Vonoprazan

for treating Helicobacter pylori infection

Technology Guidance from the MOH Drug Advisory Committee

Guidance recommendations

The Ministry of Health's Drug Advisory Committee has not recommended listing vonoprazan on the Medication Assistance Fund (MAF) for treating *Helicobacter pylori* infection due to low clinical need, uncertain clinical effectiveness and unfavourable cost-effectiveness compared to alternate treatment options.

Published on 1 April 2020

Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of vonoprazan for treating *Helicobacter pylori* (*H. pylori)* infection. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for vonoprazan was considered in line with the registered indication.

1.2 The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
- Estimated annual technology cost and the number of patients likely to benefit from the technology.

1.3 Additional factors, including social and value judgments, may also inform the Committee's subsidy considerations.

Clinical need

2.1 The Committee acknowledged that triple therapy with a proton pump inhibitor (PPI) and two antibiotics (namely omeprazole, amoxicillin and clarithromycin) is most commonly used first-line for treating *H. pylori* infection in local practice, and is associated with a high eradication rate. Bismuth quadruple therapy (omeprazole, metronidazole, tetracycline and bismuth subcitrate) is typically used second-line. Local clinical experts confirmed that generic omeprazole is commonly used as part of all treatment regimens, however, another PPI may be considered in the event of intolerance or inadequate response to omeprazole.

2.2 The Committee noted that vonoprazan is seldom used instead of a PPI as part of a combination treatment regimen in Singapore, and considered that there was low clinical need to subsidise an additional treatment option.

Clinical effectiveness and safety

3.1 The Committee reviewed three randomised controlled trials conducted in Japan which compared vonoprazan-based triple therapy with PPI-based regimens. They noted that the antibiotics used as part of the first-line combination regimens in each trial were administered at suboptimal doses and for shorter treatment course durations (7 days instead of 10-14 days) compared to standard clinical practice in Singapore. In addition, the second-line treatment regimens included in the trials did not reflect local clinical practice. Therefore, although the studies showed that vonoprazan-based triple therapy was likely to be non-inferior to PPI-based triple therapy for eradicating *H. pylori* infection, the Committee considered that the results were uncertain and unlikely to be generalisable to the Singapore setting.

3.2 The Committee acknowledged that vonoprazan-based triple therapy was well tolerated in the clinical trials.

Cost-effectiveness

4.1 No local or overseas economic evaluations of vonoprazan were available. Despite a price discount offered by the manufacturer as part of their value-based pricing proposal, the cost per treatment course with vonoprazan remained substantially higher than for generic omeprazole and the Committee considered that vonoprazan was unlikely to represent a good use of healthcare resources in the local context.

Estimated annual technology cost

5.1 The Committee noted that the annual cost impact was estimated to be less than SG$500,000 in the first year of listing vonoprazan on the MAF.

Recommendation

6.1 Based on available evidence, the Committee recommended not listing vonoprazan on the MAF due to low clinical need, uncertain clinical effectiveness and unfavourable cost-effectiveness compared to alternate treatment options.

About the Agency

The Agency for Care Effectiveness (ACE) is the national health technology assessment agency in Singapore residing within the Ministry of Health. It conducts evaluations to inform the subsidy of treatments, and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore. The guidance is based on the evidence available to the Committee as at 7 October 2019. This guidance is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at www.ace-hta.gov.sg/about

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