# CLINICAL GUIDELINE
# Olanzapine Pamoate Long-Acting Injection (ZypAdhera®)

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| Guideline Number | CLG116 |
| Version: | V1 |
| Purpose: | To support prescribers in making decisions about olanzapine pamoate long-acting injection (LAI), either for patients being transferred into the care of GHC who are already prescribed this treatment or starting it as a new treatment. |
| Consultation: | Drug and Therapeutics Committee |
| Approved by: | Clinical Policy Group / Drug and Therapeutics Committee |
| Date approved: | 16/01/2024 |
| Author: | [redacted] Lead Pharmacist, Community Mental Health Services |
| Date issued: | 30/01/2024 |
| Review date: | 01/01/2027 |
| Audience: | All GHC mental health prescribers |
| Dissemination: | Available on Intranet |
| Impact Assessments: | This guideline has been subjected to an Equality Impact Assessment. This concluded that this guideline will not create any adverse effect or discrimination on any individual or particular group and will not negatively impact upon the quality of services provided by the Trust |

**Version History**

| Version | Date Issued | Reason for Change |
|---|---|---|
| V1 | 30/01/2024 | New Guideline |

**SUMMARY**

Olanzapine pamoate long-acting injection (LAI) (ZypAdhera®) is an antipsychotic medication licensed for maintenance treatment of adults with schizophrenia who have been stabilised with oral olanzapine.

Post injection syndrome following administration of olanzapine pamoate LAI, although not common is not predictable therefore this guidance is to support prescribers in making decisions about olanzapine pamoate LAI, either for patients being transferred into the care of GHC who are already prescribed this treatment or starting it as a new treatment.

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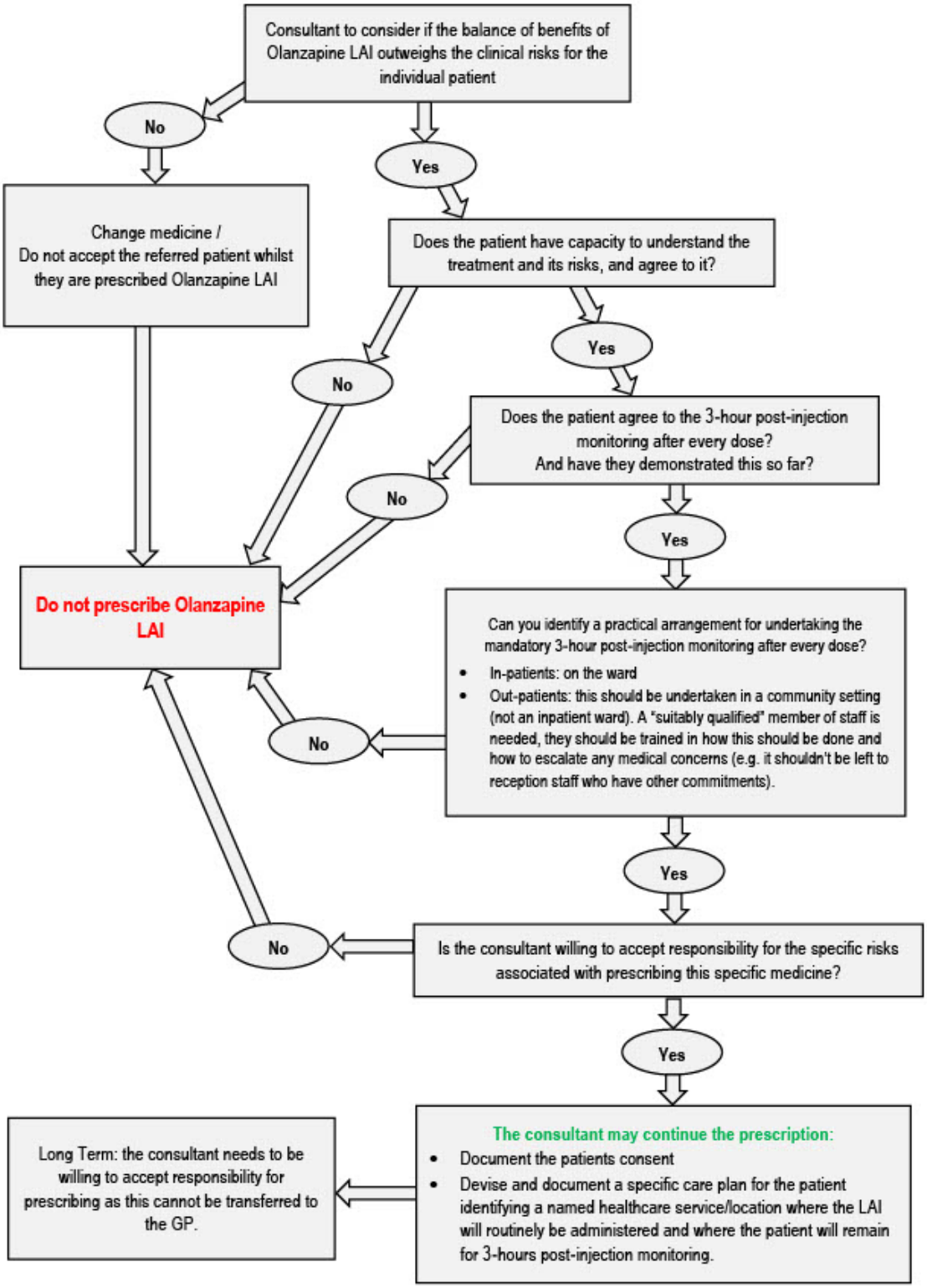
## ABBREVIATIONS

| *Abbreviation* | *Full Description* |
|---|---|
| GHC | Gloucestershire Health and Care NHS Foundation Trust |
| IM | Intramuscular |
| LAI | Long-Acting Injection |

## ACTION CARD 1
## Summary Flowchart for Management of Olanzapine LAI



**Action Card 2 - Olanzapine LAI Check List:**

**Olanzapine LAI should only be prescribed if all of the following are agreed:**

| | | Tick |
|---|---|---|
| **1.** | The consultant is familiar with the risks and benefits of this specific formulation of olanzapine and considers that on balance the overall benefit of this medicine outweighs the clinical risks for this individual patient. | |
| **2.** | The care team and those involved in the post-injection monitoring all understand the risks involved with administration of each injection, and know the clinical risks involved and how to respond to an olanzapine overdose. | |
| **3.** | The patient agrees to stay for the 3-hour post-injection monitoring after every dose, and this agreement is demonstrated in their behaviour. (If the patient doesn't engage with this treatment plan, or agree to stay, then it is not safe to administer the LAI and prescribing is not recommended.) | |
| **4.** | The patient agrees not to drive on the same day as the injection. | |
| **5.** | The nursing staff administering the LAI have completed the product specific training and are suitably skilled to administer it: ZypAdhera Training System<br>These staff must understand what to observe for and know how to escalate any medical concerns. | |
| **6.** | A suitable location and healthcare facility is identified in which to undertake the mandatory 3-hour post-injection monitoring after every dose. | |
| **7.** | Suitably qualified healthcare staff are identified to undertake the mandatory 3-hour post-injection clinical monitoring after every dose. | |
| **8.** | A specific care plan is devised for the patient identifying a named healthcare service/location in which the LAI will routinely be administered and where the patient will remain for 3 hours after the injection. This is agreed by all participants. | |
| **9.** | The consultant is willing to prescribe long term as olanzapine LAI is not in the Gloucestershire formulary so cannot be transferred to primary care. Prescriptions and administration will remain the responsibility of secondary care services indefinitely. | |
| **10.** | The care team understand and agree to deliver this safety care package in the long term as olanzapine LAI is not in the Gloucestershire formulary so cannot be transferred to primary care. Administration will remain the responsibility of secondary care services indefinitely. | |

**If any of the above are not fulfilled, olanzapine LAI should not be prescribed.**

## 1. INTRODUCTION

**1.1** Olanzapine pamoate long-acting injection (LAI) (ZypAdhera®) is an antipsychotic medication licensed for maintenance treatment of adults with schizophrenia who have been stabilised with oral olanzapine[1].

**1.2** It is administered by deep intramuscular (IM) injection into the gluteal muscle.

**1.3** Olanzapine pamoate LAI is a non-formulary preparation in Gloucestershire due to safety concerns. It is not approved for initiation in the Trust as operational services are not in place to undertake the required 3-hour post-injection safety monitoring.

## 2. PURPOSE

**2.1** The purpose of this guidance is to assist prescribers in making decisions about prescribing olanzapine pamoate LAI, either for patients being transferred into GHC care prescribed this or starting it as a new treatment.

**2.2** There are patient safety concerns that need to be addressed for it to be used safely.

## 3. SCOPE

**3.1** All prescribers in mental health services.

## 4. DUTIES

**4.1 General Roles, Responsibilities and Accountability**

**Gloucestershire Health and Care NHS Foundation Trust (GHC)** aims to take all reasonable steps to ensure the safety and independence of its patients and service users to make their own decisions about their care and treatment.

In addition, **GHC** will ensure that:

- All employees have access to up-to-date evidence-based policy documents.
- Appropriate training and updates are provided.
- Access to appropriate equipment that complies with safety and maintenance requirements is provided.

**Managers and Heads of Service** will ensure that:

- All staff are aware of and have access to policy documents.
- All staff access training and development as appropriate to individual employee needs.
- All staff participate in the appraisal process, including the review of competencies.

**Employees (including bank, agency and locum staff)** must ensure that they:

- Practice within their level of competency and within the scope of their professional bodies where appropriate.
- Read and adhere to GHC policy
- Identify any areas for skill update or training required.
- Participate in the appraisal process.
- Ensure that all care and consent complies with the Mental Capacity Act (2005) – see

section on MCA Compliance below.

## 5. MENTAL CAPACITY ACT COMPLIANCE

**5.1** Where parts of this document relate to decisions about providing any form of care treatment or accommodation, staff using the document must do the following: -

- Establish if the person able to consent to the care, treatment or accommodation that is proposed? (Consider the 5 principles of the Mental Capacity Act 2005 as outlined in section 1 of the Act. In particular principles 1, 2 and 3) Mental Capacity Act 2005 (legislation.gov.uk).
- Where there are concerns that the person may not have mental capacity to make a specific decision, complete and record a formal mental capacity assessment.
- Where it has been evidenced that a person lacks the mental capacity to make a specific decision, complete and record a formal best interest decision making process using the best interest checklist as outlined in section 4 of the Mental Capacity Act 2005 Mental Capacity Act 2005 (legislation.gov.uk).
- Establish if there is an attorney under a relevant and registered Lasting Power of Attorney or a deputy appointed by the Court of Protection to make specific decisions on behalf of the person (N.B. they will be the decision maker where a relevant best interest decision is required. The validity of an LPA or a court order can be checked with the Office of the Public Guardian) Office of the Public Guardian - GOV.UK (www.gov.uk).
- N.B. in emergency situations staff may need to act immediately in the best interests of the person. If actions need to be taken when there is not time to undertake a formal capacity assessment, then the reasons for the actions taken should be recorded in the patient notes after the incident.

## 6. GUIDANCE

### 6.1 Safety Concerns - "Post-Injection Syndrome"

- In trials "Post-injection syndrome" occurred in 0.07% of injections ("rare"), and in 1.4% of patients ("common") [2]. Symptoms are those of an olanzapine overdose, ranging from mild (e.g. sedation) to serious (e.g. unconscious or comatosed). Other symptoms include those of delirium (e.g. confusion, disorientation, agitation, anxiety, and cognitive impairment), extrapyramidal symptoms (EPS), dysarthria, ataxia, aggression, dizziness, weakness, hypertension, and convulsions.
- Post-injection syndrome is not predictable, it was not related to the dose or frequency of injection, or administration technique, it is not patient specific.
- In most cases initial signs and symptoms appeared within an hour of injection.
- There is no antidote for olanzapine overdose.
- Due to these risks, Olanzapine LAI should only be administered by healthcare professionals trained in the injection technique, in locations where post-injection observation and access to appropriate medical care in the case of overdose can be assured[1].

### 6.2 Safe Use

- The license[1] specifies that after each injection, patients should be observed in a healthcare facility by appropriately qualified staff for at least 3-hours watching for signs and symptoms consistent with olanzapine overdose. After this time patients should not

drive home, or for the rest of the day.

- A specific care plan should be devised for the patient identifying a named healthcare service/location in which the LAI will routinely be administered and where the patient will remain for 3 hours after the injection. This is agreed by all participants.

### 6.3 Transfer of Patients into GHC who are already Prescribed Olanzapine LAI

- If any patient is transferred into GHC already prescribed a non-formulary medicine and the prescriber considers this to be the most appropriate clinical plan for the patient, they are able to continue it following the non-formulary process. The Chair of the Trust Drug and Therapeutic Group should be contacted to agree the process.
- For any patient being transferred into GHC already prescribed olanzapine LAI, prescribers need to plan how to manage the safe administration and immediate safety monitoring prior to continuing olanzapine LAI.

## 7. PROCESS FOR MONITORING COMPLIANCE

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| Are the systems or processes in this document monitored in line with national, regional, trust or local requirements? | NO |

## 8. INCIDENT AND NEAR MISS REPORTING AND REGULATION 20 DUTY OF CANDOUR REQUIREMENTS

**8.1** To support monitoring and learning from harm, staff should utilise the Trust's Incident Reporting System, DATIX. For further guidance, staff and managers should reference the Incident Reporting Policy. For moderate and severe harm, or deaths, related to patient safety incidents, Regulation 20 Duty of Candour must be considered and guidance for staff can be found in the Duty of Candour Policy and Intranet resources. Professional Duty of Candour and the overarching principle of 'being open' should apply to all incidents.

## 9. TRAINING

**9.1** Every nurse administering the LAI must complete the product specific training: ZypAdhera Training System, and is suitably skilled to administer it; they must understand what to observe for, and know how to escalate any medical concerns.

**9.2** Healthcare staff undertaking the mandatory 3-hour post-injection monitoring understand what to observe for and know how to escalate any medical concerns.

## 10. ASSOCIATED DOCUMENTS

**10.1** GHC Policy For Managing Medication (Storing, Prescribing, Administration, Disposal).

## 11. REFERENCES

*Summary of Product Characteristics. ZYPADHERA® 210 mg, 300 mg, and 405 mg, powder, and solvent for prolonged release suspension for injection. Eli Lilly and Company Limited. Last updated Last updated on emc: 30 Jan 2023. ZYPADHERA 210 mg, 300 mg, and 405 mg, powder and solvent for prolonged release suspension for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)*

*European Medicines Agency. Pre-authorisation evaluation for medicines for human use. Assessment report for ZypAdhera®. EMEA/608654/2008.*