
Resmetirom and Obeticholic Acid for Non-Alcoholic Steatohepatitis: Effectiveness and Value

Public Meeting — April 28th, 2023

Meeting materials available at: <https://icer.org/assessment/non-alcoholic-steatohepatitis-2023/>



Patient Experts

Kimberly Martinez, Patient Advocate

- *No conflicts to disclose.*

Clinical Experts

Adnan Said, MD, MS, Professor, Gastroenterology and Hepatology; Director, Metabolic Liver Health Clinic, University of Wisconsin School of Medicine and Public Health

- *Dr. Said has received consulting support in excess of \$5,000 from Mallinckrodt pharmaceuticals and serves as a Site Principal investigator for the REGENERATE study.*

Danielle Brandman, MD, MAS, Medical Director of Liver Transplantation, Weill Cornell Medicine

- *Dr. Brandman has received prior research funding from Gilead and Genentech for research in the clinical area of this meeting. Dr. Brandman was previously a Principal investigator on clinical trials involving other drugs for NAFLD.*



Why are we here today?

Because I do not look physically sick, some just can't believe the seriousness of the disease. The hardest part is coming home after getting certain results and trying to keep a poker face when a recent test came back showing advanced fibrosis. It's not an easy disease to live with. I pray for a cure one day soon.

Anonymous

Why Are We Here Today?

- What happens the day these treatments receive FDA approval?
- Questions about:
 - What are the risks and benefits?
 - How do new treatments fit into the evolving landscape?
 - What are reasonable prices and costs to patients, the health system, and the government?
 - What lessons are being learned to guide our actions in the future?

The Impact on Rising Health Care Costs for Everyone



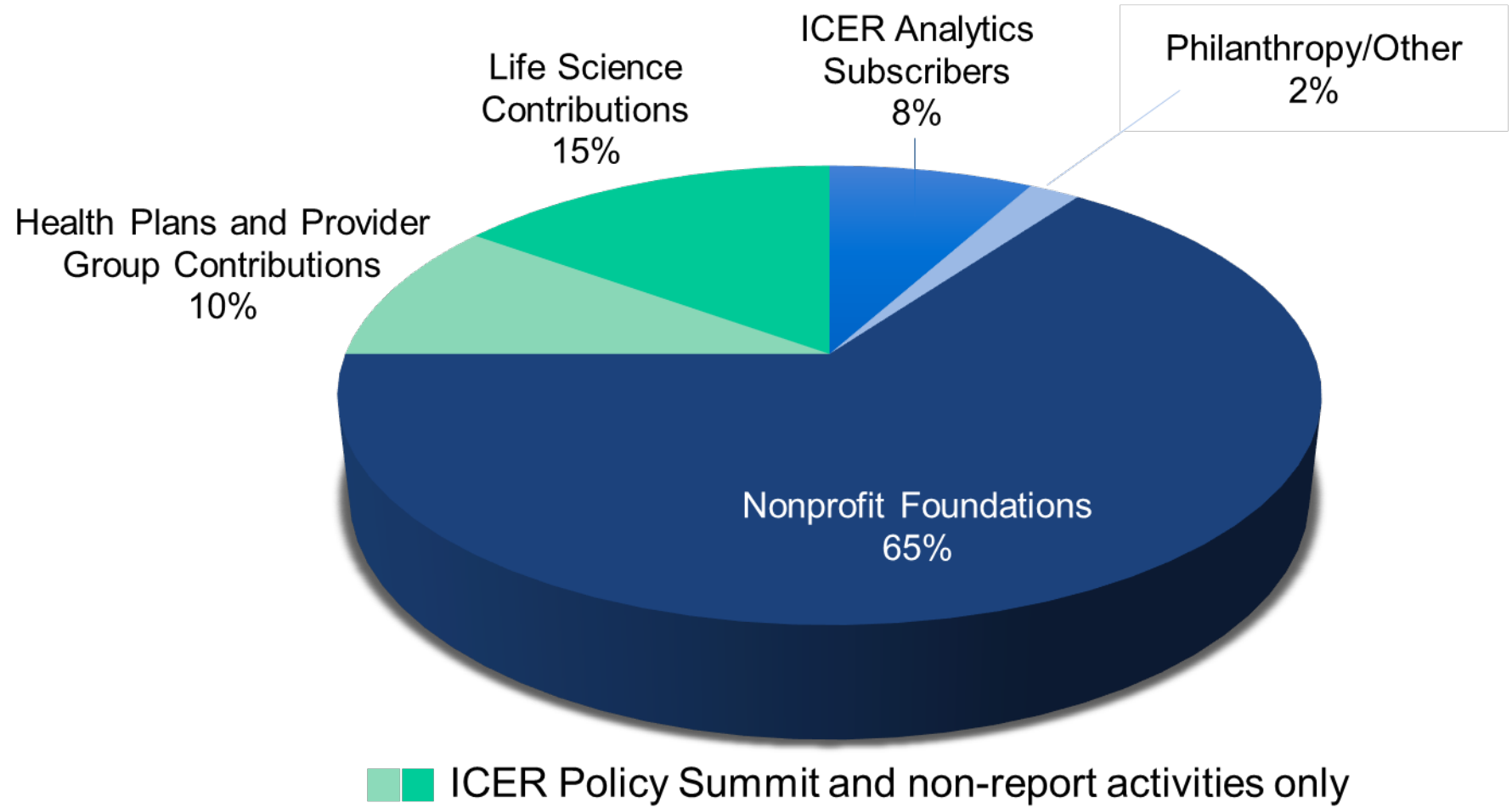
<https://khn.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/>



Organizational Overview

- Midwest Comparative Effectiveness Public Advisory Council (CEPAC)
- Institute for Clinical and Economic Review (ICER)

Sources of Funding, 2023



How Was the ICER Report Developed?

- Scoping with guidance from patients, clinical experts, manufacturers, and other stakeholders
- Internal ICER evidence analysis and cost-effectiveness modeling
- Public comment and revision
- Expert reviewers
 - Adnan Said, MD, MS
 - Meena B. Bansal, MD
 - William W. L. Wong, PhD
 - Jeff McIntyre, Global Liver Institute
- How is the evidence report structured to support CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Special Social/Ethical Priorities

Benefits Beyond “Health”

Total Cost Overall
Including Cost Offsets

Health Benefits:
Return of Function, Fewer Side
Effects

Health Benefits:
Longer Life

Agenda (CDT)

10:00 AM Meeting Convened and Opening Remarks

10:20 AM Presentation of the Clinical Evidence

11:00 AM Presentation of the Economic Model

11:40 AM Public Comments and Discussion

12:15 PM Lunch Break

12:50 PM Midwest CEPAC Deliberation and Vote

1:50 PM Break

2:00 PM Policy Roundtable Discussion

3:30 PM Reflections from Midwest CEPAC

4:00 PM Meeting Adjourned

Presentation of the Clinical Evidence

Jeffrey A. Tice, MD

Professor of Medicine

University of California, San Francisco



Key Collaborators

- **Shahariar Mohammed Fahim, PhD**, Research Lead, Evidence Synthesis, ICER
- **Belen Herce-Hagiwara, BA**, Research Assistant, Evidence Synthesis, ICER
- **Janet N. Chu, MD, MPH, MAS**, Assistant Professor of Medicine, University of California, San Francisco
 - **Research support from Gilead on NAFLD identification in Primary Care**

Disclosures:

We have no additional conflicts of interest relevant to this report.

Background: Non-alcoholic steatohepatitis (NASH)

- NASH is common
 - NAFLD in ~24% of US Adults
 - NASH in 2% - 6% of US Adults
- Risk factors for NASH
 - Obesity, diabetes, metabolic syndrome
- NASH is asymptomatic for most of its natural history
- NASH can cause severe disease
 - NASH is most common reason for liver transplantation in US

Impact on Patients

- Cirrhosis
- Fatigue / Brain Fog
- Decompensated cirrhosis (ascites, encephalopathy, varices)
- Hepatocellular carcinoma
- Liver transplantation
- Death

Standard of Care

- Lifestyle changes
 - Exercise, diet changes, weight loss
- Bariatric surgery (uncommon)
- Treat risk factors for cardiovascular disease (CVD)
 - CVD is leading cause of death for patients with NASH
- No FDA approved therapies for NASH

Population for the Review

- Adults with NASH and stage 2 or 3 fibrosis

Stages of liver fibrosis

0: No fibrosis

1: Portal fibrosis

2: Periportal fibrosis

3: Bridging fibrosis

4: Cirrhosis

Interventions

- Resmetirom compared with usual care
 - 80 mg or 100 mg by mouth once daily
 - Thyroid hormone receptor beta agonist
- Obeticholic Acid (OCA) compared with usual care
 - 25 mg by mouth once daily
 - Bile acid analog approved for the treatment of primary biliary cholangitis

Outcomes

- Intermediate outcomes for FDA
 - ≥ 1 stage improvement in fibrosis without worsening of NASH
 - Resolution of NASH without worsening of fibrosis
- Outcomes that matter to patients
 - Cirrhosis
 - Decompensated, HCC, transplant
 - Quality of life
 - Fatigue, brain fog
 - Death (all cause, liver disease)

Insights from Discussions with Patients

- Frustration with the lack of knowledge about NASH among doctors and the public
- Challenges and lack of insurance coverage for the intense lifestyle interventions needed to achieve and maintain weight loss
- Stigma of the diagnosis of cirrhosis: assumed to be due to alcoholism
- The burdens associated with living post-transplant with the costs and side effects of medicines to prevent rejection
- The financial strain of the illness and the burden it places on caregivers
- Hope that FDA covered therapies will change the course of disease



Clinical Evidence

Key Clinical Trials

Treatment	Study	Group	N	F/U Months	Primary Outcome
Resmetirom					
	MAESTRO-NASH	Placebo RES 80 mg RES 100 mg	318 321 316	12	<ul style="list-style-type: none"> • Decrease fibrosis, no increase NAS • NASH Resolution, no increase fibrosis
Obeticholic Acid					
	REGENERATE	Placebo OCA 25 mg	825 827	18	<ul style="list-style-type: none"> • Decrease fibrosis, no increase NAS • NASH Resolution, no increase fibrosis

Resmetirom

Primary Outcome: Resmetirom

	Placebo (N=318)	Resmetirom 80 mg (N=316)	Resmetirom 100 mg (N=321)
≥1 stage improvement in fibrosis with no worsening of NASH	14%	24%†	26%*
NASH resolution without worsening of fibrosis stage	10%	26%*	30%*

* p<0.0001 versus placebo

† p=0.0002 versus placebo

Lipid and QOL Outcomes: Resmetirom

	Placebo (N=318)	Resmetirom 80 mg (N=316)	Resmetirom 100 mg (N=321)
Change in LDL-chol	+1%	-12%*	-16%*

* p<0.0001 versus placebo

No results reported for quality of life, fatigue or functional status

Harms: Resmetirom

	Placebo (N=318)	Resmetirom 80 mg (N=316)	Resmetirom 100 mg (N=321)
Serious adverse events	12.1%	11.8%	12.7%
Diarrhea	16%	28%	34%
Discontinuation due to adverse events	3.7%	2.8%	7.7%

Obeticholic Acid

Primary Outcome: Obeticholic Acid

	Placebo (N=311)	OCA 25 mg (N=308)
≥1 stage improvement in fibrosis with no worsening of NASH	9.6%	22.4%*
NASH resolution without worsening of fibrosis stage	3.5%	6.5%†

* p<0.0001 versus placebo

† P NS versus placebo

Lipid and QOL Outcomes: Obeticholic Acid*

	Placebo (N=657)	OCA 25 mg (N=658)
Change in LDL-cholesterol at 1 month (mg/dL)	-3	+23.8
Change in LDL-cholesterol at 18 months (mg/dL)	-7.1	+2.7†

* From Younossi 2019. Updated data with larger n and 54 month follow-up similar.

† More than twice as many in the OCA group started statin therapy (n=159 versus 66)

No significant differences in EuroQol-5D overall or by subscale at any timepoint through 18 months

Harms: Obeticholic Acid

	Placebo (N=825)	OCA 25 mg (N=827)
Serious adverse events	21.9%	26.1%
Pruritis	24.4%	54.8%
Discontinuation due to adverse events	11.3%	21.6%

Controversies and Uncertainties

- NASH progresses to cirrhosis over many, many years. Current clinical trials provide short term outcomes on interim markers of disease. Long term outcomes remain uncertain.
- OCA raised LDL-cholesterol initially, while resmetirom lowered LDL cholesterol. It is unclear if this will translate into long-term differences in CVD events.
- When used for primary biliary cholangitis at doses lower than those for NASH, OCA had reports of hepatic decompensation and death.

Potential Other Benefits and Contextual Considerations

- The health equity landscape is complex. Hispanic population has a higher prevalence of NASH than White population and Black population has a lower prevalence. But non-Hispanic White population has a 42% greater prevalence than all other groups combined. The epidemiology of those with stage 2 or 3 fibrosis has not been described.
- Patients with less financial means have greater challenges qualifying for and receiving liver transplants. If they have access to therapies that reduce the risk for cirrhosis, the burden of this disparity will be lessened.

Public Comments Received

- Health Equity section not fully developed
 - A reduction in the need for liver transplantation for patients with NASH could increase the supply of livers available for patients with other diseases requiring transplantation.

Summary: Resmetirom

- In patients with NASH and fibrosis, resmetirom appears to reduce progression, promote regression of fibrosis, and lead to resolution of NASH compared with placebo in topline, unpublished results
- Uncertainty about the long-term benefit and magnitude of these changes
- Harms appear small, though diarrhea is common and there were more discontinuations due to adverse events in the high dose resmetirom group.
- LDL-cholesterol levels lower, but unclear if this will lead to a reduction in CVD events and death over time

ICER Evidence Ratings for Resmetirom

- There is moderate certainty of comparable to substantial net health benefits with high certainty of at least comparable benefits compared with standard of care (C++).

Summary: Obeticholic Acid

- In patients with NASH and fibrosis, OCA appears to promote regression of fibrosis compared with placebo in topline results. There is uncertainty about the long-term magnitude and impact of these changes.
- OCA commonly causes pruritus, so it can worsen quality of life in previously asymptomatic patients. OCA when used for primary biliary cirrhosis has had reports of severe harms with liver decompensation and death. The increase in LDL-cholesterol is also concerning.
- Considering all the evidence, we feel the long-term net effects of OCA on quality of life and health of patients with NASH and F2/F3 fibrosis are uncertain.

ICER Evidence Ratings for Obeticholic Acid

- The evidence for OCA in NASH is promising but inconclusive (“P/I”).

Questions?

Presentation of the Economic Model

Kangho Suh, PharmD, PhD

Assistant Professor

School of Pharmacy, University of Pittsburgh



Key Review Team Members

- **Josh J. Carlson, MPH, PhD**, Professor, CHOICE Institute, University of Washington
- **Ronald Dickerson, MA, MPH**, Research Assistant, CHOICE Institute, University of Washington
- **Marina Richardson, MSc**, Senior Health Economist, ICER

Disclosures:

Financial support was provided to University of Washington and University of Pittsburgh from the Institute for Clinical and Economic Review.

Drs. Suh and Carlson have no conflicts to disclose defined as more than \$10,000 in health care company stock or more than \$5,000 in honoraria or consultancies relevant to this report during the previous year from health care technology manufacturers or insurers.

Objective

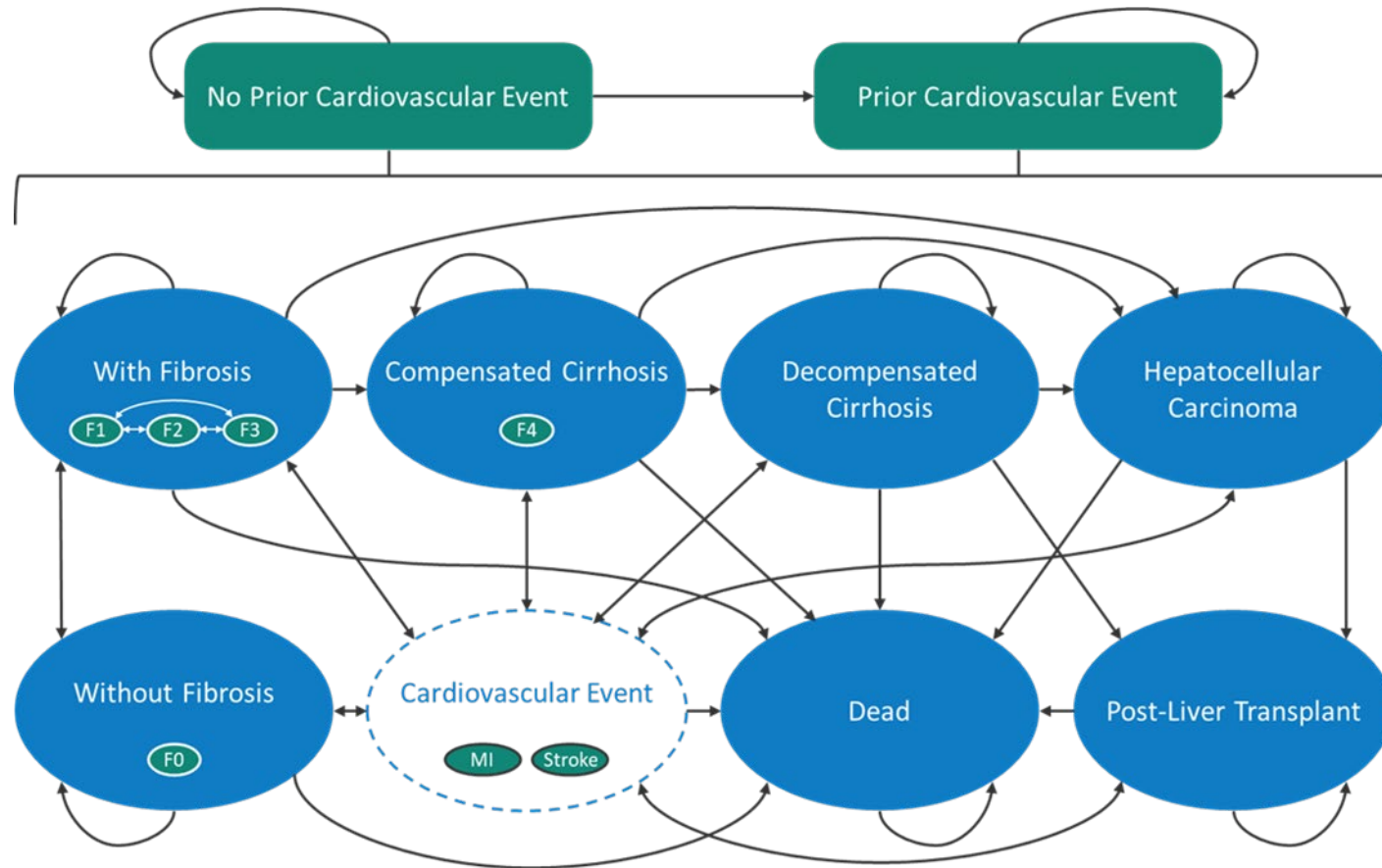
To evaluate the lifetime cost-effectiveness of resmetirom or obeticholic acid (OCA) compared to standard care for the treatment of NASH.

Methods in Brief

Methods Overview

- **Model:** Markov model
- **Setting:** United States
- **Perspective:** Health Care Sector Perspective
- **Time Horizon:** Lifetime
- **Discount Rate:** 3% per year (costs and outcomes)
- **Cycle Length:** 1 year
- **Primary Outcome:** Cost per quality-adjusted life year (QALY) gained; cost per life year (LY) gained; cost per equal value of LYs gained (evLY)

Model Schematic



Model Characteristics

- Patients with NASH fibrosis stage 2 or 3
- Two separate NASH populations were modeled
 - Comparison 1:
 - Resmetirom
 - Standard care
 - Comparison 2:
 - Obeticholic acid
 - Standard care

Key Model Assumptions

- Treatment effects for “improvement” and “worsening” were used as the basis for deriving transition probabilities among fibrosis stages and applied uniformly regardless of starting stage.
- In the absence of detailed resmetirom phase III trial data, we assumed that the composite of improvement in fibrosis without worsening of NAS between treatment groups was comparable to improvement in fibrosis alone.
- Patients who entered the “Prior CV Event” submodel had the same per-event costs, quality of life, and mortality regardless of subsequent CV events.
- Lipid levels have a direct impact on CV events and mortality.

Key Model Inputs: Efficacy

Characteristic	Value	Source
Standard Care Probabilities		
Improvement of Fibrosis	0.23	Younossi et al. 2019
Worsening of Fibrosis	0.21	
Resmetirom Absolute Risk Difference vs. Standard Care		
Improvement of Fibrosis	0.12	Topline Phase III results
Worsening of Fibrosis	-0.12	
Obeticholic Acid Absolute Risk Difference vs. Standard Care		
Improvement of Fibrosis	0.15	Younossi et al. 2019
Worsening of Fibrosis	-0.08	

Treatment-Related Efficacy: Fibrosis Transition Probabilities

Clinical trials of resmetirom and OCA

Meta analysis of previous NASH clinical trials

Adjustment to Annual Probability

Final stage-specific transition probabilities

Example:
Resmetirom

F2 patients:
• 35% improve



Among patients improving from F2:

- 23% go to F0
- 77% go to F1



Adjust from 18 months to 1 year



F2 patients:
• 6% go to F0
• 19% go to F1

Key Model Inputs: Drug Costs

Costs	Value	Source	Notes
Resmetirom, 80 mg	\$19,000	Javanbakht et al. 2022	Placeholder price
Obeticholic Acid, 25 mg	\$85,000	Redbook 2022	Placeholder price based on discounted WAC price for 5 and 10mg tablets assuming that a 25 mg tablet will be available

Key Model Inputs: Health Care Sector-related Costs

Costs	Value	Notes
F0-F2	\$7,063	Adult patients with NASH
F3	\$8,423	
Compensated Cirrhosis	\$34,275	Adults patients with NAFLD/NASH
Decompensated Cirrhosis	\$158,480	
Hepatocellular Carcinoma	\$115,002	
Liver Transplant Procedure	\$232,674	
Post Liver Transplant Procedure	\$43,358	
MI Event	\$60,425	Based on discharge and hospital data
Stroke Event	\$64,375	
Post-MI	\$2,980	
Post-Stroke	\$6,273	
CV Death Event	\$20,035	Based on administrative claims data

Key Model Inputs: Utilities

Health State	Value	Notes
NASH Fibrosis Stage 0-2	0.76	Adult patients with NASH whose HRQoL was evaluated using the EQ-5D-5L
NASH Fibrosis Stage 3	0.73	
Compensated Cirrhosis	0.66	NAFLD patients using Short Form-6D
Decompensated Cirrhosis	0.57	
Hepatocellular Carcinoma	0.50	
Liver Transplant (Year of)	0.66	Adult patients surviving 5 or more years after liver transplantation
Post Liver Transplant	0.73	
Disutility: MI Event	-0.041	Adult patients in the US Medical Expenditure Panel Survey
Disutility: Stroke Event	-0.052	
Disutility: Prior Cardiovascular Event	-0.034	



Results

Base-Case Results for Resmetirom

Drug	Drug Cost	Non-drug Cost	Total Cost	LYs	QALYs	evLYs
Resmetirom	\$76,000*	\$340,000	\$416,000	15.05	10.66	10.74
Standard care	\$0	\$439,000	\$439,000	14.56	10.05	10.05
Incremental Results	\$76,000	-\$99,000	-\$22,000	0.49	0.60	0.68

Drug	Comparator	Cost per QALY gained	Cost per evLY gained
Resmetirom	Standard care	Less costly, more effective	Less costly, more effective

evLYs: equal value of life years, LYs: life years, QALYs: quality-adjusted life years

*based on placeholder price

Base-Case Results for Obeticholic Acid

Drug	Drug Cost	Non-drug Cost	Total Cost	LYs	QALYs	evLYs
Obeticholic Acid	\$317,000*	\$359,000	\$676,000	14.88	10.48	10.53
Standard care	\$0	\$439,000	\$439,000	14.56	10.05	10.05
Incremental Results	\$317,000	-\$80,000	\$237,000	0.31	0.43	0.48

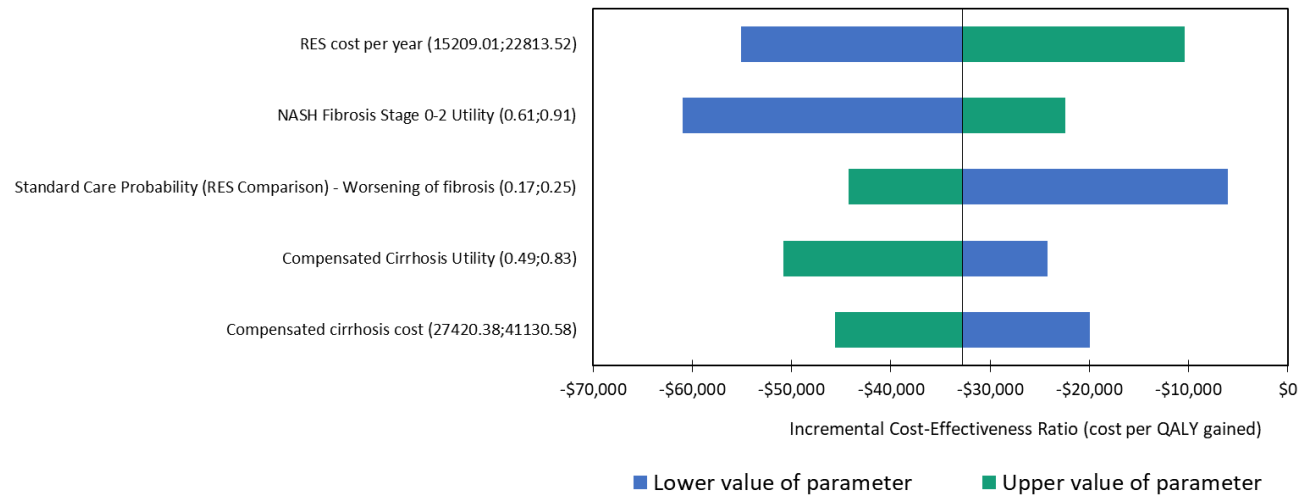
Drug	Comparator	Cost per QALY gained	Cost per evLY gained
Obeticholic Acid	Standard care	\$558,000	\$496,000

evLYs: equal value of life years, LYs: life years, QALYs: quality-adjusted life years

*based on placeholder price

Sensitivity Analyses for Resmetirom

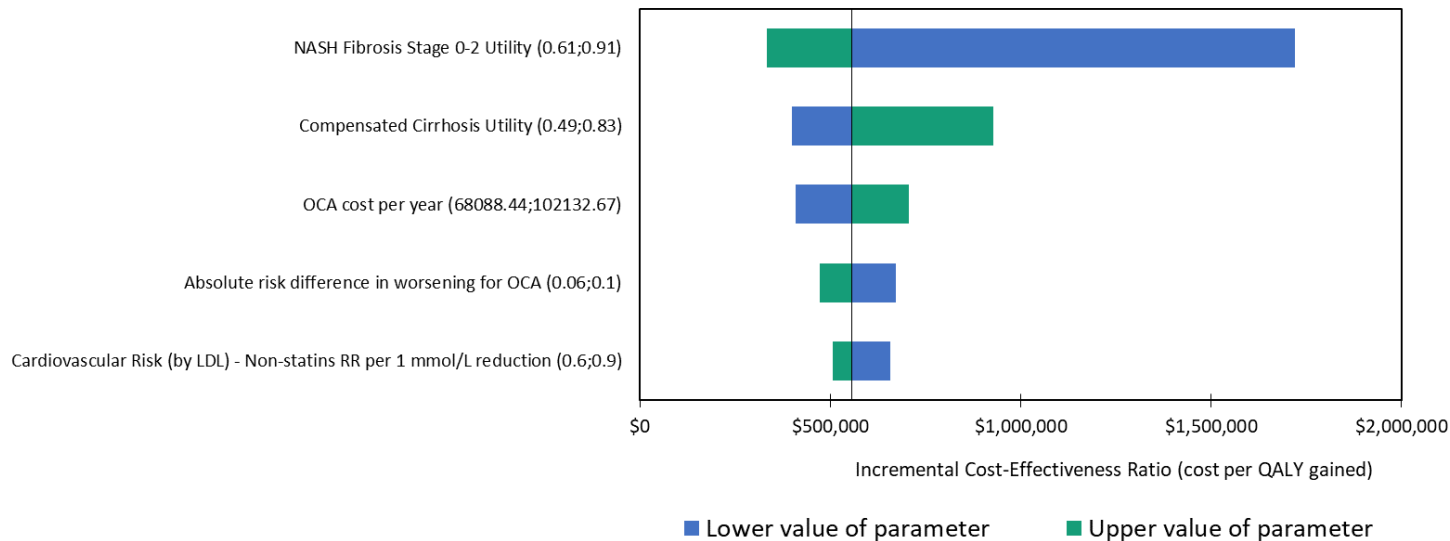
Tornado Diagram for Resmetirom



- Probabilistic Sensitivity Analyses to calculate the proportion of simulations where resmetirom were cost-effective from \$50,000/QALY to \$150,000/QALY were 99.4% to 99.8%

Sensitivity Analyses for Obeticholic Acid

Tornado Diagram for Obeticholic Acid



- Probabilistic Sensitivity Analyses to calculate the proportion of simulations where obeticholic acid were cost-effective from \$50,000/QALY to \$150,000/QALY were 0%

Scenario Analyses

	Treatment	Comparator	Cost per QALY gained	Cost per evLYG
Modified Societal Perspective	Resmetirom	Standard care	Less costly, more effective	Less costly, more effective
	Obeticholic acid	Standard care	\$533,000	\$474,000
Early vs late discontinuation for resmetirom	Resmetirom	Standard care	Less costly, more effective	Less costly, more effective
No LDL benefit for Resmetirom	Resmetirom	Standard care	Less costly, more effective	Less costly, more effective

evLYG: equal value life years gained, QALY: quality-adjusted life-year

Health Benefit Price Benchmarks (HBPBs)

Annual Price Benchmarks for Resmetirom and Obeticholic Acid

Intervention	Annual WAC (Placeholder Prices)	Annual Price at \$100,000 Threshold	Annual Price at \$150,000 Threshold	Discount from WAC to Reach Threshold Prices*
QALYs Gained				
Resmetirom	\$19,011	\$39,600	\$47,100	NA
Obeticholic Acid	\$85,111	\$32,800	\$38,500	NA
evLYs Gained				
Resmetirom	\$19,011	\$41,600	\$50,100	NA
Obeticholic Acid	\$85,111	\$34,200	\$40,700	NA

WAC: wholesale acquisition cost

*Annual price is based on a placeholder price and therefore we do not provide a discount from WAC to reach threshold prices

Limitations

- Lack of detailed data on stage specific transitions and treatment effectiveness
- For resmetirom, modeled based on top line Phase 3 results and used placeholder price
- For OCA, modeled based on per-protocol estimates and used placeholder price

Comments Received

- Discontinuation rates
 - Suggested separate discontinuation inputs for early vs. late stages of use for resmetirom
- Use of noninvasive testing
 - Possible incorporation into current and future NASH models
- NASH health state costs
 - Suggested use of updated costs

Conclusions

- Resmetirom and obeticholic acid provide clinical benefit in terms of gains in QALYs, LYs, and evLYs over their respective standard care alone
- At the currently assumed placeholder price, resmetirom would be less costly and more effective than standard care
- At the currently assumed placeholder price, obeticholic acid would not meet commonly cited cost-effectiveness thresholds

Questions?

Manufacturer Public Comment and Discussion

Stephen Dodge, PharmD, MBA

Senior Vice President, Global Medical Affairs

Madrigal Pharmaceuticals

Conflicts of Interest:

- *Dr. Dodge is a full-time employee of Madrigal Pharmaceuticals.*

00 : 05 : 00

Christopher Gasink, MD
Senior Vice President, Medical Affairs
Intercept Pharmaceuticals

00 : 05 : 00

Conflicts of Interest:

- *Dr. Gasink is a full-time employee of Intercept Pharmaceuticals.*



Public Comment and Discussion

Michael Betel, MSc

President, Fatty Liver Alliance

00 : 05 : 00

Conflicts of Interest:

- *Fatty Liver Alliance is receiving an unrestricted grant from Regeneron in excess of \$5,000.*
- *Michael Betel received consulting funds from Hoffmann-La Roche in excess of \$5,000.*
- *Michael Betel holds position as president of Fatty Liver Alliance, which is receiving <25% of funding from an unrestricted grant from Regeneron.*

Donna Cryer, JD
Chief Executive Officer,
Global Liver Institute

00 : 05 : 00

Conflicts of Interest:

- *Donna Cryer held status as a member of the Board of Trustees Sibley Memorial Hospital and receives reimbursement for services from issuance companies.*
- *Global Liver Institute received monetary value of >25% from healthcare companies and convenes more than 200 stakeholder organizations.*

Wayne Eskridge, BSEE

CEO, Fatty Liver Foundation

00 : 05 : 00

Conflicts of Interest:

- *Wayne Eskridge is the CEO of 501(C)3 nonprofit Fatty Liver Foundation, which receives grants from numerous healthcare related firms. None of the contributions are for services and no conditions or restraints are attached. They have donations by 89Bio, Amazon, Bristol-Myers Squibb, Clinical Care Options, Continuum Clinical, Echosens, Eskridge Family Trust, Fibronostics, First Line Creative, Gilead Sciences, Global Engage, google, Health Business Solutions, Intercept Pharmaceuticals, Meetrix, Merck & Co., Inc. NetNoggin, PathAI, Perspectrum, Prosciento, Pfizer, Regeneron, Terns Pharmaceuticals, TheraTech.*

Tony Villiotti

Founder, NASH kNOWledge

00 : 05 : 00

Conflicts of Interest:

- *NASH kNOWledge has received grants in excess of \$5,000 from Intercept, Madrigal, and other pharmaceuticals or diagnostic companies.*
- *Tony Villiotti has status of the founder of NASH kNOWledge which has received >25% funding from healthcare companies.*
- *NASH kNOWledge has received funding from Intercept, Madrigal, Regeneron, Pfizer.*

Betsy Villiotti

Vice President, NASH kNOWledge

00 : 05 : 00

Conflicts of Interest:

- *NASH kNOWledge has received grants in excess of \$5,000 from Intercept, Madrigal, and other pharmaceuticals or diagnostic companies.*
- *NASH kNOWledge has received funding from Intercept, Madrigal, Regeneron, Pfizer.*

Lunch

Meeting will resume at 12:50 pm CDT





Voting Questions

Patient Population for all questions:

Adults with Non-Alcoholic Steatohepatitis (NASH) with significant fibrosis (i.e., stage 2 and stage 3 fibrosis) and not cirrhosis.

Clinical Evidence



Is the evidence adequate to demonstrate that the net health benefit of resmetirom is superior to that provided by lifestyle management alone?



Is the evidence adequate to demonstrate that the net health benefit of obeticholic acid is superior to that provided by lifestyle management alone?

Contextual Considerations

When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for NASH with fibrosis, on the basis of the following contextual considerations:



Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability



Magnitude of the lifetime impact on individual patients of the condition being treated

Potential Other Benefits

What are the relative effects of resmetirom versus lifestyle management alone on the following outcomes that inform judgment of the overall long-term value for money of resmetirom?



Patients' ability to achieve major life goals related to education, work, or family life



Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life



Society's goal of reducing health inequities

Break

Meeting will resume at 2:00 pm CDT





Policy Roundtable

Participant	Conflict of Interest
Danielle Brandman, MD, MAS, Medical Director of Liver Transplantation, Weill Cornell Medicine	Dr. Brandman has received prior research funding from Gilead and Genentech for research in the clinical area of this meeting. Dr. Brandman was previously a Principal investigator on clinical trials involving other drugs for NAFLD.
Stephen Dodge, PharmD, MBA, Senior Vice President, Global Medical Affairs, Madrigal Pharmaceuticals	Dr. Dodge is a full-time employee of Madrigal Pharmaceuticals.
Anthony Grillo, PharmD, Vice President, Express Scripts	Dr. Grillo has equity interests in excess of \$10,000 in Cigna Healthcare. Dr. Grillo is a full-time employee within Cigna/Express Scripts.
Jennifer Martin, PharmD, Deputy Chief Consultant, PBM, Department of Veterans Affairs	No conflicts to disclose.
Kimberly Martinez, Patient Advocate	No conflicts to disclose.
Adnan Said, MD, MS, Professor, Gastroenterology and Hepatology, Director, Metabolic Liver Health Clinic, University of Wisconsin School of Medicine and Public Health	Dr. Said has received consulting support in excess of \$5,000 from Mallinckrodt pharmaceuticals and serves as a Site Principal investigator for the REGENERATE study.

Midwest CEPAC Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around May 26th, 2023
 - Includes description of Midwest CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: <https://icer.org/assessment/non-alcoholic-steatohepatitis-2023/>

Adjourn

