



BETTER ACCESS
— AUSTRALIA —

**PRE-BUDGET SUBMISSION
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BETTER ACCESS AUSTRALIA

Better Access Australia contributes to the public policy debate in Australia through research, publications, public discussion and advocacy.

We recognise that Australia's health, disability and social services systems (the social sector) work best when all parties, public, private and not-for-profit, engage in good faith with the existing systems and processes, and that each party's contribution is recognised and valued. We partner with consumers, peak bodies, industry, and academia to identify and promote better outcomes in Australia's social sector.

We believe the foundations of our social sector are solid and deliver reasonable quality services to most Australians. However, significant challenges and opportunities remain. Australia's governments, industry and not-for-profit sectors need quality advice and strong advocacy if they are to be responsive and agile in addressing the policy implementation reforms necessary to keep pace or surpass international best practice by 2030.

As we enter the third year of Australia's response to the COVID-19 pandemic, the community has increasingly relied upon our health and social services sector and existing and new challenges have been brought to the fore. Systemic issues such as the divide between Commonwealth and state/territory funding and management responsibilities, integration between mainstream health and other care sectors and potential trade-offs between health outcomes and the economy are all critical and current debates.

These challenges, however, also present opportunities to test and confirm our deeply held goals as a society, explore innovative solutions, consider best practice and learn from lessons from around the globe to build a better social sector.

WHAT WE ARE ASKING FOR IN THE 2022-23 BUDGET

Better Access Australia is calling on the federal government to **#MINDTHEGAP** in affordability in healthcare as part of its 2022-23 Budget: the gap in the affordability of time to access, and the affordability of the increasing financial costs for patients seeking access to healthcare in Australia.

Unfortunately, there are increasingly more gaps in costs for patients both financially and in time to access in the system. Neither of which they can afford.

Building on the findings of the Government-led [parliamentary inquiry into access to novel technologies](#), and its [previous election commitments](#) on affordability of healthcare, such as [reducing the safety net threshold for the Pharmaceutical Benefits Scheme \(PBS\)](#), Better Access Australia is seeking as a starting point six reforms as part of the forthcoming budget process.

These reforms reflect areas of high need and where Australia has fallen woefully behind global standards let alone global better practice in its administration of our healthcare system.



- 1. Protect the 300,000 babies born each year by making newborn bloodspot screening a national program by the end of 2022 and increasing the number of diseases screened for based on existing international evidence and prevalence of rare diseases in Australia by 1 July 2023.**
- 2. Make daily medicine access affordable once again by reducing the general Pharmaceutical Benefits Scheme (PBS) co-payment from \$42.50 to \$20 per script for those earning less than \$136,000 and freeze co-payment and safety net thresholds for the next five years.**
- 3. End the government mandated discrimination against those with a recognised disability by making all medicines on the PBS that treat opioid dependence subject to the PBS co-payment and safety net provisions, as provided for every other medicine on the PBS.**
- 4. End the average wait of 820 days for medicine access in Australia by establishing a government policy of 100 days from TGA approval to subsidised access for medicines and medical devices irrespective of the program that access is provided through with implementation no later than 1 July 2025.**
- 5. End the costs to patients and costs to government of unnecessary annual referrals to specialists for long-term treatment of a chronic disease.**
- 6. Change the emphasis of private health reform to better capture the consumer interest in health coverage expectations rather than an exclusive debate between government and insurers on cost of devices and annual price increases.**

These proposals are a combination of targeted reforms for some of the most vulnerable in our community as well as system-wide reforms to benefit the entire population.

A one-page summary of these measures and why they are needed are provided as well as indicative costing considerations to be taken into account.

We welcome the opportunity to discuss these matters in detail with government, the parliament, health providers and other stakeholders in our health system – most importantly patients and the community.



INTRODUCE A NATIONAL AND UPDATED NEWBORN SCREENING PROGRAM

As part of the 2022-23 Budget, Better Access Australia is asking the Government to:

1. Establish newborn bloodspot screening as a federal program by the end of 2022 based on the National Immunisation Program model for the split of funding and service delivery between federal and state governments.
2. Review the evidence for the 80 diseases currently screened for in California with a rollout of the approved new cohort of diseases screened for by 1 July 2023;
 - a. Review panel to comprise a broad spectrum of clinicians, technicians, families and carers utilising the MBS Taskforce reviews in 2015-2019 as the model for collation of evidence, consultation and quick implementation;
3. Bi-annual review of emerging technology for adding additional diseases to the newborn screening program – self-initiated by the department and not dependent on families conducting research and producing complex applications.

Why is this reform needed?

- Time to diagnosis matters, and without diagnosis there is no treatment.
- Around 300 babies are diagnosed with a rare disease in Australia each year, but another 300 babies are having their diagnosis missed despite the test being available today.
- Australia only screens nationally for 25 rare diseases, compared to California that screens for 80, New York 66, and Europe 50.
- Australia hasn't added a national newborn bloodspot screening test since the 1980s despite having treatments for rare diseases available on the Life Saving Drugs Program, Pharmaceutical Benefits Scheme, or via the National Blood Authority.
- Multiple processes over the decades have failed families and their babies, demanding families do all the heavy lifting including find the time, money, specialist clinicians and university experts to produce complex medical and economic applications. These processes have no time limits and families can wait years for a review of their application.
 - The unfairness of this approach is highlighted by the current PBS and MBS processes where pharmaceutical; pathology; and device companies invest around \$500,000 to produce a submission complaint with the complex guidelines for assessment.
- Even where an application makes it through the process such as the test for Spinal Muscular Atrophy there is no commitment to funding – leaving it to a state-by-state decision.
- This is why a baby born in NSW will be diagnosed with SMA and receive treatment before symptoms develop, but a baby in VIC will suffer irreversible damage waiting for symptoms to be diagnosed. Babies in TAS and NT are beholden to the choices of other states for screening.
- But for babies with diseases not currently screened for, the delay in diagnosis is around 90 days after onset of symptoms if they are born in an urban area, but over 180 days if they are born in rural and remote Australia. For many this is too late, and the disease becomes fatal.
- Screening should not be limited to availability of subsidised treatments. Without diagnosis there is also no access to clinical trials and disability support services.
- The federal government is funding \$100 per PCR test. For \$10-\$20 per baby Australia could be giving all 300,000 babies the best start in life with early detection and treatment of life-threatening diseases.



MAKING PBS MEDICINES AFFORDABLE FOR FAMILIES

As part of the 2022-23 Budget, Better Access Australia is asking the Government to:

1. Reduce the PBS general co-payment from \$42.50 to \$20.00 per script for individuals and families earning less than the Family Tax Benefit A income threshold for three children (currently \$136,000); and
2. Freeze indexation on the PBS co-payments and safety nets for a period of five years.

Why is this reform needed?

- Australian patients pay one of the highest co-payments for subsidised medicines in the world, fourth in the OECD after the US, Canada and Switzerland.
- Nearly 1 in 3 of the 300M scripts dispensed on the PBS are fully paid for by consumers.ⁱ
- On 1 January 2022 the Government increased the price a family of two adults and two children with a combined income over \$61,100 p.a. pay for their medicines by \$1.20 to \$42.50 per script.ⁱⁱ
- Their PBS safety net was also raised to \$1542.10, returning to pre-2019 election commitment thresholds (\$1550.70).ⁱⁱⁱ
- The Government has also increased the under co-payment costs of thousands of brands of medicines for these families by at least 50 cents per script.^{iv}
- 40.4% of people aged between 15-44 suffer from chronic conditions, with 11.6% suffering multimorbidity. Within the lowest social economic areas, 49.6% have at least one chronic condition, with 24.2% suffering from multiple morbidities.^v
- This means individuals, couples and especially families are often managing multiple chronic diseases and unable to meet the daily costs of medicines. Safety nets take too long to kick in and so they are going without treatment.
- This is a cost to patients and a cost to the health system with complications arising from poorly managed disease. Medicine compliance is good for patients and good for the health system.
- Introducing a new tier of co-payment aligned to the financial thresholds for a family of two adults and three children under Family Tax Benefit A ([currently ~\\$136,000](#)) would make medicines affordable for those struggling to meet the increasing out of pocket costs for healthcare in Australia, whilst also maintaining the higher co-payment for those most able to pay.
- The dramatic increase in both the concessional and general co-payments (and general safety net) reflect the impact of the significantly higher than forecast inflation when the Government's *2019 Cheaper Medicines* election commitment was introduced in 2020.
- A freeze on indexation for five (5) years would afford allow all families and individuals irrespective some protection from the inflationary period Australia is entering, whilst wage growth is stagnating.
- Time-limiting the freeze allows for Government to re-evaluate the measure once the future of the Australian economy is clearer.



PBS MEDICINES ACCESSED VIA THE OPIOID DEPENDENCY TREATMENT PROGRAM PROTECTED BY THE PBS CO-PAYMENT AND SAFETY NET PROVISIONS

As part of the 2022-23 Budget, Better Access Australia is asking the Government to:

1. Stop demanding pharmacists charge uncapped private fees to dispense ODTP medicines on the PBS and instead provide ODTP patient's access to the PBS co-payments and safety net system all other patients and medicines are protected by;
2. Make these medicines dual listed under s85/s100 so that pharmacies and wholesalers are appropriately remunerated for dispensing these medicines in the community; and
3. Consistent with the Government's longstanding ongoing funding for Staged Supply and Dose Administration aids for drugs of dependence and high adverse event risk, amend the rules of these programs to include the supply of ODTP medicines.

Why is this reform needed?

- Over 70% of the 53,000 patients accessing ODT medicines do so via community pharmacy.
- Unlike any other medicines on the PBS, patients accessing an opioid-dependence treatment via the PBS are charged uncapped out of pocket fees to access their medicine and the Government does not allow these charges to count towards their PBS safety net.
- These uncapped private fees are charged because the government does not pay the dispensing fees they pay for any other medicine dispensed in a community pharmacy.
- ODT patients are also denied access to Government funded Staged Supply and Dose Administration Programs specifically introduced to reduce risk of addiction or adverse events. Therefore, pharmacists directly charge the patients for the staged supply of their medicines.
- Ironically, patients access PBS co-payments, safety nets and staged supply programs if they continue to access drugs of addiction on the PBS, but not to treat the addiction itself.
- Where a patient is prescribed long-acting weekly and monthly injectables out of pocket fees of between \$20 and \$50 are being charged by GPs or pharmacists. Patients prescribed daily-dose methadone are charged between \$5 and \$10 per day to access their medication.
- This makes these medicines unaffordable to many who qualify for access.
- Multiple coronial inquiries and the PBAC itself have found that these private out of pocket costs are a barrier to access. With only 1 in 3 patients currently accessing treatment and 3 patients dying of this disease everyday this is not acceptable and inconsistent with the social compact of the PBS.
- Opioid addiction is recognised as a disability under the federal Anti-Discrimination Act. Only charging uncapped fees and removing safety-net access to one group of patients is discriminatory and inconsistent with the Government's human rights obligations.
- Further, the lawfulness of the Instrument establishing the ODTP has been questioned by the Australian Parliament's Senate Standing Committee for the Scrutiny of Delegated Legislation.^{vi}



SUBSIDISED ACCESS TO MEDICINES AND MEDICAL DEVICES IN 100 DAYS

As part of the 2022-23 Budget, Better Access Australia is asking the Government to:

1. Establish a target of 100 days from Therapeutic Goods Administration registration of a medicine, biologic, test or device to federal government subsidy on the relevant program or schedule by 1 July 2025;
2. Use the \$20M per week in new funding over five years already set aside by the Government to implement this on the Pharmaceutical Benefits Scheme (PBS) and Life Saving Drugs Program (LSDP) by 1 January 2024; and
3. Ensure the consultation process for implementing the new and listing processes of all affected programs, including the PBS, LSDP, Medical Benefits Scheme (MBS), National Diabetes Services Scheme (NDSS) and Blood Authority include consumers and clinicians and is not just limited to government and industry representatives.

Why is this reform needed?

- The health subsidy system is every consumer's chance for good health, and Australia's chance for a more productive economy.
- Most new medicines and technologies are financially outside the reach of most Australians who rely on government subsidies to determine their quality of life or duration of life.
- Australian patients are waiting an average of 820 days for a medicine to be subsidised after it has been found to be safe and efficacious by the TGA.^{vii}
- Likewise, diagnostics on the MBS are slow and new products on the NDSS have no consistent avenue for consideration. Patients simply miss out on technologies such as cancer screening, and contemporary continuous glucose monitoring which are standard in other countries. With the lifespan of new devices significantly shorter than medicines and diagnostic, this delay in access is potentially even more critical.
- This situation compares with the likes of France, Germany, Japan and others where access is prioritised and can be as quick as 10-60 days based on ongoing evaluation and pricing changes based on the performance of the technology.
- It is notable that in the COVID-19 health crisis the Australian government did not put any of the vaccines, tests or tele-health innovations it subsidised through its HTA committees. Government knew the community and economy could not wait 820 days for access via these committees. If the Government doesn't trust the HTA system in a crisis - why should the community.
- Australia does not have Key Performance Indicators (KPI) for its access programs, in contrast to the KPIs and monitoring it has for public and private hospital access.
- A National Therapeutics Policy setting subsidised access targets of 100 days after ARTG listing:
 - Would improve treatment outcomes for patients
 - Would drive innovation in processes and ongoing evaluation of listings encouraging parallel processing and greater use of clinical trials in Australia
 - Would foster novel contracting and improved post market surveillance consistent with the increasing focus of this work via the TGA
 - Supports pay for performance in health technology.



REDUCE COSTS TO THE SYSTEM OF ONGOING ACCESS TO SPECIALISTS

As part of the 2022-23 Budget, Better Access Australia is asking the Government to:

1. Set the expiration date of specialist referrals for chronic conditions at 10 years;
2. Remove access to the initiating consultation for the same patient with the same specialist within that 10-year period; and
3. Where ongoing access to a specialist is due to the prescribing rules set by the Pharmaceutical Benefits Scheme (PBS) ensure these criteria are reviewed every two years for clinical relevance.

Why is this reform needed?

- Attendance at a specialist is costly for the system and costly for the patient.
- Out of pocket costs for private specialist attendance can be considerable.
- Alternatively accessing a specialist in the public health system usually has a significant waiting time leading to deteriorating health outcomes for patients.
- The MBS does not require a referral to a specialist be limited to 12 months where treatment needs to be ongoing, e.g. chronic diseases, or where PBS medicines can only be provided through a script written by a specialist. ^{viii}
- Despite this the default position of most specialists and/or GPs is to limit a referral to 12 months.
- This reduces access to GPs for other patients and allows for the billing of an 'initiating consultation' every 12 months if it can be demonstrated a 'new history' was taken after a gap of around 9 months attendance.
- These all result in higher costs for patients and higher costs for government particularly with an increasing burden of chronic disease.
 - 40.4% of people aged between 15-44 suffer from chronic conditions, with 11.6% suffering multimorbidity.
 - 60% of people aged between 45-64 suffer from chronic conditions, with 30.1% suffering multimorbidity.
 - 79.9% of people aged over 65% suffer from chronic conditions, with 50.5% suffering multimorbidity. ^{ix}
- In combination with the increasing need for PBS medicines to be prescribed by a specialist even in chronic disease, this can unnecessarily add to costs for the system and costs for patients.
 - Specialist prescribing should be clinically based, not used as a utilisation control for the medicine.
- Reviewing PBS restrictions for chronic disease listings every two years could reduce the burden on patients and the health system.
- Introducing a default 10-year expiry for specialist referrals for:
 - Ongoing established chronic disease management
 - Ongoing access to a PBS subsidised medicine.
- Limits for acute treatments, new referrals or changes in a patient's condition would allow for overriding of this default position.



THE LINKS BETWEEN THE PUBLIC HEALTH AND PRIVATE HEALTH SYSTEMS

As part of the 2022-23 Budget, Better Access Australia is asking the Government to:

1. Conduct a consumer-needs analysis of private health insurance that sets aside current regulatory limitations as the basis for the consultation to facilitate co-design of a better integrated public and private health system for consumers and the affordability of healthcare for the community, insurers and governments

Why is this reform needed?

- COVID-19 has shown that Australia's health system relies heavily on the use of the private health system as well as the public health system to ensure timely and affordable access to treatment when patients need it.
- Over 13.6M Australians have private health insurance (PHI).
- Australia's PHI system is based on an increasingly outdated model of access that assumes the majority of private healthcare occurs in the hospital setting.
- Over the past two decades governments at all levels have sought to dramatically change healthcare practice by incentivising moving treatment of chronic and acute conditions into the primary care setting where it is more affordable for the system.
- However, with PHI not extending to primary care out-of-pocket costs outside of the hospital setting, the gap between what the self-insured are covered for, versus the out-of-pocket health costs they are continually having to meet is increasing year upon year.
- PBS medicines increasingly demand attendance at specialists and not GPs for initiating and continuing prescriptions further adding to consumer out-of-pocket costs.
- With the abolition of the Net Medical Expenses Tax Offset, many families have been left increasingly out-of-pocket as costs in the primary healthcare setting grow. Many simply do not pursue treatment or join the long waiting list for outpatient services in the public health system.
- Meanwhile Government and the insurance sector are seeking to reduce consumer choice of technologies available through their private health insurance without proper consultation with consumers. Consumers pay for their private health, not the Government.
- The focus on the annual PHI percentage increase without a discussion on what consumers genuinely want from these products must end.
- With genetic therapies emerging, the PHI system 'car insurance model' is not good for patients or the industry.
- How can insurers invest in upfront high-cost treatments without longer term commitments from patients? Why can't products have longer term commitments from both parties?
- Why can't families who spend the significant portion of their health costs in the waiting rooms of GPs, private specialists and paying for additional diagnostics and medicines have an insurance product that genuinely covers their needs?
- Why is pet insurance more flexible in what it covers than human health insurance?
- Health insurance is not car insurance - it is an intrinsic and essential part of our health system and needs to be recognised as such.
- The time for a genuine discussion on the need to change what PHI covers to support the delivery of Australia's 'universal health system' is now.



COSTING CONSIDERATIONS

Newborn Screening

- Expand the current suite of diseases screened for consistently across Australia from 25 to around 50-75 by end of 2022.
- Around 95% families have their newborns currently screened.
- There were 294,369 live births in Australia in 2020 - 806 per day.¹
- Five laboratories deliver the screening services with NSW covering the ACT, SA covering the NT and VIC covering Tas.
- Each laboratory has existing standard or tandem mass spectrometry technology in place for currently screened for diseases. Those jurisdictions piloting screening for other diseases have additional equipment but with reduced automation and higher human intervention.
- Existing infrastructure of both people and technology means some new tests can be conducted using existing infrastructure, some can be made more efficient through modernisation reducing levels of human intervention and some will require the purchase of additional equipment.
- Any screening that identifies potential levels of markers present requiring further investigation are referred to a secondary genetic screening process. This is a separate process and part of broader genetic screening already funded.
- Estimated cost of around \$14M to \$20M over four years for the expansion of the program nationally from 25 to around 50 tests, including infrastructure and assays.
- A further \$20M over four years to transfer funding for the existing screening tests into the Australian Government.
- State and territory governments will incur cost for continuing laboratory staff and lab time, with possibly some increase in staffing required.
- Initial and bi-annual review processes costed on MBS taskforce model.
- Detailed assumptions underlying this estimate are available on the Better Access Australia website at [Newborn Screening — Better Access Australia](#).

Reducing cost of PBS medicines for families

- 15.5M of the subsidised scripts on the PBS in 2020-21 were dispensed to general patients.^x
- A portion of these scripts would be reduced by \$22.50 per script based on the new threshold.
- 93M scripts per annum are currently fully funded by general patients as they fall below the \$42.50 co-payment. A portion of these would now attract a partial subsidy from the Government.
- Freezing indexation on the concessional and general co-payments and the general safety net would need to be compared against current forward estimates and balanced against the higher than forecast increase for 2022.

Opioid Dependence Treatment Program

- Currently around 53,000 patients, with 12 scripts a year (~70% community pharmacy)
- New costs of payment of the dispensing fees (community pharmacy costs)
 - \$7.78 dispensing fee

¹ Australian Bureau of Statistics, [‘Statistics about births and fertility rates for Australia, states and territories, and sub-state regions – Reference period 2020’](#), Canberra 8 December 2021



- \$4.30 to \$10 in Administration Handling and Infrastructure Fee
- \$4.82 dangerous drug fee
- 7.52% wholesale mark up
- \$1.30 safety net fee
- New revenue from patient contributions of current co-payments of \$6.80 or \$42.50 per script.
- New costs assuming higher uptake of treatment due to improved affordability for currently untreated but some will be switching from other PBS medicines.
- Inclusion of ODT medicines in Staged Supply Programs – no additional cost if prioritised under existing programs.

ⁱ Australian Government Department of Health, [PBS Expenditure Report 2020-21](#), December 2021, Table 2a

ⁱⁱ [Pharmaceutical Benefits Scheme \(PBS\) | Fees & Patient Contributions](#)

ⁱⁱⁱ *Ibid*

^{iv} Australian Government Department of Health, [GBMA Strategic Agreement with Australian Government 2022-27](#), signed September 2021

^v Australian Institute of Health and Welfare, [Chronic conditions and multimorbidity - Australian Institute of Health and Welfare](#), September 2020

^{vi} [ODTP Senate Standing Committee on Delegated Legislation](#)

^{vii} Better Access Australia, [Submission to Inquiry into processes for Access to Novel Technologies](#), October 2020, Appendix one Analysis of PBAC submissions and their related outcomes & timelines, MAESTrO Database

^{viii} https://www.aapm.org.au/Portals/1/LiveArticles/530/AskMBS_Advisory_SCP_services_August%202020_FIN_AL.pdf?ver=2020-09-02-130119-507

^{ix} AIHW, [Chronic conditions and multimorbidity - Australian Institute of Health and Welfare \(aihw.gov.au\)](#), September 2020

^x Australian Government Department of Health, [PBS Expenditure Report 2020-21](#), December 2021