SPECIALISED SERVICES CLINICAL PANEL
ASSESSMENT OF A CLINICAL COMMISSIONING POLICY PROPOSAL

Intervention Title	Metreleptin
Indication Title	Congenital leptin deficiency
Proposer is requesting for the intervention to be:	Routinely commissioned

NPOC	Internal Medicine
CRG	Specialised Endocrinology

Clinical Lead	Ismaa Sadaf Farooqi
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Date of Clinical Panel	20/12/16

Section A. Conditions that must be met in order that the development of a Clinical Commissioning Policy can be considered.

The proposal is for a prescribed specialised service	Criteria met	Yes. These are patients that are treated in a service that is commissioned by NHS England.
The proposal is NOT for inputs to a national tariff episode of care (such as drugs, devices, diagnostics or pathology tests) which have not been identified as explicit exclusions to the tariff price AND/OR where NICE guidance for the input comes with a funding directive, thus adoption is not discretionary for the NHS.	Criteria met	No.
The proposal does not duplicate other policy development processes. These may include: • *NICE TA/HST that has been published* • *NICE TA/HST that is in development* • *A proposal currently in the NICE topic selection process* • *A Clinical Policy has been published* • *A Clinical Policy is in development* • *A proposal widely accepted and implemented on the basis of existing published guidance from the Department of Health, Arm's Length Body or*	Criteria met	No.

other government departments (excluding national service frameworks, white papers and planning priorities guidance).		
Where a proposal is likely to support commissioning there should be adequate evidence and the intervention should not be 'experimental'. A policy proposition proposal that is likely not to recommend routine commission may do so on the grounds that there is inadequate evidence of effectiveness (and may therefore be considered experimental). The *Experimental and Unproven Treatments Policy of NHS England* states the criteria which indicate that an intervention may be experimental*:* • *the treatment is still undergoing clinical trials and/or yet to undergo a phase III clinical trial for the indication in question* • *there are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question* • *the treatment does not have approval from the relevant government body* • *the treatment does not conform to usual clinical practice in the view of the majority of medical practitioners in the relevant field* • *the treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body* • *the treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy* • *the evidence is not yet available for public scrutiny* • *the decision maker does not have confidence in the evidence base that has been presented (i.e. in the interpretation of the evidence).*	Criteria met	There is very limited published evidence from a very small number of patients. The condition is very rare and the panel decided that is was reasonable to proceed. The policy development process will identify and evaluate the evidence available and determine whether a policy proposal could be formed.

The NPoC lead explanation of support for the clinical commissioning policy proposal. This may highlight links to other programmes of work, issues regarding equity of access to an intervention and other important factors and areas of uncertainty
Congenital leptin deficiency is a condition that causes severe obesity beginning in the first few months of life. Affected individuals are of normal weight at birth, but they are constantly hungry and quickly gain weight. Without treatment, the extreme hunger continues and leads to chronic excessive eating (hyperphagia) and obesity. Beginning in early childhood, affected individuals develop abnormal eating behaviours such as fighting with other children over food, hoarding food, and eating in secret. People with

congenital leptin deficiency also have hypogonadotropic hypogonadism, which is a condition caused by reduced production of hormones that direct sexual development. Without treatment, affected individuals experience delayed puberty or do not go through puberty, and may be unable to conceive children (infertile). The paediatric medicine CRG will need to be included in PWG.		
The formation of a commissioning policy is the most appropriate methodology in order to achieve the desired clinical, service or resource utilisation outcome.	Criteria met	Yes.

Section B. The Clinical Panel assesses the proposal against the criteria for prioritisation

Criterion 1A or 1B must be met		Commentary on magnitude of benefit
Criterion 1A. For clinical policy propositions likely to recommend routine commissioning, the benefit of the intervention should be of clinical significance and it should be clinically meaningful for patients compared with current interventions. OR the intervention should deliver equivalent benefit compared with current interventions and offer other advantages (i.e. lower cost, more convenient for patients, better delivery methods). Benefit may be expressed as quality of life or extension to life or both. The benefits should be net of harm. The magnitude of benefit will be taken into account in prioritising policy propositions for development.	Criteria met	There is evidence from the papers submitted that in a very small case series there was significant change on an individual basis that made it reasonable to explore this further.
Criterion 1B. For policy propositions likely not to recommend routine commissioning then the converse to criterion 1 applies i.e. the benefit should not be of clinical significance and it should not be clinically meaningful for patients compared with current interventions.	Criteria not met	

Overall assessment and advice by the Clinical Panel *The panel gives a view to what degree of priority is given to development of the policy and any further actions required prior to initiation of the clinical policy development work.*
The Panel noted that this was a rare condition with a small number of patients. There is some evidence of benefit in a case series which suggests that it is worth exploring further. The policy proposition will need to include a recommendation on genetic counselling due to the genetic nature of the condition.

Panel Decision	Proceed into the work program

URN	TBA
Evidence Review	Public health
Clinical Urgency	Annual work programme

Post Panel Actions

Action	**Who**	**When**
Letter to go to Clinical Lead	Head of Clinical Effectiveness	ASAP

Panel Chair	James Palmer	