Technology Guidance

Sucroferric oxyhydroxide

for treating hyperphosphataemia in patients with end-stage renal disease on dialysis

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Sucroferric oxyhydroxide 500 mg chewable tablet for treating hyperphosphataemia in patients with end-stage renal disease on haemodialysis or peritoneal dialysis who have persistent hyperphosphataemia despite optimising treatment with calcium-based phosphate binders, or who are unable to tolerate calcium-based phosphate binders due to hypercalcaemia.

Funding status

Sucroferric oxyhydroxide 500 mg chewable tablet is recommended for inclusion on the Medication Assistance Fund (MAF) for the abovementioned indication from 1 November 2025.

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Technology evaluation

1.1. At the June 2025 meeting, the MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of sucroferric oxyhydroxide for treating hyperphosphataemia in patients with end-stage renal disease (ESRD) on haemodialysis or peritoneal dialysis. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Clinical and economic evidence for sucroferric oxyhydroxide was considered in line with its 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 funding considerations.

Clinical need

2.1. In local practice, calcium-based phosphate binders are typically used as the first-line treatment for hyperphosphataemia in patients with ESRD on dialysis. However, non-calcium-based phosphate binders are required when patients experience persistent hyperphosphataemia despite calcium-based binder treatment or are unable to receive these agents due to hypercalcaemia.

2.2. The Committee noted that sevelamer carbonate, a non-calcium-based phosphate binder, is currently subsidised on the MAF. They recognised that sucroferric oxyhydroxide is an alternative non-calcium-based option for patients with hyperphosphataemia, particularly those who cannot tolerate sevelamer carbonate.

Clinical effectiveness and safety

3.1. The Committee reviewed published clinical evidence for sucroferric oxyhydroxide from a randomised controlled trial (PA-CL-05A) conducted in patients with ESRD on haemodialysis or peritoneal dialysis. After 12 weeks of treatment, results showed that sucroferric oxyhydroxide was non-inferior to sevelamer carbonate in reducing serum phosphorus concentrations. In the per-protocol population, the mean changes in phosphorus concentrations were -0.71 mmol/L with sucroferric oxyhydroxide and -0.79 mmol/L with sevelamer carbonate. The upper bound of the confidence interval for the least-squares mean difference was 0.15 mmol/L, which was below the

predefined non-inferiority margin of 0.19 mmol/L. Results of the non-inferiority analysis were consistent between the full analysis and per-protocol sets.

3.2. The proportion of patients who reported at least one treatment-emergent adverse event (TEAE) was higher with sucroferric oxyhydroxide (83%) than with sevelamer carbonate (76%). This was largely due to higher incidences of gastrointestinal TEAEs (such as mild, transient diarrhoea, and discoloured stools) reported in the sucroferric oxyhydroxide group. In contrast, the TEAEs reported more frequently with sevelamer carbonate were nausea and constipation. The incidence of serious TEAEs was similar between treatment groups.

3.3. Similar to sevelamer carbonate, no randomised trial evidence was found for sucroferric oxyhydroxide in patients with persistent hyperphosphataemia despite calcium-based phosphate binders or those unable to receive these agents.

3.4. Overall, the Committee considered that in patients with ESRD on dialysis who have hyperphosphataemia, sucroferric oxyhydroxide and sevelamer carbonate had comparable efficacy in lowering serum phosphorus levels but different safety profiles.

Cost effectiveness

4.1. Based on the clinical conclusion, the Committee considered that a cost-minimisation approach was appropriate for evaluating the cost effectiveness of sucroferric oxyhydroxide against sevelamer carbonate.

4.2. The analysis applied the equi-effective doses accepted by Australia's Pharmaceutical Benefits Advisory Committee (PBAC). Results showed that, at the price proposed by the company, sucroferric oxyhydroxide was cost effective compared with sevelamer carbonate.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be less than SG$1 million in the first year of listing sucroferric oxyhydroxide on the MOH List of Subsidised Drugs.

Recommendations

6.1. In view of acceptable clinical and cost effectiveness, the Committee recommended sucroferric oxyhydroxide 500 mg chewable tablet be listed on the MAF for treating hyperphosphataemia in patients with ESRD on haemodialysis or peritoneal dialysis. Patients must have persistent hyperphosphataemia despite optimising treatment with calcium-based phosphate binders or must be unable to tolerate calcium-based phosphate binders due to hypercalcaemia.

Agency for Care Effectiveness - ACE Agency for Care Effectiveness (ACE)

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The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance, and education.

As the national HTA agency, ACE conducts evaluations to inform government funding decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

The 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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