

Suboxone® Fact Sheet

Prescribing and Dispensing Suboxone®
August 2019

Background

Suboxone is a sublingual film that contains the active ingredients buprenorphine and naloxone and is registered with the Therapeutic Goods Administration for use in Australia for the treatment of opioid dependence. Through the Section 100 Opiate Dependence Treatment Program established under the *National Health Act 1953*, Suboxone is fully subsidised by the Commonwealth government under the Pharmaceutical Benefits Scheme (PBS) for opioid replacement therapy.

There has been some confusion about the legality and practicalities of prescribing and dispensing Suboxone for purposes other than opioid replacement therapy (off-label use). This factsheet sets out the current regulatory, funding and supply mechanisms for Suboxone to provide clarity around these matters.

For Opioid Replacement Therapy

As Suboxone is a Schedule 8 poison for the purposes of the Victorian *Drugs, Poisons and Controlled Substances Act 1981*, in Victoria, medical practitioners require a Schedule 8 permit to prescribe Suboxone to drug-dependent persons, or to non-drug dependent persons for a period of more than 8 weeks.

When Suboxone is being prescribed for the purpose of opioid replacement therapy, pharmacists obtain the stock to fill these prescriptions via the Section 100 Opioid Dependence Treatment Program under the PBS. Pharmacies cannot obtain Suboxone for opioid replacement therapy from wholesalers unless the pharmacy has been approved by the Victorian Department of Health and Human Services to dispense Suboxone for opioid replacement therapy.

The Commonwealth funds the full cost of Suboxone under the PBS for opioid replacement therapy, however consumers prescribed Suboxone are required to pay a dispensing fee. For a consumer to access Suboxone under the Section 100 Opioid Dependence Treatment Program, the indication must be opioid dependence.

For Other Indications

There are no provisions under Commonwealth or Victorian legislation that prohibit prescribing Suboxone for off-label use. However, if Suboxone is prescribed for off-label use, the prescriber may still be required to hold a Schedule 8 permit. Additionally, there is no PBS funding for off-label use of Suboxone and pharmacists cannot dispense the Suboxone obtained via the Section 100 Opiate Dependence Treatment Program for off-label use.

As a result, access to Suboxone for off-label use will be limited to circumstances where pharmacists have obtained Suboxone from wholesalers outside of the Section 100 Opiate Dependence Treatment Program. If off-label use is being considered, enquiries should be made as to the availability of the medicine.