Submission to the Public Consultation for the Post-market Review of Opiate Dependence Treatment Program Medicines

Turning Point & Monash Addiction Research Centre

October 2021
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About

The Monash Addiction Research Centre (MARC) brings together world-leading expertise from across Monash University and the sector to provide solutions to the challenges of addiction. MARC draws on the multidisciplinary strengths and capabilities of researchers across the University to develop and test novel, scalable prevention and treatment approaches. MARC’s mission is to provide national solutions to addiction, leveraging expertise in basic and social science, clinical, and epidemiological research to develop new knowledge to shape government policy and evidence-based approaches.

Turning Point is Australia’s leading addiction treatment, research, and education centre. Turning Point provides high quality, evidence-based treatment to people adversely affected by alcohol and other drugs and gambling, integrated with world-leading research and education. Turning Point is auspiced by Eastern Health and is formally affiliated with Monash University.
1. Introduction

The Monash Addiction Research Centre and Turning Point welcome the opportunity to contribute to the Post-market Review of Opiate Dependence Treatment Program (ODTPP) Medicines. There is an urgent need for reform to ensure better access to ODT, and the recommendations in this submission echo those made in several reports over the past decade, including reports funded by the Commonwealth Government in 2008\(^1\) and 2009\(^2\) as well as a 2015 report by the Penington Institute.\(^3\) We recommend that where there is consensus in recommendations of these reports that they be taken into consideration alongside any submissions made to the post-market review.

2. Summary of recommendations

1. Ensure a wide range of evidence-based ODT medicines are available.
2. Normalise treatment of opioid use disorder in primary care, with appropriate remuneration, and supported by specialist services for referral as required.
3. Use pharmacists and nurse practitioners to their full scope of practice to build workforce capacity.
4. Ensure addiction medicine specialists are situated within all major hospitals.
5. Increase the accessibility of ODTP through new models of service delivery, including those developed in response to the COVID-19 pandemic that permit greater flexibility in treatment.
6. Facilitate access to long-acting injectable buprenorphine as a means of overcoming barriers to treatment, particularly in regional and rural areas.
7. Subsidise dispensing and administration fees to reduce the financial burden of treatment on consumers.
8. Form a working group to determine the best mechanism by which ODT can be funded through the PBS, considering the options with S85 and S100 listing in addition to MBS items for all healthcare providers that are involved in service delivery.

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3. Improved / best practice ODT service models

Essential elements of best practice models of service delivery for ODT include:

- availability of a range of evidence-based medicines;
- management in primary care, with primary care providers (prescribers and pharmacists) appropriately supported and remunerated and with access to specialist services for referral as required;
- using pharmacists and nurse practitioners to their full scope of practice to maximise workforce capacity;
- provision of addiction medicine specialists within major hospitals; and
- targeted supervision of dosing based on patient needs.

For most chronic health conditions, it is widely accepted that a diversified range of medications increases the likelihood of optimal treatment for individuals. However, for Australians living with opioid dependence available medications remain limited to methadone and buprenorphine, despite international evidence supporting the effectiveness of other medications. While methadone or buprenorphine are effective treatments for opioid use disorder, approximately 5–10% of people who are opioid-dependent do not respond to these medications.\(^4\)

Injectable hydromorphone and slow-release oral morphine are part of standard care internationally,\(^5,6\) and are safe and effective alternatives that have the potential to address gaps in opioid use disorder (OUD) treatment engagement and retention in Australia. Given recent increases in opioid overdose deaths,\(^7\) it is essential that this evidence is taken into consideration and evidence-based solutions are implemented. Decades of evidence from European (and, more recently, North American) models support the effectiveness of these treatment options,\(^8,9,10\) and there is little evidence to suggest that they lead to excessive demand for a single medication; rather, these appear

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to be associated with specific patient characteristics, highlighting a need for diversified treatment options.11

Efforts should be made to normalise opioid agonist treatment (OAT) as a routine part of care for GPs and facilitate collaborative approaches to align the treatment of OUD with other chronic health conditions.12 Regulatory barriers may perpetuate negative attitudes among prescribers, with the additional training requirements, lengthy approval processes, permits for treatment for special conditions, and administrative burdens associated with OAT prescribing sending a message that it is difficult and dangerous.13 Limited coordination between GPs in the community and addiction specialists means that, unlike other chronic mental and physical health conditions, GPs effectively practice in isolation and have limited support for consumers with complex needs.14,15

Building workforce capacity by using pharmacists and nurse practitioners is consistent with efforts undertaken internationally to improve treatment access for patients with other chronic conditions, including asthma, hypertension, and diabetes.16,17 A shortage of medical practitioners willing or able to prescribe medication assisted treatment for opioid dependence (MATOD) is a significant issue in Australia, with research indicating that the majority of services are provided by a small number of high-volume prescribers, many of whom are nearing retirement age.18 As such, there is a need for innovative models of care that expand access to treatment, particularly in rural and regional areas where prescriber shortages are most acutely felt.

In Victoria, the Enhancing Pharmacist Involvement in Care for Medication Assisted Treatment for Opioid use Disorder (EPIC-MATOD) pilot study19 will use pharmacists at their full scope of practice, in collaboration with prescribers, as an innovative means of improving access in regions where access to prescribers is difficult. Potential advantages include more accessible and convenient access to services, with flow-on benefits including reductions in prescriber workloads, medical fees, and transport costs. As the pharmacist has more frequent contact with the patient, collaborative arrangements also have the potential to improve monitoring (including aiding early identification of

19 https://www.monash.edu/medicine/ehcs/marc/research/current/EPIC-MATOD
problems) and strengthen patient participation in decision-making. Information from the pilot study will inform scale-up to other regions of Victoria, or nationally, where similar treatment barriers exist.

A critical aspect of sustainability for these models of care is mechanisms for remuneration of health professionals’ time. Currently, MBS item numbers for nurse practitioners are insufficient to cover their time in providing pharmacotherapy treatment, and there is no MBS item number to cover pharmacists time spent providing clinical reviews. These issues urgently need to be addressed if these workforces are going to be able to fill the growing gap between treatment needs and availability.

Hospitals are an important component of the continuum of care for OUD, however, the under-treatment of people with OUD in the acute care system remains largely unaddressed. Providing addiction medicine specialist services in hospitals would help minimise inadequate or inappropriate treatment during hospitalisation and avoid gaps in care by facilitating better linkages to community ODTP services following discharge. Specialists have a key role in building capacity in hospital settings and integrating training and education on OUD to reduce harms (e.g., by providing naloxone on discharge for patients with OUD).

Recent changes to ODTP guidelines and service delivery arrangements have been made in response to COVID-19 restrictions to ensure continuity of access to ODT medicines, including the use of telehealth, provision of additional take-home doses, and third-party collection of take-home doses. Preliminary evidence indicates that treatment provided with these modifications is safe and effective, with no relationship between the provision of more takeaway doses and increased substance use. Data released by the Coroner’s Court of Victoria has confirmed that reducing requirements for daily attendance for dosing has not led to any increased harm or diversion. Subject to evaluation and consumer feedback, these should be extended to ensure improved access

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20 Le, P.-P., A. Braunack-Mayer, and C. Laurence, Collaborative pharmacist prescribing within the opioid substitution treatment program in South Australia: patient and pharmacist views.


and retention in ODT, particularly for consumers in regional and rural areas who face additional barriers to treatment due to lack of access to reliable and affordable transport.

4. Consumer experience

The affordability of the Australian pharmacotherapy program has been well established as a central issue for consumers. Out-of-pocket costs are incurred via dispensing fees, travel costs, and other appointment-related costs, which vary depending on whether prescribers are funded by their State/Territory government in public clinic settings, via the Medicare Benefits Scheme, or in private clinics. A 2015 report by the Penington Institute details how the system of payments compounds the financial hardship already experienced by people on the program, many of whom rely on income support and are already financially vulnerable.27

More recent studies continue to emphasise the impact that treatment costs have on consumers’ psycho-social wellbeing, and the ways in which these add to their distress in managing other regular expenses, such as rent, water/electricity, gas, food, and travel bills.28, 29 While a lack of detailed information on out-of-pocket costs has hampered efforts to mitigate them, recent research indicates that 87% of consumers incur out-of-pocket costs, spending an average of $2,220 AUD per year – or 13% of their income – on ODT treatment.30 Of these, dispensing fees were the most substantive cost, accounting for 70% of the total out-of-pocket costs incurred by those who pay them.

Heightened barriers to treatment among consumers in rural and regional areas has also been repeatedly documented in the literature. Many consumers are required to travel long distances to access ODT due to a shortage of prescribers, often in areas with a lack of readily available public transport to get to the prescriber and/or dispenser. Having to make multiple trips per week to and/or from dosing points adds an additional financial burden, and may be exacerbated by inconsistencies in pricing between pharmacies in urban and regional areas.31, 32 While travel costs are less frequently measured and reported, these can place a substantial burden on consumers: recent research has estimated that travel costs (including dispensing travel costs and OAT-related

appointment travel costs) account for 52% of total out-of-pocket costs paid. Mitigating the total cost of treatment is critical to prevent financial barriers to receiving effective care.

Research examining consumer experience in rural and regional areas has also highlighted a lack of equitable access to services for other health conditions, due in part to a lack of coordination among various government agencies, such as Centrelink, the prescriber, the dispenser, the general practitioner and allied health services. Consumers managing comorbid mental and physical health conditions often feel their GPs do not adequately address their other health needs when they are also their prescriber, due to time pressures, a shortage of appointments, limited access to specialists, and lack of other allied referral services to manage complex health conditions.

Stigma is a major barrier to help-seeking and the quality of care received by people with OUD. Stigmatisation occurs through routine interaction in pharmacy settings, in addition to treatment policies, systems and programs that require daily supervised dosing, and frame only certain consumers as ‘trustworthy’ enough to receive takeaway doses. This is compounded by a lack of privacy in some community pharmacies and processes that separate OAT consumers from other customers (e.g., requiring them to queue).

These barriers highlight the benefits of long-acting injectable buprenorphine (LAIB) to consumers in regional and rural areas, where daily dosing can be particularly burdensome and stigma is more pronounced due to a lack of anonymity. By delivering prolonged therapeutic doses of buprenorphine in weekly or monthly formulations, LAIB has the potential to overcome barriers associated with sublingual buprenorphine/methadone including poor adherence, diversion, and non-medical use of takeaway doses. This is supported by recent research that identified benefits to consumers, most notably increased flexibility with treatment and a reduction in stigma experienced at pharmacies/clinics, compared to programs requiring daily attendance for dosing. The benefits of allowing consumers to form new, non-stigmatised identities and engage in meaningful activities (e.g., travel, work) cannot be overstated, and highlight the need to ensure broad access to ODT.

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34 Op. cit. 3.
It should be noted that there are key gaps in the literature regarding the experiences of consumers, particularly those living in remote regional/rural areas. A recent review found studies examining barriers to treatment often considered these from the pharmacist or prescriber perspective, with less focus placed on the everyday experiences of consumers.\textsuperscript{42} Appropriate consultation with people on the ODT program should be undertaken to ensure any recommendations are informed by their direct lived experience.

5. Utilisation of PBS subsidised ODT medicines

Methadone, buprenorphine and buprenorphine/naloxone are all PBS listed medicines under Section 100 (S100) when used for the treatment of opioid dependence. However, unlike other PBS medicines, the listings for S100 Opiate Dependence do not include any remuneration for dispensing (for oral and sublingual daily dosing) or administration (in the case of LAIB). As a result, there is little equity in costs: the cost for most other PBS subsidised medications is $6.60/month for Centrelink payment recipients, compared to an average of $127/month for consumers receiving methadone, buprenorphine, or buprenorphine/naloxone (when travel and appointment-related costs and are included to accommodate daily collection of medicines, mean costs are as high as $185, or $201 for consumers in treatment for <1 year).\textsuperscript{43} As discussed in the previous section, dispensing and administration fees represent a significant burden on consumers, and there is an urgent need for reform to ensure they do not act as barriers to treatment.\textsuperscript{44}

The disparities in remuneration between medications for opioid use disorder and medications also impacts pharmacists, and their relationships with consumers, with payment issues and the accumulation of debt with pharmacies a common cause of conflict.\textsuperscript{45} As there is no standardised fee-for-service, remuneration is limited to fees paid by patients directly to the pharmacy. These have remained unchanged (at $5 a dose or $30 a week) for over 3 decades, while the costs of providing the service vary considerably depending on the needs of the consumer, and are also accrued by administrative activities, consumables, and other overheads, e.g., set-up costs.\textsuperscript{46} A revised funding model should reflect improved affordability for consumers in addition to adequately remunerating pharmacists.

\textsuperscript{43} Op. cit. 30.
\textsuperscript{44} Op. cit. 3.
\textsuperscript{46} Op. cit. 1.
Given growing clinical trial evidence demonstrating that LAIB is a safe and effective treatment for opioid use disorder, it is critical that PBS listings do not restrict access. LAIB provides a crucial opportunity for many who would not otherwise be able to engage in treatment delivered through daily dosing in a pharmacy or clinic. It would be a mistake to consider LAIB a third-line treatment for those who do not respond to methadone or buprenorphine, as it has substantial value for people who may otherwise remain untreated due to their inability to access treatment which is provided with daily supervised dosing due to work, childcare, travel, or other access barriers. Delivery of LAIB through community pharmacies provides an opportunity to extend the geographic reach of LAIB further, with implementation research to develop these models of care underway. As there is no current mechanism for pharmacists who are administering LAIB to be remunerated for their time, treatment models and PBS arrangements for payment (including $100 listings) must consider these issues to ensure that administration fees do not become a barrier to treatment.

A working group should be established to define the best mechanism by which ODT can be funded through the PBS, and ensure those providing services can be adequately remunerated, so that there is parity with funding and cost to the consumer with other PBS medications for chronic conditions. This should be funded by the Commonwealth and activities to determine the best funding model should include experts from all States and Territories to ensure those working outside funded clinic settings are appropriately remunerated for providing supervised dosing. PBS and MBS funding needs to include a consideration of health professionals such as nurse practitioners and pharmacists who currently do not have appropriate Medicare reimbursements to provide clinical services.

6. Improved service delivery arrangements

There is significant opportunity to improve access to ODT in Australia so that treatment is offered in a way that provides parity with other chronic health conditions. The World Health Organisation has designated methadone and buprenorphine as essential medicines, intended to be available at all times and at a price the individual and the community can afford. However, in Australia, the cost of these medications is substantially more than other essential medicines, and the cost burden of ODT to the consumer, particularly when compared to other PBS medicines, is untenable.

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50 WHO Essential Medicines http://www.who.int/topics/essential_medicines/en/
The bulk of dispensing fees should be subsidised by the government, not consumers. As with other medications, a more reasonable arrangement would be for consumers to pay a small amount, which contributes towards the PBS safety net annual amount. This is likely to be mutually beneficial, as economic modelling has demonstrated that the annual health and crime cost savings associated with ODT treatment would more than offset the costs of subsidising dispensing fees for existing medications.\textsuperscript{51} Moving towards a more equitable arrangement where access to treatment does not depend on the consumer’s ability to pay will better align the ODT program with the fundamental principles governing healthcare in Australia.\textsuperscript{52}

Like other chronic health conditions such as asthma and diabetes, opioid dependence can be managed effectively within primary health care settings. However, varied approaches across all states and territories allow for considerable difference in the accessibility of ODTP. A coordinated national approach to ODT (including standardised dispensing and supply arrangements) is necessary to ensure that consumers have equitable access to ODT medicines irrespective of where they live.


\textsuperscript{52} Op. cit. 2.