



LIVER HEALTH MATTERS TO SELF-INSURED EMPLOYERS: NONINVASIVE TESTS COST-EFFECTIVELY IDENTIFY INDIVIDUALS AT RISK FOR LIVER DISEASE, HALT DISEASE PROGRESSION, REDUCE COSTS

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Even prior to the COVID-19 pandemic, costs associated with providing healthcare in the U.S. were escalating, with premiums for employers on the rise. Rather than seeking immediate, short-term solutions, such as raising deductibles, decision makers are turning to sustainable solutions designed to create a more resilient U.S. health care system, improve care quality and lower costs.

The first step is to address one of the most pervasive significant health issues, such as the silent epidemic of liver disease. Nearly one-third of Americans have asymptomatic liver disease, most commonly fatty liver disease (FLD), while the CDC estimates that only 1.8% are diagnosed.

Part of the challenge is that many employers do not see the prevalence of FLD in their workforce by simply examining their claims or biometric screening data. These reports often mask or do not accurately represent the incidence of diabetes or obesity – the conditions which lead to onset of FLD, including non-alcoholic fatty liver disease (NAFLD).

Furthermore, there is not yet an approved pharmacological treatment for this disease, making it more critical to detect, prevent, halt and monitor every worker, particularly those at risk. The opportunity to turn the tide on this health crisis and curb associated costs is within reach, and employers are starting to take action.

In an anecdotal survey sponsored recently by Echosens to elicit employer understanding of the prevalence of FLD in the workforce, decision-makers reported:

“Not aware where this ranks in our population.”

“Not a good understanding.”

“Not well understood.”

“Very limited unless we are paying for a transplant.”

“Moderate”

“Liver disease has not surfaced as a primary issue within our population, at this time.”

“Unknown at this time. However, after having read up on the subject, it sounds like it's the next upcoming healthcare crisis given nearly 75% of the population is expected to have this disease and don't know it.”

But the statistics are alarming: approximately 85 million Americans have NAFLD, and 20% have the more problematic non-alcoholic steatohepatitis (NASH). Ten-year market projections for the direct costs of FLD are estimated to reach more than \$1 trillion, and the disease often leads to developing other issues such as advanced fibrosis, increased risk of cardiovascular events and -- at the extreme -- liver cancer, liver transplantation and death.

HIGH COST OF LIVER EPIDEMIC

Not simply a result of alcohol consumption, NAFLD is the most common type of liver disease in the Western world. Today, NAFLD is an asymptomatic disease affecting 1 in 3 American adults and costs the health care system over \$100 billion. Between 5% and 12% of people with NASH will progress to cirrhosis.

One study determined that the mean total annual per patient cost of NASH was \$3,306, \$5,883, and \$6,592 for direct medical, direct non-medical and indirect costs, respectively. Costs increased with fibrosis and decompensation, driven by hospitalization and comorbidities, while indirect costs were driven by work loss.

Because NAFLD and NASH are so tightly intertwined with obesity, diabetes and lifestyle, a “whole person” approach to patient engagement can help support behavioral changes that will lead to better outcomes across the co-morbid conditions affecting the individual patient. What’s more, recent studies show that noninvasive exams at the point of care can cost-effectively identify individuals at risk for liver disease.

UNDERSTANDING LIVER DISEASE

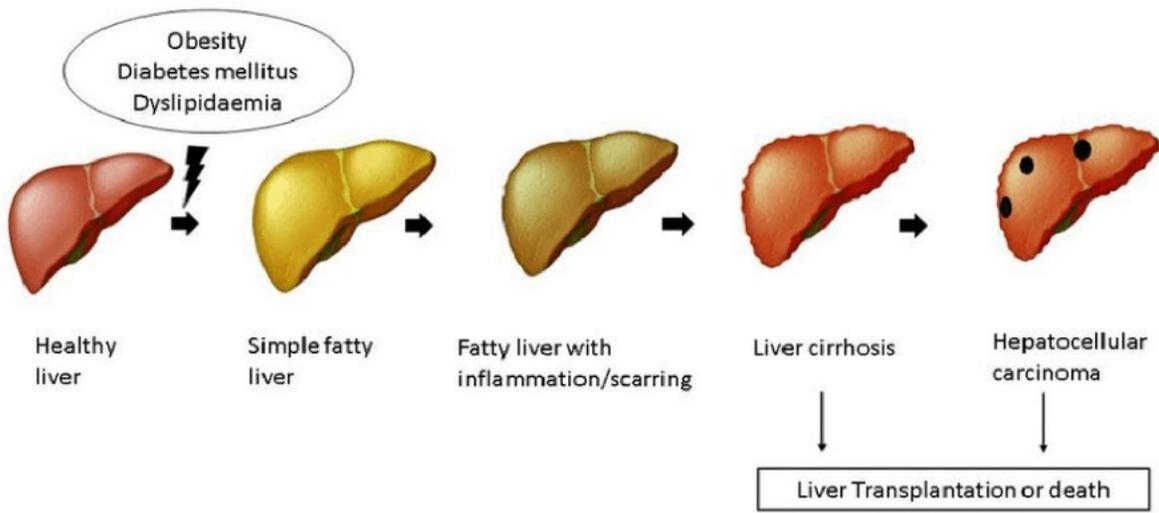
NAFLD is a spectrum of diseases, ranging from elevated liver fat to cirrhosis, and not all patients progress to more severe forms: about 25% of people with elevated liver fat progress to fibrotic-NASH and of those 25% progress to cirrhosis.

This asymptomatic condition is characterized by elevated levels of fat in the liver and is the most common type of liver disease in the Western world. Over 30% of the U.S. population has some degree of NAFLD, which is linked to diabetes, obesity, insulin resistance and other metabolic risk factors.

NAFLD without advanced fibrosis has a 1.1% five-year mortality rate and advanced fibrosis has an 18% mortality

rate. NAFLD alone costs on average \$19,000 per year, while cirrhosis ranges from \$26,000 to \$66,000 per year depending on degree of damage.

amount of free fatty acids circulating in the blood and inside the liver cells.



Source: Than, New & Newsome, Philip. (2016). *Fatty liver disease: a condition caused by modern day lifestyle.*

As employers struggle to find the most optimal way to manage population health, chronic care disease management (CCDM) promises to be the most effective approach for treating patients with liver disease and comorbidities, such as obesity and Type 2 diabetes.

FIRST-LINE TREATMENT FOR

LIVER DISEASE

NASH is a potentially progressive liver disease that can lead to cirrhosis, hepatocellular carcinoma (HCC) or liver cancer. Estimates show that 357 million people will have NASH globally by 2030. What's more, NASH has created a global treatment market projected to reach \$21.5 billion by 2025, and is on track to becoming the leading cause of liver transplantation in the United States.

Liver disease rates have risen along with obesity rates in the United States. In 2000, 30.5% of American adults had obesity, meaning they had a body mass index of 30 or higher. That rate increased through 2015-2016, helping to fuel related health issues like diabetes, cardiovascular disease and some cancers. Recent data from the CDC that the obesity rate reached 42.4% in 2017- 2018 – surpassing 40% for the first time.

ROLE OF OBESITY

Obesity is not simply a matter of over-eating, but rather a complex disease that involves an excessive amount of body fat. To overcome the stigma of obesity, it's important to view this disease as a complex medical issue that increases the risk of heart disease, diabetes, high blood pressure and certain cancers. Given its overwhelming prevalence—obesity is now recognized as a chronic disease by several organizations, including the American Medical Association.

The Centers for Disease Control and Prevention (CDC) defines chronic disease as conditions that last one year or more and require ongoing medical attention or limit activities of daily living, or both. Of the \$3.3 trillion spent annually on medical care for chronic conditions, obesity alone is associated with \$1.4 trillion.

The impact of obesity on vital organs can be devastating, especially on the liver, causing insulin resistance that leads to buildup of blood sugar and increases the

Implementing a CCDM program that targets liver health can address the broader needs of individuals and prevents them from developing NASH. In fact, this is essential given the costs and complications associated with NASH—a challenging, high-volume and chronic condition that lacks a standardized care delivery model.

Diet and exercise interventions have been shown to be effective at reversing steatosis and modification of cardio-metabolic risk factors. For many patients, a 3% reduction in body weight has been associated with reversal of steatosis and a reduction of greater than 7% may resolve NASH in many patients.

In recent years, the fibrosis stage of liver disease has been identified as the most important predictor of liver outcomes.

For this reason, identifying patients with NAFLD and NASH with more advanced stages of fibrosis is critical for management.



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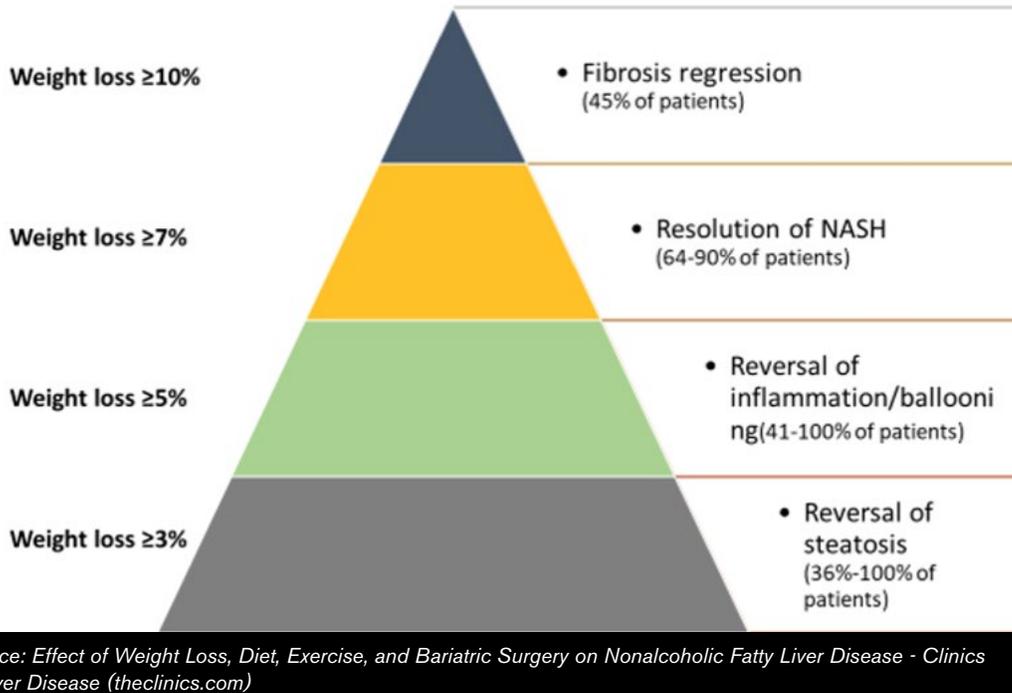
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A follow-up visit ensures that the patient is following the weight loss program, consulting with a dietician or nutritionist and adhering to the program. It's also useful to share the patient's liver exam score with them to illustrate the change in liver fat and the need for adjusting their treatment. This is where noninvasive tests play a key role.



COST-EFFECTIVE, NONINVASIVE LIVER EXAMS

Fortunately, employers can turn to the medical community for diagnostic and treatment assistance. Increasingly, primary care physicians and specialists understand the growing need for cost-effective ways to detect and monitor liver disease. Current approaches for identifying fibrotic NASH, however, are complicated, expensive and potentially wasteful. A recent expert review conducted through the Chronic Liver Disease Foundation suggests a streamlined approach that is cost-effective.

This approach begins with a practical decision tree/algorithm to risk stratify NAFLD/NASH in clinical practice. These algorithms use serum biomarkers, which offer the strongest evidence for identifying fibrosis in NAFLD. In addition, clinicians can risk stratify patients with NAFLD using noninvasive tests (NITs), such as NAFLD Fibrosis Score (NFS), Fibrosis-4 Index (FIB-4) or liver stiffness measured by elastography.

Researchers identified Vibration Controlled Transient Elastography (VCTE) as a useful direct biomarker of liver stiffness and fat in point of care. Other direct biomarkers include magnetic resonance elastography (MRE) and ultrasound-based 2D shear wave elastography (2D-SWE), often available in specialist or radiology departments.

Moreover, the researchers identified combinations of direct biomarkers with circulating blood biomarkers, such as the FAST™ Score as cost-effective options to identify the probability of active fibrotic NASH among people suspected of having NAFLD.

A CCDM program can leverage a noninvasive tool, like FibroScan, to quickly provide a quantitative assessment of liver stiffness and liver fat at the point of care to make the detection of liver disease and long-term care for individuals with NAFLD and NASH more effective.

With the introduction of new treatment options, a targeted CCDM program can integrate non-invasive, point of care liver examinations to leverage the launch of these drugs in a way that improves outcomes and lowers costs for employers.

FibroScan in point of care, for example, provides a simple, validated and reliable exam that creates savings to benefit payers in two ways: 1) early identification of patients with fatty liver disease to allow for proactive intervention and behavior change to slow disease progression; and for those identified with liver fibrosis, 2) reduce the aggregate volume of some current diagnosis methods, such as liver biopsy.

Researchers who conducted scenario testing demonstrated positive net savings within two years across most scenarios and regions. They concluded that broad deployment of VCTE devices is a financially advantageous solution to address the fatty liver disease epidemic.

VALUE OF INNOVATIVE TECHNOLOGY

The most effective non-invasive liver exam tools are highly mobile, can be operated by a medical assistant and interpreted by the healthcare professional. They produce numeric measurements—not images—for simplified interpretation and consistency of measurement. This enables clinicians to monitor changes in liver tissue over time. Experts anticipate that such rapid tools that provide consistent liver measurements will be performed as a routine part of patient management.

The first drug, Ocaliva is expected to launch in late 2021 with a potential price tag of \$15,000-20,000 per year, followed by later entrants with likely pricing ranging from \$10,000-15,000 annually. Given these extraordinary, projected expenses, it will prove to be more cost-effective for employers to address liver

disease with diet and lifestyle interventions. ■



FDA-cleared point-of-care device to aid diagnosing and monitoring adult patients with liver disease, as part of an overall liver assessment.

For employers and employees alike, it is critical to recognize liver disease, such as NAFLD and NASH, so that early intervention can be implemented. Lifestyle modifications and strict control of metabolic risk factors are the most effective treatment. The benefits of managing chronic disease are to not only improve health and reduce medical costs, but also to create a more productive and healthier workforce.

Now more than ever, it is a strategic imperative for self-insured employers to address the serious health and cost challenges associated with liver disease. The opportunity to embrace and leverage new technology and work with physicians and specialists who are keeping pace with this silent epidemic must become a top priority.

As the pharmaceutical industry begins to introduce Rx treatments with associated high costs of specialty drugs, employers will face extraordinary expenses. Major pharmaceutical companies are now targeting fatty liver and developing new chronic therapies that should be on the market in the next year or two.