South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**146**
Intervention:	**Alimemazine oral liquid (7.5mg/mL and 30mg/5mL) for the management of dystonia associated with poor sleep and/or vomiting in paediatrics** (Alimemazine is a phenothiazine derivative antihistamine (H1 antagonist) with antipruritic, sedative, hypnotic and antiemetic properties)
Date of Decision	**September 2023**
Date of Issue:	**October 2023 (time limited approval for 12 months)**
Recommendation:	**RED – suitable for prescribing, supply and administration by hospital only**
Further Information	• Dystonia is condition characterised by abnormal, often repetitive movements and/or postures that are caused by sustained or intermittent muscle contractions. • Alimemazine (in oral liquid formulation) is accepted for use in South East London for the management of dystonia associated with poor sleep and/or vomiting. • Use of alimemazine in this setting is restricted to patients not tolerating other treatments, where dose reductions of agents such as clonidine, benzodiazepines and chloral hydrate would be helpful for the child. Treatment will remain under the supervision of the specialist. • Alimemazine is **not licensed*** for use in this indication (off-label use). The applicant's submission included use in children from the age of 6 months. Alimemazine is contraindicated for use in children less than 2 years of age due to the risk of marked sedation and respiratory depression. However, dosing for alimemazine in children less than 2 years old is acknowledged and provided in the BNF for Children. • Informed consent should be gained from the parent/carer before treatment is initiated. • Treatment is usually for one month, but long term use may be helpful in certain cohorts of patients who benefit from treatment. • Given the paucity of data on use of alimemazine in this setting but acknowledging the rarity of the condition, the Committee has agreed that this approval is **time limited to 12 months.** The formulary applicant is to present back a report to the Committee summarising outcomes with alimemazine over this period, at which point the formulary status of alimemazine in this setting will be subject to review This report will be **coordinated by the original formulary applicant** and will include: - The total number of patients initiated on alimemazine (including the proportion from SEL) for the management of dystonia - Whether the use of alimemazine is in line with this formulary recommendation and the rationale for any deviation - The proportion of patients who have had dose reductions in alternative agents including clonidine, benzodiazepines and chloral hydrate - Reporting on patient related outcomes, including: (i) Clinical response to treatment i.e. reduction in dystonic movements, sleep disturbances & gastrointestinal disturbances (ii) Adverse effects (iii) Number of of patients switching from alimemazine to alternative treatments and the reasons for switching *Alimemazine oral liquid (7.5mg/5mL and 30mg/5mL) is licensed for the management of (i) urticaria and pruritis and (ii) pre-medication as a sedative before anaesthesia in children aged between 2 to 7 years
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	• The application estimates that ~5 patients per annum may be eligible for treatment with alimemazine in this setting, of which ~10 - 25% will be from SEL (1 - 2 patients). The applicant confirmed that the majority of patients would require a liquid formulation. • The cost impact will be determined by the age of the child, their weight and the formulation of alimemazine used. Based on the least conservative scenario modelled in the evidence review, a cost impact of ~£26,000 per year is estimated for two patients (or ~£1,300 per 100,000 population per year).
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor and audit usage and outcomes from use of alimemazine in this setting as outlined in the "For information" section and report back the Committee in 12 months (data to be collated and presented no later than **November 2024**)
	SEL Borough Medicines Teams: • Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care
Evidence reviewed	**References (from evidence review)** 1. Gorodetsky C, Fasano A. Approach to the treatment of pediatric dystonia. Dystonia 2022 doi:10.3389/dyst.2022.10287 2. Treatment of dystonia in children and adults, UpToDate. Available here [Accessed 07/09/2023] 3. Forman E, King M, Gorman K. Fifteen-minute consulation: approach to investigation and management of childhood dystonia. Arch Dis Child Educ Pract Ed 2021 106 p71-77. 4. Allen N, Lin JP, Lynch T et al. Status dystonicus: a practice guide. Dvelopmental Medicine & Child Neurology 2013 doi: 10.1111/dmcn.12339 5. Forsyth R, Newton R. Paediatric Neurology 3rd Edition 2017 Oxford University Press ISBN: 9780198784449 6. Alimemazine – Summary of Product Characteristics. Available here [Accessed 08/09/2023] 7. Dupre L, Stieglitz P. Extrapyrimidal syndromes after premedication with droperidol in children. British Journal of Anaesthesia 1980 52 p831-833

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.
b) This SEL IMOC 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.**