South East London Area Prescribing Committee
Formulary recommendation

Reference	**013**
Intervention:	**Hydrocortisone modified release (Plenadren®) tablets for Primary adrenal insufficiency in adults.** Plenadren® is an oral modified-release formulation of hydrocortisone designed to more closely mimic the natural cycle of cortisol release and is licensed to treat adults with adrenal insufficiency (AI).
Date of Decision	**August 2014**
Date of Issue:	**September 2014**
Recommendation:	**Red - suitable for prescribing and supply by hospital only (see below).**
Further Information	Recommended for hospital only use in patients who meet the following criteria: a. Have *Primary* Adrenal Insufficiency AND b. Have experienced at least two hospital admissions in the last 12 months due to unstable AI. Patients might experience increased fatigue for the first weeks of treatment with Plenadren when changing from conventional hydrocortisone. **Use in secondary AI is not currently recommended.**
Shared Care/Transfer of care document required:	N/A
Cost Impact for agreed patient group	Plenadren® 20 mg daily instead of hydrocortisone IR 20 mg daily represents a **cost increase** of **£1,664.40 per patient per year.** Plenadren® 20 mg daily in South East London based on: o 10 patients per year = **£16,644** o 20 patients per year = **£33,288** o 30 patients per year = **£49,932** Plenadren® doses greater than 20 mg daily would result in significant increases on the annual costs above: o Plenadren® 25 mg daily = £4,690.25 per patient per year o Plenadren® 30 mg daily = £6,460.50 per patient per year
Usage Monitoring & Impact Assessment	Acute Trusts. Exception reports from CCGs if transfer of prescribing to primary care is requested. Audit use and outcomes (e.g. impact on hospital admissions for primary AI) and report back in 12 months, when this recommendation will be reviewed.
	CCGs. Monitor EPACT data.
Evidence reviewed	**References** 1. UKMi New Medicines Profile: Hydrocortisone modified-release. Issue No. 12/01, October 2012 2.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002185/human_med_001495.jsp&mid=WC0b01ac058001d124 3. Johannsson et al, 2012 (a) Johannsson G, Nilsson AG, Bergthorsdottir R, Burman P, Dahlqvist P, Ekman B, Engström BE, Olsson T, Ragnarsson O, Ryberg M, Wahlberg J, Biller BM, Monson JP,Stewart PM, Lennernäs H and Skrtic S. Improved cortisol exposure-time profile and outcome in patients with

	adrenal insufficiency: a prospective randomized trial of a novel hydrocortisone dual release formulation. J Clin Endocrin Metab. 2012; 97 (2): 473-481. 4. Johannsson et al, 2012 (b)Johannsson G, Nilsson AG, Bergthorsdottir R, Burman P, Dahlqvist P,Ekman B, Engström BE, Ragnarsson O, Ryberg M, Wahlberg J and Skrtic S. An open, multi-centre, phase IIIb, long term follow-up study to assess the safety, tolerability and efficacy of once-daily oral dual-release hydrocortisone in patients with adrenal insufficiency. Presented at: 15th International Congress of Endocrinology and 14th European Congress of Endocrinology ICE ECE 2012; P78.

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.
b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS