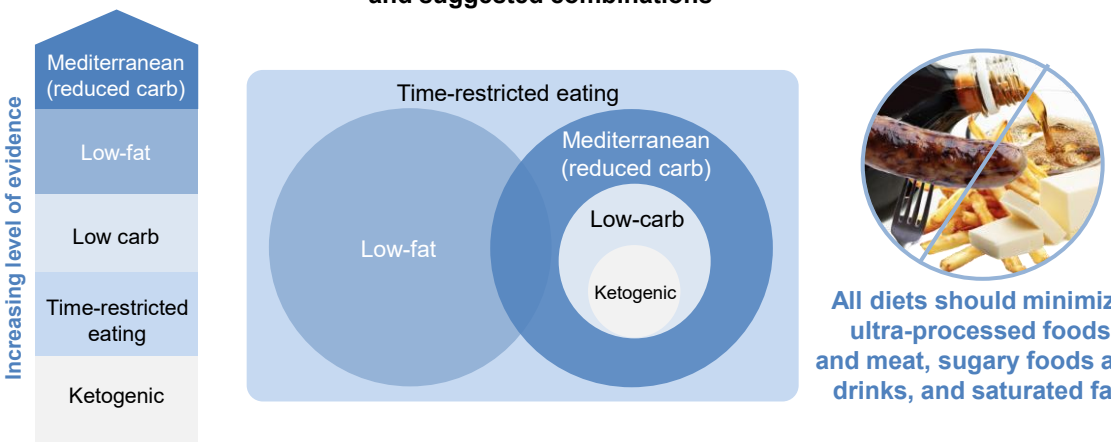
Type of Diet for the Treatment of MASLD

Conceptual summary of level of evidence of diets for MASLD treatment and suggested combinations



All diets should minimize ultra-processed foods and meat, sugary foods and drinks, and saturated fat.

Zelber-Sagi S. *Liver International*. 2022;42:1731-1750.

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MASLD Diet: Clinical Pearls

- Prescribe a diet that leads to a caloric deficit
- Tailor dietary modifications to patient's cultural and personal preferences
- **Coffee** consumption: ≥3 cups/day reduces risk of MASLD, fibrosis and HCC
- NO support for other nutraceuticals
- Minimize alcohol
  - NONE in MASH F2 or greater
  - Emphasize risks of binge drinking on liver health

EASL-EASD-ESO MASLD Clinical Practice Guidelines 2024

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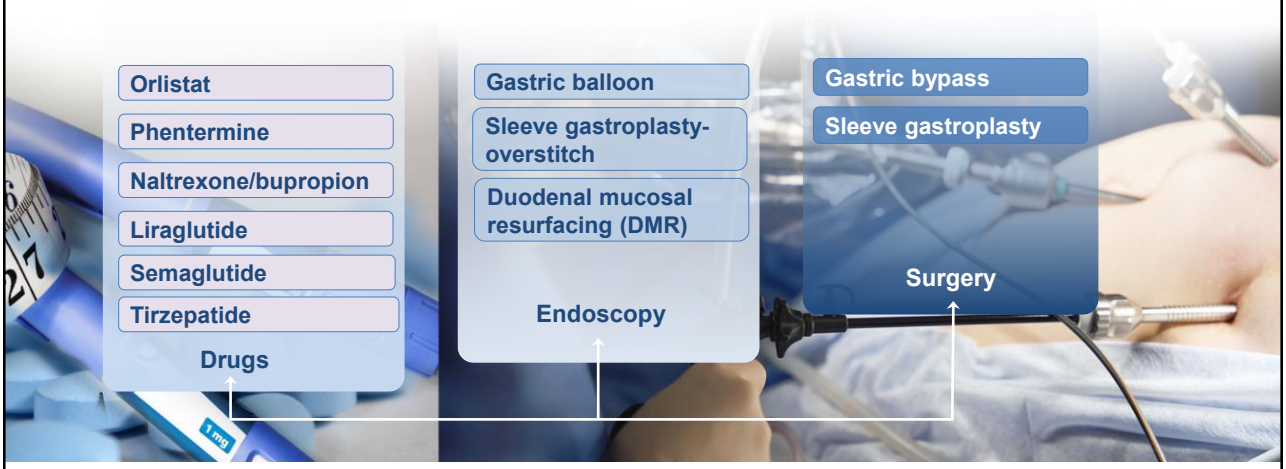
Weight Loss Beyond Lifestyle Modifications



NOTE: None of the strategies listed are approved for the treatment of MASH.

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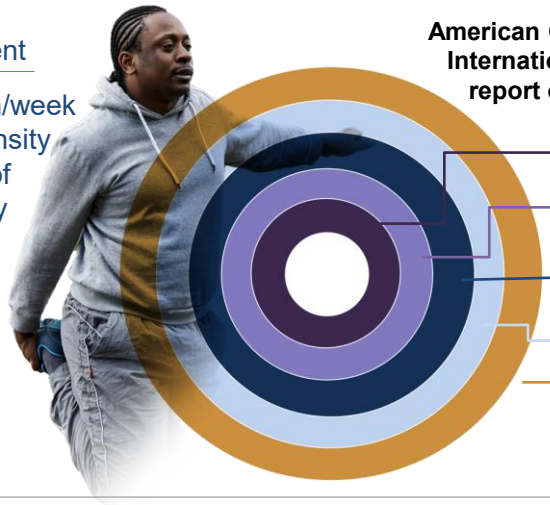
Recommendations for Physical Activity

Tailor to the patient

Aim for >150 min/week of moderate-intensity or 75 min/week of vigorous-intensity physical activity

Minimize sedentary time



American College of Sports Medicine (ACSM) International Multidisciplinary Roundtable report on physical activity and MASLD

- Liver fat
- CV health
- Body composition
- Cardiorespiratory fitness
- Health-related QoL

Stine JG. *Hepatol Comm*. 2023;7(4):e0108.

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Lifestyle: Optimizing Cardio-Metabolic Risks

MASLD with overweight /obesity

MASLD with class II or III obesity

MASLD with normal weight

Type of weight-loss diet chosen based on the individual's preferences and clinical condition

Weight loss goals

- ≥5% for steatosis reduction
- ≥7%-10% for MASH and fibrosis reduction
- Consider incretin-based weight loss drugs
- Consider bariatric procedures

3-5% weight reduction

Recommendations to all MASLD

Diet quality
- Mediterranean diet
- Minimizing processed meat, ultra-processed foods and sugar-sweetened beverages
- Increasing unprocessed/minimally processed foods

Physical activity
- Tailored to the individual's preference and ability
- >150 min/week of moderate- or 75 min/week of vigorous-intensity physical activity
- Minimizing sedentary time

Other lifestyle habits
- Smoking: avoidance
- Alcohol: discourage or avoidance in advanced fibrosis or cirrhosis

MASH cirrhosis
- Lifestyle adapted to the severity of liver disease and nutritional status
- Sarcopenia or decompensated cirrhosis: high-protein diet and late-evening snack
- Compensated cirrhosis with obesity: moderate weight reduction plus high-protein intake and physical activity

Implementation
- Multidisciplinary care
- Lifestyle evaluation during healthcare visits
- Affordable structured lifestyle interventions
- Individualized plan depending on the patient's preferences and economic constraints
- Behavioral therapy

Prevention of MASLD and HCC
- Preventing obesity
- Healthy diet
- Regular physical activity
- Avoiding smoking and alcohol

Long-term goals:
Quality of life and survival
Cardiometabolic benefits
Prevention of cirrhosis, HCC, T2D, cardiovascular disease

EASL–EASD–EASO Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD)
Tacke, Frank et al. Journal of Hepatology, Volume 81, Issue 3, 492 - 5

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Second Step of MASH Management:
Liver Targeted MASH Treatment

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Major 2025 Updates in MASH Pharmacotherapy

FDA Accepts Letter of Intent for VCTE as a Surrogate Endpoint in MASH trials[1]

Semaglutide Receives Conditional Approval (F2–F3)[2,3]

Next-Generation Agents Move Toward Registration

Resmetirom entering post-approval outcomes phase.
FGF21 analogs (e.g., pegozafermin) show *fibrosis + NASH resolution*.
Dual agonists (GLP-1/GIP, GLP-1/GCGR) advance as combination-strategy candidates.

1. U.S. Food and Drug Administration. WEGOVY (semaglutide) injection, for subcutaneous use: Official prescribing information. Aug 2025. 2. Sanyal AJ et al. *N Engl J Med* 2025 Jun 5; 392:2089;

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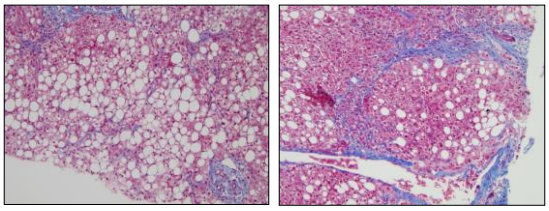
Currently Accepted FDA Endpoints for Non-cirrhotic MASH Conditional Approval

Resolution of MASH, *no worsening of fibrosis*



Stage 2-3 Stage 3-4

Resolution or improvement of MASH could reflect disease progression

Reduction in fibrosis, *no worsening of MASH*

- Fibrosis linked to hard clinical outcomes
- Needs to not adversely impact metabolic or inflammatory activity

Courtesy of M. Rinella

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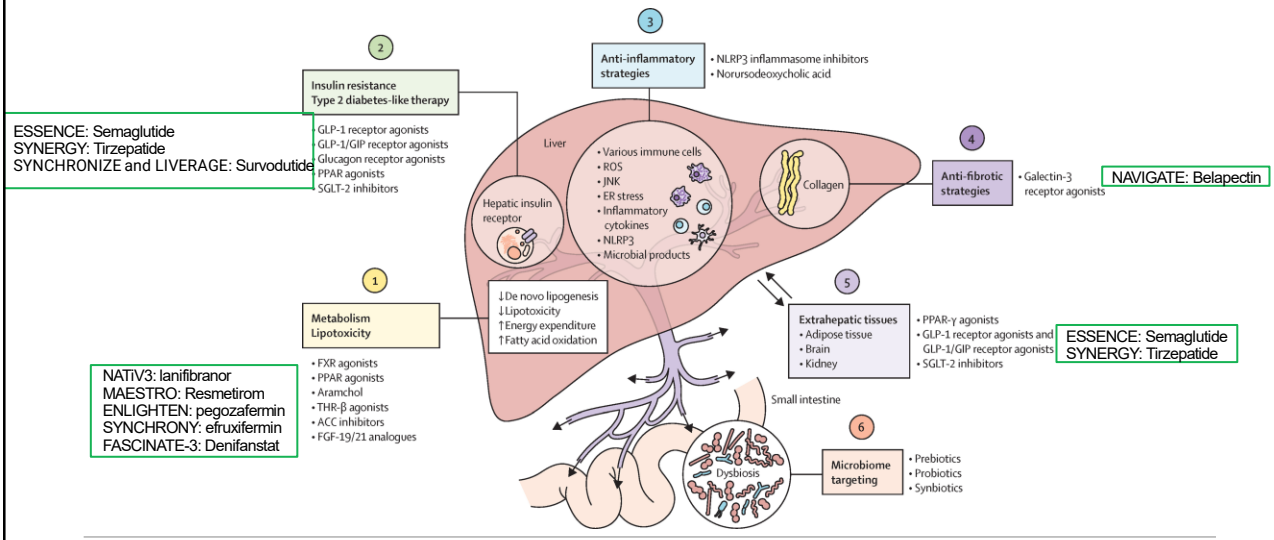
Targeting Pathophysiological Processes in MASH



In Phase III study

Tilg et al. Lancet Gastroenterol Hepatol 2023 Oct;8(10):943-954

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Resmetirom Was the First Approved Drug for MASH

Oral, partial agonist of thyroid hormone receptor-beta (THR-β)[1]

Approved March 2024 for the treatment of adults with **NASH[a] with moderate-to-advanced fibrosis in conjunction with diet and exercise[2]**

Cost: ~$47,000 per year

[a]*NASH* used due to publication date.
1. Harrison SA et al. *N Engl J Med*. 2024;390(6):497-509; 2. Rezdiffra [prescribing information]. Madrigal Pharmaceuticals, Inc.

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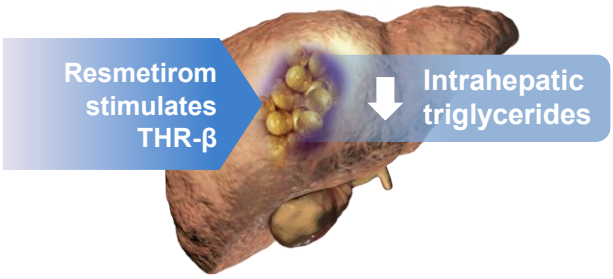
Resmetirom Mechanism-of-Action



Liver-targeted activity

- Stimulates THR-β receptors in the liver
- Selectively effective in activating THR-β over THR-a outside the liver (heart and bones)

Reduces hepatic steatosis

- Stimulates lipophagy
- Stimulates mitochondrial biogenesis
- Inhibits lipogenesis

May interfere with fibrogenesis by inhibiting TGF-β signaling

1. Harrison SA et al. *N Engl J Med*. 2024;390(6):497-509; **2.** Rezdiffra (resmetirom) [prescribing information]. Madrigal Pharmaceuticals, Inc.; West Conshohocken, PA; 2024.

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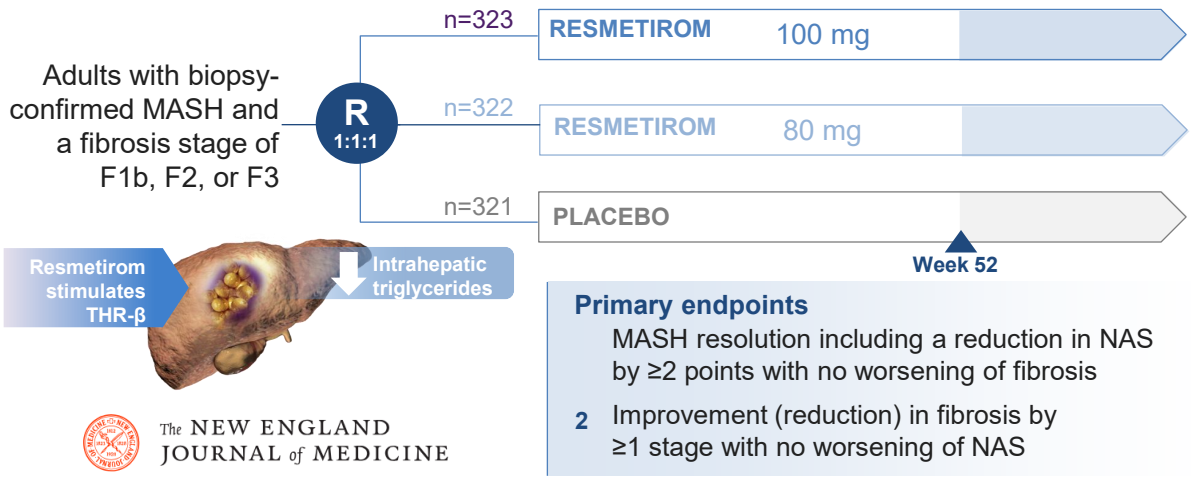
MAESTRO-NASH: Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis



Primary endpoints

1. MASH resolution including a reduction in NAS by ≥2 points with no worsening of fibrosis
2. Improvement (reduction) in fibrosis by ≥1 stage with no worsening of NAS

Harrison S et al. N Engl J Med 2024;390:497-509

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Resmetirom Phase 3 (MAESTRO) Study: Patient Population

Characteristic	Overall (N=966) %
Fibrosis stage	
F1b	5.1
F2	33.0
F3	61.9
Type 2 diabetes	67.0
Hypertension	78.1
Dyslipidemia	71.3
Statin use	48.9
GLP-1 receptor agonist use	14.3

Harrison SA et al. *N Engl J Med*. 2024;390(6):497-509.

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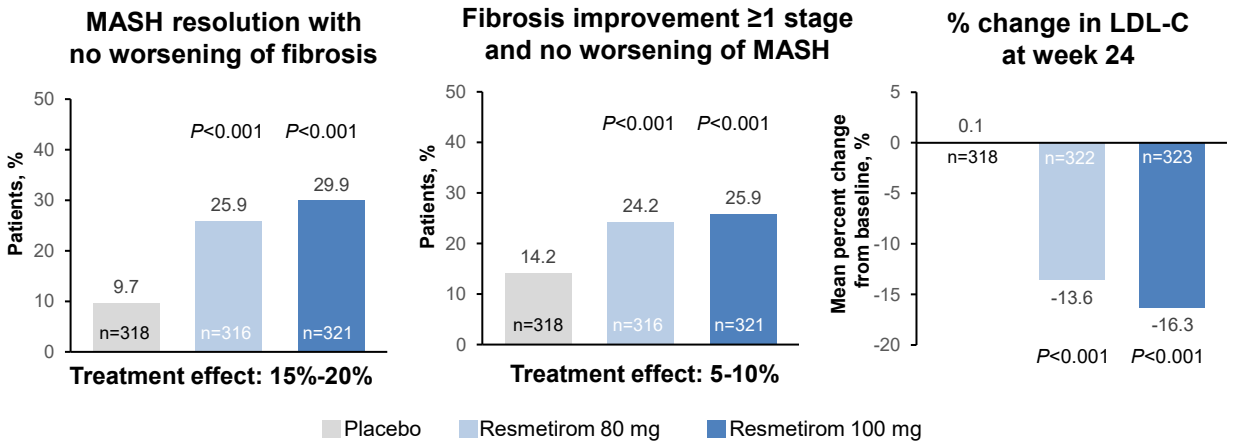
Resmetirom Phase 3 (MAESTRO) Study: Primary and Key Secondary Endpoints



Harrison SA et al. *N Engl J Med*. 2024;390(6):497-509.

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Resmetirom: Phase 3 Safety (MAESTRO Study)

Adverse events >10% of patients in any group

	Resmetirom 80 mg (n=322) %	Resmetirom 100 mg (n=323) %	Placebo (n=321) %
Diarrhea	**27.0**	**33.4**	**15.6**
Covid-19	21.4	16.7	20.6
Nausea	**22.0**	**18.9**	**12.5**
Arthralgia	14.9	10.8	12.5
Back pain	10.9	8.4	11.8
Urinary tract infection	10.2	8.4	8.4
Fatigue	10.2	8.0	8.7
Pruritus	8.1	11.5	6.9
Vomiting	8.7	10.8	5.3

NOTE: Increases in mean ALT and AST (<1.5x baseline) were observed in the first 4 weeks after initiating treatment. Values returned to baseline ~8 weeks after initiating treatment.

Harrison SA et al. *N Engl J Med*. 2024 Feb 8;390(6):497-509.

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Resmetirom Dosing and Other Considerations

Dosing
<100 kg (220 lbs) 80 mg QD
≥100 kg (220 lbs) 100 mg QD

- Rule out additional causes of liver disease, including autoimmune hepatitis
- Resmetirom is **not approved** in patients with **cirrhosis**
- Prior to starting therapy, review for possible drug-drug interaction potential, including statins, gemfibrozil, clopidogrel, cyclosporine

Rezdiffra (resmetirom) [prescribing information]. Madrigal Pharmaceuticals, Inc.; West Conshohocken, PA; 2024.

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Semaglutide 2.4 mg Is the Second FDA Conditionally Approved Drug for MASH

Injectable, GLP-1 Agonist

Approved August 2025 for the treatment of adults with **MASH with moderate-to-advanced fibrosis in conjunction with diet and exercise**[2]

Cost: ~$16,200 per year

1. Sanyal A. et al. N Engl J Med 2025;392:2089-2099; 2. Wegovy [prescribing information]. Novo Nordisk, Inc

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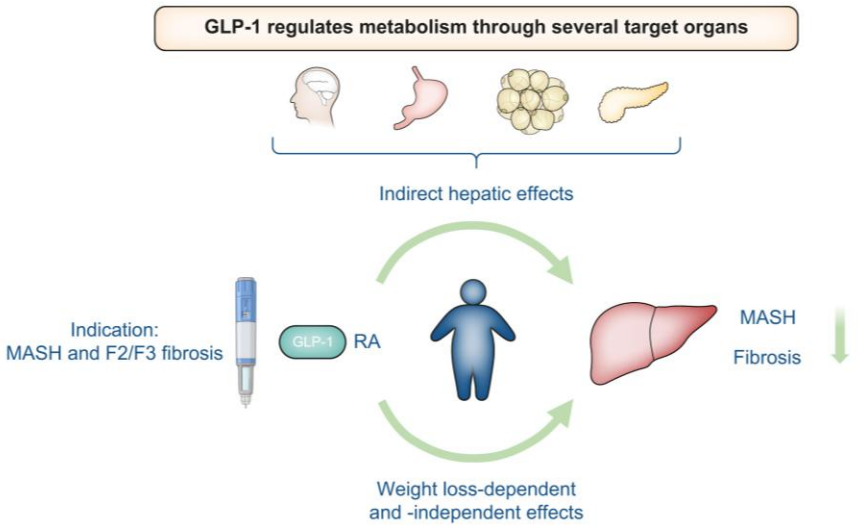
GLP-1 Agonists in MASH



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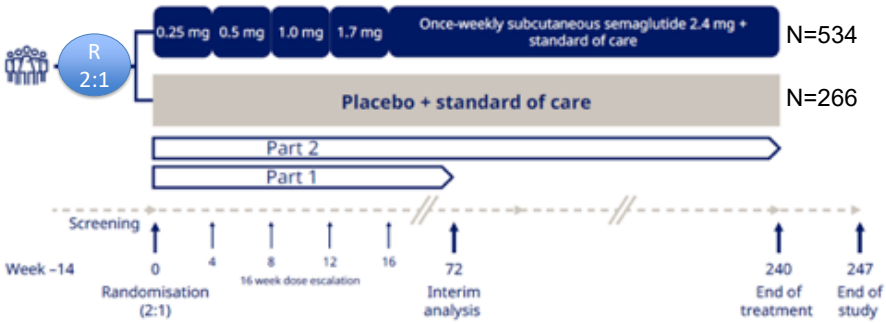
ESSENCE Study: Phase 3, Randomized, Controlled Trial of Semaglutide in MASH with Liver Fibrosis

Adults with biopsy-confirmed MASH and a fibrosis stage of F2, or F3



The NEW ENGLAND JOURNAL of MEDICINE

Primary endpoints

MASH resolution including a reduction in NAS by ≥2 points with no worsening of fibrosis

2 Improvement (reduction) in fibrosis by ≥1 stage with no worsening of NAS

Sanyal A. et al. N Engl J Med 2025;392:2089-2099

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Semaglutide Phase 3 (ESSENCE) Study: Patient Population

Characteristic	Overall (N=800) %
Age, year (SD)	56.0 ± 11.6
BMI, kg/m2	34.6 ± 7.2
Fibrosis stage, % F2 F3	 31.3 68.8
Type 2 diabetes, %	55.9
FIB-4, median (IQR)	1.56 (1.12-2.27)
Liver stiffness (VCTE), kPa	12.8 ± 16.9

Sanyal et al. NEJM Apr 30, 2025. ePub

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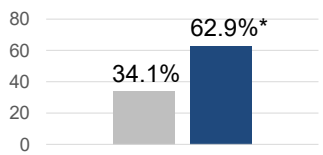
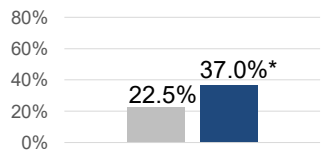
Semaglutide Phase 3 (ESSENCE) Study: Primary and Key Secondary Endpoints

MASH Resolution* and No Worsening of Fibrosis



Treatment difference
28.9 [21.3, 36.5]

Fibrosis Improvement ≥1 Stage & No Worsening of MASH



Treatment difference
14.4 [7.5, 21.4]

Week 72 ITT Analysis

	Placebo (N=266)	Sema 2.4mg (N=534)
△weight, mean	-2.0%	-10.5%*

Placebo Sema 2.4

*P<.0001

Sanyal et al. NEJM Apr 30, 2025. ePub

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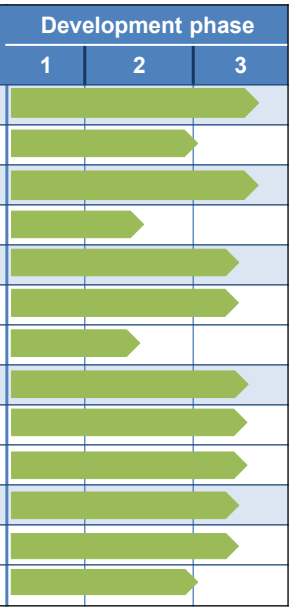
MASH Therapy Pipeline

Class;	Agent	Description	Development phase
THR-β agonists	Resmetirom	Oral	
	VK2809	Oral	
GLP1R agonists	Semaglutide	GLP1, 2.4mg dose, injection	
	Tirzepatide	Dual GLP1 and GIP agonist	
	Survodutide	Dual GLP-1 and GCG agonist	
	Pemvidutide	Dual GLP-1 and GCG agonist	
	Efinopegdutide	Dual GLP-1 and GCG agonist	
FGF21 agonists	Efruxifermin	Injection, weekly	
	Pegozafermin	Injection, weekly	
	Efimosfermin	FGF-21 agonist, monthly	
PPAR agonist	Lanifibranor	Pan PPAR, oral	
FASN inhibitor	Denifanstat	Fatty acid synthase, oral	
DGAT2 inhibitor	ION224	Injection, monthly	



DGAT2, diacylglycerol O-acyltransferase 2; FASN, fatty acid synthase; FGF-21, fibroblast growth factor-21; GCG, glucagon receptor agonist; GIP, glucose-dependent insulinotropic polypeptide; GLP-1, glucagon-like peptide; PPAR, peroxisome proliferator-activated receptor. www.clinicaltrials.gov Accessed November 26, 2025.

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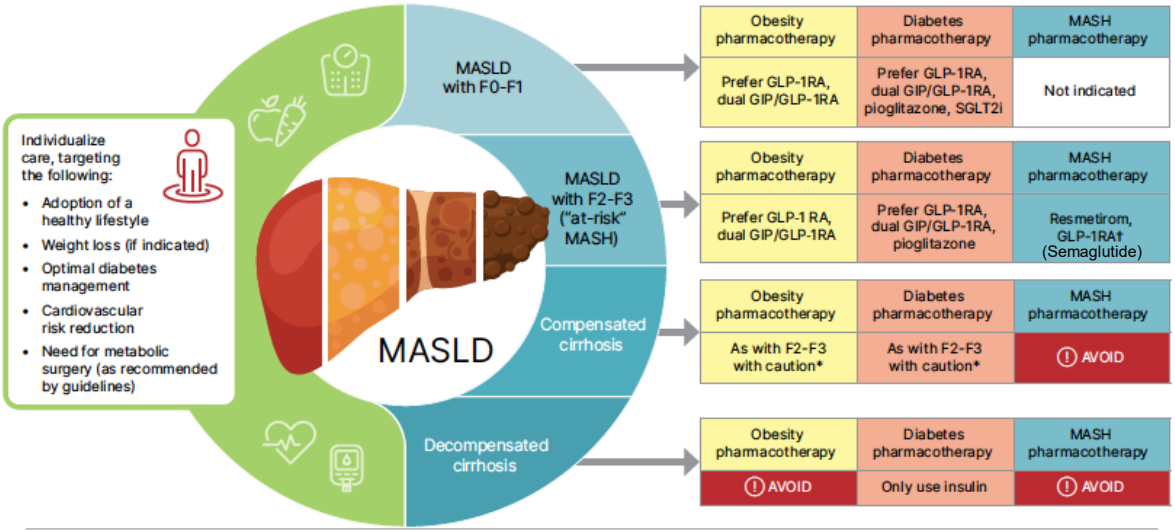
Bringing it Home: MASLD Management in 2026



Cusi K et al. Diabetes Care 2025; 8:1–26 | https://doi.org/10.2337/dci24-0094

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When You Identify Hepatic Steatosis in a Patient with Metabolic Risk Factors, What Is the *Best Next Step*?

A. Reassure if ALT/AST are normal
B. Order ultrasound and follow clinically
C. Calculate FIB-4
D. Refer directly to GI/hepatology
E. Screen for viral hepatitis

What Should You Usually Emphasize to Patients with MASLD as Their *Greatest Long-term Health Risk*?

A. Progression to cirrhosis
B. Hepatocellular carcinoma
C. Liver Transplantation
D. Cardiovascular disease
E. Diabetes mellitus

Which Patient with MASLD Should Be Referred to GI/Hepatology for *Consideration of Liver-directed MASH Therapy*?

A. Steatosis on imaging with normal labs
B. Low-risk FIB-4 (score <1.3)
C. Compensated cirrhosis
D. Confirmed stage 2 or 3 (F2-F3) fibrosis
E. Decompensated cirrhosis

Key Take Aways

MASLD for Frontline Providers

New nomenclature recognizes a continuum between metabolic risk and alcohol use on steatotic liver disease

Risk stratification in MASLD starts with use of the FIB4 score followed by VCTE or ELF and/or referral to GI/Hepatology

Lifestyle modification remains the backbone

Resmetirom and semaglutide 2.4 mg are FDA-approved* for F2–F3 MASH

*conditionally approved

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Thank you!
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