NHS
Fylde and Wyre
Clinical Commissioning Group

Patiromer sorbitex calcium (Veltassa) powder for oral suspension
for the treatment of hyperkalaemia in adults.

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed to fund the prescribing of Patiromer sorbitex calcium (Veltassa) powder for oral suspension for the treatment of hyperkalaemia in adults.

Patiromer is recommended as a once daily alternative to Calcium Resonium for the treatment of hyperkalaemia in adults. The following conditions apply:

- Medicine is supplied by the hospital for the duration of the treatment course.
- Primary care initiation or continuation of treatment is not recommended unless exceptional circumstances such as specialist GP.

This medicine is classified as RED for this indication

Summary of supporting evidence:

The safety and efficacy of Veltassa were demonstrated in a two-part, single blind randomised withdrawal study (RLY5016-301) that evaluated the treatment in hyperkalaemic patients with chronic kidney disease (CKD) on stable doses of at least one RAAS inhibitor (i.e. angiotensin converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB] or aldosterone antagonist [AA]).
In Part A, 243 patients were treated with Veltassa for 4 weeks. Patients with a baseline serum potassium of 5.1 mEq/L to <5.5 mEq/L (mmol/L) received a starting dose of 8.4 g patiromer per day (as a divided dose) and patients with a baseline serum potassium of 5.5 mEq/L to <6.5 mEq/L received a starting dose of 16.8 g patiromer per day (as a divided dose). The dose was titrated, as needed, based on the serum potassium level, assessed starting on Day 3 and then at weekly visits to the end of the 4 week treatment period, with the aim of maintaining serum potassium in the target range (3.8 mEq/L to <5.1 mEq/L). The mean daily doses of Veltassa were 13 g and 21 g in patients with serum potassium of 5.1 to <5.5 mEq/L and 5.5 to <6.5 mEq/L, respectively.
The mean age of patients was 64 years (54% aged 65 and over, 17% aged 75 and over), 58% of patients were men, and 98% were Caucasian. Approximately 97% of patients had hypertension, 57% had type 2 diabetes, and 42% had heart failure.
Mean serum potassium levels and change in serum potassium from Part A Baseline to Part A Week 4 is shown in Table 1. For the Part A secondary outcome, 76% (95% CI: 70%, 81%) of patients had a serum potassium in the target range of 3.8 mEq/L to <5.1 mEq/L at Part A Week 4.

Veltassa Treatment Phase (Part A): Primary Endpoint

	Baseline Potassium		Overall Population (n=237)
	5.1 to <5.5 mEq/L (n=90)	5.5 to <6.5 mEq/L (n=147)	
	Serum Potassium (mEq/L)		
Baseline, mean (SD)	5.31 (0.57)	5.74 (0.40)	5.58 (0.51)
Week 4 Change from Baseline, Mean ± SE (95% CI)	−0.65 ± 0.05 (−0.74, −0.55)	−1.23 ± 0.04 (−1.31, −1.16)	−1.01 ± 0.03 (−1.07, −0.95)
p value			<0.001

In Part B, 107 patients with a Part A baseline serum potassium of 5.5 mEq/L to <6.5 mEq/L and whose serum potassium was in the target range (3.8 mEq/L to <5.1 mEq/L) at Part A Week 4 and still receiving RAAS inhibitor treatment were randomised to continue Veltassa or to receive placebo for 8 weeks to evaluate the effect of withdrawing Veltassa on serum potassium.
In patients randomised to Veltassa, the mean daily dose was 21g at the start of Part B and during Part B.
The Part B primary endpoint was the change in serum potassium from Part B baseline to the earliest visit at which the patient's serum potassium was first outside of the range of 3.8 to <5.5 mEq/L or to Part B Week 4 if the patient's serum potassium remained in the range. In Part B, serum potassium in patients on placebo increased significantly relative to patients who remained on Veltassa (p<0.001).
More placebo patients (91% [95% CI: 83%, 99%]) developed a serum potassium ≥5.1 mEq/L at any time during Part B than Veltassa patients (43% [95% CI: 30%, 56%]), p<0.001. More placebo patients (60% [95% CI: 47%, 74%]) developed a serum potassium ≥5.5 mEq/L at any time during Part B than Veltassa patients (15% [95% CI: 6%, 24%]), p<0.001.
The potential of Veltassa to enable concomitant RAAS inhibitor treatment was also assessed in part B. Fifty two percent (52%) of subjects receiving placebo discontinued RAAS inhibitor treatment because of recurrent hyperkalaemia compared with 5% of subjects treated with Veltassa.
The effect of treatment with Veltassa for up to 52 weeks was evaluated in an open label study of 304 hyperkalaemic patients with CKD and type 2 diabetes mellitus on stable doses of a RAAS inhibitor (RLY5016-205) . The mean age of patients was 66 years (59.9% aged 65 and over, 19.7% aged 75 and over), 63% of patients were men, and all were Caucasian. Decreases in serum potassium with Veltassa treatment were maintained over 1 year of chronic treatment, with a low incidence of hypokalaemia (2.3%) and the majority of subjects reaching (97.7%) and maintaining target serum potassium levels (overall during maintenance period, serum potassium was within the target range for approximately 80% of the time). In patients with a baseline serum potassium of >5.0 to 5.5 mEq/L who received an initial dose of 8.4 g patiromer per day, the mean daily dose was 14 g; in those with a baseline serum potassium of >5.5 to <6.0 mEq/L who received an initial dose of 16.8 g patiromer per day, the mean daily dose was 20 g during the entire study.

For details around the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/