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PERSPECTIVE ON THE Rx PIPELINE

Understanding changes in the medication market and their impact on cost and care.

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CRAFTED Rx SOLUTIONS

Perspective on the Rx Pipeline

Elixir continuously monitors the drug pipeline. As treatment options change, we evaluate and share our perspective on the clinical benefits, cost-effectiveness and overall impact to payers and patients. Our Perspective on the Rx Pipeline report provides ongoing actionable insights from our team of clinical experts and the steps we are taking to protect and improve plan performance.

INCLUDED IN THIS EDITION:

NASH: The growing and costly disease you probably don't know about but should

NASH

The growing and costly disease you probably don't know about but should

Nonalcoholic steatohepatitis (NASH) is a type of nonalcoholic fatty liver disease (NAFLD). Like its name states, NASH occurs without excessive alcohol consumption. It causes inflammation of the liver that may damage or cause scarring, known as liver fibrosis.[1]

While symptoms of NASH include loss of appetite, swelling in the legs, jaundice, and nausea, many patients are often asymptomatic and are unaware that something is wrong. Without symptoms to identify and treat, NASH can proceed to end-stage liver disease or the need for a liver transplant. In fact, 20% of patients with NASH may develop cirrhosis[2] and they have a reported 12x increased risk of liver cancer.

Even with its high prevalence of disease, there are currently no FDA-approved medications for NASH. However, two pipeline drugs, obeticholic acid and resmetirom, have been submitted for approval. These drugs–most likely classified as specialty–could have significant impact to plan sponsors, providers and patients due to cost, safety and appropriateness.

Let's break down NASH to understand the disease, who is most at risk, and its causes and treatments.

An advanced form of NAFLD

NASH falls in the spectrum of NAFLD along with fatty liver and cirrhosis (scar tissue replaces liver cells). NAFLD develops due to a buildup of excess fat in the liver and its prevalence is growing. Currently, it is estimated to be present in 25% of the world's population.[3] This includes 1.5% to 6.5%.[3] of U.S. adults. A genetic component may exist that contributes to NAFLD, which is being researched.

NAFLD is also costly. In the U.S., the estimated annual health care cost associated with NAFLD was approximately $103 billion and a 10-year economic burden of $908 billion.[4]

Those at risk for developing NASH

Patients with NASH vary in race and age, and no one is immune, but NASH is most prevalent in the Hispanic, Asian and Caucasian communities and/or those 40 to 60 years of age. Obesity is the largest contributor to developing NASH, and other associated comorbidities include dyslipidemia, type 2 diabetes and metabolic syndrome.

Multiple pathways to NASH development

There are multiple pathways to NASH and the buildup of fat in the liver. This, along with the patient variability, has made NASH a notoriously difficult condition to develop a pharmacological treatment.[5,6]

Possible ways NASH may develop

1. Free fatty acids (FFA) are released from body fat due to insulin resistance and dietary sugar induced lipid synthesis.[7] The insulin resistance contributes to the development of NAFLD and may promote progression of the disease.[5]
2. FFA are stored as triglycerides or metabolized into lipotoxic lipids (such as cholesterol or diacylglycerol) and create oxidative stress, which can cause damage to organs and tissues, including the liver.
3. Reduced activity of antioxidants such as:
   - Coenzyme Q10 used for growth and maintenance
   - Superoxide dismutase enzyme that may prevent tissue damage.
4. Reduced levels of glutathione that helps with tissue building and repair.
5. The endoplasmic reticulum (ER), which produces proteins for the cell to function, may be stressed due to increased FFA. This can cause cell injury and inflammation.[6]
6. A leaky gut causes microbiota imbalance and contributes to inflammation in the liver.

WHAT PLAN SPONSORS NEED TO KNOW ABOUT NASH AND NAFLD

- Impacts 1.5% to 6.5%[3] of U.S. adults
- Many patients are asymptomatic
- 20% of patients may develop cirrhosis[2]
- Patients have 12x increased risk of liver cancer
- Annual health care cost ≈$103 billion
- There are no FDA-approved medications for NASH

NASH

There's no simple test to diagnose NASH and NAFLD

Even with a growing prevalence of NAFLD and NASH, the American Association for the Study of Liver Diseases (AASLD) does not advise for the screening of the general population for NAFLD. High-risk individuals, such as those with type 2 diabetes, medically complicated obesity, a family history of cirrhosis, or take part in more-than-mild alcohol consumption, should be screened for advanced fibrosis.

Diagnostic evaluation may include laboratory liver enzyme tests to rule out other causes of hepatic steatosis. Radiographic examination or imaging such as ultrasound, magnetic resonance imaging (MRI) and elastography may be used to diagnose NAFLD.

As NASH is a more severe form of NAFLD, a liver biopsy assessment remains the gold standard for the grading and staging of NASH. However, a liver biopsy can be an invasive and expensive procedure, so it should usually be considered:

- If a NASH evaluation leads to an unclear diagnosis.
- For patients with, or at high risk of, cirrhosis or fibrosis.

Currently, genetic testing for NASH is not recommended as it does not change patient management strategies.[5, 8]

Treatments to prevent further fibrosis and complications

Cardiovascular complications are one of the most common cause of death in patients with NASH.[8]

There are no FDA-approved treatments for NASH. In 40% of NASH patients, their fibrosis may progress about one stage per decade.[2] So treatment should focus on preventing further fibrosis and other liver-related and cardiovascular complications.

As obesity is the largest contributor to developing NASH, weight loss is paramount for improvement in many patients and may improve liver histology, liver biochemical test, insulin levels and the patient's quality of life. A weight loss goal of 7% to 10% is recommended in most overweight (BMI >25 kg/m2) or obese (BMI >30 kg/m2) patients.

Bariatric surgery may be considered for select patients who have not achieved their weight loss goal after six months. One study noted, one year post bariatric surgery, 80% of patients had resolution of NASH without worsening of fibrosis that was maintained at five years.[9,10] Some patients may not be candidates for bariatric surgery, such as certain patients with cirrhosis.[6]

Two pipeline drugs for NASH may be available in the near future. If approved, these drugs, obeticholic acid and resmetirom:

- **Will likely impact commercial and Medicare plans**
- **May be on the prescription benefit and be self-administered**
- **May be classified as specialty drugs**

LIMITED PHARMACOLOGIC TREATMENT OPTIONS

With no FDA-approved treatments for NASH, physicians and providers may prescribe other options.

Treatment	Notes
Vitamin E	• Weigh risk versus benefit in those with prostate cancer or cardiovascular events of concern[5] • Does not have supportive outcomes evidence for those with diabetes
Pioglitazone or GLP-1 agonist	• For those with diabetes and NASH[8] • May improve biochemical and histologic parameters • Pioglitazone side effects- exacerbating congestive heart failure and weight gain[11] • May improve NAFLD due to insulin resistance in NASH

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NASH is a notoriously difficult condition for development of pharmacological treatment.[6, 7]

NASH pharmaceuticals in the pipeline

Successful drug development and FDA approval is dependent on the selection of accurate efficacy endpoints. While the goal of NASH treatment is to slow or reverse disease progression and improve clinical outcomes including liver-related mortality, these markers are not practical as clinical endpoints.[12]

To add to the complexity, drug development for NASH is limited by the need for multiple biopsies to monitor disease progression and the lack of non-invasive biomarkers that could improve study design and feasibility.[13] The chronic nature of the disease may require a study duration exceeding 10 years or more to show improvement in clinical outcomes.[13]

As a result of these challenges, the FDA has recommended liver histological improvements as appropriate surrogate endpoints that could support a clinical benefit and lead to an accelerated approval.

The recommended endpoints are based on the NAFLD Activity Score (NAS), which is a numerical score that measures steatosis, inflammation and improvement of liver fibrosis stage.[12] Since the positive relationship between improvement in liver histology and clinical outcomes has not been proven, the FDA recommends that additional studies are run concurrently to verify clinical benefit.

Two products that could receive FDA accelerated approval by 2024 are obeticholic acid and resmetirom.

OBETICHOLIC ACID AND RESMETIROM[14] OVERVIEW

Drug	Manufacturer	Route	Mechanism	Estimated Approval
Obeticholic acid	Intercept Pharma	Oral	Farnesoid X receptor agonist	06/22/2023
MGL-3196 Resmetirom	Madrigal Pharmaceuticals	Oral	Thyroid hormone receptor agonist	Q4 2023

NASH

PIPELINE STAGE

R & D | **Submitted for FDA approval** | In Market Brand | Off Patent Exclusive Generic | Open Source Alternative | Off Market

Obeticholic Acid Clinical Trials

Obeticholic acid is an oral, once daily farnesoid X receptor (FXR) agonist. It works by regulating bile acid levels and metabolism. In addition, activation of the FXR can reduce hepatic fibrosis and inflammation.[15] The drug was already approved for adults with primary biliary cholangitis (PBC).

NOTE: *The dose used for PBC is lower than the proposed dose for NASH.*

CLINICAL TRIALS

REGENERATE

Phase III - Multicenter, randomized, double-blind, placebo-controlled

Included:
- Adults with NASH with moderate to severe fibrosis.
- Adults with NASH with mild fibrosis and at least one risk factor (obesity, type 2 diabetes, or ALT greater than 1.5 times the upper limit of normal).[17]

Patients received either:
- obeticholic acid 10 mg
- obeticholic acid 25 mg
- placebo

REANALYSIS OF REGENERATE EFFICACY DATA [17,19]

Primary Endpoint	Placebo (n=311)	Obeticholic acid 10mg (n= 312)	Obeticholic acid 25mg (n= 208)
Resolution of NASH with no worsening of liver fibrosis	3.5%	6.1% p= not significant	6.5% p= not significant
≥1 stage of fibrosis improvement with no worsening of NASH	9.6%	14.1% p= not significant	22.4% p<0.0001

REVERSE

Phase III - Multicenter, randomized, double-blind, placebo-controlled

Included:
Adults with NASH with a fibrosis score of 4 based upon the NASH CRN scoring system, a numerical grading system for fibrosis.[20]

Patients received either:
- obeticholic acid 10mg for 18 months
- obeticholic acid 10mg for three months with option to titrate to obeticholic acid 25 mg for the remainder of study
- placebo for 18 months

Results:

Primary Endpoint	Placebo	Obeticholic acid 10mg	Obeticholic acid titrated to 25mg
≥1-stage improvement in fibrosis with no worsening of NASH	9.9%	11.1% p= not significant	11.9% p= not significant

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OBETICHOLIC ACID CLINICAL TRIAL TIMELINE AND DATA INTERPRETATION

2019	2020	2022	2023
Interim analysis of REGENERATE clinical data found that the only primary endpoint met was fibrosis improvement with no worsening of NASH for the higher dose.	The FDA issued a Complete Response Letter (CRL) stating that current efficacy data was insufficient to grant an accelerated approval.[18]	REVERSE trial results showed obeticholic acid did not meet the primary endpoint of fibrosis improvement with no worsening of NASH. A reanalysis of REGENERATE trial was performed using improved methodology,[17, 19] which showed similar results to 2019 trial.	• Application for accelerated approval filed • A PDUFA date of June 22, 2023, assigned. • An FDA advisory committee meeting is scheduled for May 19, 2023.

Overall, the clinical trial results for obeticholic acid have been lackluster. The only statistically significant finding was improvement in fibrosis stage with no worsening of NASH for patients receiving the higher, 25mg dose. This raises efficacy and safety concerns as an FDA MedWatch safety alert was already issued regarding serious liver injury in use of the lower, 5-10mg dose when prescribed for adults with primary biliary cholangitis (PBC).

In addition, the clinical trials highlighted two concerns for obeticholic acid:

1. Side effect of itchiness, which could hinder patient adherence.
2. Increased cholesterol levels, a clinically significant barrier given the NASH patient population.

Despite these findings, an application for accelerated approval of obeticholic acid was filed and a Prescription Drug User Fee Act (PDUFA) date of June 22, 2023, was assigned. An FDA advisory committee meeting is scheduled for May 19, 2023. However, if approved, prescribing of obeticholic acid may be limited to patients with moderate-severe fibrosis and gastroenterologists or hepatology specialists until more is known about safety and efficacy.[17]

NASH

PIPELINE STAGE

R & D | **Submitted for FDA approval** | In Market Brand | Off Patent Exclusive Generic | Open Source Alternative | Off Market

Resmetirom Clinical Trial

Resmetirom, a once daily oral product, is a thyroid hormone receptor (THR) agonist that decreases fat in the liver.[19] Resmetirom is 28 times more selective for THR-β than THR- α and therefore has poor tissue penetration outside the liver.[21] This selectivity is theorized to provide metabolic benefits of thyroid hormone such as reduction of hepatic fat and low-density lipoprotein cholesterol (LDL-C) without the unwanted systemic effects of excess thyroid hormone in heart and bone.

CLINICAL TRIAL

MAESTRO-NASH

Phase III - Ongoing, multinational, double-blind, randomized, placebo-controlled

Included:
Patients with liver biopsy-confirmed NASH

Patients received either:
- resmetirom 80mg
- resmetirom 100mg
- placebo[22]

MAESTRO-NASH EFFICACY DATA[17,23]

Primary Endpoint Histological response by liver biopsy at 52 weeks	**Placebo (n=311)**	**Resmetirom 80mg (n= 316)**	**Resmetirom 100mg (n= 318)**
NASH resolution (with ≥2-point reduction in NAS*) and no worsening of fibrosis stage	10%	26% p <0.0001	30% p <0.0001
≥1-point improvement in fibrosis stage with no worsening of NAS*	14%	24% p <0.0002	26% p <0.0001
Secondary Endpoint LDL-C lowering at 24 weeks	1%	-12% p <0.0001	-16% p <0.0001

**NAS= NAFLD Activity Score: steatosis (0-3), hepatocyte ballooning (1-2) and lobular inflammation (0-3)*

RESMETIRON CLINICAL TRIAL DATA INTERPRETATION

In comparison to obeticholic acid, resmetirom appears to have more robust efficacy results, cardiovascular benefits in LDL-C reduction and a better safety profile. Resmetirom is also being studied in those with NAFLD that has yet to progress to NASH. Given its good safety profile, and that it could be used in earlier stages of NASH, prescribing could be expanded to primary care providers as comfortability increases with use.[17]

Application for Resmetirom's accelerated approval is expected to be filed in the first half of 2023, with the earliest approval at the end of 2023.[17]

NASH

PIPELINE STAGE

R & D | Submitted for FDA approval | In Market Brand | Off Patent Exclusive Generic | Open Source Alternative | Off Market

Other investigational treatment options in Phase III trials

ADDITIONAL EXAMPLES OF NASH IN THE PIPELINE[14]

Drug	Manufacturer	Route	Mechanism	Estimated Approval
Aramchol Arachidyl amido cholanoic acid	Galmed	Oral	Stearoyl-CoA desaturase 1 (SCD1) inhibitor	2027
• Inhibits the liver enzyme, SCD1, which decreases fatty acid synthesis and increases fatty acid breakdown • Phase 2b ARREST trial enrolled NASH patients with obesity and diabetes and had mixed results • Phase 3 ARMOR study was granted Fast Track designation status by the FDA. Results have shown that higher doses resulted in better fibrosis improvement.				
GR-MD-02 Belapectin	Galectin Therapeutics	Intravenous	Galectin inhibitor	2025
• Binds to galectin-3 proteins in liver macrophages to mitigate fibrogenesis • Clinical trial underway to evaluate its use in preventing esophageal varices in those with NASH • Topline data expected in Q2 2024				
Lanifibranor	Inventiva Pharma	Oral	Peroxisome proliferator-activated receptor (PPAR) agonist	TBD
• PPAR agonist that promotes antifibrotic and anti-inflammatory changes • First product to have significant results on NASH resolution with no worsening of fibrosis and improvement of fibrosis with no worsening of NASH in a phase 2b trial				
MEDI-0382 Cotadutide	AstraZeneca MedImmune	Subcutaneous	Glucagon-like peptide-1 agonist	2026
• Once daily subcutaneous injection • Phase 2b study showed significantly reduced A1c, body weight, lipids, AST, ALT and fibrosis • Phase 3 study underway with data anticipated in 2025				
MSDC-0602K TBD	Cirius Therapeutics	Oral	Thiazolidinedione	2025
• Second-generation thiazolidinedione that is designed to have reduced side effects such as edema and hypoglycemia compared to first-generation thiazolidinedione products (pioglitazone) • Being studied in those with NASH and either prediabetes or type 2 diabetes • Phase 3 MMONARCh-1 trial has an estimated completion of 2024, with an approval potentially in 2025				
Wegovy Semaglutide	Novo Nordisk	Subcutaneous	Glucagon-like peptide-1 agonist	2025
• Currently approved for diabetes (Ozempic®, Rybelsus®) and weight loss (Wegovy®) • Data from a phase 2 trial in those with stage 4 compensated cirrhosis was not significant for NASH resolution • Further trials with semaglutide will only be combination trials with cilofexor and firsocostat, FXR agonists • Semaglutide monotherapy will only be studied in patients with stage 2/3 cirrhosis				

The impact of NASH medication approvals will likely be in commercial and Medicare plans.

Pipeline approvals may mean impact to pharmacy care experience

NASH has a high prevalence of disease, so a new medication approval could have significant patient and provider interest. However, a universal screen for NASH is not recommended and many patients are asymptomatic or only experience mild symptoms. A possible increase in screening of high-risk NASH patients may impact future pharmacological treatment utilization. As such, lifestyle changes, including weight loss, if necessary, continue to be the first-line treatment for NASH.

When it comes to medication approvals, patients may not see the benefits of a NASH drug for many years, as some of the biggest disease concerns are progression to liver fibrosis, cirrhosis, or cancer. If a new drug has significant safety concerns, the provider will need to weigh the risk versus the benefit before prescribing.

Oral obeticholic acid and resmetirom will likely be pharmacy spend if approved. Self-administered, subcutaneous and intravenous infusions are also in the pipeline. Some products may find themselves with specialty designation.

Payer action plan

Due to the various possible mechanisms of disease development and the variation in patients, development of one drug that resolves NASH and halts fibrosis in all patients is unlikely. In other words, a NASH treatment may not be a one-size-fits-all answer.

Due to the prevalence of disease and no current FDA-approved treatment options, NASH is considered a possible blockbuster indication. The impact of NASH medication approvals will likely be in commercial and Medicare plans due to the age range of the diagnosed patients. NASH medications, if approved, may also find their way on the prescription benefit and be self administered.

Elixir will continue to monitor the pipeline and approval process. Once any of the NASH medications are FDA approved, a drug or biologic undergoes clinical review by the Elixir P&T Committee. Utilization management, especially prior authorizations, may be expected for NASH treatments until their place in therapy is well defined and clinical practice provides more real-world results.

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Our Clinical Steering Committee

The Elixir Clinical Steering Committee brings together leaders from across our national pharmacy care company to monitor the drug landscape, provide recommendations on how to address changes, and to ensure our clients and patients are prepared—in advance.

With any new development, we partner with our Pharmacy & Therapeutics (P&T) committee and consult with our best-in-class specialty pharmacy, to provide a balanced perspective on the clinical effectiveness of all available options, the cost impact to our plan sponsors and patients, and the impact on the overall patient experience.

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