

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

Reference:	093
Intervention:	Low dose desmopressin oral lyophilisate (Noqdirna®) for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults (Desmopressin is a synthetic analogue of naturally occurring anti-diuretic hormone arginine vasopressin [AVP]).
Date of Decision:	August 2018
Date of Issue:	September 2018
Recommendation:	Red – suitable for prescribing and supply by the hospital only
Further Information:	<ul style="list-style-type: none"> • Low dose desmopressin oral lyophilisate is accepted for use in SEL for use within its licensed indication, i.e.: the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. • Use outside the product license is not supported by this formulary recommendation. • Use is restricted to adults who meet the following criteria (once treatable causes of nocturia have been excluded or managed): <ul style="list-style-type: none"> – There is a significant impact on quality of life (QoL) - see next main bullet point – Lifestyle measures have been trialed as a first line option but have failed to provide symptom relief. Lifestyle advice can be found at the European Association of Urology website and within a GSTT patient information leaflet about nocturia. • Impact on QoL should be measured through: <ul style="list-style-type: none"> – Objective evidence of nocturia and underlying nocturnal polyuria using a bladder diary – Subjective assessment of bother caused – including patient symptoms related to waking and daytime sleepiness (including ≥2 night time voids) – Health Related QoL (HRQoL): for example, the Kings Health Questionnaire or other similar tools (refer to NICE summary). • Treatment with low dose desmopressin oral lyophilisate should be stopped if there is no improvement in symptoms after 2 weeks (based on clinical review of the patient on a case by case basis). • This approval is time limited to 1 year to allow experience of use with the preparation. A report summarising outcomes with low dose desmopressin oral lyophilisate over this period will be presented back to the Committee after 1 year. This report will be coordinated across all trusts in SEL by the original formulary applicant and will include: <ul style="list-style-type: none"> – The total number of patients treated with low dose desmopressin oral lyophilisate across SEL – Whether use is in line with this recommendation (including the licensed indication) – Impact on patient related outcomes, such as (i) adverse effects [including impact on sodium levels] (ii) Efficacy, including symptom resolution and quality of life improvements. – The number of patients discontinuing treatment and reasons for stopping. <p>Useful information – this is not exhaustive, refer to the Summary of Product Characteristics for further detail (25mcg and 50mcg)</p> <ul style="list-style-type: none"> • The dose in women is 25 micrograms daily. The dose in men is 50 micrograms daily. • Doses are administered sublingually without water, one hour before bedtime. • A dose increase with this product is not recommended in elderly patients (aged ≥ 65 years). • In elderly patients (65 years or over) serum sodium must be within the normal range, before initiating treatment, in the first week (4-8 days after initiation) and again at one month. Thereafter sodium levels should be periodically monitored. • If higher doses are considered for patients under the age of 65 years in case of an insufficient response to low dose oral lyophilisate desmopressin (Noqdirna®), other desmopressin oral lyophilisate products should be used.

Further Information (continued):	<ul style="list-style-type: none"> In the event of signs or symptoms of water retention and/or hyponatremia (headache, nausea/vomiting, weight gain, and, in severe cases, convulsions) treatment should be interrupted and reassessed. When restarting treatment strict fluid restriction should be enforced and serum sodium levels monitored. Low dose oral lyophilisate desmopressin should be discontinued if the serum sodium level falls below the lower limit of normal range (i.e.135 mmol/L).
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> The applicant estimates that approximately 4 patients per month at their trust will be started on treatment, or 48 patients per year. The cost of low dose desmopressin oral lyophilisate is £15.16 per patient month (for both doses) or £185 per patient per year. If it is assumed a total of 100 patients per year will be started on this treatment by the Trusts across South East London, this will result in a cost implication of around £18,500 for South East London. Note: this does not include savings due other non-licensed treatments that might be discontinued.
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> Monitor use and submit usage data and audit reports (against this recommendation) upon request to the APC. Collate data at a SEL level as outlined in “Further Information” section and present report to APC by November 2019 at the latest. <p>CCGs:</p> <ul style="list-style-type: none"> Monitor ePACT data. Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence review)</p> <ol style="list-style-type: none"> Desmopressin acetate (Noqdirna) oral lyophilisates. Assessment report 3282 – All Wales Therapeutics and Toxicology Centre Jun 2017. Hashim H, Blanker M, Djurhuus J et al. The International Continence Society standardisation of terminology in nocturia. Sep 2016. Available online at: https://www.ics.org/Documents/DocumentsDownload.aspx?DocumentID=3571 (accessed 06/08/2018) Summary of Product Characteristics: Noqdirna oral lyophilisates. Available online at: https://www.medicines.org.uk/emc/product/4368/smpc (accessed 06/08/2018) NICE CG171: Urinary incontinence in women: management. Available online at: https://www.nice.org.uk/guidance/cg171 (accessed 06/08/2018) NICE CG97: Lower urinary tract symptoms in men: management. Available online at: https://www.nice.org.uk/guidance/cg97 (accessed 06/08/2018) Sand P, Dmochowski R, Reddy J et al. Efficacy and safety of low dose desmopressin tablet in women with nocturia: results of a multicentre randomised double-blind placebo controlled parallel group study. The Journal of Urology 190 p958-964 Weiss J, Herschorn S, Albei C et al. Efficacy and safety of low dose desmopressin orally disintegrating tablet in men with nocturia: results of a multicentre, randomised, double blind, placebo controlled parallel group study. The Journal of Urology 2013 190 p965-972. Desmopressin oral lyophilisate (Nordiq). Resubmission – Scottish Medicines Consortium 1218/17, July 2017. Drug Tariff, August 2018. Desmopressin (Noqdirna). All Wales Medicines Strategy Group ref 3282 October 2017.

NOTES:

- Area Prescribing Committee recommendations, position statements and minutes are available publicly via the [APC website](#).
- 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.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**

South East London Area Prescribing Committee. A partnership between NHS organisations in South East London: Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark Clinical Commissioning Groups (CCGs) and GSTFT/KCH /SLAM/ & Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust