GUIDELINES FOR THE USE OF OLANZAPINE LONG-ACTING INJECTION (ZYPADHERA®)

Indications

Olanzapine Long-acting Injection (OLAI) is licensed for the maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine. OLAI is restricted for use in a subpopulation of patients more appropriately managed with a long acting injection formulation because of difficulties adhering to an oral olanzapine regimen, indicated by recurrent relapse or exacerbation of symptoms.

Prescribing

All patients must have a previously responded to and tolerated treatment with oral olanzapine before initiating OLAI.

Patients must be advised of the risk of post-injection syndrome and the need for them to be observed on healthcare premises for three hours after each injection. If it is felt that the patient is unwilling to accept this ongoing requirement then OLAI should not be initiated. Useful patient information can be obtained here.

Recommended dose schedule:

Target oral olanzapine dose	Recommended starting dose of ZYPADHERA	Maintenance dose after 2 months of ZYPADHERA treatment
10 mg/day	210 mg/2 weeks or 405 mg/4 weeks	150 mg/2 weeks or 300 mg/4 weeks
15 mg/day	300 mg/2 weeks	210 mg/2 weeks or 405 mg/4 weeks
20 mg/day	300 mg/2 weeks	300 mg/2 weeks

The maximum licensed dose is 300mg 2-weekly or 405mg 4-weekly.

Supplementation with oral olanzapine was not used in double-blind clinical studies. If oral olanzapine supplementation is clinically indicated, then the combined total dose of olanzapine from both formulations should not exceed the corresponding maximum oral olanzapine dose of 20 mg/day.

OLAI has not been systematically studied in elderly patients (> 65 years). OLAI is not recommended for treatment in the elderly population unless a well-tolerated and effective dose regimen using oral olanzapine has been established. A lower starting dose (150 mg/4 weeks) is not routinely indicated, but should be considered for those 65 and over when clinical factors warrant. OLAI **is not** recommended to be started in patients >75 years.

OLAI is not licensed for use in those less than 18 years old.

Post-injection Monitoring

OLAI may only be administered in healthcare premises where three hours of observation of the patient by nurses or doctors, able to identify post-injection syndrome can be assured. For this three hour period the patient should be located where they can be seen and or heard by healthcare staff. The monitoring sheet (Appendix 1) should be completed following each injection and placed in the patients notes upon completion.

Nurses administering OLAI should access the information is available from the drug company before giving it for the first time. https://www.zypadhera.co.uk. This includes information on injection site, needle size, reconstitution of the product and detail on post-injection syndrome.

Rapid access to medical or paramedical care (including dialling 999 if a doctor is not on the premises) must be available throughout the three hour observation period.

During the time following administration and prior to the patient leaving the healthcare facility, it must be confirmed that the patient is alert, orientated and absent of any signs and symptoms of olanzapine overdose. If overdose is suspected, close medical supervision and monitoring must continue until examination indicates that signs and symptoms have resolved. Alternatively, if a doctor is not available, an ambulance must be called.

Signs of post-injection syndrome can usually include sedation (from mild to severe, including coma) and delirium, as well as (less commonly) extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension and convulsions. In trials the syndrome occurred in most cases within one hour of injection and rarely up to three hours after. Very rarely it appeared more than three hours after injections. Patients should be advised to alert for the development of the syndrome for the remainder of the day and advised not to drive or use machinery until the next day.

In clinical trials post injection syndrome events occurred in 0.07% of injections (approximately 2% of patients experienced the syndrome).

Administration

Administration should only be undertaken by staff trained in the appropriate injection technique.

OLAI is for deep intramuscular gluteal injection only. Extreme care must be taken to avoid intravenous or subcutaneous injection. Differing needle sizes are available for use and selection depends on the patients' weight to ensure a correct depth of administration can be achieved.

Monitoring Usage

The Mental Health Medicines Management Group requires that a formal intention to prescribe request is made to the chair of the Mental Health & Learning Disabilities Drug & Therapeutics Group, using the 'Atypical LAI **REQUEST FORM**'.

Spending on Olanzapine LAI in ABUHB will be monitored as part of ensuring that the guidelines are being followed.

Appendix 1 – Post Injection Monitoring form

Observations for post injection syndrome – to be carried out for at least THREE HOURS after every olanzapine depot injection.

Patient name …….. NHS number……

Date of birth …….. Ward ……

Post injection syndrome:

- Usually occurs within three hours of olanzapine depot.
- The risk of post injection syndrome does NOT decrease. It remains the same at **EVERY** injection.
- Needs urgent medical attention.
- Symptoms are: sedation and delirium (disorientation, confusion, agitation, anxiety and other cognitive impairment).
- Symptoms also include: extrapyramidal symptoms, dysarthria (slurred speech), ataxia (staggering, uneven gait), aggression, dizziness, weakness, hypertension and convulsion.
- **The three hour observation period should be extended as clinically appropriate for patients who exhibit any signs or symptoms consistent with olanzapine overdose.**

Date/time of injection:	**Allocated staff member:**	
Time	**Observations – Patient alert and mobilising? Any evidence of sedation or delirium?**	**Staff name/signature**
___:___ (15 mins post injection)		
___:___ (30 mins post injection)		
___:___ (1 hr post injection)		
___:___ (1hr 15 mins post injection)		
___:___ (1hr 30 mins post injection)		
___:___ (1hr 45 mins post injection)		
___:___ (2hrs post injection)		
___:___ (2hr 15 mins post injection)		
___:___ (2hr 30 mins post injection)		
___:___ (2hr 45 mins post injection)		
___:___ (3 hr post injection)		