Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

Prescribing Support Document
Melatonin for insomnia in adult and paediatric patients with a learning disability

Change History

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Prescribing Support Document
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1. Introduction

The document aims to support prescribing of melatonin for adult and paediatric patients with a learning disability.

The clinical management of adult and paediatric patients with a learning disability in Hertfordshire and west Essex Integrated Care System (HWE ICS) is the responsibility of the following organisations: Hertfordshire Community NHS Trust, Hertfordshire Partnership University NHS Foundation Trust, Essex Partnership University NHS Foundation Trust, HCRG Care Group (Essex Child and Family Wellbeing Service), West Hertfordshire Teaching Hospitals NHS Trust, East and North Hertfordshire NHS Trust and Princess Alexandra Hospital NHS Trust .

Melatonin can be prescribed for the treatment of insomnia and dysregulation of the sleep cycle in both adult and paediatric patients with a learning disability. It is prescribed as part of a management plan including clinical assessment of sleep disturbances following the implementation of environmental, behavioural and educational approaches.

HWE ICS approval for melatonin use in patients with a learning disability is as follows:

- For children and adults under specialist care (e.g. a paediatrician, psychiatrist or a specialist involved in the patient's care) – AMBER initiation status with initiation and stabilisation by specialists with continuation in primary care.

NB: Primary care prescribing of melatonin for adult patients who are <u>not under specialist care</u> is <u>not approved</u>; further work planned to address melatonin use in this cohort.

The aim of this guideline is to ensure that the transfer of care of people with a learning disability prescribed melatonin for sleep disturbance to primary care is safe and appropriate by providing the following information:

- Clinical information on melatonin for sleep disturbances
- The roles and responsibilities of the secondary care specialist team, GP, Integrated Care Board (ICB) and the patient/carer
- Monitoring/review requirements for patients on melatonin
- Criteria for the transfer of prescribing of melatonin to primary care
- Criteria for when melatonin should be stopped

2. Criteria for transfer of prescribing to primary care

The following must apply before the GP is asked to accept on-going prescribing responsibility for melatonin:

The ***inclusion*** criteria:

- The patient has a confirmed formal diagnosis of learning disability and is under the care of a learning disability specialist (e.g. a paediatrician, psychiatrist or a specialist involved in the patient's care)
- The patient is taking more than 2 hours to fall asleep on a regular basis **and** sleep disturbance is causing significant family disturbance (where applicable)
- The patient must have undergone the appropriate assessments and shown a beneficial response to treatment
- The patient is stable on a maintenance dose of melatonin for at least 3 months
- The patient meets the continuation criteria for on-going melatonin prescribing
- The specialist will ensure on-going review of melatonin including treatment holidays to ensure continued benefit of medication

The ***exclusion*** criteria:

- Sleep disturbance in patients **without** a formal confirmed diagnosis of a learning disability
- Patient not under the care of a specialist (e.g. a paediatrician, psychiatrist or a specialist involved in the patient's care)

3. Areas of responsibility

SPECIALIST RESPONSIBILITIES	
1.	The specialist team will have undertaken sleep hygiene measures, environmental stimulus control and adjustment of stimulant medication prior to melatonin prescribing as follows: ▪ Non-pharmacological interventions must be trialled for a minimum of at least 4 weeks before considering melatonin. These include: o Fixed bedtime routine o Reduce light levels in the bedroom o Avoid extremes of temperature o Avoid sources of distraction in the bedroom o Avoid using screens and electronics at least two hours before bedtime o Ensure that the bed is for sleeping. Avoid reading, working, watching television in bed as this will stimulate the brain rather than prepare the mind for sleep o Avoid strenuous physical activity or exercise before bedtime o Avoid caffeine-containing drinks in the hours leading to bedtime ▪ Melatonin must only be considered when the child/adult is taking more than 2 hours to fall asleep on a regular basis **and** sleep disturbance is causing significant family disturbance (where applicable). ▪ Behavioural sleep interventions should be continued even when melatonin is prescribed. ▪ A sleep diary (example in Appendix 1) must be used to determine the baseline sleep pattern prior to any intervention and following any change in treatment in order to inform decisions on changing dose and stopping treatment.
2.	The initiating specialist is responsible for discussing treatment with melatonin as well as its side effects with the service user/parent/carer and obtaining informed consent to treatment. They will be responsible for explaining the off-license use of melatonin. A written patient/parent/carer information leaflet on melatonin is available from the Medicines for Children website: https://www.medicinesforchildren.org.uk/medicines/melatonin-for-sleep-disorders/.
3.	Following initiation of melatonin, a trial is given for 3 months and continuation of treatment will only be considered if the specialist considers a significant improvement has been made. Significant improvement is considered as follows: ▪ When melatonin results in the child/adult having a reduction in sleep latency of at least 40 minutes and/or ▪ Increase in total sleep duration of at least 40 minutes or more and/or ▪ Qualitative improvement in sleep quality where child/adult wakes up feeling rested and refreshed and/or ▪ Qualitative positive impact on the quality of life of the child/adult and/or positive impact on family life as described by carers The Melatonin Clinic Review Form (Specialist Service) can be used for assessment (see Appendix 2).
4.	For paediatric patients, monitoring of growth and sexual development is recommended i.e. to check height, weight and pubertal development.
5.	Initiate and stabilise treatment with melatonin. The specialist is responsible for choosing the most appropriate brand and formulation of melatonin. Please see HWE ICS guidance document on the lowest cost melatonin product options; clinicians should select the least expensive clinically appropriate option.
6.	Service users that require long term treatment of melatonin should be instructed by the specialist to withdraw use of melatonin for a period of time known as a 'drug-holiday' in order to assess the need for on-going treatment. Approximately every 12 months, patients should try a drug-free holiday for between 7 and 14 days. Patients and their carers can choose a suitable time to undertake a drug-free holiday and do not have to inform their GP

	or specialist. An opportunity to undertake the drug-free holiday could be two-four weeks before the specialist's annual review; recording the outcomes on and off melatonin on a sleep diary (example in Appendix 1). Alternatively, paediatric patients could try having a drug-free holiday during the school holidays to avoid adverse effects on school days and their sleep diary reviewed at their next specialist review. If the break from melatonin has resulted in no deterioration in sleep cycle, the patient can remain off melatonin. If withdrawal of medication has impacted the patient's sleep cycle, melatonin should start again at the same dose the patient was stable on. The specialist and GP should be informed if the drug withdrawal trial has been successful and that melatonin is no longer required. Patients should be informed that if a trial withdrawal is not attempted on the advice of the specialist then melatonin prescriptions will be discontinued. In those requiring long-term treatment, consider a reduction in dose after several months if patients have a regular sleep pattern.
7.	If melatonin is no longer effective after months or years of effective treatment, or a lower treatment effect is seen with melatonin after titration to a higher dose of melatonin, consider a down-titration to a lower dose, or a 2 – 3 week period off melatonin followed by re-starting at the lowest dose again. If this is not effective, consider complete discontinuation of treatment. Melatonin can be stopped abruptly. No discontinuation effects are documented. Melatonin is not generally considered to produce tolerance, rebound insomnia or dependence.
8.	A review of melatonin will be undertaken 3 months after initiation (see point 3 above). For paediatric patients, the specialist is responsible for carrying out 6 monthly reviews to monitor the young person's height, weight and pubertal development. For all patients, the specialist is responsible for ensuring that on-going treatment is warranted and improvements (as per continuation criteria above) are still being maintained. This should be undertaken at least yearly.
9.	Patients prescribed melatonin preparations other than the products listed in the HWE ICS guidance document on the lowest cost melatonin options should be reviewed for a switch to a preferred option. The preparation of melatonin must be reviewed at each appointment to ensure the most cost effective clinically appropriate preparation is prescribed.
10.	Write to the GP to transfer prescribing once the patient is stable on a maintenance dose (for at least 3 months). Information that needs to be provided to the GP is set out in Section 4 of this document.
11.	Ensure the patient has 4 weeks supply of medication prior to transfer to GP.
12.	Specialist to ensure that patient/carer is informed and made aware of their responsibilities (see patient/carer responsibilities). This includes the importance of attending review appointments with the specialist; failure to attend appointments will result in GP being asked to stop prescribing melatonin.
13.	Contact GP if patient does not attend review appointments, or drug withdrawal trial not attempted (to advise GP to stop prescribing melatonin).
14.	Children and young people approaching the age of 18 years of age must have a medication review to decide whether the melatonin should be prescribing into adulthood. **Melatonin should only be continued into adulthood where a patient remains under the care of a specialist**; patients who will <u>not</u> transfer to a specialist adult service should have their melatonin reviewed/stopped by the paediatric specialist. The paediatric specialist should inform the GP that this review has taken place, and if melatonin is to continue, advise which specialist service the patient will be transferred to.
15.	For paediatric patients, the specialist team is to inform service users/parents/carers (at initiation of melatonin and/or on transfer to GP prescribing) that GPs will not be expected to prescribe melatonin once service users reach the age of 18 years **unless** they remain under the care of a specialist service. Service users to be advised

	that they will have a medication review with their specialist when they approach 18 years of age (as outlined in point 14).

GP RESPONSIBILITIES	
1.	Review the request from the specialist to take on prescribing of melatonin. Acceptance is assumed. Promptly communicate to the specialist if prescribing responsibility is not accepted (within 2 weeks), including the clinical reason. Responsibility cannot be declined on grounds of cost of medication.
2.	Check sufficient information has been provided to take on the responsibility for continued prescribing see Section 4 of this document. Request any missing information to be provided from the specialist before taking on the prescribing in primary care. Transfer of care can be refused by GP if information is insufficient.
3.	Prescribe melatonin at the maintenance dose recommended.
3.	Link melatonin to indication on GP prescribing system.
4.	Seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
5.	Check for possible drug interactions when newly prescribing or stopping concurrent medication.
6.	Discontinue treatment where drug holidays have been successful or on the advice of the specialist.
7.	Refer patient back to secondary care when appropriate, see Section 8 'Triggers for referral to secondary care'.
8.	Discontinue melatonin if advised by the specialist that patient has not attended review appointments, or drug withdrawal trial not attempted.
9.	Ensure all patients with a learning disability are placed on the GP practice learning disability register.
10.	Ensure all patients with a learning disability above the age of 14 years are offered a learning disability Annual Health Check.

PATIENT/CARER RESPONSIBILITIES	
1	Report to their specialist if they do not have a clear understanding of or have any concerns with their treatment with melatonin.
2.	Following the transfer of prescribing, obtain further prescriptions for melatonin from the GP and not the specialist.
3.	Inform their GP of any over the counter products (the GP will know the patients prescribed medications). Inform the community pharmacist that they are prescribed melatonin when buying over the counter medications.
4.	Report any adverse effects to the GP whilst taking melatonin.
5.	Report any changes in sleep disturbance to the GP or specialist.
6.	Approximately every 12 months, patients should try a drug-free holiday for between 7 and 14 days. Patients and their carers can choose a suitable time to undertake a drug-free holiday and do not have to inform their GP or specialist. An opportunity to undertake the drug-free holiday could be two-four weeks before the specialist's annual review; recording the outcomes on a sleep diary (example in Appendix 1) on and off treatment. Alternatively, paediatric patients could try having a drug-free holiday during the school holidays to avoid adverse effects on school days and their sleep diary reviewed at their next specialist review. If the break from melatonin has resulted in no deterioration in sleep cycle, the patient can remain off melatonin. If withdrawal of medication has impacted the patient's sleep cycle, melatonin should start again at the same dose the patient was stable on. The specialist and GP should therefore be informed if the drug withdrawal trial has been successful and that melatonin is no longer required. If a drug withdrawal trial is not attempted on the advice of the specialist then melatonin prescriptions will be discontinued.
7.	Attend review appointments with specialist as requested; if patients miss appointments GPs will be unable to continue to supply melatonin.
8.	All patients above the age of 14 years to attend the learning disability Annual Health Check where possible.

ICB RESPONSIBILITY	
1	The ICB will review the prescribing support document when new information becomes available.

Communication and Handover from Secondary to Primary care

The following information should be provided by the specialist when requesting the transfer of prescribing of melatonin to the GP (see Appendix 3 for a GP letter template):

- Clear diagnosis and care plan including information that has been discussed with patient and carer
- Confirmation that sleep hygiene measures have been implemented
- Confirmation that the continuation criteria for melatonin prescribing have been met
- Details of melatonin preparation and dose
- Confirmation that the patient is stable on a maintenance dose
- At least four weeks supply of melatonin from last appointment
- Specialist team contact details for GPs to obtain advice and support

4. Supporting Information on Melatonin

For full details, please refer to the current individual drug Summary of Product Characteristics (SmPC), BNF, and BNFc.

Please see HWE ICS guidance document on the lowest cost melatonin product options; clinicians should select the least expensive clinically appropriate option. Also includes advice on administration (e.g. crushing/halving tablets).

Absolute Contraindications to melatonin[1]	
Hypersensitivity	To the active substance or any of the excipients.
Liver Disorders	Melatonin is not recommended for use in patients with hepatic impairment. There is no experience of the use of melatonin in patients with liver impairment. Published data demonstrates markedly elevated endogenous melatonin levels during daytime hours due to decreased clearance in patients with hepatic impairment. The manufactures of melatonin recommended avoiding use in patients with hepatic impairment.
Autoimmune disease	No clinical data exist concerning the use of melatonin in individuals with autoimmune diseases. Therefore, melatonin is not recommended for use in patients with autoimmune diseases.

Cautions – to be used with caution in the following[1]	
Melatonin may cause drowsiness	Melatonin may cause drowsiness. Therefore, the product should be used with caution if the effects of drowsiness are likely to be associated with risk to safety.
Renal impairment	The effect of any stage of renal impairment on melatonin pharmacokinetics has not been studied. Caution should be used when melatonin is administered to such patients.
Rare hereditary glucose tolerance disorders	Some brands of melatonin contains lactose. Patients with rare hereditary problems of galactose intolerance, LAPP lactase deficiency or glucose malabsorption should not take preparations containing lactose.

Adverse effects of melatonin[1] **Melatonin is generally well tolerated and adverse reactions reported are at a similar level to those reported with placebo**		
Adverse effects	***Symptoms/signs***	***Frequency***
Psychiatric disorders	Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety	Uncommon
	Mood altered, aggression, agitation, crying, stress symptoms, disorientation, early morning awakening, libido increased, depressed mood, depression	Rare
Nervous system disorders	Migraine, headache, lethargy, psychomotor hyperactivity, dizziness, somnolence	Uncommon
	Syncope, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, paraesthesia	Rare

Vascular disorders	Hypertension	Uncommon
	Hot flush	Rare
Gastrointestinal disorders	Abdominal pain, abdominal pain upper, dyspepsia, mouth ulceration, dry mouth, nausea	Uncommon
	Gastro-oesophageal reflux disease, gastrointestinal disorder, oral mucosal blistering, tongue ulceration, gastrointestinal upset, vomiting, bowel sounds abnormal, flatulence, salivary hypersecretion, halitosis, abdominal discomfort, gastric disorder, gastritis	Rare
Hepatobiliary disorders	Hyperbilirubinaemia	Uncommon
Skin and subcutaneous tissue disorders	Dermatitis, night sweats, pruritus, rash, pruritus generalised, dry skin	Uncommon
	Eczema, erythema, hand dermatitis, psoriasis, rash generalised, rash pruritic, nail disorder	Rare
	Angioedema, oedema of mouth, tongue oedema	Unknown
Musculoskeletal and connective tissue disorders	Pain in extremity	Uncommon
	Arthritis, muscle spasms, neck pain, night cramps	Rare
Renal and urinary disorders	Glycosuria, proteinuria	Uncommon
	Polyuria, haematuria, nocturia	Rare
Reproductive system and breast disorders	Menopausal symptoms	Uncommon
	Priapism, prostatitis	Rare
	Galactorrhoea	Unknown
General disorders and administration site conditions	Asthenia, chest pain	Unknown
	Fatigue, pain, thirst	Rare
Blood and lymphatic system disorders	Leukopenia, thrombocytopenia	Rare
Infections and infestations	Herpes zoster	Rare
Cardiac disorders	Angina pectoris, palpitations	Rare
Ear and labyrinth disorders	Vertigo positional, vertigo	Rare
Eye disorders	Visual acuity reduced, vision blurred, lacrimation increased	Rare
Immune system disorders	Hypersensitivity reaction	Unknown
Investigations	Liver function test abnormal, weight increased	Uncommon
	Hepatic enzyme increased, blood electrolytes abnormal, laboratory test abnormal	Rare

If the patient has a suspected adverse reaction report it to the specialist and also report the adverse reaction via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard.

Drug Interactions[1]		
Pharmacokinetic Interactions		
Medication	**Effect**	**Action**
Fluvoxamine*	Plasma concentration of melatonin significantly increased	Avoid – potentially serious interaction
5 and 8-methoxypsoralen (psoralen)	Plasma concentration of melatonin increased	Review / reduce dose of melatonin

Cimetidine	Plasma concentration of melatonin increased	Review / reduce dose of melatonin
Oestrogens (e.g. contraceptive or hormonal replacement therapy)	Plasma concentration of melatonin increased	Review / reduce dose of melatonin
Quinolones	Plasma concentration of melatonin may be increased	Review / reduce dose of melatonin if quinolones prescribed for long term use
Carbamazepine and rifampicin	Plasma concentration of melatonin may be decreased	Review / increase dose of melatonin
Cigarette smoking	Plasma concentration of melatonin may be decreased	Review if there is a change in smoking habit
Pharmacodynamic Interactions		
Medication	**Effect**	**Action**
Alcohol	Reduces effectiveness of melatonin on sleep	Advise alcohol will reduce effectiveness of melatonin
Hypnotics and CNS depressants	Melatonin may enhance the sedative properties of other drugs acting on the CNS	Monitor for over sedation and review
Sedative antipsychotics*	Increased sedative effects	Monitor for over sedation - Advise and review

* potentially serious interactions

Pregnancy and breast feeding[1]	
Pregnancy	**Breast feeding**
In view of the lack of clinical data, use in pregnant women and by women intending to become pregnant is not recommended.	Breastfeeding is not recommended in women under treatment with melatonin.

Long term effects of melatonin:

The long-term effects of melatonin are unknown. A previously published NICE Key Therapeutic Topic on Hypnotics stated that the risks associated with the long-term use of benzodiazepine and 'Z-drug hypnotics' have been well recognised for many years. Recent data also suggest a similar safety concern with melatonin.[4] An observational study discussed in NICE's medicines evidence commentary on fracture risk associated with melatonin and other hypnotics found that in people aged 45 years and over, receiving 3 or more melatonin prescriptions were associated with an increased risk of fracture compared with no use of any hypnotic drugs.[4] There is uncertainty over what effects exogenous melatonin has on other circadian rhythms including endocrine or reproductive hormone secretion. Whilst there is no clinical data so far supporting the risk of hormonal disturbances or effects on pubertal development by melatonin treatment, long-term studies are warranted.[5]

6. Monitoring requirements

Secondary Care monitoring	
6-12 monthly reviews of the patient by the specialist to:	
1.	Ensure that on-going treatment is warranted and improvements as per continuation criteria have been maintained (at least yearly).
2.	Paediatric patients: 6-monthly monitoring of growth and sexual development is recommended i.e. to check height, weight and pubertal development.
3.	Ensure that the patient has undertaken a 'drug-holiday' from melatonin at least once a year.
Primary Care monitoring	
Monitor for adverse effects and drug interactions (see Section 5 for details). Contact specialist for advice where necessary.	

7. Stopping Medication

- Melatonin should be stopped in patients who do not continue to benefit from its use or experience intolerable side effects.
- Melatonin should be stopped if treatment holidays are successful.
- Children and young people approaching the age of 18 years of age must have a medication review prior to deciding on continuing with the melatonin treatment. **Melatonin should only be continued into adulthood where a patient remains under the care of a specialist**; patients who will not transfer to a specialist adult service should have their melatonin reviewed/stopped by the paediatric specialist (see page 4 for further details).

8. Triggers to refer to secondary care

- Difference of opinion between primary care team and carer about stopping medication.
- If there is no benefit from treatment with melatonin and there are ongoing sleep problems.
- Patient is experiencing side effects.
- Paediatric patients: if there is delayed sexual development or failure to gain weight and height for the expected age and familial characteristics.

9. References

1. Medicines.org.uk. (2019). Circadin MR 2mg Prolonged Release tablets. *Summary of Product Characteristics (SmPC) - (eMC)*. [online] Available at: https://www.medicines.org.uk/emc/product/2809
2. Joint Formulary Committee (2022) British National Formulary (online). BMJ Group and Pharmaceutical Press. https://bnf.nice.org.uk
3. Paediatric Formulary Committee. *BNF for Children* (online) London: BMJ Group, Pharmaceutical Press, and RCPCH Publications <http://www.medicinescomplete.com>
4. National Institute for Health and Care Excellence (NICE). Key therapeutic topic (KTT6): Hypnotics. 2015. Last updated September 2019.
5. European Medicines Agency. Assessment report for Slenyto. July 2018. Available from: https://www.ema.europa.eu/en/documents/assessment-report/slenyto-epar-public-assessment-report_en.pdf

Appendix 1 – Sleep diary **Week beginning ……./……./…….**

Patient's name: **Date of birth:**

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Time put to bed/bedtime							
Time fell asleep							
Did anything help to fall asleep							
Night-time waking (number of times/how long)							
Details of night-time waking *Explain why patient woke up e.g. nightmare, environment*							
Time awoke							
How many daytime naps/sleeps and length of time							

Appendix 2

Insert trust logo

Melatonin Clinic Review (Specialist Service)

Date:

Address Label

1. **Name of the patient:** **Date of birth:**
2. **Name of Melatonin used:** **Date of last prescription:**
3. **Type of Melatonin prescribed?**
   Circadin, liquid melatonin, Other (ps. state)…….
4. **Are tablets crushed before use?**
   Yes No

5. **Dose prescribed:** **Time given:**

4. **Has the patient experienced any side effects from Melatonin?**
   Yes No don't know
   If yes, please state which side effects:

5. **Is the Melatonin effective helping the patient to fall sleep?**
   Yes No don't know
   Time to fall sleep <1 hour ❑ 1-2 hours ❑ >2hours ❑
6. **Does the patient wake up frequently at night?**
   Yes No don't know

7. **How long has the patient been off Melatonin if you're doing a 'wash out'?**

   Please remember also to fully complete a 2 week sleep diary and mail to your Specialist or take to your next appointment.

_____

Will be completed by your doctor on receipt of above information

a. **Repeat Melatonin prescription justified**

Yes❑ No ❑ State reasons ……. ……

b. Dose changed Yes ❑ No ❑

If Yes, state new dose and type of Melatonin: _____

c. Date of new prescription issue: _____

d. Name of doctor _____

e. Signature _____

Updated by Dr S Ozer/ Dr N Bajaj March 2020

Appendix 3

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Template Letter to GP

Ref:

Team Details:

Date:

Tel No:

Address:

Dear Dr…….

Re:……

NHS No. ……

DOB:……..

Diagnosis: ……

Care plan for the management of insomnia: ……
……

I have seen ……. in clinic today.

……..(insert name)…….has been stable on melatonin for over three months and I kindly request that you take over the prescribing on melatonin in primary care.

Melatonin preparation prescribed:

…… Dose……..mg at night.

I can confirm prior to initiating melatonin non-pharmacological interventions were trialled for a minimum of at least 4 weeks. Despite sleep hygiene measures implemented melatonin was initiated.

……..(insert name)…….has demonstrated proven benefit to being on melatonin and continues to have (*please tick):*

☐ A reduction in sleep latency of at least 40 minutes and/or

☐ Increase in total sleep duration of at least 40 minutes or more

and/or

☐ Qualitative improvement in sleep quality where the patient wakes up feeling rested and refreshed

and/or

☐ Qualitative positive impact on the quality of life of the patient and/or positive impact on family life as described by carers

……..(insert name)…….parents/carers have been instructed to withdraw use of melatonin for a period of time known as a 'drug-holiday' at least once a year in order to assess the need for on-going treatment.

Today I have supplied them with 4 weeks of melatonin.

Further information on the use of melatonin for patients with a learning disability can be found in the Herts & West Essex Integrated Care Board (HWE ICB) prescribing support document (available on the HWE ICB website). Please feel free to contact me should you wish to discuss any of the afore-mentioned issues further.

With best regards.

Yours sincerely

Specialist sign off here

Date of next review _____