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CCG logo

Commissioning Statement

Treatment	**Modified Release Hydrocortisone Tablets** (Plenadren®)
For the treatment of	Treatment of adrenal insufficiency in adults.
Commissioning position	**…….CCG does not routinely commission the use of modified release hydrocortisone (Plenadren®) tablets to treat adrenal insufficiency in adults.**
Date effective from	…….. November 2019
Policy to be reviewed by	…….November 2022 (to be reviewed earlier if NICE issues guidance at an earlier date)
Background information	Using a modified release formulation of hydrocortisone, the dose may be given once daily in the morning, rather than two or three times daily with conventional immediate release preparations. However, in situations when the body is exposed to excessive physical and/or mental stress, patients may need additional substitution of immediate release hydrocortisone tablets especially in the afternoon or evening. Plenadren® is an oral modified-release formulation (5mg and 20mg) of hydrocortisone licensed to treat adults with adrenal insufficiency. The traditionally recommended dose of hydrocortisone of 20 to 30mg daily may be too high for many patients. New techniques for measuring natural cortisol production indicate that the rate is much lower than previously estimated and most adults with adrenal insufficiency can be treated successfully with 15 to 20mg daily (or 10 to 12mg/m^2/day). NICE has not issued guidance (technology appraisal) on modified release hydrocortisone (searched up until September 2019). In December 2016 the Scottish Medicines Consortium (SMC) did not recommend hydrocortisone (Plenadren®) for use in NHS Scotland to treat adrenal insufficiency in adults due to insufficient evidence submitted by the manufacturer. The All Wales Medicines Strategy Group (AWMSG) stated that hydrocortisone could not be endorsed for use within NHS Wales for the treatment of adrenal insufficiency due to no submission being made by the manufacturer. Not supported for use in the Leeds Health Economy due to significantly higher costs than immediate release tablets.
Summary of evidence/rationale	The amount of hydrocortisone absorbed systemically from Plenadren® is about 20% less than from immediate-release

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	(IR) hydrocortisone. Although this could be beneficial in some patients (over-substitution with current glucocorticoids is common), for others on lower doses (20mg daily or less), it could lead to under-substitution. There is no evidence that Plenadren's® concentration-time profile and the short-term changes in some surrogate measures of disease reduce morbidity or mortality. Some patients may prefer Plenadren® once daily to hydrocortisone IR taken three times a day but compliance with the two formulations is similar. Quality of life data are difficult to interpret and should be viewed with caution as they come from open-label studies with small numbers of patients. Plenadren® and hydrocortisone IR cause similar adverse effects of abdominal pain, diarrhoea, nausea and fatigue. However, patients switched to Plenadren® may feel less well for the first few months as they adjust to the change in cortisol levels. Plenadren® is an option for patients with poor compliance, but its use will significantly increase the cost of therapy*. Patients need to be monitored closely when switching to avoid under-substitution *(UKMI Oct 2012).* In the absence of a submission from the holder of the marketing authorisation the SMC does not recommend hydrocortisone (Plenadren®) for use within NHS Scotland for the treatment of adrenal insufficiency in adults *(SMC: Jan 2016).*
Contact for this policy	Head of Medicines Optimisation