Specialised Medication – Olanzapine Pamoate - Zyprexa Relprevv® Guideline

1. Purpose

The purpose of this document is to provide guidance to staff for the prescription, administration, and monitoring of olanzapine pamoate long-acting injection in adult consumers.

This document should be read in conjunction with appropriate references, including:

- WACHS High Risk Medications Procedure
- Australian Medicines Handbook
- Therapeutic Guidelines
- Statewide Medication Formulary
- MIMS Product Information
- Australian Injectable Drugs Handbook

ATTENTION

The potential signs and symptoms of sedation and/or delirium consistent with olanzapine overdose exists after every injection of olanzapine pamoate. Olanzapine pamoate should be administered by appropriately qualified health professionals and patient monitored for at least two hours after each injection. Refer to Section 2.5 Post Injection Syndrome

2. Guideline

2.1 Presentation

Olanzapine pamoate (Zyprexa® Relprevv®) is a long acting, injectable form of olanzapine used for the maintenance treatment of schizophrenia. It is not to be confused with the short acting olanzapine injection (Zyprexa® IM) which is used for acute agitation and arousal.

Olanzapine pamoate comes in the following strengths:

- Olanzapine pamoate monohydrate 210 mg long-acting injection
- Olanzapine pamoate monohydrate 300 mg long-acting injection
- Olanzapine pamoate monohydrate 405 mg long-acting injection

2.2 Indication for Use

Olanzapine pamoate is used for maintenance treatment of schizophrenia in adult consumers sufficiently stabilised during acute treatment with oral olanzapine.

2.3 Prescribing

Olanzapine pamoate must be prescribed in accordance with the manufacturer's product information and PBS requirements PBS Online. Prescribing outside of these limits

constitutes off label prescribing and must go through the appropriate WACHS region-specific approval process.

Prescriptions for olanzapine pamoate must be documented on MR170.9 WA Intramuscular Long-Acting Injection Chart (Depot Antipsychotic).

Consumers must demonstrate tolerability and response to oral olanzapine before switching to olanzapine pamoate.

The consumer must receive verbal and written information on olanzapine pamoate, the risk of post injection syndrome, post injection monitoring requirements and any actions that may be taken if post injection syndrome (PIS) occurs including potential transfer to emergency services. Choice and Medication is a recommended written resource.

Following the provision of meaningful information about olanzapine pamoate, including the benefits, monitoring requirements, material risks and alternative options available, informed consent (written or verbal should be sought through a process of communication, discussion, and shared decision making. Consent must be documented in the consumer's health record.

Olanzapine pamoate must not be prescribed unless the consumer agrees to adhere with the observation requirements and to not drive or operate machinery for the rest of the day after administration of the injection.

Consideration must be given to the ability of community based mental health clinics (or other primary care facilities) to be able to accommodate and perform the required monitoring after each administration and be able to transfer the consumer to emergency services in the event of PIS. Olanzapine pamoate must not be commenced if clinics are unable to accommodate these requirements.

2.4 Administration

Administration may only take place in a healthcare facility such as an inpatient setting or community mental health clinic.

Prior to administration, the consumer's informed consent to receiving the injection and adhering to the monitoring requirements must be confirmed. Document the consent in the consumer's health record.

Ensure the consumer has transport arranged from the clinic and agrees not to drive or operate heavy machinery for the remainder of the day.

Reconstitution must be performed as per the manufacturer's product information. The reconstituted product must not be stored for more than 6 hours at room temperature.

Olanzapine pamoate must be administered by deep intramuscular injection in the ventrogluteal sites. Gluteal administration is thought to reduce the risk of PIS. Administration of olanzapine pamoate must be documented on the MR170.9 WA Intramuscular Long-Acting Injection Chart (Depot Antipsychotic), the consumer's health record, and recorded in PSOLIS.

2.5 Post Injection Syndrome

Administration of olanzapine pamoate long-acting injection is associated with a PIS. PIS is an unpredictable reaction resulting from the inadvertent intravascular administration of a portion of the injected olanzapine pamoate dose.

Symptoms of PIS present like an olanzapine overdose. Symptoms include excessive sedation, confusion, slurred speech, weakness, malaise, disorientation, and extrapyramidal side effects.

Development of PIS is relatively rare. During premarketing clinical trials PIS occurred in approximately 0.07% of all injections and in 1.85% of patients. The risk of PIS is present with each injection.

PIS typically appears within the first 1 - 2 hours after administration and is rarely reported after 3 hours. If experienced, symptoms resolve within 24 – 72 hours.

Consumers must be monitored for 2 hours after the administration of olanzapine pamoate long-acting injection in both inpatient and outpatient settings. Refer to Section 2.6 Monitoring Period.

2.6 Monitoring Period

Throughout the monitoring period engagement with the consumer is essential to support accurate and safe monitoring and to provide an opportunity for therapeutic interaction.

The MR170.9.1 WACHS Olanzapine Pamoate Post Injection Checklist is to be used to record post injection monitoring.

The consumer must be monitored for the signs of PIS after each injection of olanzapine pamoate every 30 minutes for a total of 2 hours. Monitoring is conducted by observing the consumer and asking how they feel. The response is to be recorded on the MR170.9.1 WACHS Olanzapine Pamoate Post Injection Checklist.

Post injection monitoring should be conducted by the administering nurse but may be delegated to a staff member trained in recognising the symptoms of PIS and able to escalate care to nursing and medical staff if signs and symptoms of PIS become evident.

Physiological observation and response monitoring is not routinely unless signs and symptoms of PIS become evident.

In the event of PIS symptoms occurring:

- notify the administering nurse to commence physiological observation and response monitoring every 15 minutes. Document on the MR 140A WACHS Adult Observation and Response Chart (A-ORC)
- notify medical officer for medical review
- follow the Recognising and Responding to Acute Deterioration (RRAD) Procedure.
- where the consumer continues to show signs of deterioration follow medical emergency response as per the specific site:
  - inpatients activate a Medical Emergency Response (MER)
  - Community Clinic call 000 for an ambulance
- following PIS, a medication review should be undertaken at the next point of contact.

2.7 Consumers who wish to leave prior to the end of the monitoring period

The following process is to be followed in the event a consumer wishes to leave prior to completing the monitoring period:

- Explain the reasons for and the risks of leaving prior to the end of the monitoring period. Consider therapeutic interactions to engage consumers throughout the monitoring period.
- Escalate to medical officer/care coordinator/senior clinician for review.
- In the event of non-adherence to monitoring requirements, complete time of leaving and request consumer to sign on MR170.9.1 WACHS Olanzapine Pamoate Post Injection Checklist. Document event in consumer health record and PSOLIS
- Consumers who leave prior to the completion of the monitoring period who have not been reviewed are to be followed up via phone. If the consumer is not contactable, the next of kin is to be contacted.
- The treating consultant psychiatrist will review suitability of continuing olanzapine long-acting injection therapy. Where a consumer is unwilling or unable to comply with the monitoring period olanzapine pamoate is not to be prescribed.

2.8 Follow up requirements

Prior to the end of the service interaction, the monitoring clinician should undertake a final check for signs or symptoms of PIS and confirm that the consumer is not travelling alone, driving or operating machinery for the remainder of the day.

Consumers must be provided with information of when their next injection is due and how to access services (including after hours and crisis support) if further support is required prior to the next planned appointment, including if signs and symptoms of PIS occur.

3. Roles and Responsibilities

The **Medical Officer** is responsible for:

- completing orders for medication on the appropriate medication chart or PBS prescriptions for outpatient consumers
- documenting a comprehensive monitoring plan
- reviewing recorded observations and monitoring parameters regularly and adjusting treatment where required
- documenting the reason for therapy changes
- conducting comprehensive consumer education regarding olanzapine pamoate
- communicating a comprehensive handover at transitions of care. It is the responsibility of the Health Service Team (inpatient or community) to ensure routine monitoring is completed until care has been formally handed over to the receiving service.

The **Nursing staff member/s** is responsible for:

- ensuring they are appropriately skilled, competent and confident to perform the administration and monitoring requirements
- monitoring the consumer for symptoms of adverse reactions, including PIS, and escalating for review
- conducting consumer education regarding olanzapine pamoate
- liaising with the consumer carer/case worker/GP to arrange required follow up appointments to ensure continuity of care.

- Ensuring staff member attending to PIS monitoring is adequately trained in recognising signs and symptoms of PIS, recording monitoring, and aware of escalation pathways before delegating PIS monitoring activity.

The **staff member/s attending to PIS monitoring** is responsible for:
- performing the monitoring requirements and escalating care where indicated.

The **Pharmacist (where available)** is responsible for:
- endorsing the medication order as suitable to administer
- escalating any issues with regards to prescription or administration
- providing clinical information regarding prescribing, administration, and monitoring of olanzapine pamoate
- ensuring supply arrangements.

All staff are required to comply with the directions in WACHS policies and procedures as per their roles and responsibilities. Guidelines are the recommended course of action for WACHS and staff are expected to use this information to guide practice. If staff are unsure which policies procedures and guidelines apply to their role or scope of practice, and/or are unsure of the application of directions they should consult their manager in the first instance.

4. Monitoring and Evaluation

Managers of clinical areas, health sites and services are responsible for monitoring compliance with this guideline.

Clinical incidents involving issues relating to olanzapine pamoate are monitored via the DATIX Clinical Incident Management reporting processes. SAC 1 events are reviewed by Regional Medicines and Therapeutics Committees and the WACHS Safety and Quality Steering Committee.

Any incident that meets the criteria for a notifiable incident as defined by the *Mental Health Act 2014* (WA), must be reported to the Chief Psychiatrist in accordance with the Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist.

This guideline is to be reviewed every two (2) years. Evaluation of this guideline is to be carried out by WACHS Mental Health directorate in consultation with WACHS Pharmacy Service and regional WACHS Health Services.

Policy evaluation methods and tools may include:
- staff feedback / consultation
- carer and consumer feedback / consultation
- survey
- compliance monitoring
- benchmarking
- reporting against organisational targets.

5. References

1. Australian Medicines Handbook Pty Ltd. (2023) online (Olanzapine). [Accessed 10/2023] Available from: amh.net.au)

2. Zyprexa Relprevv® (Approved Product Information) [Accessed from MIMS Australia internet database] [Accessed 10/2023]
3. Taylor D., Barnes T.R.E and Young A.H (2021) The Maudsley Prescribing Guidelines in Psychiatry. 14th Edition. John Wiley & Sons
4. Olanzapine [monograph]. Australian Injectable Drugs Handbook 9th ed. Collingwood, Victoria, Australia: The Society of Hospital Pharmacists Australia; 2023
5. Bazire S et al Choice and Medication [Internet]. Mistura Enterprise Ltd. [Accessed 10/2023]

6. Definitions

Term	Definition
Long-Acting Injection	Long-Acting Injection (LAI) is a pharmacological agent with a prolonged effect because of a formulation resulting in the slow release of the active principle or the continued absorption of small amounts of the dosage of the drug over an extended period.
Post Injection Syndrome	Signs and symptoms following injection of olanzapine Zyprexa (Relprevv®) consistent with Post Injection Syndrome (PIS) include: • sedation • confusion/disorientation • impairment of speech (Dysarthria) and motor (Ataxia) • dizziness • agitation/anxiety/aggression • extrapyramidal symptoms (EPSE)
Informed Consent	Informed consent is a person's decision (in writing or verbally), given voluntarily, to agree to a healthcare treatment, procedure or other intervention that is made: • following the provision of accurate and relevant information about the healthcare intervention and alternative options available; and • with adequate knowledge and understanding of the benefits and material risks of the proposed intervention relevant to the person who would be having the treatment, procedure or other intervention.
Therapeutic interaction	The purposeful engagement and gathering of information from consumers receiving care to inform interventions and clinical decision making.

7. Document Summary

Coverage	WACHS wide
Audience	All clinical staff involved in prescribing, administration or monitoring of olanzapine pamoate
Records Management	Clinical: Health Record Management Policy
Related Legislation	• *Medicines and Poisons Act 2014* (WA) • *Mental Health Act 2014* (WA)
Related Mandatory Policies / Frameworks	• MP 0122/19 Clinical Incident Management Policy 2019 • MP 0175/22 Consent to Treatment Policy • MP 0131/20 High Risk Medication Policy • MP 0078/18 Medication Chart Policy • MP 139/20 Medicines Handling Policy • MP 0104/19 Medication Review Policy • MP 0077/18 Statewide Medicines Formulary Policy • MP 0171/22 Recognising and Responding to Acute Deterioration Policy • Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist • Clinical Governance, Safety and Quality Framework • Mental Health Framework
Related WACHS Policy Documents	• Adults with Impaired Decision Making Capacity Procedure • Clinical Documentation Policy • Clinical Observation and Assessments Clinical Practice Standard – physiological. neurovascular, neurological, fluid balance • High Risk Medications Procedure • Medication Prescribing and Administration Policy • Recognising and Responding to Acute Deterioration (RRAD) Policy • Recognising and Responding to Acute Deterioration Procedure
Other Related Documents	• DoH Guidelines for Managing Specific High Risk Medications Relevant to the Organisation
Related Forms	• MR170.9 WA Intramuscular Long-Acting Injection Chart (Depot Antipsychotic) • MR170.9.1 WACHS Olanzapine Pamoate Post Injection Checklist • MR140A Adult Observation and Response Chart (A-ORC)
Related Training Packages	Available from MyLearning: • High Risk Medications: Introduction (HRMINT EL2)
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 3213

National Safety and Quality Health Service (NSQHS) Standards	4.01, 4.03, 4.04, 4.11, 4.13, 4.15, 8.04, 8.05, 8.06, 8.08, 8.09, 8.10, 8.13.
Aged Care Quality Standards	Nil
Chief Psychiatrist's Standards for Clinical Care	• Assessment • Physical Health Care of Mental Health Consumers • Risk Assessment and Management
Other Standards (please specify and include link)	Nil

8. Document Control

Version	Published date	Current from	Summary of changes
1.00	30 January 2025	30 January 2025	New guideline

9. Approval

Policy Owner	Executive Director Mental Health
Co-approver	Executive Director Clinical Excellence Executive Director Nursing and Midwifery Services
Contact	Director of Psychiatry Clinical Governance
Business Unit	WACHS Mental Health
EDRMS #	ED-CO-24-116517

This document can be made available in alternative formats on request.