

**Patient Group Direction**

**Administration or Supply of Zopiclone**

By Registered Nurses employed by South Staffordshire & Shropshire Healthcare  
Foundation NHS Trust in **Crisis Resolution Teams**

**This Patient Group Direction for use in South Staffordshire & Shropshire  
Healthcare NHS Foundation Trust and is authorised by:**

<b>Position of Signatory</b>	<b>Name</b>	<b>Signed</b>	<b>Date</b>
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Nursing	Alison Bussey		
Director of Quality & Clinical Performance	Therèsa Moyes		

**The named below, being employees of  
South Staffordshire & Shropshire Healthcare NHS Foundation Trust  
are authorised to administer or supply Zopiclone, to patients, under this  
Patient Group Direction**

<b>Name</b>	<b>Job Title</b>	<b>Signed</b>	<b>Date</b>

**This Patient Group Direction is operational from 1<sup>st</sup> Nov 2016. Review  
date: Sept 2018. Expires on: 30<sup>th</sup> Nov 2018.**

**This PGD replaces 3315**

## Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire HealthCare NHS Foundation Trust are authorised to administer/supply Zopiclone, as specified under this Patient Group direction, in Crisis Teams, following demonstration of the competencies below:

### Professional Responsibility / Competencies

- The registered nurse will have undertaken appropriate training to carry out clinical assessment of patient that requires treatment according to the indications listed in the PGD (see PGD Operational Policy)
- All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
- Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
- The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and standards for Medicines Management (Nursing & Midwifery Council)
- Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
- All registered nurses details and signature must be entered on the PGD
- Following **administration** a record of the date, and dose of the medicine should be recorded in the clients records, and within the Crisis PGD Administration Record Sheet.
- Following **supply** a record of the date, and dose of the medicine should be recorded in the clients records, and within the Record of Medications supplied using the PGD Framework.

**For full product information, always refer to the latest SPC (Summary of Product Characteristics).**

**If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (<http://emc.medicines.org.uk>)**

<b>Supply/Administration of</b>	Zopiclone
<b>Legal Classification</b>	POM, CD Schedule 4, Part 1
<b>Black Triangle?</b>	No
<b>Type</b>	Tablets
<b>Storage</b>	Supply/administration of <b>Zopiclone</b> Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to service user. Information leaflets must be given. Any relevant documentation must be completed.
<b>Condition to be treated</b>	Zopiclone is supplied for service users presenting with acute sleep impairment/ insomnia. The severity of sleep impairment must indicate that they are at risk of their own coping resources being exhausted.
<b>Inclusion Criteria</b>	Clinical criteria for inclusion: Zopiclone may be supplied to a service user fitting the following criteria: <ul style="list-style-type: none"> <li>▪ Not currently receiving another hypnotic for sleep disturbance, prescribed and OTC (over the counter)</li> <li>▪ Assessment demonstrates that it has been reported and/or evidenced that there has been significant impairment for at least 48 hours.</li> <li>▪ Owing to severity of clinical presentation alternative strategies are inappropriate without initial support of medication</li> <li>▪ In the absence of rapid treatment, the service user is at risk of exhausting coping resources leading to significant deterioration and a possible need for hospital admission</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>• Service user should be excluded if they present with the following: <ul style="list-style-type: none"> <li>• Pre-existing complex physical health needs</li> <li>• Known hyper-sensitivity to zopiclone</li> <li>• Pre-existing prescription with supply for benzodiazepine or hypnotic medication</li> <li>• Is pregnant (confirmed or suspected) or</li> </ul> </li> </ul>

	<p>lactating</p> <ul style="list-style-type: none"> <li>• A history of renal/liver impairment</li> <li>• A history of respiratory disease or myasthenia gravis</li> <li>• A history of sleep apnoea</li> <li>• Is currently intoxicated with alcohol and/or other illicit substance</li> <li>• A history of dependence on zopiclone or benzodiazepines</li> </ul>
<b>Action if excluded or patient declines</b>	<p>Seek medical advice Document refusal</p>
<b>Reasons for seeking further advice from doctor</b>	<p>Advice should be sought for the following side-effects:</p> <ul style="list-style-type: none"> <li>▪ Gastro-intestinal disturbances</li> <li>▪ Confusion</li> <li>▪ Dizziness</li> </ul> <p>And if the service user meets any of the exclusion criteria</p>
<b>Administration Route</b>	<p>Oral</p>
<b>Dose</b>	<p>3.75 - 7.5mg nocte Elderly: 3.75mg nocte</p>
<b>Administration/ Supply Schedule</b>	<p><u>Administration Period:</u> Maximum 72hr period The PGD can only be operated for an individual service user for THREE days in any seven day period and not for more than two consecutive seven-day periods. Following the use of the PGD for a second consecutive period it cannot be used again for that individual for a four-week period.</p> <p><u>Supply:</u> Maximum THREE days supply (only after comprehensive risk assessment)</p>
<b>Warnings/Adverse Reactions</b>	<p><u>Warnings:</u> Causes drowsiness which may continue the next day. If affected do not drive or operate machinery. Avoid alcoholic drink.</p> <p><u>Adverse Reactions:</u> Are rare but may include:</p> <ul style="list-style-type: none"> <li>▪ Metallic taste</li> <li>▪ Urticaria</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Rashes</li> <li>▪ Hallucinations</li> <li>▪ Nightmares</li> <li>▪ Amnesia</li> <li>▪ Behavioural disturbances</li> </ul>
<b>Advice/Management of Adverse Reactions &amp; Follow-up Action</b>	<p><u>Follow-Up:</u> Service user must agree to be seen by the most appropriate person (team to make that decision) the next working day.</p> <p><u>Arrangements for referral:</u> CRHT to discuss who needs to be informed and fax a copy of the assessment documentation to them. This could be a GP, psychiatrist or other teams from the Mental Health Trust.</p>
<b>Use in Pregnancy &amp; Lactation</b>	Not appropriate via PGD
<b>Records</b>	<p>Use of medications via a PGD will be clearly documented within the Individual Care Plan and the MDT notes.</p> <p><u>and</u> administration also recorded in the Crisis PGD Administration Record Sheet <u>or</u> supply also recorded in the Record of Medications Supplied Using the PGD Framework sheet.</p>