

**Prescribing Protocol SESLHDPR/707
Safe use of Buprenorphine subcutaneous
depot Injection (Sublocade®) for opioid dependence**



Depot Buprenorphine (Sublocade®) IS A HIGH RISK MEDICINE

USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY

Areas where applicable	District
Areas where not applicable	Paediatrics
Authorised Prescribers	<p>The current 'Opioid dependent persons admitted to hospital in NSW – management' policy directive allows medical practitioners to prescribe a drug of addiction (including depot buprenorphine), for up to 14 days, to a person who is inpatient, without the need to obtain authority.</p> <p>If a patient on Sublocade® is admitted to hospital, it is strongly recommended to contact the Drug & Alcohol Services and/or their community prescriber regarding ongoing treatment options.</p>
Indication for Use	Treatment of opioid dependence
Important Safety Considerations	<p>The product must not be handled by patients.</p> <p>Sublocade® must only be administered subcutaneously into the abdomen. Intravenous injection presents significant risk of serious harm or death as Sublocade® forms a solid mass upon contact with body fluids. Occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, could result if administered intravenously. Do not administer intravenously or intramuscularly.</p> <p>The administered dose should be in a single injection and not divided. Pre-filled syringes are for <u>single use in one patient only</u>.</p> <p>Sublocade® is administered once-monthly and may not need to be administered during a brief inpatient hospital admission. However, it is important that its use is accurately documented and handed over at transfers of care to ensure that it is considered in the overall management of the patient.</p> <p>If a patient on Sublocade® is admitted into hospital, Drug & Alcohol Services and/or their community prescriber should be contacted in regards to ongoing treatment and overall management.</p>
Contraindications	<ul style="list-style-type: none"> • Hypersensitivity to buprenorphine or any other component of the ATRIGEL® Delivery System. • Severe hepatic insufficiency (Child -Pugh C). • Patients less than 16 years of age. • Severe respiratory insufficiency • Opioid naïve patients
Precautions	<ul style="list-style-type: none"> • Patients with head injury, intracranial lesions, history of seizures or raised intracranial pressure • Poor respiratory function • Acute abdominal conditions • Hypotension, prostatic hypertrophy or urethral stenosis • Myxoedema, hypothyroidism or adrenal cortical insufficiency • Patients with biliary tract dysfunction • Severe renal impairment • Hepatitis and hepatic impairment

Prescribing Protocol SESLHDPR/707
Safe use of Buprenorphine subcutaneous
depot Injection (Sublocade®) for opioid dependence



	<ul style="list-style-type: none"> • Patients at risk of arrhythmia e.g. hypokalaemia, hypomagnesaemia, taking medications that prolong the QT interval • Acute intoxication with alcohol or other CNS depressants • Patients above 65 years old • Patients 16-18 years of age • Pregnancy & Lactation
Important Drug Interactions	<p>Benzodiazepines and other central nervous system depressants (e.g. alcohol, tricyclic antidepressants, antipsychotics, clonidine, gabapentinoids)</p> <p>Other opioid analgesics</p> <p>Naltrexone and other opioid antagonists</p> <p>CYP3A4 inhibitors & inducers</p>
Dosage	<p>Patient should be initiated and stabilised on a transmucosal buprenorphine-containing product, delivering the equivalent of at least 8 mg/day of buprenorphine for at least 7 days before starting Sublocade®; unless otherwise advised by an addiction specialist.</p> <p>The recommended dose of Sublocade® is 300 mg monthly for the first two months. The recommended maintenance dose is 100 mg monthly. Patients who do not show a satisfactory clinical response following the second dose of 300mg, or from maintenance treatment with 100mg doses, can receive a maintenance dose of 300 mg monthly.</p> <p>Refer to Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence(2019) for further guidance.</p>
Duration of therapy	Individualised
Patient education	<p>Consumers should be educated regarding the risks of polysubstance use (including use of prescribed sedating medication) and cautioned regarding driving or operating machinery under such conditions.</p> <p>The provision of take home naloxone should be considered.</p> <p>Patients should be advised to report their use of depot buprenorphine to other healthcare practitioners providing care, where appropriate.</p>
Prescribing Requirements	<p>Schedule 8 medication handling requirements apply according to PD2013 014 Medication Handling in NSW Public Health Facilities</p> <p>Drug & Alcohol services should be consulted if unsure.</p>
Administration Instructions	<p>Sublocade® must only be administered by a healthcare professional.</p> <p>Administration is by subcutaneous injection into the abdominal region. Injection sites should be rotated.</p> <p>Remove Sublocade® from the refrigerator prior to administration. The product requires at least 15 minutes to reach room temperature. Do not return to the refrigerator after this time. Do not open the foil pouch until the patient is ready for his or her injection.</p> <p>Do not attach the needle until time of administration.</p> <p>Product is for single use in one patient only. Discard any residue.</p> <p>Follow schedule 8 medication handling procedures according to PD2013 014 Medication Handling in NSW Public Health Facilities</p> <p>For further details refer to TGA product information.</p>

Prescribing Protocol SESLHDPR/707
Safe use of Buprenorphine subcutaneous
depot Injection (Sublocade®) for opioid dependence



Monitoring Requirements	Regular review and monitoring as per NSW Clinical Guidelines: Treatment of Opioid Dependence (2018) , including: <ul style="list-style-type: none"> - Opioid dependence treatment outcomes, including client's substance use, health, social conditions, engagement with treatment and related risks (e.g. BBV, overdose, child protection, DV) - Subjective and objective adverse drug reactions - Patient experience of treatment
Management of Complications	Individualised, based on TGA product information and NSW Clinical Guidelines: Treatment of Opioid Dependence (2018) and Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence (2019)
Storage requirements	Store at 2 - 8°C. Refrigerate. Do not freeze. Once outside the refrigerator this product may be stored in its original packaging at room temperature (below 25°C) for up to 7 days prior to administration. Discard Sublocade® if left at room temperature for longer than 7 consecutive days. Follow schedule 8 medication handling procedures according to PD2013_014 Medication Handling in NSW Public Health Facilities
Additional Resources	RACGP webinar on Depot Buprenorphine: https://www.racgp.org.au/education/professional-development/online-learning/webinars/drugs-and-alcohol/buprenorphine-in-the-treatment-of-opioid-dependent
Basis of Protocol/Guideline:	NSW Ministry of Health (2018). <i>NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018</i> . NSW Ministry of Health, Sydney Australia. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_019.pdf NSW Ministry of Health (2019). <i>Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence</i> . NSW Ministry of Health, Sydney Australia. https://www.health.nsw.gov.au/aod/Publications/full-depot-bupe-interim-gl.pdf
Groups consulted in development of this guideline	Prof Nicholas Lintzeris SESLHD Drug and Alcohol Services Pharmacists

AUTHORISATION	
Author (Name)	Prof Nicholas Lintzeris
Position	Director, Drug & Alcohol Services, South East Sydney Local Health District, NSW Health
Department	SESLHD Drug and Alcohol Services, The Langton Centre

**Prescribing Protocol SESLHDPR/707
 Safe use of Buprenorphine subcutaneous
 depot Injection (Sublocade®) for opioid dependence**



Department Contact (for ongoing maintenance of Protocol/Guideline)	Nicholas.lintzeris@health.nsw.gov.au
GOVERNANCE	
Enactment date	April 2021
Expiry date:	April 2023
Ratification date by SESLHD Drug and QUM Committee	25 March 2021
Chairperson, QUM Committee	Ms Amy Murray
Version Number	1