A Budget Impact Model for Two Investigational Agents for the Treatment of Nonalcoholic Steatohepatitis

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A Budget Impact Model for Two Investigational Agents for the Treatment of Nonalcoholic Steatohepatitis (NASH)

Objective

- NASH is a type of nonalcoholic fatty liver disease (NAFLD) that affects approximately 15 million adults in the U.S.
- Although largely asymptomatic, NASH can progress to cirrhosis, liver failure, and cancer, and is projected to become the most common indication for liver transplantation between 2020 and 2023.
- There are no Food and Drug Administration (FDA)-approved therapies for NASH. The American Association for the Study of Liver Diseases (AASLD) recommends pioglitazone and vitamin E as options for select patients.
- Several agents are currently in development for NASH, of which obeticholic acid and elafibranor are being tested in Phase III registration trials.
- Given limited treatment options for NASH, the clinical interest in using novel therapies may be great once they become available.
- A budget impact model may provide valuable insight to health insurers on the financial consequences of adopting novel therapies.
- A budget impact model was created to forecast the clinical and economic impact of two emerging investigational agents, elafibranor and obeticholic acid.

Methods

- A Medline search was conducted (timeframe: Jan. 1, 1995 to Oct. 30, 2017) to identify all published Phase II and Phase III clinical trials of elafibranor and obeticholic acid for NASH.
- Conference abstracts, manufacturer press releases, and value assessments evaluating elafibranor and obeticholic acid for NASH during the same timeframe were also reviewed.
- A clinical and economic assessment was performed to determine the budget impact.

Results

- The authors have no financial disclosures.

Economic Assessment

- Estimated annual drug cost: $14,051
- Estimated prevalence of NASH: 3.3% in 1% of the U.S. population
- An estimated ~5% of patients who have NASH have been diagnosed.
- Approximately 567,000 individuals in the U.S. may have the diagnosis and be eligible for treatment.
- Only ~20% of patients responded to therapy in clinical trials.
- Despite the treatment advancements these agents may offer, only ~20% of patients responded to therapy in clinical trials.
- Based on available peer-reviewed literature, elafibranor and obeticholic acid may offer clinical advantages over currently available non-FDA approved therapies.
- The FDA-approval of elafibranor and obeticholic acid for NASH may present opportunities for innovative cost-containment strategies.
- Several assumptions were made in estimating budget impact:
- - Presence of disease in the Medicaid plan
- - Number of members diagnosed
- - Number of members who would seek treatment
- - Cost of the agents
- The current analysis did not utilize medical claims data to determine the prevalence of NASH in the Medicaid-specific population.
- Uptake of new therapies is difficult to assess due to the many variables that may influence it.

Limitations

- Clinical impact was based on Phase II trial data which assessed surrogate endpoints; Phase III trials are ongoing.
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- The current analysis did not utilize medical claims data to determine the prevalence of NASH in the Medicaid-specific population.
- Uptake of new therapies is difficult to assess due to the many variables that may influence it.

Conclusions

- New agents for the treatment of NASH are likely to have a significant impact on state Medicaid program budgets.
- The projected budget impact of elafibranor and obeticholic acid highlights the need for innovative cost-containment strategies.
- Proactive pipeline monitoring and high-level budget impact modeling may assist state Medicaid programs in preparing for high-cost specialty medications that are likely to have significant cost implications.

Future Studies

- Continuous review and adjustment to assumptions made in this budget impact model are necessary as more clinical and economic data become available.

Disclosures/Acknowledgments

- The authors have no financial disclosures.