Prescribing Protocol SESLHDPR/649
Varenicline for smoking cessation

Prescribing Protocol	
Title	**Varenicline as an aid to smoking cessation in adults**
Areas where Protocol/Guideline applicable	District
Areas where Protocol/Guideline not applicable	Patients under the age of 18 years
Authorised Prescribers	All Senior Medical Officers and supervised JMOs
Indication for use	Aid to smoking cessation
Clinical condition	Patients (age over 18 years) who indicate they are ready to quit smoking and are enrolled in a comprehensive support and counselling program. Patients must be eligible for continued supply on the Pharmaceutical Benefits Scheme (PBS) post-discharge and therefore must meet the PBS Authority criteria (available at: http://www.pbs.gov.au/medicine/item/9128K).
Contra-indications	Hypersensitivity to varenicline or to any of the excipients
Precautions	• History of psychiatric illness: Patients and their families, friends or carers should be advised that the patient should stop taking varenicline and contact a healthcare professional immediately if changes in behaviour or thinking, agitation or depressed mood that are not typical for the patient are observed, or if patient develops suicidal ideation or suicidal behaviour • History of seizures: use cautiously • Effects of smoking cessation: Physiological changes resulting from smoking cessation, with or without varenicline, may alter pharmacokinetics or pharmacodynamics of some drugs for which dosage adjustment may be necessary. As smoking induces CYP1A2, cessation may result in an increase of plasma levels of CYP1A2 substrates • Renal impairment (ClCr < 30 mL/min) • Not recommended in end stage renal disease • Caution driving and operating machinery • Use in pregnancy (Category B3) and lactation

Place in Therapy	First line therapy together with comprehensive smoking cessation support and counselling program (e.g. NSW Quitline or hospital smoking cessation clinics)
Dosage	1 mg twice daily following a 1 week titration as follows: Days 1 to 3: 0.5 mg once daily Days 4 to 7: 0.5 mg twice daily Day 8 to end of treatment: 1 mg twice daily - If nausea is intolerable, consider reducing dose to 1 mg once daily The patient should set a date to stop smoking. Varenicline dosing should start 1-2 weeks before this date. Alternatively, a flexible approach to quitting smoking may be adopted. Patients can begin varenicline dosing and then quit smoking between days 8 and 35 of treatment. Initial treatment is for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with varenicline at 1 mg twice daily is recommended to further increase the likelihood of long-term abstinence. *Severe renal impairment (CrCl <30mL/min):* 0.5 mg once daily for 3 days, then increase to 1 mg once daily, if tolerated. Not recommended in end stage renal disease No dosage adjustment is necessary for patients with mild to moderate renal impairment, hepatic impairment or in elderly.
Duration of therapy	12 to 24 weeks (see above)
Important Drug Interactions	Based on varenicline characteristics and clinical experience to date, varenicline has no known clinically meaningful drug interactions Physiological changes resulting from smoking cessation, with or without varenicline, may alter pharmacokinetics or pharmacodynamics of some drugs for which dosage adjustment may be necessary (e.g. theophylline, warfarin, insulin) Alcohol may increase risk of neuropsychiatric event
Administration instructions	Varenicline tablets should be swallowed whole with water, and can be taken with or without food. Dose tapering is not required at the end of treatment.

Monitoring requirements	• Adverse effects (commonly nausea and headache) • Changes in cigarette smoking habits • Patients and their families, friends or carers should be advised that the patient should ***stop taking varenicline and contact a healthcare professional immediately*** if changes in behaviour or thinking, agitation or depressed mood that are not typical for the patient are observed, or if patient develops suicidal ideation or suicidal behaviour
Management of complications	Immediate cessation and review by medical staff if reports of neuropsychiatric, seizure or skin adverse events occur. In case of overdose, standard supportive measures should be instituted as required. Contact the Poisons Information Centre on 131 126 for advice on the management of an overdose.
Basis of Protocol/Guideline	MIMS/TGA Product Information Varenicline monograph, Australian Medicines Handbook (2019)
Groups consulted in development of this protocol	Department of Respiratory Medicine, St George Hospital Department of Respiratory Medicine, Sutherland Hospital Drug & Alcohol Service, St George Hospital Quality Use of Medicines Lead Pharmacist

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GOVERNANCE	
Enactment date Review date	April 2019 March 2022
Expiry date:	April 2025
Ratification date by SESLHD QUM Committee	7 April 2022
Chairperson, QUM Committee	Dr John Shephard
Version Number	2.0