

HERTFORDSHIRE MEDICINES MANAGEMENT COMMITTEE – April 2013

**HYDROCORTISONE MODIFIED RELEASE (PLENADREN®) –
NOT RECOMMENDED FOR ROUTINE USE IN HERTFORDSHIRE**

Name: generic	What it is	Date decision last revised	Decision status	NICE / SMC Guidance
Hydrocortisone MR (Plenadren®)	Corticosteroid licensed to treat adults with adrenal insufficiency (AI).	April 2013	Final	NICE - No guidance SMC – Not recommended

HMMC Recommendation:

Modified release hydrocortisone is NOT RECOMMENDED for routine prescribing in adults with adrenal insufficiency within Hertfordshire.

Specialists wishing to initiate the product for individual patients with severe compliance problems on standard release hydrocortisone, leading to admissions for Addisonian crises must:

- Seek approval for individual patients through their Trust’s usual non-formulary request processes, **AND**
- Communicate the factors that have been considered when making the switch to the GP, **INCLUDING** details of how compliance will be measured

The pharmacy department within the Trust must communicate any such patients approved for treatment to the Pharmacy and Medicines Optimisation Team at Central Eastern Commissioning Support Unit.

<u>EFFECTIVENESS</u>			<u>SAFETY</u>	
<ul style="list-style-type: none"> • Limited evidence comparing Plenadren® with immediate release hydrocortisone suggests similar efficacy. • Study primary end-points used surrogate markers rather than patient orientated outcomes • The absorption of hydrocortisone from Plenadren® is significantly lower than from immediate release hydrocortisone so switching products requires dose adjustment. 			<ul style="list-style-type: none"> • Limited safety data. Main side effects in trial were fatigue, abdominal pain, diarrhoea and nausea • Plenadren® is not recommended for patients with increased gastrointestinal motility as absorption of hydrocortisone may be affected 	
<u>COST</u>			<u>PATIENT FACTORS</u>	
Drug	Dose and frequency	Annual cost/patient (VAT not included)	<ul style="list-style-type: none"> • Administered once daily so may be preferred by patients. • Trial results demonstrated patient preference for Plenadren® but tolerability and patient compliance were similar with both preparations. 	
Plenadren®	20mg od	£2,920		
Hydrocortisone	10mg bd	£1,204		
<small>Drug Tariff March 2013 and DM&D- Doses shown are for general comparison only and do not imply therapeutic equivalence</small>				

This HMMC recommendation is based upon the evidence available at the time of publication. The recommendation will be reviewed upon request in the light of new evidence becoming available.

Assessment against Ethical Framework

Evidence of Clinical Effectiveness

- A small, short term study demonstrated similar efficacy to immediate release hydrocortisone.
- Limited long-term efficacy data.
- Study primary end-points used surrogate markers rather than patient orientated outcomes.

Cost of treatment and Cost Effectiveness

- Plenadren[®] is more than double the cost of standard release hydrocortisone.
- No information available on cost effectiveness

The needs of the population

- The needs of the population appear to be low as there are alternative immediate release preparations available.

The needs of the community

- The needs of the community are low. The prevalence of primary AI in adults is 2 to 4 per 10,000. A population of 500k would be expected to have 150 patients requiring treatment. If Plenadren[®] was used for all eligible patients then this would create a cost pressure which may have an impact on the local health economies which already have to identify savings.

Equity

- No impact anticipated.

Policy drivers

- Newly licensed and marketed product
- AWSMG and SMC have made decisions not to recommend, as no evidence submission has been submitted by the manufacturer

Implementability

- No issues identified.

References

- Johannsson G, Nilsson AG, Bergthorsdottir R et al. 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 Endocrinol Metab 2012; 97: 473-81.
- UKMi new medicines profile, Hydrocortisone modified release, October 2012, Issue 12/01, <http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20Specific%20Reviews/NMP%20Hydrocortisone%20MR.1.pdf>
- SPC, Plenadren, accessed on emc 11/04/2013 <http://www.medicines.org.uk/emc/searchresults.aspx?term=plenadren&searchtype=QuickSearch>

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