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AUTHOR	SESLHD HYDROmorphone working party	
POSITION RESPONSIBLE FOR THE DOCUMENT	Quality Use of Medicines, Lead Pharmacist SESLHD-DrugCommittee@health.nsw.gov.au	
FUNCTIONAL GROUP(S)	Medicine Pharmacy/Pharmaceutical	
KEY TERMS	HYDROmorphone	
SUMMARY	The aim of this procedure is to ensure the safe prescribing, storage and administration of the different formulations and strengths of HYDROmorphone across all SESLHD acute care facilities.	



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

1. POLICY STATEMENT

HYDROmorphone is a potent opioid analgesic used to treat moderate to severe acute or chronic pain. **HYDROmorphone is 5 to 7 times more potent than morphine**. Due to its high potency, incorrect or inappropriate dosing carries a very high risk of adverse patient outcomes. Deaths due to errors in HYDROmorphone prescribing and administration have occurred internationally and in Australia, including within South Eastern Sydney Local Health District (SESLHD) facilities.

NSW Ministry of Health Policy Directive PD2024 006 – High-Risk Medicines Management has been revised with updated with information that is relevant to NSW Health clinicians. The HYDROmorphone standards within PD2020_045 have been updated and is available on the CEC High-Risk Medicines HYDROmorphone webpage.

2. BACKGROUND

Incidents involving HYDROmorphone occur for several reasons, including:

- Inadvertent administration of HYDROmorphone instead of morphine
- Dose calculation errors with injectable HYDROmorphone
- Lack of awareness of the differences between oral and parenteral dosing schedules
- Inappropriate dosing when converting to HYDROmorphone from other opioids
- Confusion between the various strengths and formulations of HYDROmorphone (see table below).

The following HYDROmorphone products are available in SESLHD:

Originator Brand name	Examples of alternative brands	Form	Strengths available in SESLHD facilities	Formulary Restriction	
Dilaudid®	JUNO [®] , Medsurge [®]	Injection	2 mg/1 mL		
Dilaudid – HP®	JUNO-HP®, Medsurge-HP®	Injection	10 mg/1 mL	On the advice of an authorised specialist as defined by	
Dilaudid [®]		Immediate release Tablet	2 mg 4 mg 8 mg	SESLHDPR/669 Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities	
Varies (19A product)		Immediate release Oral Solution	1 mg/1 mL	Additional Restriction for HYDROmorphone oral solution: [R] doses less than 2mg or where HYDROmorphone IR tablets are unsuitable.	

Note: All strengths of Jurnista® (HYDROmorphone hydrochloride) modified release tablets were discontinued on 30 April 2023. Currently there are no other brands of modified release HYDROmorphone tablets listed on the Australian Register of Therapeutic Goods (ARTG). Immediate release tablet and injectable formulations continue to be available.

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 1 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

Patient safety must be the core priority of all staff involved in the management of HYDROmorphone. The aim of this procedure is to ensure the safe prescribing, storage and administration of the different formulations and strengths of HYDROmorphone.

3. **DEFINITIONS**

Authorised specialist:

A person authorised to recommend the initiation of HYDROmorphone, being either:

- a. A Senior Medical Officer in Palliative Care, Renal Medicine, Pain Medicine, Medical Oncology, Anaesthetics, Intensive Care Medicine, Emergency Medicine or Geriatric Medicine [or at Sutherland Hospital ONLY: Respiratory Medicine], or
- b. A Medical Registrar, Advanced Trainee or Nurse Practitioner working in the following specialties: Palliative Care, Kidney Supportive Care, Cancer Care, Anaesthetics or Pain Management.

Authorised prescriber:

A person authorised to write a HYDROmorphone order or prescription. This may be a Registrar, Career Medical Officer, Advanced Trainee or Senior Medical Officer from any discipline, or a nurse practitioner specialising in Palliative Care, Kidney Supportive Care, Cancer Care, Anaesthetics or Pain Management.

Opioid naïve:

Patients who are either not currently taking/receiving opioids OR those who are taking/receiving opioids in whom tolerance has not yet developed (e.g. recently commenced or infrequent use only).

Opioid tolerant:

Patients with a reduced response to, OR reduced sensitivity to the effects of, opioids due to consistent recent exposure to opioids

Fixed Interval Variable Dose (FIVD):

Medication orders with a variable dosage range (for example, 5 to 10 mg) over a fixed interval for administration (for example every 6 hours)

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 2 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

4. RESPONSIBILITIES

4.1 All Medical Officers and authorised Nurse Practitioners will:

- Understand and implement the principles of safe use of HYDROmorphone. This includes understanding and adhering to the prescribing requirements, dosing, contraindications, precautions and monitoring as set out in this procedure
- Consider patient specific factors such as age, renal function, hepatic function, other medications (including current and past opioid use) and comorbidities when prescribing HYDROmorphone
- Include patients and their carers in the decision to prescribe HYDROmorphone and provide written and verbal information on treatment as appropriate
- Review the patient regularly for efficacy of treatment and/or adverse effects
- Include an overview/update about HYDROmorphone treatment at transfers of care, for example Emergency Department (ED) to ward, ward to ICU
- Escalate any adverse events occurring to patients receiving HYDROmorphone.

4.2 Registered Nurses (RN) / Registered Midwives (RM) will:

- Include an overview/update about HYDROmorphone treatment during clinical handover (high risk medicine alert)
- Understand and implement the principles of safe use of HYDROmorphone as set out in this
 procedure, including confirming that the prescribing requirements have been met before
 administering HYDROmorphone (see section 5.5)
- Ensure patients receiving HYDROmorphone are monitored for efficacy of treatments and/or adverse effects (see section 5.6)
- Escalate any adverse events occurring to patients receiving HYDROmorphone (<u>see section</u> <u>5.7</u>)
- Monitor stocks of HYDROmorphone products on the ward and notify pharmacy for removal or destruction of unused products as required.

4.3 Enrolled Nurses (ENs) will:

- Include an overview/update about HYDROmorphone treatment during clinical handover (high risk medicine alert)
- Understand and implement the principles of safe use of HYDROmorphone as set out in this procedure
- ENs without a notation who have completed the board approved additional units of study for administration of medicines can provide a second person check and witness the administration of HYDROmorphone
- Ensure patients receiving HYDROmorphone are monitored for efficacy of treatment and adverse effects (see section 5.6)
- Practice in accordance with SESLHDPD/160 Medication: Administration by Enrolled Nurses.

4.4 Pharmacists will:

- Understand and implement the principles of safe use HYDROmorphone as set out in this
 procedure
- Review newly commenced, amended existing or recharted HYDROmorphone orders where appropriate
- Provide advice on appropriate use of HYDROmorphone to the clinical team as required
- Assist with appropriate patient/carer education regarding HYDROmorphone

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 3 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

- Report any adverse events occurring to patients receiving HYDROmorphone
- Perform regular reviews of ward Schedule 8 (S8) drug storage units to ensure that unused products are not stocked and promptly remove unwanted HYDROmorphone products upon request.

4.5 Nursing/Midwifery Unit Managers will:

- Ensure HYDROmorphone is stored in their ward/area in accordance with the requirements of this procedure (section 5.8)
- Implement processes to ensure S8 drug storage units are checked on a weekly basis for HYDROmorphone products that are no longer required
- Support nursing/midwifery staff to escalate concerns with the safe management of HYDROmorphone as required.

4.6 SESLHD Facilities will:

- Implement and monitor completion of mandatory education for medical, nursing and pharmacy staff in relation to the use of HYDROmorphone
- Audit and review clinical practice in relation to HYDROmorphone in their facility
- Review in detail any adverse clinical outcome of HYDROmorphone
- Ensure safe use of HYDROmorphone, in accordance with <u>NSW Ministry of Health Policy</u> <u>Directive PD2024 006 – High-Risk Medicines Management</u>.

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 4 of 17
COMPLIANCE WITH THIS DOCUMENT IS MANDATORY



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

5. PROCEDURE

5.1 Contraindications to HYDROmorphone use

HYDROmorphone is contraindicated in the following clinical scenarios:

- Patients with known hypersensitivity to HYDROmorphone
- Respiratory depression with hypoxia or hypercapnia where resuscitative equipment is not immediately available
- Status asthmaticus
- Paralytic ileus (see precautions)
- Concurrent or recent use of a Monoamine Oxidase Inhibitor (MAOI) e.g. phenelzine, tranylcypromine (within 14 days)
- Pregnancy (category C).

5.2 Precautions

HYDROmorphone is 5 to 7 times more potent than morphine. This means that the dose prescribed should be at least 5 times less than an equivalent dose of morphine. There is an increased risk of adverse events if incorrect or inappropriate doses are used.

Use of HYDROmorphone in opioid-naïve patients is hazardous. There are rare occasions where HYDROmorphone would be considered the most appropriate analgesic for an opioid-naïve patient. The low doses required for safe initiation of therapy cannot be administered with the available oral formulations of HYDROmorphone. Initiation of oral therapy should occur only in opioid-tolerant patients.

HYDROmorphone must only be used in patients for whom other opioid medicines are ineffective, inappropriate or not tolerated. Prior to use of HYDROmorphone, rule out all other analgesic options (e.g. non-opioid analgesia, other opioids or other modes of analgesia) and optimise use of adjuvant analgesia (multi-modal analgesia).

Clinical response to HYDROmorphone may vary considerably from patient to patient. HYDROmorphone should be dosed cautiously and titrated gradually according to response.

HYDROmorphone (and other opioids) should be used with caution in the following circumstances:

- Renal or hepatic impairment and the elderly (see table below).
- Impaired respiratory function, for example: restrictive/obstructive airways disease (e.g. asthma, COPD), risk of airway obstruction (e.g. sleep apnoea), other conditions associated with hypoxia/ hypercapnia (see table below)
- Patients with ileus or bowel obstruction (note: use of HYDROmorphone in palliative patients with malignant bowel obstruction is accepted practice).
- Patients requiring biliary tract procedures as opioid may cause spasm of the sphincter of Oddi
- Recent head injury, raised intracranial pressure, decreased level of consciousness or coma
- Uncorrected endocrine abnormalities; hypothyroidism or adrenocortical insufficiency, acute alcoholism, myasthenia gravis, central nervous system (CNS) depression
- Epilepsy or a recognised risk for seizure, e.g. head injury, metabolic disorders, alcohol and drug withdrawal, CNS infections
- Hypotension or shock

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 5 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

- Phaeochromocytoma
- Patients with previous history of hypersensitivity or adverse effects from other opioids

The following table shows factors known to increase sensitivity to the effects of HYDROmorphone. Note that the combination of multiple precautions, including those listed above (e.g. elderly patient with COPD and renal impairment), may significantly compound the associated risks.

Precautionary Factor	Issues and Risks
Age > 65 years old	Suitability of HYDROmorphone must be carefully considered. Very low (i.e. 25-50% of usual adult dose) initiation doses are recommended, with slow titration to effect.
Renal Impairment	Start with lower doses, titrate dose carefully and monitor closely for signs of respiratory depression. Accumulation of toxic metabolites may cause neurotoxicity, including features of encephalopathy and hallucinations. Consider alternatives such as fentanyl or oxycodone if available routes are appropriate.
Hepatic Impairment	Dose reductions are recommended for moderate hepatic impairment. HYDROmorphone use in patients with severe hepatic impairment has not been well-established and should be avoided.
Impaired Respiratory Function	Due to its potency there is an increased risk of respiratory depression with HYDROmorphone compared with other opioids. Use with caution, start with low doses and monitor closely.
Complete or Relative Opioid- Naivety	As a potent opioid with significant dose-response variability, use of HYDROmorphone in opioid-naïve patients carries a high degree of risk. There are few occasions where HYDROmorphone would be considered the most appropriate analgesic for an opioid-naïve patient. Mandatory maximum initiation doses for opioid naïve or relatively opioid naïve patients are provided in Section 5.4.2 .

In all of the above circumstances, **specific advice on dosing and monitoring** should be sought from the team or specialist who recommend use of HYDROmorphone (<u>see section 5.4.1</u>) and clearly documented before prescribing.

5.3 Drug Interactions

- Other CNS depressants, e.g. benzodiazepines, pregabalin, gabapentin: avoid if possible or use with caution ensuring each drug is at the lowest effective dose, and monitor closely.
- Monoamine Oxidase Inhibitors (MAOI) e.g. phenelzine, tranylcypromine: avoid with concurrent or recent use (within 14 days).

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 6 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

5.4 Prescribing

5.4.1 Restrictions on prescribing of HYDROmorphone

HYDROmorphone must only be used in patients for whom other opioid medicines are inappropriate or not tolerated. Consider alternative analgesic options such as other opioids or modes of analgesia prior to use of HYDROmorphone. Multi-modal analgesia may reduce opioid requirements.

Commencement of HYDROmorphone for a specific patient must only be on the advice of an Authorised Specialist.

After-hours, the relevant on-call <u>Authorised Specialist</u> should be consulted for advice. In the exceptional circumstance where expert advice cannot be obtained, one or more doses of <u>an alternative opioid</u> must be used until specialist review can occur.

All new HYDROmorphone orders must be written by an Authorised Prescriber.

Adjustments to existing orders may be made by a Junior Medical Officer (JMO) (below registrar level) on the recommendation of an <u>Authorised Prescriber</u>.

Transcription of existing orders onto discharge prescriptions or new medication charts may be made by a Junior Medical Officer (JMO) (below registrar level). All prescribers MUST adhere to the Documentation Requirements (see section 5.4.3).

HYDROmorphone must not be prescribed simultaneously with any other opioid except in the following instances:

- i. When prescribed for PRN use for breakthrough pain with another opioid prescribed regularly
- ii. When short acting HYDROmorphone is prescribed with a transdermal patch as part of a titration process or during initiation phase whilst awaiting steady state of the transdermal preparation.
- iii. Where a patient is receiving opioids as part of an opioid treatment program. Advice from the Drug & Alcohol service should be sought to develop an analgesic plan that is appropriate and safe.

5.4.2 Dosing

5.4.2.1 Initiating HYDROmorphone

In opioid naïve patients, those with risk factors for toxicity (see section 5.2) or those receiving other medications that can potentiate the effects of HYDROmorphone, dosing should be individualised, but appropriate suggested adult starting doses are as follows:

- **Subcutaneous route:** 0.25mg up to every 4 hours (to a maximum of 1.5mg in 24 hours)
- **Oral route:** Not suitable for initiation in opioid naïve patients or those with risk factors for toxicity:
- The smallest available immediate release tablet is 2mg (equivalent to approx. 10mg oral morphine). This is <u>inappropriate and unsafe</u> as an initiation dose.
- IV route For dosing in the post-operative Recovery Unit setting refer to <u>SESLHDPR501 - Acute Pain Management in the Post Anaesthetic Care Unit:</u> <u>Intravenous Opioid Pain Protocol for Adults Fentanyl, HYDROmorphone, Morphine and Oxycodone.</u>

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 7 of 17
COMPLIANCE WITH THIS DOCUMENT IS MANDATORY



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

• Via PCA – refer to local PCA guidelines

Fixed Interval Variable Dose (FIVD) regimens must not be used for HYDROmorphone. Once a patient's response to the initial doses of HYDROmorphone has been assessed, the dose may be carefully titrated according to analgesic need in consultation with the relevant specialist.

5.4.2.2 Converting to HYDROmorphone from another opioid

Opioid conversion may be required when:

- a) Patient is allergic to a certain opioid.
- b) Patient has become intolerant to their current opioid.
- c) Patient's pain remains poorly controlled despite titration of the current opioid dose.
- d) Patient is unable to continue to take the opioid in its current form, e.g., no longer able to swallow oral medications requiring conversion to the parenteral route most commonly subcutaneous infusion via a Syringe Driver

Use of the Opioid Calculator Application by the Australian and New Zealand College of Anaesthetists (ANZCA) Faculty of Pain Medicine is recommended to estimate the dose equivalency between the current opioid and HYDROmorphone. The ANZCA calculator is appropriate for use in both opioid-naïve and opioid-tolerant patients.

In Oncology and Palliative Care settings other opioid conversion tools may be used, for example the <u>eviQ opioid conversion calculator</u> or locally-approved opioid conversion guidelines.

When using an opioid conversion calculator it is important to note that incomplete cross-tolerance and inter-patient variability can be significant. When converting from a different opioid to HYDROmorphone a dose reduction of 25% to 50% should be applied to the suggested ('converted') dose of HYDROmorphone, and the dose titrated thereafter according to analgesic need.

Depending on the reason for opioid conversion, expert advice may be required. Consider consulting Palliative Care, Pain Medicine, Anaesthetics or Addiction Medicine.

The smallest available immediate release HYDROmorphone tablet is 2mg. Do not round calculation up to achieve a 2mg dose. An alternative opioid must be used if doses lower than 2mg are calculated.

5.4.2.3 Patients admitted on HYDROmorphone

The formulation, dose, route and frequency used by the patient must be confirmed with the patient and another reliable source (e.g. patient's GP, community pharmacist or medication list) prior to prescribing.

Patients admitted via an Emergency Department (ED) should have treatment reviewed by an ED Specialist or the senior ED registrar/team leader at the earliest opportunity. Where concerns about the appropriateness of treatment are identified, the patient should be referred to a relevant speciality for consultation or review within an appropriate timeframe.

Patients admitted via other areas should be referred to an <u>Authorised Specialist</u> at the earliest opportunity for advice on appropriate management.

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 8 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

5.4.3 Documentation Requirements

All orders for HYDROmorphone must include:

- i. Drug, including both generic and trade (brand) name
- ii. Dose, route and frequency
- iii. Maximum daily dose as _x_mg/24 hours for PRN orders
- iv. Indication

Handwritten orders must be legible and clear and include the full name of the prescriber.

Each individual order should be for one route only; there must never be more than one route on each individual HYDROmorphone order.

Both the generic and trade names must be included in the order to distinguish between the modified-release and immediate-release formulations. If a modified-release (MR) formulation is intended this must be indicated by ticking the MR box on the medication chart or selecting a MR formulation in an electronic system. *Note: All strengths of Jurnista® (HYDROmorphone hydrochloride) modified release tablets will be discontinued from 30 April 2023. Currently there are no other brands of modified release HYDROmorphone tablets listed on the Australian Register of Therapeutic Goods (ARTG).*

Additional documentation requirements depend on the reason for writing the medication order and are detailed below (5.4.3.1 to 5.4.3.4).

5.4.3.1 Patients admitted on HYDROmorphone

After confirmation with the patient and a second information source, the formulation, dose, route and frequency taken by the patient and details of information source must be documented in the medical record before prescribing.

5.4.3.2 Newly initiating HYDROmorphone

When newly initiating HYDROmorphone the following must be clearly documented in the medical record (in addition to prescribing on the medication chart for items i-v):

- i. Drug and formulation
- ii. Dose, route and frequency
- iii. Maximum daily dose as _x_mg/24 hours for PRN orders
- iv. Indication
- v. Name and designation of the <u>Authorised Specialist</u> who has recommended initiation of HYDROmorphone (where this is different from the person documenting)
- vi. If switching from another opioid, the PREVIOUS drug, formulation, dose and route and the mathematical rationalisation of the dose conversion.

5.4.3.3 Adjusting a HYDROmorphone order

When adjusting an order for HYDROmorphone (e.g. increasing the dose, changing the route), the previous order should be discontinued and a new medication order must be prescribed.

The following must be clearly documented in the medical record (in addition to prescribing on the medication chart for items i-iv):

- i. Current formulation, dose, route, frequency and maximum dose for PRN orders
- ii. New formulation, dose, route and frequency and maximum dose for PRN orders
- iii Indication
- iv. Name and designation of the <u>Authorised Prescriber</u> who has recommended the adjustment of HYDROmorphone (where this is different from the person documenting)
- v. Reason for change (e.g., dose decreased due to persistent drowsiness).

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 9 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

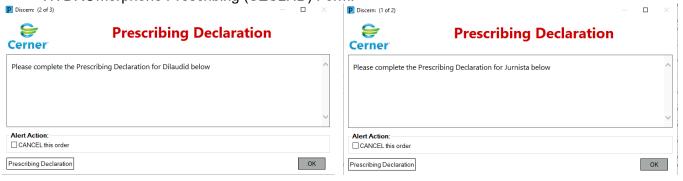
5.4.3.4 Re-charting a HYDROmorphone order

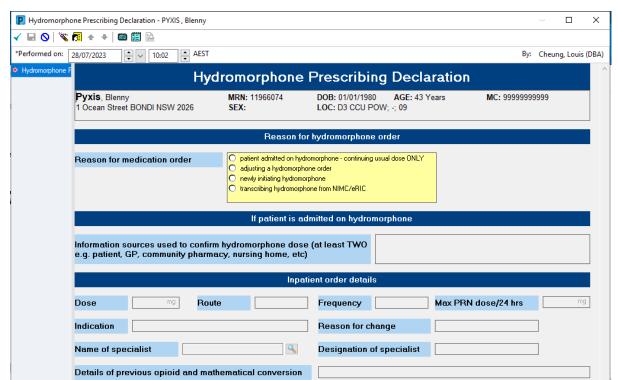
Care should be taken when re-charting an order for HYDROmorphone (at the same, dose, route and frequency), to ensure all details are transferred correctly to the new medication chart.

The following must be clearly documented in the medical record, in addition to prescribing on the medication chart:

- i. Current formulation, dose, route, frequency and maximum dose for PRN orders
- ii. Indication

To assist with documenting the above information, and eMR pop-up will direct clinicians to the HYDROmorphone Prescribing (SESLHD) Form.





Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 10 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

The HYDROmorphone Prescribing (SESLHD) Form can also be accessed via Ad Hoc:

P Ad Hoc Charting - PYXIS , Blenny		
 ➢ Inpatient ➡ Assessments · Adults ➡ Paediatrics (Inpatients) ➡ Clinical Pharmacy ➡ Discharge Referral ➡ HITH ➡ Hereditary Cancer Care ➡ Allied Health ➡ Mental Health ➡ Pre Admission Clinic ➡ Community Health · Adult Services ➡ Community Health · Child, Youth and Family Serv ➡ Outpatients ➡ Trial Forms ➡ All Items 	□ Acute Pain Service Review Form □ Admin Note □ Admin Note □ Antimicrobial Allergy Assessment □ Blood Glucose Level □ BIF Escalation - Red Zone - ISLHD □ BTF Escalation - Red Zone - ISLHD □ BTF Rrs Assess & Action Plan - Yellow Zone - ISLHD □ Cane Type Change □ Clinical Procedure Safety Checklist Level 1 □ Clinical Procedure Safety Checklist Level 2 □ Clinical Review (Yellow Zone) □ COVID-19 and Infectious High Risk Screening Tool □ COVID-19 Intubation Documentation □ COVID-19 Repoperative Checklist □ COVID-19 Rapid Antigen Test Bedside □ COVID-19 Rapid Antigen Test - Patient Reported □ COVID-19 Response Test - Patient Reported	□ ICU Outreach Form □ Mantoux/ Tuberculin Skin Test □ Medication Reconciliation □ Medications □ Melipatient screening safety checklist □ Nurse Practitioner Consultations □ Obstetric Anaesthetic Interventions □ Obstetric Anaesthetic Interventions □ Other Charts in Use □ Other Charts in Use □ Patient Belongings □ Post Fall Management □ Point of Care (Bedside) Blood Tests □ Prescribing Declaration - Hydromorphone □ Prescribing Declaration - Molnupiravir □ Prescribing Declaration - Nirmatrelvir & Ritonavir □ Prescribing Declaration - Nirmatrelvir & Ritonavir

5.4.4 Medication Review

A suitably trained health professional (ideally a pharmacist) should prioritise patients prescribed HYDROmorphone for clinical pharmaceutical review during business hours. Within each SESLHD facility, mechanisms should be in place to assist clinicians to identify these patients.

When clinically reviewing a HYDROmorphone order, the clinician is responsible for the following:

- Confirming that the prescribed HYDROmorphone order is safe and appropriate in the clinical context of the individual patient, by ensuring the appropriateness of the drug, formulation, dose, route and frequency in the context of the individual patient's clinical parameters (e.g., the patient's comorbidities and other medicines prescribed).
- Where changes to a previously charted HYDROmorphone regimen are involved, confirming that these changes are intentional, appropriate and justified
- Where dose calculations or conversions are involved, confirming both the accuracy of the calculations and the applicability of the references used to the clinical context of the individual patient.

The clinician should also ensure that all prescribing requirements (<u>under section 5.4</u>) have been met.

Once satisfied with the order, the clinician reviewing should either:

- 1. sign a Pharmaceutical Review task in eMEDs, or
- 2. electronically verify the order, or
- 3. initial the pharmaceutical review section on a paper chart.

5.5 Administration

Perform a full set of vital sign observations immediately prior to any dose administration (excluding patients on an End of Life Care Plan (EOLCP)). Refer to section 5.7 for management of results outside of normal ranges.

When administering doses of HYDROmorphone (including newly prescribed, adjusted or recharted orders), the person administering together with the witness to administration must confirm all prescribing requirements (under section 5.4) have been met.

If these documentation requirements are not met, the dose should not be administered.

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 11 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

Before each administration confirm that the order details are complete (including dose, route, frequency brand and maximum daily dose for PRN orders). Always check that the order appears appropriate for the individual patient, with reference to the patient's medical record.

Any identified issues must be raised immediately with the prescriber. If a satisfactory resolution is not met, concerns should be escalated to the Nursing/ Midwifery Unit Manager or After Hours Nurse Manager.

A second person check, including witnessing of the administration, is mandatory as per <u>NSW</u> <u>Health Policy Directive PD2022 032 - Medication Handling</u>. Both parties must individually and independently check and confirm the correct drug, dosage, route, frequency and formulation before each administration.

5.6 Monitoring

Version: 2.2

The frequency and type of monitoring will be determined by the individual circumstances. For example:

- in patients on long-term stable therapy routine observations may be sufficient;
- patients on an EOLCP may be excluded from monitoring;
- patients with risk factors for adverse effects (<u>see section 5.2</u>) or patients taking other
 medications which may potentiate the sedation and respiratory depressant effects of
 HYDROmorphone (e.g. benzodiazepines, antipsychotics etc.) may require increased
 monitoring.

The Attending Medical Officer and/or Specialist team should specify in the progress notes the specific monitoring requirements for the individual patient.

For all other patients, the following is a guide:

Mode of administration	Perform and Record	Frequency	
Oral	Sedation score,	One hour after initial dose (or dose	
	respiratory rate, pain score	increase) then every four hours if dosing continues	
Subcutaneous (intermittent	Sedation score,	30 minutes after initial dose (or dose	
dosing)	respiratory rate, pain score	increase) then every four hours if dosing continues	
Continuous subcutaneous	Sedation score,	30 minutes after initiation of the	
infusion (CSCI) (Palliative Care)*	respiratory rate, pain score	infusion (or dose increase) then	
	and as per CSCI	every four hours	
	Monitoring Chart		
Post Anaesthetic Care Unit	Sedation score,	Every 3 to 5 mins while on pain	
(Pain Protocol)	respiratory rate, BP, pain	protocol	
	score		
Patient Controlled Analgesia	Sedation score,	Every hour for six hours then every	
(PCA)	respiratory rate, pain score	two hours for the duration of the PCA	
*patients on an EOLCP may be excluded from monitoring			

The patient must also be observed for other side effects, e.g. light headedness, visual disturbances, tinnitus, constipation, pruritis, nausea, vomiting. Refer to medical team for review if necessary.

Date: 3 April 2024

Page 12 of 17

Ref: T20/59710



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

5.7 Management of Complications

Ensure naloxone is available wherever HYDROmorphone is used.

For the deteriorating patient activate the Between the Flags (BTF) rapid response system as per <u>SESLHDPR/697 – Management of the Deteriorating ADULT inpatient (excluding maternity)</u> and <u>SESLHDPR/705 – Management of the Deteriorating MATERNITY woman</u> and local facility Clinical Emergency Response System (CERS) business rules.

In the event of complications when using modified release preparations, further advice should be sought from an <u>Authorised Specialist</u>. The long half-life of the drug may necessitate increased monitoring and extended treatment e.g. naloxone infusion.

In patients who have an EOLCP in place, complications should be managed in accordance with their individualised plan. CPR or CERS calls may not be appropriate. The Medical Emergency Treatment Limitation Section on the reverse side of the Resuscitation Plan form should be completed with specific instructions for the management of any opioid-related complications.

5.8 Storage of HYDROmorphone

HYDROmorphone products must be supplied to clinical areas from pharmacy in an orange bag with clear labelling to distinguish them from morphine products. They must remain in this bag throughout storage in the clinical area.

Where possible, an additional sticker using Tall Man Lettering stating 'HYDROmorphone' should be applied to all inpatient hydromorphone packets and bottles. The sticker must not obscure original packet or bottle labelling.

HYDROmorphone must be stored separately from morphine products, for example in a separate safe or on a different shelf. Where possible, clear shelf labelling should be applied utilising tallman lettering.

HYDROmorphone products must only be stocked in clinical areas where they are in regular use. Where practicable, HYDROmorphone should be supplied from pharmacy on an individual patient basis and the patient's medication chart clinically reviewed by a pharmacist prior to supply.

A list of areas permitted to stock HYDROmorphone 10mg/mL injection must be kept at each site. Review of storage areas should be undertaken on a six-monthly basis. Where the 10mg/mL injection is required for a specific patient outside of these areas, clear labelling and education strategies must be in place to mitigate the risk of product selection error.

HYDROmorphone products dispensed for a specific patient must not be used for another patient (exceptions may be made after hours at the discretion of the After Hours Nurse Manager and/or the on-call pharmacist.)

Where current or imminent need for a dispensed product cannot be demonstrated, the supply should be removed from the clinical area at the earliest opportunity. All medication safes should be checked at least once per week by the NUM/MUM (or their delegate) to identify any stock of HYDROmorphone that is not in use and pharmacy notified promptly for its removal.

The 50mg/mL injection must not be stocked in SESLHD facilities. Where high doses are required, manufactured pre-filled syringes must be used.

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 13 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

5.9 Staff Education

All nursing, pharmacy and medical staff should undertake the HETI eLearning module 'Safe Use of HYDROmorphone' which can be accessed via HETI My Health Learning (Course Code 199776392).

Please note: In contradiction to the information in the HETI module:

- 1. SESLHD endorses the use of HYDROmorphone in renal failure under the conditions of this procedure, based on references below.
- 2. HYDROmorphone can be initiated in SESLHD by Nurse Practitioners specialising in Palliative Care, Kidney Supportive Care, Cancer Care and Pain Management.
- Clinical Pharmacology Considerations in Pain Management in Patients with Advanced Kidney Failure. Clinical Journal of the American Society of Nephrology, 14(6), pp.917-931. (note page 926 opioids section)
- Ashley, C. and Dunleavy, A., 2014. The Renal Drug Handbook. 4th ed. London: Radcliffe publishing, p.468.

5.10 Patient Information

Patients and/or their carers should be provided with education and written information regarding HYDROmorphone appropriate to their level of understanding. The SESLHD HYDROmorphone discharge medication leaflet available from Stream Solutions (NHSIS1091 Oral HYDROmorphone) is recommended for use for most patients. Consumer Medicines Information for the relevant product(s) should also be provided if considered appropriate.

Sydney Health Care Interpreter Services should be utilised for education of patients and/or carers who are not fluent in English (Tel: 95150030). For patients who are deaf, Auslan interpreters should be used (Tel: 1300 287526).

The patient's family and/or carer should be advised to alert the patient's nurse or a medical officer if they have any concerns regarding the patient's clinical condition.

6. DOCUMENTATION

- Medication Chart: depending on the route of administration, HYDROmorphone is to be prescribed on an approved paper or electronic medication chart, NSW Health pain management chart or fluid chart.
- Medical Record
- Observation charts
- Relevant clinical pathways

7. AUDIT

- HYDROmorphone prescribing audits to be completed at least annually and results reported to the facility Safe Use of Medicines Committee and the SESLHD Drug and Therapeutics Committee
- Continual monitoring and review of IMS+ notifications

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 14 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

8. REFERENCES

- 1. NSW Ministry of Health Policy Directive PD2022 032 Medication Handling
- 2. NSW Ministry of Health Policy Directive PD2024 006 High-Risk Medicines Management
- 3. SESLHDPR/697 Management of the Deteriorating ADULT inpatient (excluding maternity)
- 4. SESLHDPR/705 Management of of the Deteriorating MATERNITY woman
- 5. Therapeutic Guidelines Limited, Pain and Analgesia, Version 7. Published 2202.
- 6. Therapeutic Guidelines Limited, Palliative Care, Version 4. Published 2016.
- 7. Therapeutic Guidelines Limited, Toxicology and Toxinology, Version 1. Published 2020.
- 8. Australian Medicines Handbook Pty Ltd HYDROmorphone, last modified January 2023.
- NSW Health Safety Alert 022/22 Discontinuation of Jurnista® (HYDROmorphone hydrochloride) modified release tablets in Australia, 2022. Available at: https://www.health.nsw.gov.au/sabs/Pages/default.aspx
- 10. NSW Health Safety Alert 004/23 Potential for error: look-alike HYDROmorphone and morphine sulfate Medsurge® solution for injection, 2023. Available at: https://www.health.nsw.gov.au/sabs/Pages/default.aspx

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 15 of 17



Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

9. VERSION AND APPROVAL HISTORY

Date	Version	Author and approval notes	
June 2020	0.1	Katie Hargreaves	
3 July 2020	0.2	Feedback from Working Party incorporated	
23 July 2020	0.3	Feedback from Working party and other specialists incorporated	
3 August 2020	0.4	Feedback from Working party and other specialists incorporated	
21 August 2020	0.5	Feedback from Working party and other specialists incorporated	
4 December 2020	0.6	Feedback from district-wide consultation discussed with Working Party and incorporated where agreed.	
January 2021	DRAFT	Final version approved by Executive Sponsor. Processed by Executive Services for tabling at Quality Use of Medicines Committee and Clinical and Quality Council for approval to publish.	
February 2021	0.7	Approval deferred by QUM Committee due to notification of discontinuation of HYDROmorphone oral liquid. Changes made in discussion with working group to reflect discontinuation of product.	
March 2021	0.7	Approved at Quality Use of Medicines Committee. To be tabled at Clinical and Quality Council for approval.	
May 2021	0.7	Approved at Clinical and Quality Council.	
April 2023	2	Reviewed by Quality Use of Medicines, Lead Pharmacist. Updated to reflect SESLHD Formulary restrictions and availability of Jurnista®. Checking requirements removed. HYDROmorphone Prescribing (SESLHD) Form in eMR referenced. Extensive consultation undertaken with key stakeholders.	
August 2023	2.1	Approved by SESLHD Drug and Therapeutics Committee.	
3 April 2024	2.2	Amendment to update Appendix 1 -Prescribing Restrictions to reflect content in section 5.4. Approved by SESLHD Drug and Therapeutics Committee and Executive Sponsor. Hyperlinks updated including updated NSW Health PD2024_006. Formatting updates by Policy team.	

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 16 of 17





Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities

SESLHDPR/669

APPENDIX 1: HYDROmorphone Prescribing Flowchart

Type of HYDROmorphone Order				
Continuing	Newly initiated	Dose adjustment	Re-charting	
The patient has been admitted to hospital taking HYDROmorphone.	HYDROmorphone is being commenced as a NEW medication for this patient	HYDROmorphone is not new for this patient, but the regimen (dose, route or frequency) is being changed.	HYDROmorphone is not new for this patient, but the order is being re-charted (e.g., transferred to/from NIMC, eRIC, eMEDs, paper chart, discharge prescription).	
	Prescribin	g Restrictions	,	
The prescriber MUST confirm the HYDROmorphone formulation, dose, route and frequency taken by the patient with a reliable source, such as the patient's community pharmacist, general practitioner or medical specialist prior to prescribing.	On the advice of an Authorised Specialist either: A Senior Medical Officer in Palliative Care, Renal Medicine, Pain Medicine, Medical Oncology, Anaesthetics, Intensive Care Medicine, Emergency Medicine or Geriatric Medicine [or at Sutherland Hospital ONLY: Respiratory Medicine], OR A Medical Registrar, Advanced Trainee or Nurse Practitioner working in the following specialties: Palliative Care, Kidney Supportive Care, Cancer Care Anaesthetics or	On the advice of an Authorised Specialist: OR Authorised Prescriber A Registrar, Career Medical Officer, Advanced Trainee or Senior Medical Officer from any discipline, or a nurse practitioner specialising in Palliative Care, Kidney Supportive Care, Cancer Care, Anaesthetics or Pain Management.	Nil restrictions.	
	Pain Management. HYDROmorphone Documentat	ion in the patient's medical recor	d	
The information sources used to confirm HYDROmorphone dose.		Prescribing Form recommended Current formulation, dose, route, frequency and maximum dose for PRN orders New formulation, dose, route and frequency and maximum dose for PRN orders		
Indication	Indication	Indication	Indication	
	Name and designation of the Authorised Specialist who has recommended initiation of HYDROmorphone (where this is different from the person documenting)	Name and designation of the Authorised Specialist who has recommended the adjustment of HYDROmorphone (where this is different from the person documenting)		
	If switching from another opioid, the PREVIOUS drug, formulation, dose and route and the mathematical rationalisation of the dose conversion.	Reason for change		
Any Medical Officer or	All new HYDROmorphone	Any Medical Officer or	Any Medical Officer or	
authorised Nurse Practitioner	orders must be written by an <u>Authorised Prescriber</u> .	authorised Nurse Practitioner	authorised Nurse Practitioner	
For further details refer to SESLHDPR669 – Management of HYDROmorphone in Adult Inpatients in SESLHD Acute Care Facilities				

Version: 2.2 Ref: T20/59710 Date: 3 April 2024 Page 17 of 17