Prescribing Buprenorphine – Medication Assisted Treatment for Opioid Dependence (MATOD) Program

Buprenorphine - Subutex®, Suboxone®

This policy sets out the general circumstances under which the Drugs of Dependence Unit will grant section 18A Controlled Substances Act 1984 authorities to prescribers of buprenorphine for the treatment or maintenance of opioid dependence.

Background:

Opioid pharmacotherapy has recognised health, social and economic benefits to individuals, their families, and the broader community. These benefits are in no small way derived from committed prescribers and pharmacists as part of the South Australian Medication Assisted Treatment for Opioid Dependence (MATOD) Program.

While opioid pharmacotherapy provides tangible benefits, there are identified risks that require mitigation to help minimise harms to clients and the wider community. Probably the biggest perceived risk is associated with diversion of prescribed opioid pharmacotherapy – whether diverted opioids are subsequently used by the client for whom they were prescribed or another person. This occurs despite the significant efforts of dispensing pharmacists in supervising dose administration.

Reports exist about diversion of buprenorphine products particularly. Comprehensive supervision of administered doses of buprenorphine is less likely than with doses of methadone due to the difference in product formulations. Consequently, buprenorphine initially taken into the mouth may be diverted in a variety of creative ways for administration later. The intravenous administration of diverted buprenorphine may result in life-threatening infection. Moreover, deaths have been reported following buprenorphine mostly in combination with other CNS depressants like benzodiazepines and alcohol. While buprenorphine has a ceiling effect on respiratory depression, this may still be significant enough to be fatal for an opioid-naïve individual.

In 2006 Suboxone® sublingual tablets¹ became available to help reduce risks associated with buprenorphine diversion. As expected though, diversion of Suboxone® has not been eliminated.

In 2011 Suboxone® sublingual film was released for use in opioid pharmacotherapy programs. The film provides the following advantages over tablet formulations of both Suboxone® and Subutex®;

- Reduced chance of diversion due to strong adherence of the film to oral mucosa;
- Improved compliance due to superior taste;
- Less time required for supervised dosing;
- Superior packaging offers greater child-resistance when providing unsupervised doses.

¹ Buprenorphine and naloxone in combination in a ratio of 4:1.
This policy should be read in conjunction with the following:

**GP Program - Medication assisted treatment for opioid dependence**

This policy helps ensure:

- The relative advantages of Suboxone® film are maximised in South Australian opioid pharmacotherapy programs, and
- Clients are transferred to Suboxone® film prior to the tablet formulation being phased out by the product’s manufacturer.

**Policy Detail:**

All opioid pharmacotherapy proceeds in accordance with a Controlled Substances Act 1984 authority granted by the Drugs of Dependence Unit. The following requirements apply to such authorities:

- **Prospective treatment** with buprenorphine proceeds in the form of Suboxone® Film unless the client:
  - Is pregnant;
  - Suffers an allergy to naloxone.
  
  In either case, treatment may be provided with Subutex®.

- **Current treatment** with buprenorphine as Subutex® may continue for a maximum of six weeks from the date of approval where the client is:
  - Gradually ceasing opioid pharmacotherapy;
  - In the opinion of the treating doctor, experiencing clinically-significant anxiety about ceasing treatment from a 2mg daily dose; and
  - Prescribed Subutex® pursuant to approval granted by the Drugs of Dependence Unit.

- The Drugs of Dependence Unit’s Policy for Non-Supervised dosing of Methadone and Buprenorphine in Drug Treatment Programs (MATOD unsupervised dosing policy) remains unchanged for Suboxone® Film.

For more information

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