

Evaluation Cont'd

- If elevated transaminases or if there is suspicion of other chronic liver and biliary disease:
 - Order labs to evaluate for viral etiology, e.g., HCV, HBV
 - HCV ab with reflex testing of HCV RNA
 - HBsAg, HBsAb, HBcAb
 - If clinically indicated, evaluate for other causes such as medication-induced hepatitis, Wilson Disease, Hereditary Hemochromatosis, Autoimmune Hepatitis, etc.
 - When indicated, consider antinuclear antibodies (ANA), antimitochondrial antibodies (AMA), anti-smooth muscle antibodies (ASMA), immunoglobulins, ferritin, Alpha-1 antitrypsin (A1AT)

Laboratory Findings In Patients With NAFLD ⁵

Transaminases	<p>Patients with NAFLD may have mild or moderate elevations in the aspartate aminotransferase (AST) and alanine aminotransferase (ALT), although normal aminotransferase levels do not exclude NAFLD.</p> <p>When elevated, the AST and ALT are typically 2-5 times the upper limit of normal, with an AST to ALT ratio of < 1 (unlike alcoholic fatty liver disease, which typically has a ratio > 2).</p> <p>The degree of aminotransferase elevation does NOT predict the degree of hepatic inflammation or fibrosis, and a normal alanine aminotransferase does not exclude clinically important histologic injury.</p>
Alkaline phosphatase	May be elevated to 2-3 times the upper limit of normal.
Serum albumin	Typically, within the normal range, but may be abnormal in patients who have developed cirrhosis.
Bilirubin	Typically, within the normal range, but may be abnormal in patients who have developed cirrhosis.
Serum ferritin or transferrin saturation	May be elevated in patients with NAFLD. There is evidence that a serum ferritin greater than 1.5 times the upper limit of normal in patients with NAFLD is associated with a higher nonalcoholic fatty liver disease activity score (and thus, NASH) and with advanced hepatic fibrosis.

Radiographic Findings

Radiographic findings in patients with NAFLD include increased echogenicity on ultrasound, decreased hepatic attenuation on CT, and an increased fat signal on magnetic resonance imaging (MRI). Note that abdominal ultrasound has good accuracy for detecting moderate and severe steatosis but has suboptimal sensitivity for detecting mild steatosis or evaluating the stages of fibrosis.

Liver Biopsy

A liver biopsy is currently the only reliable means to diagnose NASH and is the reference standard for fibrosis staging. However, liver biopsy may not be feasible to obtain in a significant number of patients. Besides the accompanied pain, discomfort, and small risk of complications due to its invasive nature, liver biopsy is associated with potential sampling error and interobserver variation. It is also impractical to repeatedly perform liver biopsy to assess disease progression. Therefore, national guidelines (i.e., American Gastroenterological Association (AGA) page 7, Algorithm 1, page 10) recommend further workup and noninvasive efforts to predict and evaluate the stage of hepatic fibrosis.

SCREENING FOR NAFLD WITH ADVANCED FIBROSIS ^{1,2,3,6}

Hepatic fibrosis is the most important determinant of liver and non-liver outcomes in patients with NAFLD. Not all patients with NAFLD will progress to significant hepatic fibrosis. Identifying patients with clinically significant hepatic fibrosis (F2 or higher) is important for targeted efforts at preventing disease progression.

Note: Patients who have either spontaneously recovered from HCV infection, or had sustained viral response from HCV treatment, can also develop liver fibrosis related to NAFL/NASH when they have risk factors such as T2D and/or obesity. If these patients have not been evaluated regarding their liver fibrosis, they should be screened for advanced fibrosis related to NAFL/NASH. Consult central care team for questions.

The AGA developed an algorithm (see page 10) for screening for advanced fibrosis related to NAFL/NASH with the goal of detecting those patients with clinically significant fibrosis early and starting intervention accordingly.

For those patients who are considered to have cirrhosis (clinically or based on non-invasive testing (NIT) or liver biopsy), providers should follow the appropriate management, including HCC and esophageal variceal screening and advance care planning. (Refer to [Liver Cirrhosis Care Guide](#) for details.)

AMERICAN GASTROENTEROLOGICAL ASSOCIATION SCREENING RECOMMENDATIONS – STEPS 1 - 4

STEP 1: Identify the three groups known to be at greatest risk of NAFL/NASH related fibrosis:

Group 1:	Group 2:	Group 3:
Patients with Type 2 Diabetes	Patients with two or more metabolic conditions including: <ul style="list-style-type: none"> • Central obesity (also known as abdominal obesity, waist circumference >35 inches in women and >40 inches in men). • ↑ triglycerides ≥150 mg/dL, or specific treatment for hypertriglyceridemia • ↓ Reduced HDL <40 mg/dL in men, <50 mg/dL in women, or specific treatment • Hypertension, systolic blood pressure ≥130 mm Hg or diastolic blood pressure ≥85 mm Hg, or specific treatment • ↑ fasting plasma glucose, between 100 mg/dL and 125 mg/dL (prediabetes) 	Patients with incidental findings of hepatic steatosis on any imaging modality, or ↑ aminotransferases.

STEP 2: Conduct Standard History and Blood Tests to Obtain Key Measures

All at-risk patients identified in Step 1 should be screened for advanced fibrosis related to NAFL/NASH with the following:

1. Conduct standard history, (to include alcohol intake history), physical exam, and clinical signs of advanced liver disease or cirrhosis. (See page 4)

Screening Cont'd

- Order screening labs to rule out other causes of liver disease, treating the underlying etiology if applicable, and to calculate FIB-4 fibrosis score when NAFLD is suspected. (See page 4)

STEP 3: Conduct Noninvasive Testing for Liver Fibrosis Using Simple Scores

While NAFL and NASH are diagnoses made on liver histology findings, there have been increasing efforts to predict the existence of clinically significant fibrosis in patients with NAFLD using Non-invasive testing (NIT). Different NITs were studied and validated in patients with various chronic liver diseases.

The two main categories of NIT are lab tests and imaging. Among the many NIT methods that have been evaluated for the accuracy of detecting the clinically significant fibrosis in patients with NAFLD, some of the most validated tools include:

- FIB-4 (NOTE: decision thresholds for FIB-4 used for NAFLD are different than that used for HCV. Refer to [Hepatitis-C-Care-Guide](#) for more information)
- ELF blood test (Preferred) (NOTE: the Fibrotest used in patients with HCV is NOT recommended in evaluating NAFLD)
- Fibroscan

Patients are first stratified using the FIB-4 score. $FIB-4 = [Age(y) \times AST(U/L)] / [PLT(10^9/L) \times ALT(U/L)^{1/2}]$

Online calculator: <https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4>

- Note that the FIB-4 score may not accurately represent the extent of liver fibrosis in the setting of advanced age and/or low platelet count⁷, even in the absence of liver disease, because age and platelet count are included in the calculation.
- Liver enzymes can be affected by several conditions. (See [Liver biochemical tests that detect injury to hepatocytes](#) (UpToDate) for more details) Moreover, the value of AST and ALT may be markedly elevated during acute hepatic injury⁸. Thus, it is important to monitor the lab values over time and the calculation may need to be repeated to see if the FIB-4 score is consistently elevated.

Interpretation of FIB-4 score in patients with NAFLD

FIB-4 in Patients with NAFLD	Interpretation^{2,6,9} Fibrosis staging system (NASH Clinical Research Network staging system) for NAFLD ¹⁰
<1.3*	Unlikely to have advanced fibrosis Likely representing: F0- No fibrosis F1- Mild fibrosis
1.3*-2.67	Indeterminate range, further evaluation required
>2.67	Likely to have advanced fibrosis and likely representing: F2- Clinically significant fibrosis F3- Advanced fibrosis F4- Cirrhosis

* For patients 65+, use FIB-4 <2.0 as the lower cutoff. Higher cutoff does not change⁶.

Screening Cont'd

STEP 4: Obtain additional fibrosis testing or Liver Stiffness Measurement

Based on the FIB-4 score, patients will be determined as having low, indeterminate, or high risk of having advanced fibrosis related to NAFL/NASH and should be followed-up and managed accordingly (See Table 1, page 13).

Low Risk FIB-4 <1.3	Indeterminate Risk FIB-4 1.3 to 2.67 (2.0 – 2.67 for patients 65+)	High Risk FIB-4 >2.67
Repeat NIT in 2-3 years unless clinical circumstances change.	Complete ELF or Fibroscan testing	Check for clinical signs of cirrhosis, obtain ELF or Fibroscan testing as needed

Patients at Indeterminate or High risk of advanced fibrosis should have additional assessment using the ELF blood test (preferred) or liver stiffness measurement by FibroScan to further stratify their liver fibrosis level (when clinical signs of cirrhosis are absent) and identify those with increased risk of NASH and advanced fibrosis who require aggressive treatment¹¹.

- **Enhanced Liver Fibrosis (ELF)** test is a noninvasive blood-derived panel of biomarkers consisting of three components:
 - Type III procollagen peptide,
 - Hyaluronic acid, and
 - Tissue inhibitor of metalloproteinase-1

Providers can order the ELF test in the EHRs: *Enhanced Liver Fibrosis (ELF) score (Quest Test code 10350)*.

Note: Fibrotest blood test, which is used for HCV, is NOT recommended to evaluate for NAFLD.

- **Liver Stiffness Measurement by FibroScan** is usually ordered by the central care team or specialists when further evaluation is needed to rule in or rule out advanced fibrosis.

The LSM interpretation for fibrosis stages in NAFLD are cited from the American Association for the Study of Liver Disease (AASLD)¹, American Gastroenterological Association (AGA)⁶, and American Association of Clinical Endocrinology (AACE)², though various studies have reported other values^{12, 13}. It is important to recognize that these are different than those for HCV¹⁴. Thus, indication for the Fibroscan needs to be specified on the EHRs order.

Advanced Fibrosis Risk Stratification

Low Risk	Indeterminate Risk	High Risk
FIB-4 <1.3	FIB-4 1.3 to 2.67	FIB-4 >2.67
ELF 7.7 or Liver Stiffness Measurement (LSM) <8 kPa by Fibroscan	ELF 7.7 – 9.8 or LSM 8 to 12 kPa by FibroScan	ELF >9.8 or LSM >12 kPa by FibroScan
Likely representing F0 – F1	Likely representing F1 - F2	Likely representing F2 and above While studies show FIB-4 ≥3.48 and ELF ≥11.3 correlate well with identifying patients with cirrhosis; this approach can still miss some patients with cirrhosis ¹ . Further evaluation with magnetic resonance elastography or liver biopsy may be indicated.

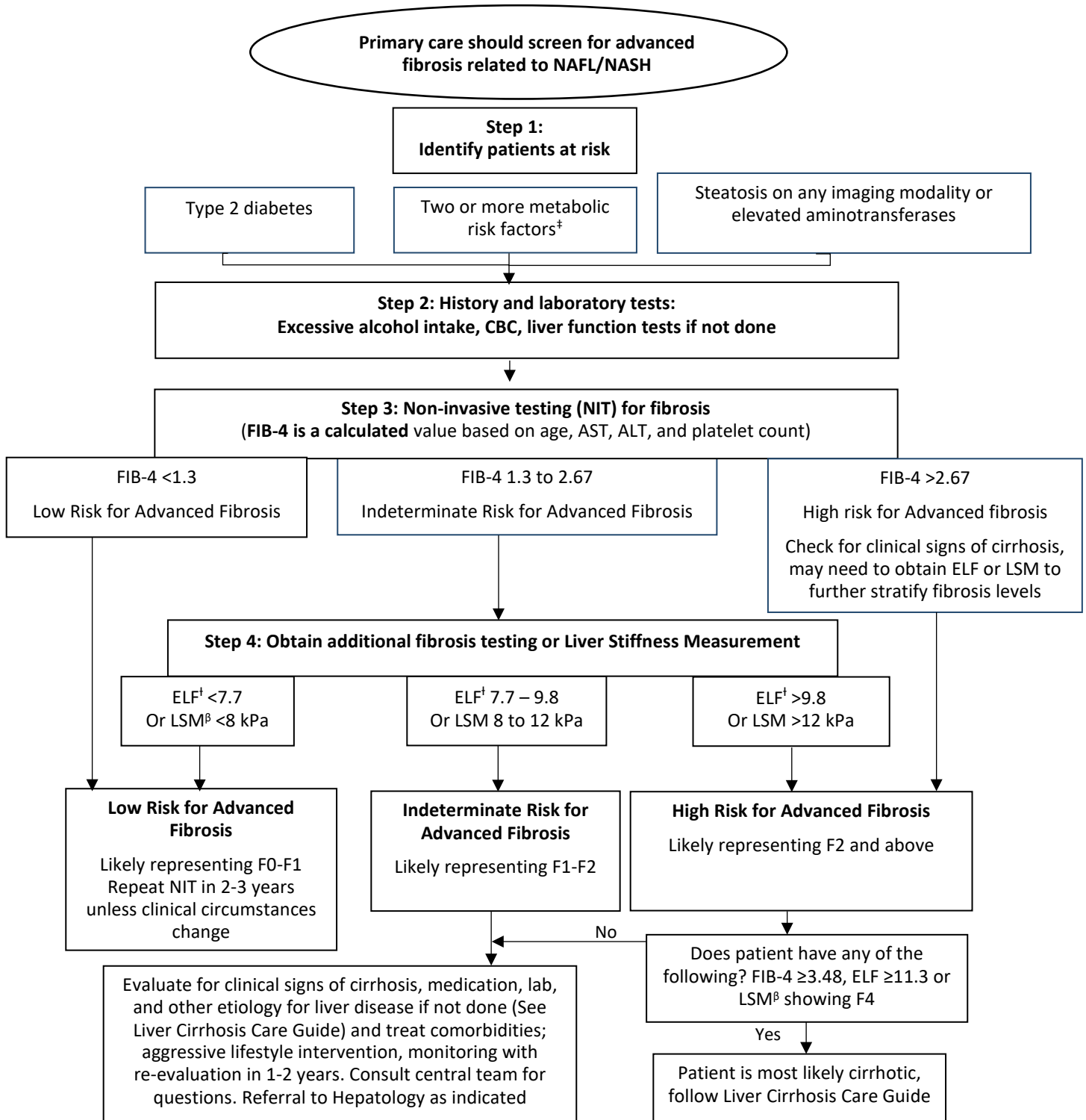
Screening Cont'd

Various cut-off values in these NITs have been demonstrated as reliable indicators for ruling in or ruling out advanced fibrosis in patients with NAFLD (see Algorithm 1, page 10).

Further workup may also be needed to confirm the diagnosis of NASH. A liver biopsy provides helpful information and should be considered for cases where there is diagnostic uncertainty, as in patients with discordant or indeterminate NITs; discordance between NITs and clinical, radiologic, or laboratory results suggesting the existence of advanced fibrosis; or possible other etiology of liver disease.

[Screening continued, page 10]

Algorithm 1: Screening for Advanced Fibrosis Related to NAFL/NASH



‡ Metabolic risk factors: central obesity, high triglycerides, low HDL cholesterol, hypertension, prediabetes, or insulin resistance.

† Preferred method of determining LSM

β LSM Cut-off values for the fibrosis stages in NAFLD are different than those for HCV and other causes. Note that for patients 65+, use FIB-4 <2.0 as the lower cutoff. Higher cutoff does not change. LSM measured by FibroScan. F0 - F4, liver fibrosis staging levels. See page 6 for details.

Adapted and revised from AGA Kanwal et al. 2021⁶ Figure 1 and AASLD NAFLD guidance 2023¹ Figure 2

MANAGEMENT OF NAFL/NASH ^{1,2,3,6}

The most common causes of death in patients with NAFLD without advanced fibrosis are cardiovascular disease, nonhepatic malignancy, followed by liver disease. However, liver-related mortality increases exponentially with an increase in the stage of fibrosis and predominates in patients with advanced fibrosis.

While general measures such as lifestyle changes and weight loss are recommended for all patients with NAFLD, intensity of treatment recommendations vary based on risk for/presence of advanced fibrosis. (See Table 1: Management of NAFL/NASH on page 13.)

General measures for all patients

The following measures apply to all patients with NAFLD^{15, 16}:

- **Abstain from alcohol** – Recommend patients avoid heavy alcohol use, which is associated with disease progression. Patients with clinically significant liver fibrosis (\geq F2) should abstain from alcohol use completely¹.
- **Immunizations** – Vaccination for hepatitis A virus and hepatitis B virus should be given to patients without serologic evidence of immunity.
 - Additional vaccines for patients with chronic liver disease include pneumococcal vaccination and standard immunizations that are given to the general population (See [Preventive-Services-Care Guide](#), Section 1).
- **Modify risk factors for cardiovascular disease** – Patients with NAFLD are at increased risk for cardiovascular disease and often have multiple risk factors for cardiovascular disease (e.g., hypertension, hyperlipidemia).
 - Management of patients with NAFLD and diabetes includes optimization of blood glucose control.
 - Most patients with NAFLD who have hyperlipidemia are candidates for lipid-lowering therapy.
- **Lifestyle interventions** for all patients include diet modification and exercise.^{15, 18}
 - Diet changes should include the following recommendations:
 - Limit intake of fats (e.g., butter, cheese, red meat, sausage, bacon)
 - When available, replace foods with saturated and trans fats for those with unsaturated fats, especially those high in omega-3 fatty acids. (e.g., vegetables, fruits, beans, nuts, whole grains, turkey, and fish)
 - Attempt to avoid foods with large amounts of fructose commonly found in canteen items. (e.g., honey buns, soda, sport drinks, juices)
 - Regular physical activity, independent of weight loss, has hepatic and cardiometabolic benefit; it should be considered for patients with NAFLD, with a target of 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity aerobic exercise per week.
 - Resistance training exercise can be complementary to aerobic exercise and can have independent effects on NAFLD.
 - The impact of exercise on NAFLD can enhance the positive effect of hypocaloric diet.
- **Weight loss:** Weight loss is the primary therapy for most patients with NAFLD. Weight loss is recommended for all patients with NAFLD who are overweight (body mass index [BMI] >25 kg/m²) or have obesity (BMI >30 kg/m²) because it can lead to improvement in liver biochemical tests, liver histology, insulin sensitivity, and quality of life in patients with NAFLD. Weight loss is recommended for cardiometabolic benefits and reversal of steatosis. (See [Weight Management Care Guide](#) for details.)
 - Clinically significant weight loss generally requires a hypocaloric diet targeting 1200–1500 kcal/d or a reduction of 500–1000 kcal/d from baseline.
 - Among patients with NASH, weight loss of:
 - 5% of total body weight can decrease hepatic steatosis

Management of NAFL/NASH Cont'd

- 7% of total body weight can lead to nonalcoholic steatohepatitis resolution
- 10% of total bodyweight can result in fibrosis regression or stability
- For patients with nonalcoholic steatohepatitis (NASH) or advanced fibrosis who do not meet weight loss goals after six months, weight loss medication or bariatric surgery may be considered in certain patients.

Pharmacologic Management

There are currently no FDA-approved pharmacological agents for the treatment of NASH.

There are medications that have demonstrated histological improvement in randomized controlled trials (RCTs) in patients with NASH, such as pioglitazone and some Glucagon Like Peptide-1 Receptor Agonists (GLP-1 RAs).

- For patients with T2D as a comorbidity, such medications can be used, provided patients have no contraindications.
 - Pioglitazone improves insulin resistance by primarily targeting adipose tissue and improving lipid storage/redistribution and glucose utilization². However, it has side effects such as:
 - Dose-dependent weight gain (1% with pioglitazone 15mg/day up to 3-5% with 45mg/day)
 - Increased fracture risk
 - Heart failure, if used in persons with a preexisting heart disease
 - Bladder cancer
 - Consider using pioglitazone together with other strategies that can lead to weight loss. It is to be avoided in patients with decompensated cirrhosis or peripheral edema.
 - GLP-1 RAs. Refer to [CCHCS Diabetes Care Guide](#) for the use of these agents in patients with T2D. Note that some of the GLP-1 RAs included in these RCTs, such as liraglutide and semaglutide, are non-formulary in CCHCS. More data on the other GLP-1RA, dulaglutide, which is formulary in CCHCS, may become available in the future.
- For patients without T2D, such medications may be considered, if recommended by Central team or specialist.

[Management of NAFL/NASH continued, page 13]

Management of NAFL/NASH Cont'd

Table 1: Management of NAFL/NASH ^{1,2,6} Adapted and revised from Figure 3 in Kanwal et al. AGA 2021⁶

	Low Risk for Advanced Fibrosis FIB-4 <1.3 or ELF [†] <7.7 or LSM [‡] <8 kPa by FibroScan (Likely representing F0 – F1)	Indeterminate Risk for Advanced Fibrosis FIB-4 1.3 - 2.67 and/or ELF [†] 7.7 - 9.8 or LSM 8 -12 kPa by FibroScan (Likely representing F1 - F2)	High Risk for Advanced Fibrosis FIB-4 >2.67 or ELF [†] >9.8 or LSM > 12 kPa by FibroScan (Likely representing F2 and above)
	Management by PCP, dietician, and others	Management by central care team with multidisciplinary team	Management by central care team with multidisciplinary team
Lifestyle Intervention	Yes	Yes	Yes
Weight loss recommended if overweight or obese	Yes May benefit from structured weight loss programs, anti-obesity medications, possible bariatric surgery	Yes Greater need for structured weight loss programs, anti-obesity medications, possible bariatric surgery	Yes Strong need for structured weight loss programs, anti-obesity medications, possible bariatric surgery
Pharmacology for NASH	Not recommended	Yes*	Yes*
CVD risk reduction	Yes	Yes	Yes
Diabetes care	Standard of care	Prefer medications with efficacy in NASH (Pioglitazone, GLP-1 RA)	Prefer medications with efficacy in NASH (Pioglitazone, GLP-1 RA)

[‡]LSM Cut-off values for the fibrosis stages in NAFLD are different than those for HCV and other causes.

[†] Preferred method of determining LSM

*Note that currently no pharmacological agent is FDA-approved for the treatment of NASH. There are RCTs reporting certain medications achieving histological improvement regarding liver fibrosis. These medications may be reasonable if recommended by hepatologist.

MONITORING

Laboratory Monitoring ¹⁶

Some experts obtain serum aminotransferases (ALT and aspartate aminotransferase) every 3-6 months after patients implement lifestyle interventions to achieve and maintain their weight loss goals.

If the aminotransferases do not return to normal levels with weight loss or if they increase, they evaluate the patient for an alternative cause of liver disease.

Monitoring For Fibrosis ^{1,6}

For patients who are at low risk for advanced fibrosis related to NAFLD, repeating the NITs in 2-3 years is recommended, unless clinical circumstances change, indicating a need for sooner follow up.

For patients who are at indeterminate or high risk for advanced fibrosis, reassess in 1-2 years. Consult central care team for questions, especially when ELF is 9.5 or greater¹⁷.

Patients with F4 - cirrhosis (clinically or based on NIT or liver biopsy)

- Should undergo HCC surveillance
- Screening for varices is recommended for patients with a platelet count of <150,000/microL or LSM >20 kPa by FibroScan, or decompensated cirrhosis (see [Liver Cirrhosis Care Guide](#)).

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PATIENT EDUCATION

Non-alcoholic Fatty Liver Disease (NAFLD): What you should know

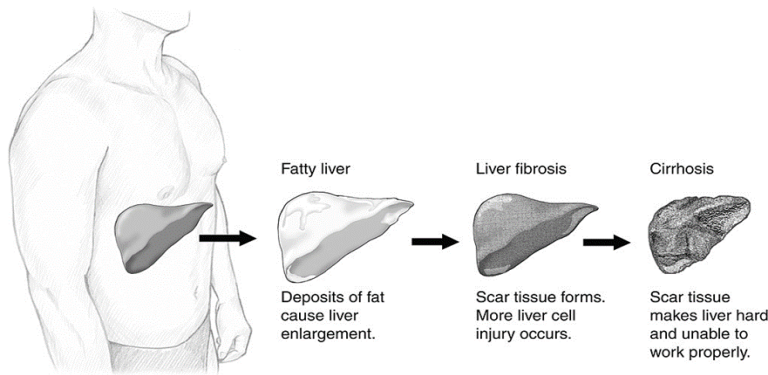
What is the liver?

- Your liver is one of the largest organs in the body
- When the liver does not work well, you can get very sick or even die if your liver stops working



What is NAFLD?

- NAFLD is the most common cause of chronic liver disease in the U.S.
- It is due to a buildup of fat in the liver that is not caused by drinking a lot of alcohol.
- If you are overweight, have diabetes, or high blood pressure, you are at risk for NAFLD.
- A fatty liver alone does not damage the liver. However, a severe form of NAFLD, called Non-alcoholic Steatohepatitis (stee-at-o-hep-a-tite-is) or NASH, can cause damage to the liver that can lead to cirrhosis (sir-o-sis).



How do you know if you have NAFL/NASH?

- At first, you may not notice any symptoms of NAFL/NASH.
- Some early symptoms are:
 - ◆ Feeling tired
 - ◆ Pain in the right upper stomach area



What should you do if you have NAFL/NASH?

- The most important treatment for NAFL/NASH is to lose weight slowly along with healthy diet changes and regular exercise.
- The goal is to lose weight slowly, around 1-2 pounds per week, or 7-10% loss of body weight, over a year.
- You can help yourself manage NAFL/NASH by:
 - ◆ Increasing physical activity
 - ◆ Making health food choices
 - ◆ Slowly losing weight
 - ◆ Not drinking alcohol
 - ◆ Working with your health care team to keep all medical conditions under control



EDUCACIÓN DEL PACIENTE/AUTOCONTROL

Enfermedad del hígado graso no alcohólico (NAFLD, por sus siglas en inglés): lo que debe saber

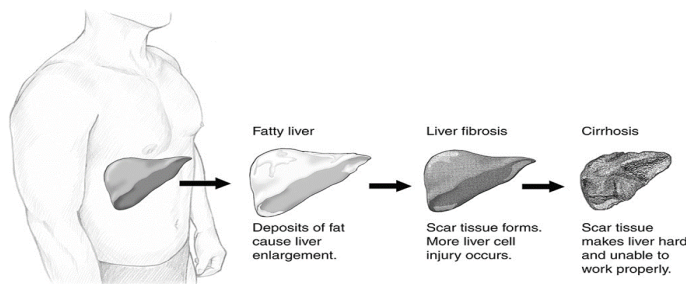
¿Qué es el hígado?

- El hígado es uno de los órganos más grandes del cuerpo.
- Cuando el hígado no funciona bien, la persona puede enfermarse gravemente o incluso morir si éste deja de funcionar.



¿Qué es la NAFLD?

- La NAFLD es la causa más común de enfermedad hepática crónica en EE. UU.
- Se debe a una acumulación de grasa en el hígado que no es causada por beber alcohol en gran cantidad.
- Si tiene sobrepeso, diabetes o hipertensión, corre el riesgo de padecer la NAFLD.
- Un hígado graso por sí solo no daña el hígado. Sin embargo, una forma grave de la NAFLD, llamada esteatohepatitis no alcohólica o NASH, puede causar daños en el hígado que pueden provocar cirrosis.



¿Cómo saber si padece la NAFL/NASH?

- Al principio, es posible que no note ningún síntoma de la NAFL/NASH.
- Algunos síntomas tempranos son:
 - ◆ Sensación de cansancio.
 - ◆ Dolor en la parte superior derecha del estómago.



¿Qué debe hacer si tiene NAFL/NASH?

- El tratamiento más importante para la NAFL/NASH es perder peso lentamente acompañado de cambios saludables en la dieta y hacer ejercicio con regularidad.
- El objetivo es perder peso lentamente, alrededor de 1/2 o 1 kilo por semana, o 7-10 % de pérdida de peso corporal, durante un año.
- Para controlar la NAFL/NASH puede:
 - ◆ Aumentar la actividad física
 - ◆ Tener una alimentación saludable
 - ◆ Perder peso lentamente
 - ◆ No consumir alcohol
 - ◆ Trabajar con el equipo médico para controlar todas las enfermedades

