

Pharmaceutical Benefits Scheme

Post-market Review

of

PBS Opioid Dependence Treatment Program medicines

Report to the Pharmaceutical Benefits Advisory Committee

Executive Summary and Review Outcomes

March 2023

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Terminology and Abbreviations

Terminology

The report uses the term “consumer” rather than “client” or “individual” to mean people with opioid dependence in the context of opioid dependence treatment programs. The term “patient” is used in contexts that are medical in nature.

Varying terms (and their acronyms) are often used to describe treatment of opioid dependence with medicines, including opioid agonist treatment (OAT), opioid substitution therapy (OST), opioid maintenance treatment (OMT), opioid replacement therapy (ORT) and medication assisted treatment for opioid dependence (MATOD). In this report we use **‘opioid dependence treatment (ODT) medicines’ to refer to the pharmacotherapy (or medicines) used for the treatment of opioid dependence listed on the Pharmaceutical Benefits Scheme (PBS), although all terms have limitations.**

The term **‘ODT programs’ is used to describe the broader treatment of opioid dependence provided by individual jurisdictional programs.**

The abbreviation **‘PBS ODTP’ is used to identify the Australian Government’s Section 100 (S100) PBS Opiate Dependence Treatment Program specifically.**

The abbreviation ‘ODTP PMR’ is used to identify the Post-market Review of Opioid Dependence Treatment Program medicines. The term ‘the Review’ is also used.

The term buprenorphine + naloxone is used to describe the buprenorphine with naloxone combination. Where referred to together, the term buprenorphine +/- naloxone is used to describe both buprenorphine without naloxone and the buprenorphine with naloxone combination.

Abbreviations

Abbreviation	Full Name / Wording
ACCHO	Aboriginal Community Controlled Health Organisations
CTG	Closing the Gap
GP	General Practitioner
LAIB	Long-acting injectable buprenorphine (or modified release buprenorphine)
MBS	Medicare Benefits Schedule
National Guidelines	National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014
NH Act	<i>National Health Act 1953</i>
NOPSAD	National Opioid Pharmacotherapy Statistics Annual Data
ODT	Opioid Dependence Treatment
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PBS ODTP	Australian Government's PBS Section 100 (S100) Opiate Dependence Treatment Program
PMR	Post-market Review
S100	Section 100 of the <i>National Health Act 1953</i>
S85	Section 85 of the <i>National Health Act 1953</i> (also known as the general schedule)
TOR	Term(s) of Reference

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Executive Summary

The Executive Summary brings together the Key Findings sections of each chapter and presents the deliberations of the Review.

1.1. Timing of the PMR

An amendment to the *National Health Amendment (General Co-payment) Bill 2022* passed by the Senate on 26 October 2022 introduced a change to S100 of the *National Health Act 1953 (NH Act)*. This change requires S100 programs on the Pharmaceutical Benefits Scheme (PBS), such as the Opiate Dependence Treatment Program (ODTP), to be made via a legislative instrument from 1 July 2023. Consequently, the process and timelines for the ODTP Post-market Review (PMR) needed to be adjusted so that what the Department has heard to date through stakeholder consultation processes and matters arising from the Review could be considered by the Pharmaceutical Benefits Advisory Committee (PBAC).

On 20 November 2022 the Minister for Health and Aged Care, the Hon Mark Butler MP wrote to the Chair of the PBAC seeking advice on timelines for the Review to ensure the 1 July 2023 legislative timeframe can be met. On 22 November 2022 the Chair of the PBAC responded to the Minister recommending the PBAC present an early report on research, consultation undertaken and key findings for Government consideration. The Chair of the PBAC recommended the PMR then be put on hold pending the Australian Government's response to the amendment following which PBAC can review whether there is a continued need for the PMR. The response noted the significant consultation undertaken as part of the Review to date and advised this approach would best facilitate the timely consideration by government of the issues raised by stakeholders and the progression of discussions with state and territory governments on service delivery options. The Minister subsequently accepted the Chair's recommendations per the above.

This report consolidates the evidence, deliberations and matters raised to date through the PMR consultation processes with stakeholders, literature review, and data analysis. In this context, initial outcomes summarising what the Department has heard are presented below to the PBAC to assist in their consideration of the priority issues arising from the Review and formulation of recommendations and advice to government.

1.2. Background

The PBS ODTP is established under Section 100 of the NH Act. Under the PBS ODTP, the Australian Government pays the full cost of the medicines made available under state and territory government ODT programs in both pharmacy and non-pharmacy settings.

There are currently three medicines available for the treatment of opioid dependence under the PBS ODTP. These medicines are buprenorphine (tablets and modified release injections), buprenorphine with naloxone (films) and methadone (oral liquid).

Stakeholders raised several issues with access to ODT medicines under the PBS including patient access and affordability, remuneration for pharmacies and consistency in service and program delivery across each jurisdiction.

The ODTP PMR is an opportunity to review the current program arrangements to ensure that Australians who have an opioid dependency continue to have access to medicines to help treat their opioid dependence. The ODTP PMR also examines the important issues of affordability of ODTP medicines, equity of access, and the future delivery of opioid dependence treatment.

The ODTP PMR is being carried out under the Australian Government's post-market monitoring program, which aims to ensure the continued safe, cost-effective, and quality use of medicines listed on the PBS.

1.3. Term of Reference 1: Key Findings

TOR 1: Describe and compare essential elements of models of service delivery for ODT in Australia (and internationally) including best practice guidelines and current models (including models developed in response to the COVID-19 pandemic) that support timely access to ODT medicines through both pharmacy and non-pharmacy settings*

***Non-pharmacy settings include a range of service settings where ODT medicines are delivered in Australia including, but not limited to, correctional facilities, hospitals, public and private clinics, Aboriginal Community Controlled Health Organisations (ACCHOs), general practices and specialist clinics.**

On a snapshot day in 2021, 47,563 people in Australia (excluding data for Queensland) were receiving treatment for their opioid dependence.¹ Most people received methadone (58%), the median age was 44 years and over two-thirds were male. It is estimated that most consumers were unemployed and lived in a major city, approximately 8% were homeless and an estimated 71% had been incarcerated previously.²

MedicineInsight data indicates ODT medicines were mostly prescribed by a private health practitioner with approximately 10% of prescribers responsible for 80% of the prescribing of ODT medicines. ODT medicines were mainly dispensed in pharmacies (around 68%). Prior to the COVID-19 pandemic, 32% of people had received takeaway doses, which increased to 47% during the pandemic.² However, access to takeaway doses may have since reduced in some jurisdictions, e.g. in NSW the amendment to policy guidance that allowed for consideration of higher numbers of takeaway doses during the COVID-19 pandemic was rolled-back to pre-pandemic ODT policies.³

Examination of treatment guidelines and current models of ODT service delivery demonstrate significant variability in how ODT has been implemented across different jurisdictions. While a direct comparison of individual features is challenging, a range of elements across both international and domestic ODT service delivery models were identified as being essential for improved ODT service delivery (refer Section 2.6). These findings are also consistent with the essential elements raised by stakeholders.

Affordability for people accessing ODT programs, especially ODT medicines, was identified as a key issue throughout the Review. Most consumers are charged private, unregulated fees particularly when accessing ODT medicines through community pharmacies. Approaches to address the affordability of ODT for consumers across jurisdictional ODT programs are

variable. While some jurisdictions, such as ACT, NSW and Tasmania, provide a subsidy or targeted incentives for community pharmacy participation in ODT programs, most other jurisdictions have not adopted this approach. The ACT ODT program has a framework in place that sets a cap on the amount that pharmacies can charge through private fees thereby ensuring consistent (and capped) fees for consumers. In some jurisdictions, such as Victoria, fees associated with the dispensing of ODT medicines are only subsidised for priority population groups, such as young people or newly released prisoners. In most cases, dosing at public clinics, where available, is free but stakeholder input to the review suggests places are limited.

In addition, the Review found that the continued growth in the demand for access to ODT is constrained by a reliance on public clinics to assist with the initiation of pharmacotherapy, affordability of treatment, workforce challenges, access to specialist review, and prescriber caps in many jurisdictions compared with other countries with less rigid supervision and prescriber restrictions.

The Review also found that ODT consumer access to equitable and affordable medicines for the treatment of opioid dependence could be improved to align with other medicines for chronic conditions listed on the PBS, including the provision for consumers to be able to access the Safety Net threshold for their ODT medicines.

The literature review found that community pharmacy dosing is considered appropriate for: consumers already stabilised on treatment, consumers who do not require the high levels of supervision and monitoring provided by private or public ODT clinics, or where clinic dosing is unavailable (e.g., consumers are unable to geographically access clinics due to mobility or transport issues).

Although research evidence suggests long-acting injectable buprenorphine (LAIB) is an attractive cost-saving option for some consumers due to reduced dosing fees, it is important to note that many people who are opioid dependent would not choose LAIB. It is noteworthy that a significant proportion of consumers have been on methadone treatment for extended periods (decades in some cases). The importance of consumer choice in treatment formulation, and potential erosion of this choice, is a recurring concern reported across LAIB studies.

The Review also found that ODT medicines, while important, are but one element of ODT. Holistic treatment for opioid dependence is a combination of ODT medication and psychosocial support which includes addressing the often-complex components of mental and physical health, as well as the social environment of a person with opioid dependence. The additional support required may vary by person and over time and should be adapted to the patient's changing needs.

1.4. Term of Reference 2: Key Findings

TOR 2: Examine the consumer experience, focussing on equity of access, geographical barriers to access, cultural safety, and affordability of ODT medicines across the different models of service delivery. This will include consideration of access to ODT for at risk population groups including people living in rural and remote areas, Aboriginal and Torres Strait Islander peoples and other populations who may have limited access to health care services, including ODT.

Though both domestic and international studies, as well as stakeholder input to the review, a range of factors were identified as facilitators and barriers to initiation and ongoing access to treatment for people with opioid dependence. Facilitators include shared decision making in treatment, flexibility of supervised dosing schedules and access to takeaways; and staff that act with discretion and treat consumers equitably. Barriers include stigma and discrimination (against both participants and the program itself), community and clinician belief that the program doesn't treat addiction, cost of private, unregulated fees associated with accessing ODT medicines and accompanying costs such as transport, time, rigidity of dosing hours and location, particularly when consumers need to travel interstate.

Prescribers, pharmacists, and other health care workers have identified a range of common facilitators to engage health care workers in providing ODT medicines. These include financial incentives, interdisciplinary support and collaboration, and additional dispensing pharmacies to share the ODT medicine dispensing workload. Common barriers to providing ODT reported by health care workers include lack of financial remuneration for the workload associated with supply of ODT medicines, and among prescribers and pharmacists a lack of education, knowledge, and training around drug dependence and ODT, as well as belief that ODT is not a valid treatment. These barriers contribute to ongoing stigma and discrimination experienced by consumers who access ODT.

Although experienced by many ODT consumers, people in rural areas in particular commonly reported that their access or retention to ODT was impeded by time consuming, costly, and restrictive daily medication collection; and the lack of privacy at dosing sites, leading to a fear of identification, stigma and discrimination. Accordingly, in addition to affordability, the most reported facilitators to treatment by ODT consumers in rural settings were access to takeaway doses to alleviate issues with travel and time constraints, and the establishment of separate dosing areas in pharmacies to offer privacy to ODT consumers.

In Australia, the affordability for consumers due to the high cost of private, unregulated fees associated with dispensing of ODT medicines was consistently identified as a barrier for both consumer access to treatment and for the provision of ODT through prescribers and pharmacists and was also the most common theme arising from stakeholder submissions to the Review. Addressing the matter of private fees associated with accessing ODT medicines should therefore be a priority in reformed ODT programs.

1.5. Terms of Reference 3: Key Findings

TOR 3: Explore the utilisation of PBS subsidised ODT medicines in Australia, including funding, benefits (health system and societal) and costs incurred in the supply and dispensing of ODTP medicines in pharmacy and non-pharmacy settings. This will include examination of current PBS restriction criteria and the impact of the listing of modified release buprenorphine injections on the PBS ODTP.

There is strong evidence for a wide range of health and social benefits for people with opioid dependence associated with ODT medicines. Being in a methadone/buprenorphine program reduces injecting risk behaviour, the risk of HIV/Hepatitis C virus acquisition, criminal activity and overdose deaths and increases quality of life including mental and physical health. In terms of societal costs, ODT is also highly cost-effective, and actually cost-saving when costs of crime are included.⁴ Addressing cost barriers to treatment entry and retention (through the PBS and with states and territories) has the potential to improve a wide range of health and other outcomes for people with opioid dependence.

By and large, there are few clear differences between methadone and sublingual buprenorphine +/- naloxone in terms of impacts on a wide range of primary and secondary outcomes (e.g., drug use, mental health); one clear exception identified through the literature review is that people are retained better on methadone than on sublingual buprenorphine +/- naloxone.

LAIB presents potential cost savings in terms of monthly dosing staff costs compared to other more frequent dosing treatments and consumer travel costs. Preliminary data indicates high retention rates associated with LAIB treatment, but this requires further study given the very small evidence base to date. A recent yet to be published study of LAIB found the adjusted mean days in treatment was longer for the LAIB group compared to the combined methadone and sublingual buprenorphine group as was the time to first stopping treatment.^{5,6} Further, not all consumers feel that LAIB is a suitable treatment choice for them personally.

Approximately half of all consumers on oral and sublingual ODT medicines receive any takeaway doses as estimated in the quantitative systematic review undertaken as part of the ODTP PMR, with slightly more consumers on sublingual buprenorphine +/- naloxone receiving takeaways compared to methadone.

There are limited clinical and research data, and no population-based data on individual-level ODT medicine doses and dosing patterns in Australia, a limitation of the current funding model particularly for methadone where one bottle can be shared among multiple patients. Such data, including daily dose variability and frequency of dispensing where possible, are very important to consider real-world patterns of ODT medicine use.

Commonwealth expenditure on the PBS ODTP has been steadily increasing over the years. In 5 years, expenditure has doubled from the 2016-17 financial year (\$51.5 million) to 2021-22 (\$108.6 million) and has grown by 20% from the 2020-21 financial year alone (\$90.3 million).

PBS ODTP expenditure growth was mostly steady before the introduction of LAIB in September 2019. In 2021-22 approximately half of all expenditure on the PBS ODTP was for

LAIB products. The listing of this new medicine was followed by a sharp increase in overall expenditure growth, as well as a decrease in growth across other ODT medicines. Further analysis of PBS ODTP expenditure data indicates that the acceleration of program expenditure growth is likely due to a growth in patient numbers due to LAIB facilitating the removal of both logistical and cost-based barriers to ODT medicines, as well as potentially due to improved retention rates. It is important to note the uptake of LAIB is also likely as a result of implementation of new state and territory ODT policies and guidelines, particularly in correctional facilities.

Costs borne by consumers, especially pharmacy-charged private dosing fees to consumers, create burdensome expenditures for consumers, especially those on fixed or limited incomes, thereby creating barriers to treatment entry and retention with flow-on impacts to social, mental and physical health more broadly. Dosing fees vary widely across states and territories because pharmacies set their own fees based on their own cost assessments. Costs to patients through private, unregulated fees typically range from \$5-8 per day⁷ (and can be higher). Input to the Review suggests remuneration for pharmacies (through alternative funding sources rather than being borne by patients) may help maintain or improve their involvement in ODT, and/or for dosing fees charged to consumers to be standardised, reduced, or eliminated.

Through analysis of Commonwealth expenditure data, approximately 80% of oral and sublingual PBS ODTP medicines are supplied through community pharmacies. In contrast, LAIB is supplied across a wider range of dosing points, with 29% going through community pharmacies. Notably, 18% of LAIB is supplied through correctional facilities, while only 3% of oral and sublingual PBS ODTP doses are supplied directly to these sites.

1.6. Term of Reference 4: Key Findings

TOR 4: Propose improved service delivery arrangements for access to ODT medicines, with an aim of identifying an ODTP that is equitable, timely, reliable, and affordable for consumers and stakeholders involved in the supply and delivery of ODT medicines and cost-effective for the Australian Government.

The essential elements of ODT service delivery outlined in Section 2.6 of the Report could serve as guiding principles for collaborative efforts by Commonwealth and jurisdictions toward improved ODT service delivery arrangements.

Addressing the affordability of access to ODT medicines for consumers due to the high cost of private, unregulated fees is a primary issue raised throughout the Review. This issue is closely intertwined with remuneration for pharmacists as one cannot be resolved without the other. In addition, solving for affordability of access to ODT medicines may also need to consider management and implications of daily dosing requirements, clinical aspects regarding models of service delivery and considerations regarding Commonwealth and jurisdictional responsibility for ODT programs. Close engagement between the Commonwealth and jurisdictions will likely be required to resolve ODT service delivery issues raised throughout the Review.

Currently dispensed ODT medicines do not attract PBS co-payments and consequently there is no annual limit of dispensing charges to the consumer. PBS listings of ODT medicines with PBS co-payments from consumers would mean these payments contribute to the Safety Net threshold as well as providing remuneration for PBS approved suppliers like pharmacists, like other medicines for chronic conditions on the PBS. This means pharmacists would not be able to (and would not need to) charge private fees on top of the PBS co-payment as with other medicines on the PBS. However, it is important to note that PBS remuneration for pharmacist dispensing activities associated with ODT medicines may need to consider whether separate fees are required for supervised dosing/dose management, and if so, consider options for how these could be implemented including whether they could be supported within the PBS framework.

Improved support for delivery of jurisdictional ODT programs through ACCHOs may assist in improving accessibility to culturally safe treatment for First Nations for people wishing to access ODT medicines through these settings. Under the PBS, the Closing the Gap (CTG) Co-payment measure aims to improve access to affordable PBS medicines for First Nations people living with, or at risk of, chronic disease. Similarly, the eligibility of the CTG program could be extended to ODT medicines listed on the PBS, ensuring access to culturally secure treatment from both ACCHOs and mainstream ODT dosing sites. Stakeholders suggest this could occur through specific programs to enhance uptake and provide support for ACCHOs. Possible programs could include specific prescriber training (and clinical staff such as Aboriginal Health Practitioner and ACCHO nurse), support for on-site dosing and funding for ODT medicine provision within ACCHOs, and prison in-reach services.

To provide guidance towards consistency in jurisdictional policy the Review highlighted the importance of updating the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014* (National Guidelines) to incorporate and revise clinical evidence regarding treatment pathways since the introduction of LAIB to the ODT medicines landscape. This could also include considerations regarding updated evidence with regards to improved flexibility of supervised dosing and reviewing prescriber accreditation requirements to encourage and support greater prescriber participation in ODT programs.

Aspects of the current ODT service delivery model can pose significant barriers to ongoing treatment for consumers, especially some more populations with specific needs. For example, in the context of daily dosing, consumers who live in regional, rural and remote areas and consumers with no permanent address face challenges in attending dosing points regularly. Changes to ODT policies by state and territory governments due to the COVID-19 pandemic demonstrate the adaptability of the service model to support unsupervised dosing, primarily through an increase in takeaway doses (despite these initiatives now being rolled back to pre-pandemic ODT policies in some jurisdictions).

Evidence suggests that a small number of prescribers are caring for a high concentration of ODT consumers. Stakeholder input indicated that typically, these prescribers are elderly and nearing retirement age which represents a significant risk to the program. This risk is also present for the Addiction Medicine Specialty where less than 20% of fellows are under the age of 50 years and more than half of them are older than 60 years. Many health professionals participate in prescribing ODT medicines under state and territory programs for only short

periods. There is a need to identify and respond to the reasons for this. It is critical to put in place strategies to increase retention of prescribers and broaden the base of health professionals involved in the delivery of ODT.

While system complexities, multiple stakeholders, and a lack of data availability across domains mean that the consequences of any changes to the current PBS listing of ODT medications are difficult to predict, stakeholders are of a view that a revised PBS listing arrangement for ODT medicines that provided equitable and affordable access would significantly improve patient health and societal outcomes. Regular reviews of consumer and provider responses should be monitored following any changes to the treatment listing.

The Review identified ongoing access to the breadth of ODT medicines is important to support improved patient outcomes.

1.6.1 Medicines with daily dosing requirements

For oral methadone and sublingual buprenorphine, more frequent dispensing may be required related to the often daily preparation and supervision of doses. Remuneration for these activities needs to be considered if access to ODT medicines is to be made affordable for consumers. It is also important to note supervised dosing policy for ODT medicines is determined by state and territory governments and is also a decision made by the patient's prescriber.

Stakeholders are of a view that one option to address community pharmacy remuneration for dispensing ODT medicines would be to enable pharmacies to claim the 7CPA staged supply payment for patients accessing OPD medicines or to use this program as a model for a similar program for ODT medicines. The Staged Supply Program is designed to assist patients who are at risk of drug dependency or who are otherwise unable to manage their medicines safely and the program rules state that pharmacies can claim payments for the provision of Staged Supply Services for up to 15 eligible patients.

1.6.2 Medicines with a prolonged duration

By nature of their longer duration, LAIB align more closely with the usual pattern of use of PBS medicines where the quantity dispensed is often a month's supply. Although LAIB may be considered as an attractive, and potentially cost-saving option for some consumers due to sometimes reduced private dosing fees, some consumers prefer sublingual buprenorphine or oral methadone and the importance of patient choice of medicine has been consistently noted in this review; there are no cost-effectiveness data comparing these treatments directly. It is suggested future research focus on comparing new and existing formulations in relation to essential elements of care, including modes of delivery and costs to both the consumer, treatment provider, and health system.

Stakeholders are of the view that on-site pharmacist administration of LAIB may develop further in future, noting pilot programs have commenced in some jurisdictional ODT programs. As treatment with LAIB evolves, additional consideration could be given to the option of remuneration for on-site pharmacist administration as this is not covered by current PBS arrangements.

Review outcomes

2.2. Outline of matters arising from the PMR

In addressing the ODTP PMR TOR and proposing improved service delivery arrangements for access to ODT medicines the PBAC may wish to consider the following summary of key matters arising from the PMR.

Research evidence, stakeholder input, consumer consultation and Reference Group members suggests solving for the core issue of affordability is the number one priority area for change that will result in the most positive impact on the lives of people in ODT. The review found there is a significant opportunity cost that could be improved through universal and equitable access to these medicines facilitated through the implementation of revised PBS listing arrangements for ODT medicines that address the high out of pocket costs currently paid by consumers through a PBS co-payment arrangement and PBS Safety-Net provisions.

The review also highlighted broader concerns about access for people participating in state and territory ODT programs, particularly the low number of prescribers engaging in ODT, that present a significant challenge and need a collaborative Commonwealth and state and territory government response. The review also highlighted the importance of updating the National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014 to reflect current clinical evidence and practice, including for LAIB which was PBS listed under the ODTP subsequent to the development of these guidelines.

In line with the PMR Framework, the PBAC may wish to respond to matters concerning the operation of the PBS and also provide interim advice to Government on broader matters impacting consumers access to ODT medicines.

As with any PBS medicines undergoing a change in the PBS listing, alteration to the circumstances under which medicines for opioid dependence are available on the PBS would need to consider the impact to the net cost to the PBS and importantly on consumer access. Given state and territory governments manage ODT services in accordance with relevant state and territory policy, program guidelines and drugs and poisons legislation, any changes to PBS listings or remuneration arrangements will need to consider ongoing consultation with state and territories to ensure there are no unintended consequences that may affect patient choice of treatment, the number of patients able to access treatment or potential impacts to the number of participating prescribers and pharmacies.

2.2.1 *Affordability*

Affordability is the primary concern raised throughout the review. Most consumers (80%) access their PBS listed oral or sublingual ODT medicines through community pharmacies where costs to consumers through private, unregulated fees typically range from \$5-8 per day (and can be higher). Conservatively, this means consumers may pay an estimated \$120 million per year in out-of-pocket costs for medicines to treat their opioid dependence. The consumer consultation report at Appendix 3 of full report presents a powerful insight into the lives of people accessing ODT medicines and the significant impact of the out of pocket costs.

The review found that mechanisms for access to ODT medicines that directly address the issue of private, unregulated patient fees is the primary priority for the sector. Improving

affordability and ensuring equitable access to ODT medicines has broader societal benefits. Research evidence demonstrates that participating in ODT programs increases quality of life including mental and physical health, and reduces injecting risk behaviour, the risk of HIV/Hepatitis C virus acquisition, criminal activity, and overdose deaths. In terms of societal costs, ODT is also highly cost-effective, and actually cost-saving when costs of crime are included.

Addressing cost barriers to treatment entry and retention (through the PBS and with state and territory governments) has the potential to significantly improve a wide range of health and other outcomes for people with opioid dependence. Throughout the review stakeholders, including consumers participating in ODT programs and Reference Group members strongly considered that the high financial cost of private fees was the most important barrier to treatment initiation, adherence and retention.

The review found, strongly supported by stakeholders and Reference Group members, that a response to address affordability and equity of access issues could be addressed through a revised S100 ODTP program that introduces a PBS co-payment and Safety Net provisions for consumers thereby ensuring that some of the most vulnerable people in the Australian community are receiving equitable and affordable access to medications that can save their lives.

2.2.2 Summary of other matters arising from the PMR

In conducting the PMR, the Department heard a broad range of concerns that are likely beyond the PBS alone to address (refer Section 2.6 of the Report). These often relate to policies and regulations for ODT programs that are managed at a state and territory government level and includes suggestions to review the processes and requirements for the approval of patients, prescribers and dosing sites, and supervised dosing arrangements as well as public treatment options for those who cannot manage treatment through private health services (i.e., through GP practice/community pharmacy).

The Commonwealth and state and territory governments would need to work in partnership to address the broad range of issues with current service delivery arrangements identified through the PMR.

In addition to considering how the affordability of treatment through community pharmacies is addressed and ensuring equity of access for population groups at greater risk, stakeholders have identified the lack of prescriber participation in ODT as an important issue and suggest improved support for GPs, ODT specialists, nurse practitioners and First Nations prescribers to encourage participation and reduce the burden on existing prescribers. The insufficient number of prescribers and voluntary participation of dosing sites results in long waiting lists and delays in commencing treatment which can mean consumers continue to use opioids while waiting for a place. The lack of consistency in ODT service delivery across jurisdictions also complicates access to ODT for consumers.

Relying entirely on the community pharmacy sector for dispensing ODT medicines also presents very significant service delivery issues. While many patients can access treatment as private patients, this is not an area of treatment which can be exclusively provided by the private sector (i.e., by GP practice/community pharmacy). Stakeholders suggest the issues of

equity of access and affordability could be addressed to a large extent through a revised PBS listing. In addition, to ensure patients with specific needs for whom GP charges and PBS co-payments may still put treatment out of reach, the review highlights the need for treatment to be available in a range of settings including the need for an ongoing state and territory public treatment option. The review notes that this includes supporting First Nations people to access ODT services through their preferred setting, including through ACCHOs, in a culturally safe manner. Research evidence and stakeholders also indicate that supporting transitions to and from correctional facilities and between other settings is an important aspect of improved ODT service delivery, particularly for First Nations people who are greatly overrepresented in custodial settings.

Stakeholder views also suggested the focus on ODT services as simply relating to medication access is a narrow and a suboptimal conceptualisation of health care for many people with opioid dependence. The review also raised the importance of coordinated social, mental and other health services being made available as options to support best possible outcomes beyond ODT medicines alone. The review found that while moving access to ODT medicines into primary care increases accessibility and coverage of treatment, a stepped care approach to opioid dependence treatment delivery should continue to be provided. That is, using less restrictive treatment approaches for those with low severity dependence and more intensive treatment options reserved for people initiating treatment and/or people more severe and complex health and social problems where necessary, while maintaining patient autonomy and appropriate clinical care.

2.3. Review outcomes for PBAC consideration

2.3.1 *Solving for affordability and equity of access*

Opioid dependence has been characterised as a chronic, relapsing condition with periods of active use, abstinence, and relapse which can occur over many years. As noted in the National Guidelines, the chronic relapsing nature of drug dependence links opioid dependence with other chronic medical conditions such as asthma, hypertension and diabetes. Stakeholders consider that, given ODT medicines provide treatment for the chronic condition of opioid dependence, they should therefore be provided at the same or similar costs to the consumer as other PBS medicines for other chronic conditions.

Research evidence and the stakeholder consensus response to the primary issue of affordability is for consumers accessing ODT medicines on the PBS to have equitable access to the PBS co-payment and PBS Safety Net, as they would for any other PBS listed medicine, as well as remuneration for community pharmacies which would replace all private, unregulated dispensing and dosing fees. This would allow greater flexibility for variable dosing arrangements and provide national consistency and universal access through the PBS to these medicines for patients who dose at community pharmacies regardless of jurisdiction, type and formulation of drug, or supervision requirements.

The review acknowledges the unique nature of methadone and sublingual buprenorphine medicines due to their more frequent (often daily) dosing requirements which a) often does not align with the usual pattern of use of other S85 PBS medicines where people are dispensed a full script quantity to take home and b) require more frequent activities to be performed by the pharmacist associated with the often-daily preparation, dispensing and supervision of doses. However, stakeholder input to the PMR also notes that it is not unusual for medicines with specific dosing and dispensing requirements to be listed on the PBS under S100 programs that accommodate alternative supply arrangements such as the Highly Specialised Drugs (HSD) or Efficient Funding of Chemotherapy (EFC) Programs.

This suggests there is a need to consider how ODT medicines can be listed differently on the PBS to align it more closely with some elements of PBS practice (i.e. PBS co-payment and Safety Net provisions) while at the same time acknowledging the features that are unique and may require an exception to the usual operation of the PBS. These include elements such as more frequent dispensing requirements and the need for access to ODT medicines from a range of settings, not just community pharmacy.

Therefore, in order to solve for the primary issue of affordability in a nationally consistent manner, an option before the PBAC is to consider revised listings of ODT medicines through the PBS under a revised S100 program to accommodate the unique features of most ODT medicines.

It is important to keep in mind that regardless of how ODT medicines might be listed on the PBS, jurisdictions operate and manage the broader aspects of ODT programs including approvals, eligibility, accreditation and supervised dosing requirements as well as regulation of controlled substances which occur independent of the Commonwealth. In exploring an S100 model, it will be important this is done in consultation and collaboration with jurisdictions to ensure the S100 model alignment with their policy and regulations. This means

the Commonwealth and state and territory governments will need to work collaboratively to solve for the issues of affordability as well as equity of access.

While the majority of ODT medicines supplies occur through community pharmacies, access to ODT medicines also occurs through a range of other settings including alcohol and drug treatment centres, correctional facilities and medical centres. The Department acknowledges the importance of ongoing engagement with state and territory governments to ensure continued patient access to ODT medicines provided outside of PBS approved suppliers, for example to correctional facilities and that an option is that this could continue to be supported under a revised S100 model.

The PBAC may wish to respond to the issues of affordability that could be solved through a PBS S100 arrangement for all ODT medicines (methadone, buprenorphine tablets and injections, buprenorphine with naloxone film) that provides affordable and equitable access to ODT medicines in a nationally consistent manner in line with the following principles:

- **Acknowledges the unique dosing frequency requirements of ODT medicines**
- **Patients no longer pay unregulated private fees to access medicines for ODT**
- **Patients instead pay a PBS contribution amount that counts towards their Safety Net threshold when accessing treatment from a community pharmacy**
- **Aligns with usual aspects of the PBS such that pharmacists dispense a prescription quantity and receive remuneration for supply and managing in-pharmacy and take-away dosing**
- **Similar to other PBS medicines, pharmacists cannot seek additional payment from patients (other than PBS-related e.g. co-payment)**
- **Considers improved access for First Nations people through expansion of the Closing the Gap (CTG) program**
- **Considers continued support for ODT medicines that are supplied through non-pharmacy settings such as correctional facilities**
- **Acknowledges the importance of ongoing engagement with state and territory governments.**

2.4. Other advice the PBAC may wish to consider providing to Government

In addition to the primary issue of affordability (and equity of access) discussed above, the review highlights additional areas of improvement across ODT service delivery more broadly. The PBAC may also wish to consider providing advice to Government on these matters.

2.4.1 *Issues arising from the PMR relating to state and territory policy*

In addition to changes to the PBS to better support affordable and equitable access to ODT medicines, research evidence and stakeholder input are of the view improvements should be made in program delivery aspects that are managed by state and territory governments i.e.:

- changing policy to allow for greater access to and more flexible unsupervised dosing for stable consumers
- changing policy to support consistent ODT program rules across states and territories while maintaining and/or improving autonomy and equity of access for consumers
- loosening of accreditation requirements for prescribers and increasing support for the prescriber workforce more broadly (e.g. to encourage the participation of GPs/nurse practitioners/nurses) with more proactive triage of initiating/complex vs stable consumers, case management support and assistance with facilitating referral pathways for social/mental health workers and other support services (e.g., housing)
- encourage participation of community pharmacies in ODT programs
- investment in ongoing jurisdictional treatment options (e.g. public clinics), to provide additional choices for patients, particularly those initiating treatment and/or patients with more specific and complex needs, who may benefit from jurisdictional support
- more effective care coordination and management of continuity of access to ODT medicines for patients when transferring from custody to community settings, when travelling interstate and between care settings (i.e., hospital and community)
- improved access to culturally safe ODT for First Nations people through ACCHOs, including within custodial settings
- improved ODT data collection – i.e., improved reporting and categorisations of medicines for the National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection.

Stakeholders acknowledge solving for these matters will likely require collaborative engagement across different levels of government and have provided their views on possible solutions presented within the report to inform future discussions. Holistic reform of ODT will require the Commonwealth and state and territory governments to work together on strategies to best support people with opioid dependence to access equitable and affordable treatment services when required, of which ODT medicines are an important, but not necessarily the sole, element.

The PBAC may wish to respond to matters relating to the varying nature and models of service delivery used to provide ODT, jurisdictional dosing policies and access to treatment through jurisdictional public treatment options with advice to Government to progress discussions with state and territory governments.

2.4.2 Update of opioid dependence treatment guidelines

There is no formal partnership agreement between the Commonwealth and jurisdictions for opioid dependence treatment. Each state and territory government manages individual treatment programs which are reflected in jurisdictional clinical and policy guidance documents. Complimentary to jurisdictional regulatory, policy and governance frameworks for opioid dependence treatment are national guidelines intended to assist decision makers across various Australian jurisdictions in establishing a consistent framework for opioid dependence treatment.

Through the PMR, stakeholders and members of the review Reference Group have emphasised the importance of updating these guidelines to reflect current treatment pathways, standards, and practice. Published in 2014, there is a significant gap in the National Guidelines as they do not include clinical guidance for LAIB. During the COVID-19 pandemic changes were made to the delivery of ODT programs at a jurisdictional level, particularly regarding takeaways and as such this section of the guidelines warrants specific review.

The PBAC may wish to endorse an update of the overarching National Guidelines to reflect current evidence regarding pathways of care and service delivery of ODT, including for LAIB.

2.4.3 Prescriber workforce issues

Throughout the review research evidence, stakeholder input and Reference Group members have identified that there is a shortage of prescribers who participate in ODT programs, particularly in regional and remote areas. This negatively impacts access to ODT medicines, additional support and further contributes to stigmatisation of people with opioid dependence, and the financial impacts of accessing ODT for clients. The review identified recruitment and retention of GPs as a primary barrier to access and suggests there needs to be innovative solutions that include greater use of Medicare Benefits Schedule (MBS) telehealth items, case management support, assessable and ongoing undergraduate and postgraduate training (for all health professionals) as well as jurisdictional level solutions.

Stakeholders are of a view that support to encourage increased participation and retention of addiction specialists, GPs and in particular nurse practitioners is critical to ODT at both a Commonwealth and jurisdictional level and could consider funding and/or incentive payments that acknowledge the case complexity of many ODT patients, with one option possibly being MBS items that give specific consideration to supporting ODT patients and their prescribers.

Currently, to support services to patients, there are several service items and payment available under the MBS which include time-tiered general attendance items with general practitioners, addiction medicine specialist attendance items (for assessment and treatment) as well as chronic disease management and mental health items. Noting the Strengthening Medicare Taskforce currently underway, consideration of matters raised in relation to the MBS was not considered in detail as part of the TOR for this review.

The PBAC may wish to respond to prescriber workforce issues with advice for Government consideration and progression of discussions with state and territory governments on options for ensuring people have equitable and affordable access to treatment programs for opioid dependence.

2.4.4 Access to LAIB administration in community pharmacies

Evidence and stakeholder input to the review suggests that the use of LAIB is anticipated to continue to grow and for some patients the injections have the potential benefits of eliminating the need for daily supervised and/or takeaway dosing with methadone or sublingual buprenorphine (where this is their choice and preferred treatment) and improving accessibility of treatment, particularly where clinic dosing is unavailable (e.g., consumers are unable to geographically access clinics due to mobility or transport).

Separate to the PBS, the PBAC may wish to consider a mechanism to support remuneration for on-site pharmacist administration of LAIB an option to further improve the accessibility of treatment. It may also ease pressure on the prescriber workforce and on patients that find it difficult to find an appointment with a GP or who find it difficult to regularly visit a GP practice for administration of the injection.

The PBAC may wish to endorse an option for consideration by Government for community pharmacies to administer LAIB injections.

2.4.5 Access to ODT for First Nations People

The Review highlighted specific patient populations such as First Nations people and people either within or recently released from custodial settings (in which First Nations people are greatly overrepresented) experience disproportionate barriers to access and will need specific consideration in any service delivery arrangements for access to ODT medicines.

Approaches raised by stakeholders during the review include:

1. improved access to culturally safe care through ACCHOs and other settings (including correctional facilities)
2. strategies to increase the First Nations workforce in the delivery of ODT (e.g. Aboriginal Health Practitioners and ACCHO nurses)
3. extension of the PBS CTG program to include PBS listed medicines for opioid dependence treatment.

The PBAC may wish to respond to matters relating to access to ODT medicines and services for First Nations and other populations with specific needs progressed with advice for Government consideration and discussion with state and territory governments.

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