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ICER issues final report for add-on therapies to treat Type 2 Diabetes

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The Institute for Clinical and Economic Review (ICER) has released a Final Evidence Report and Report-at-a-Glance assessing the comparative clinical effectiveness and value of oral semaglutide (Rybelsus® Novo Nordisk), a GLP-1 receptor agonist for the treatment of Type 2 diabetes mellitus (T2DM).

This new therapy is an oral version of the injectable Ozempic® (Novo Nordisk), which was approved by the FDA in 2017. For this analysis, adding oral semaglutide was compared to background therapy with metformin alone, and to three competitors for add-on therapy: liraglutide (Victoza®, Novo Nordisk), sitagliptin (Januvia®, Merck), and empagliflozin (Jardiance®, Boehringer Ingelheim). ICER's report on these therapies was reviewed at the November 2019 public meeting of the New England Comparative Effectiveness Public Advisory Council (New England CEPAC), one of ICER's three independent evidence appraisal committees.

During the meeting, CEPAC members unanimously voted that the evidence was adequate to demonstrate that adding oral semaglutide to ongoing background therapy provides a positive net health benefit, and that this benefit is superior to that provided by adding sitagliptin. However, a majority of the CEPAC found that the evidence did not adequately demonstrate that the net health benefit of adding oral semaglutide was superior to that of adding liraglutide, nor did the evidence adequately distinguish the net health benefit of adding oral semaglutide from that provided by adding empagliflozin.

During their deliberation, panel members also weighed the therapies' other benefits and contextual considerations. Noting that diabetes represents a particularly high lifetime burden of illness, the panel members voted that the oral version of semaglutide offers reduced complexity compared to injectable liraglutide, and this reduced complexity may significantly improve patient outcomes.

Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, the CEPAC panel voted that oral semaglutide provides "intermediate" long-term value for money. When compared to background therapy alone, oral semaglutide's annual estimated net price of $6,103 falls within ICER's value-based price benchmark range of $6,000-$6,400 per year. However, oral semaglutide is

unlikely to reach commonly cited thresholds compared with empagliflozin.

ICER's value-based price benchmarks suggest a price range, net of any discounts and rebates, that aligns fairly with a treatment's added benefits for patients over their lifetime. The ranges reflect commonly cited cost-effectiveness thresholds between $100,000 and $150,000 per Quality-Adjusted Life Year (QALY) gained. Prices at or below these thresholds help ensure that the health benefits gained by patients using new treatments are not outweighed by health losses due to long-term cost pressures that lead individuals to abandon care or lose health insurance. To reach thresholds of between $100,000 and $150,000 per life year gained, oral semaglutide would need to be priced between $6,400-$7,100 per year.

Key Policy Recommendations

Following the voting session, a policy roundtable of experts — including clinicians, patient advocates, and representatives from manufacturers and payers — convened to discuss the implications of the evidence for policy and practice. Key recommendations stemming from the roundtable discussion include:

- Manufacturers with new diabetes agents should seize the opportunity to come to market with a lower list price to benefit patients.
- To provide high quality head-to-head evidence on the comparative effectiveness of emerging treatment options for patients with diabetes, manufacturers should look to the example set by the PIONEER trials of oral semaglutide.
- As the treatment options for T2DM continue to evolve, primary care providers should make themselves aware of the updated clinical guidelines to ensure that all treating clinicians know how to identify the varying risks and benefits of different agents for particular subpopulations.
- Given the high rate of gastrointestinal side effects with oral semaglutide, real-world evidence on adherence should be studied and reported.