ICER's 12/9/2019 Final Evidence Report on

ORAL SEMAGLUTIDE FOR TYPE 2 DIABETES MELLITUS

ICER's Findings In Brief

On December 9, 2019, ICER released its Final Evidence Report on the use of Oral Semaglutide in Type 2 Diabetes Mellitus (T2DM).

ICER determined that Semaglutide results in better control of blood sugar than the other options, and better weight reduction than any of the options except empagliflozin. Specifically, ICER determined that when oral semaglutide was added to current antihyperglycemic treatment versus (i) ongoing background antihyperglycemic treatment; (ii) sitagliptin; (iii) empagliflozin; and (iv) liraglutide, the evidence is adequate to provide high certainty that oral semaglutide delivers a substantial net health benefit compared to ongoing background therapy with metformin alone.

ICER also generated, from its lifetime microsimulation model, that from its threshold value assessment, discounts from the Wholesale Acquisition Cost (WAC) of between 32% and 36% were warranted. Given ICER's self-appointed budget impact assessment, further recommendations proposed limiting patient access.

ICER's recommendations for price discounting and limited access do not take physician or patient choice of therapy into account and should not be taken seriously. They are based on a value assessment framework that fails to meet the standards of normal science. **There is the potential for patient harm if health systems take the recommendations at face value.**

The Patient Voice

This evidence report, in common with all of ICER's previous evidence reports, ignores the interests of the patients.

For this Evidence Report, ICER used the flawed EuroQol (EQ-5D-3L) utility measure, which is concerned only with functional status of patients, making it completely inappropriate for this purpose. The measure yields no information about the needs of the patient and how oral semaglutide may meet those needs. In choosing the EQ-5D-3L generic measure of response to therapy, ICER focused on a limited number of clinical symptoms, not on a measure that accurately reflects the importance of oral semaglutide in T2DM to patients.

If ICER wants to contribute to discovering new evidence, then it should propose a measure of patient response that focuses on T2DM and the needs of patients rather than a measure that is mathematically absurd.

Other Issues with ICER's Report

Scientific Credibility: ICER is not interested in the standards of normal science; it is not interested in providing a value assessment framework that produces credible, evaluable and replicable claims for oral semaglutide in patient populations.

ICER is fixated on creating imaginary lifetime worlds that fail to produce, and were never intended to produce, credible claims. They are intended only to produce what is vaguely described (and undefined) "approximate information." The great advantage is that formulary committees cannot challenge these claims.

The model presented is only one of a multitude of competing models which can be engineered to produce the opposite recommendations.

Quality Adjusted Life Years (QALYs): ICER's use of QALYS and cost per QALY claims for this purpose are simply absurd. The EQ-05D-3L utility is mathematically nothing more than a manifest score. It does not meet required fundamental measurement standards for even addition and subtraction; it is an ordinal rather than an interval measure.

Attempting to use the EQ-5D-3L to create imaginary lifetime QALYs is mathematical nonsense. The threshold cost-per-QALY value framework has no meaning and is irrelevant, if not misleading for pricing and access decisions.

The Bottom Line:

If health systems are interested in providing the best possible care for T2DM, then the ICER report on oral semaglutide should be rejected. In spite of ICER's claim it is using "gold standard" techniques to assess product value, these attempts should be rejected.

T2DM is a complex disease state. **Physician and patient choice of therapy should be focused on the extent to which new entrants to the pharmacy meet patient needs.** Creating imaginary claims and asking health systems to take them at face value is not the way forward.

Reference: Langley PC. More Unnecessary Imaginary Worlds - Part 1: The Institute for Clinical and Economic Review's Evidence Report on Janus Kinase (JAK) Inhibitors in Rheumatoid Arthritis. Innov Pharm. 2020;11(1):No. 2
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