

**South East London Area Prescribing Committee
Formulary recommendation**

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| Reference | 088 |
| Intervention: | Specific antidepressants (clomipramine and fluoxetine) for the management of cataplexy associated with narcolepsy (Clomipramine is a tricyclic antidepressant and fluoxetine is an antidepressant in the class selective serotonin reuptake inhibitors) |
| Date of Decision | July 2018 |
| Date of Issue: | August 2018 |
| Recommendation: | Amber 3 – initiation and minimum 3 months supply by the specialist sleep service |
| Further Information | <ul style="list-style-type: none"> • Clomipramine and fluoxetine are accepted for use in South East London in line with the local pathway as treatment options for the management of cataplexy associated with narcolepsy. • Clomipramine, at a dose of 10mg – 75mg at night, is one of the first line options (alongside venlafaxine). • Fluoxetine, at a dose of 20mg to 60mg in the morning, is a second line option if clomipramine or venlafaxine are not tolerated. • The patient's first line therapy will be withdrawn slowly and overlapped with the next treatment option. The weaning and cross tapering of anti-depressants will be initiated and supervised by the sleep clinic. • Treatment will be initiated and monitored by the sleep service, which will regularly review patients for ongoing effectiveness of treatment. • The sleep service will prescribe and supply treatment for a minimum of 3 months. • Prescribing will only be transferred to primary care under the agreed shared care guideline once the therapy is confirmed as effective, the patient is on a stable dose and has been confirmed to be tolerating the medication. • The sleep service will provide the patient's GP with the shared care guideline, information for GPs and pharmacists and sleep hygiene information. • It should be noted that clomipramine and fluoxetine are not licensed for use in cataplexy associated with narcolepsy. Informed consent should be gained from the patient before treatment is started. • Dosages employed are in line with licensed use, and non-specialist prescribers are likely to be familiar with these treatments for their licensed indications. |
| Shared Care/ Transfer of care required: | Yes – shared care guideline |
| Cost Impact for agreed patient group | • It is anticipated that patient numbers will be low for South East London (~5 patients per year) and the cost impact is likely to be negligible (£200 per year). |
| Usage Monitoring & Impact Assessment | <ul style="list-style-type: none"> • Providers to monitor use and submit usage data and audit reports (against this recommendation and the treatment pathway) upon request to the APC. • CCGs to monitor ePACT data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care. |

| Evidence reviewed | References (from evidence evaluation) |
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| | <ol style="list-style-type: none"> 1. Dauvilliers Y, Siegel J, Lopez R et al. Cataplexy—clinical aspects, pathophysiology and management strategy. <i>Nature reviews neurology</i> 2014 (10) p386-395 2. European Federation of Neurological Societies guidelines on the management of narcolepsy. <i>European Journal of Neurology</i> 2006 13 p1035-1048 3. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin – an American Academy of Sleep Medicine Report. <i>Sleep</i> 2007 30 (12) p1705-1711 4. Parkes J, Schachter M. Clomipramine and Clonazepam in Cataplexy. <i>The Lancet</i> 1979 314 (1851) p1085-1086. 5. Guilleminault C, Takahashi S, Carskadon M et al. Evaluation of short term and long term treatment of the narcolepsy syndrome with clomipramine hydrochloride. <i>Acta Neurologica Scandinavia</i> 1976 54 p71-87 6. Shapiro W. Treatment of cataplexy with clomipramine. <i>Archives of Neurology</i> 1975 32 p653-656 7. Schachter M, Parkes J. Fluvoxamine and clomipramine in the treatment of cataplexy. <i>Journal of Neurology, Neurosurgery and Psychiatry</i> 1980 43 p171-174 8. Langdon N, Shindler J, Parkes J. Fluoxetine in the treatment of cataplexy. <i>Sleep</i> 1986 9 (2) p371-372 9. Fluoxetine supresses human cataplexy: a pilot study. <i>Neurology</i> 1994 44 (4) p707-709 10. Summary of Product Characteristics: clomipramine. Available online at: https://www.medicines.org.uk/emc/product/2553 (accessed 03/04/2018) 11. Summary of Product Characteristics: fluoxetine: Available online at: https://www.medicines.org.uk/emc/product/6013 (accessed 03/04/2018) 12. Drug Tariff April 2018. Available online at: https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff (accessed 03/04/2018) |

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.**