Attention Deficit Hyperactivity Disorder: Utilisation Analysis

Drug utilisation sub-committee (DUSC)

September 2023

Abstract

Purpose

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To review the utilisation of the Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (R/PBS) listed medicines used in the management of attention deficit hyperactivity disorder (ADHD). This includes a predicted versus actual analysis of the first 24 months of R/PBS listing of lisdexamfetamine extended use, to allow use in adults with ADHD persisting from childhood, even if diagnosed after 18 years of age. Lisdexamfetamine was first R/PBS-listed for this indication on 1 February 2021.

Date of listing on the PBS

- Dexamphetamine - 1 December 1973
- Methylphenidate immediate release (IR) - 1 August 2005
- Methylphenidate modified release (MR) (Concerta®) - 1 April 2007
- Methylphenidate modified release (MR) (Ritalin LA®) - 1 April 2008
- Atomoxetine - 1 July 2007 requiring authority approval. On 1 August 2014, the restriction was simplified and changed to streamlined authority
- Lisdexamfetamine - 1 September 2015 requiring authority approval
- Guanfacine – 1 September 2018 requiring streamlined authority approval

Subsidy of atomoxetine and guanfacine is limited to people diagnosed between the ages of 6 and 18 years of age inclusive.

Atomoxetine and guanfacine are subsidised for people unable to take dexamphetamine or methylphenidate due to specific circumstances set out in the PBS restriction. People need to have been diagnosed by a paediatrician or psychiatrist according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria.

Lisdexamfetamine and modified-release methylphenidate (Concerta®) are for people requiring coverage over 12 hours. A shorter modified-release methylphenidate (Ritalin LA®) is available for people requiring coverage over 8 hours.

To use modified-release methylphenidate, people need to have demonstrated a response to immediate-release methylphenidate with no emergence of adverse events.

Data Source / methodology

The analysis used data from the supplied prescriptions database maintained by the Department of Health and Aged Care, processed by Services Australia and Australian Bureau of Statistics (ABS) estimated residential population (ERP) at 31 December for the specific financial year.

Key Findings

Over the ten financial years period, 2013-14 to 2022-23:

- The rate of growth of prescriptions and people across all age groups and genders being treated with R/PBS medicines for ADHD has risen.
- The average annual growth rate of prescriptions since 2013-2014 is just under 18%. However, the growth rate has greatly accelerated since the 2019-20 financial year. The growth rate over the four financial years, 2019-20 to 2022-23, is just over 25%. This increase is due to an increased use of all ADHD medications with the highest increases found in the prescribing of guanfacine (which was PBS listed on 1 September 2018), and lisdexamfetamine (which had a restriction change allowing use in the >18 year old population without prior diagnosis on 1 February 2021).
- The growth in the number of prevalent people treated with R/PBS medicines for ADHD has risen at a similar rate to prescription growth, with an overall growth of 28% from 2021-22 to 2022-23. When this cohort is broken down into above 18 year old (>18 year old), and 18 and under year old (≤18 year old), population groups the growth rate was 40%, and 20% respectively.
- The medicine used by the most people, in terms of prevalence, is different for the two age groups. Since the February 2021 restriction change, lisdexamfetamine has become the most used medication for >18 year olds. Prior to the restriction change dexamfetamine was the most used medicine in this age group. In the ≤18 year old population, the modified-release formulation of methylphenidate (MPH-MR) has consistently been the highest used medication.
- For initiating people, more males than females were treated across all age groups apart from the 13-18 year old and over 18 year old female cohort (since the 2020-21 financial year), when their initiating rates overtook male initiating rates.
- In the 2022-23 financial year, 41% of initiating people over 18 years old were male and 59% were female.
- In the 2022-23 financial year, 48% of prevalent people over 18 years old were male and 52% were female. This was the first time an analyses undertaken by DUSC of ADHD medicine utilisation that female prevalent numbers have been higher than males.
- In the 2022-23 financial year, of all initiating people treated with R/PBS listed ADHD medicines:
    - children under 6 years old account for 4.1% of the treated population
    - children aged 6-12 years old account for 30.8% of the treated population
    - adolescents aged 13-18 years old account for 15.2% of the treated population
    - adults aged over 18 years old account for 49.9% of the treated population
        - In the 2019-20 financial year, prior to the lisdexamfetamine restriction change, this group accounted for 32.8% of all initiating people treated

- In the 2022-23 financial year, of all prevalent people treated with R/PBS listed ADHD medicines:
    - children under 6 years old account for 1.7% of the treated population
    - children aged 6-12 years old account for 32.7% of the treated population
    - adolescents aged 13-18 account for 21% of the treated population
    - adults aged over 18 years account for 44.6% of the treated population
        - In the 2019-20 financial year, prior to the lisdexamfetamine restriction change, this group accounted for 33.4% of all prevalent people treated

An analysis of medicine use in 2022-23 shows that:

- The majority of prescriptions were written by paediatricians or psychiatrists.
- The initial prescription of methylphenidate, lisdexamfetamine and dexamfetamine for the treatment of ADHD is generally restricted to specialists in most Australian states and territories.
- Rates of prescribing vary across states and territories. In the 2022-23 financial year, the rates of treatment in >6 year olds were highest in Tasmania (Tas) and Queensland (QLD) and lowest in the Northern Territory (NT), while rates in school-aged children (6-12 years old) were highest in Tas, and lowest in South Australia (SA). Rates of treatment for 13-18 year olds was highest in ACT and lowest in SA, while rates of treatment in adults were highest in Western Australia (WA) and the Australian Capital Territory (ACT), and lowest in Tas and the NT. The adult rates of prescribing were much higher in WA and the ACT compared to the other States and the NT.

Lisdexamfetamine:

- The restriction change of lisdexamfetamine in February 2021 has contributed towards an increase in the use of ADHD medicines.
- Prior to the restriction change, in the 2019-20 financial year 10,195 prevalent people >18 years old were treated with lisdexamfetamine.
- In the 2020-21 financial year, which included five months of the restriction change, 27,546 prevalent people >18 years old were treated with lisdexamfetamine.
- The 2021-22 financial year was the first full year to incorporate the restriction change.
- In this financial year, 59,308 prevalent people >18 years of age were treated with lisdexamfetamine.
- In the first year of the lisdexamfetamine restriction change, the actual scripts dispensed were [redacted] than the amount predicted. In the second year, the actual scripts dispensed were [redacted] the predicted amount.

<u>Clonidine</u>

This ADHD utilisation report examines the use of clonidine as a medication prescribed for ADHD. While definitive results are difficult to establish due to clonidine's unrestricted listing (i.e. the indication for which it is prescribed is not specified), it is estimated that clonidine is being used as an ADHD medication across all age groups. There is a high level of confidence that clonidine is being prescribed for ≤18 years old for ADHD, as this age group would not usually be prescribed clonidine for other diseases / disorders.

Purpose of analysis

To review the utilisation of R/PBS-listed medicines used in the management of attention deficit hyperactivity disorder (ADHD). This includes a predicted versus actual analysis of the first 24 months of R/PBS listing of lisdexamfetamine extended use, to allow use in adults with ADHD persisting from childhood, even if diagnosed after 18 years of age. Lisdexamfetamine was first R/PBS-listed for this indication on 1 February 2021.

The ADHD medicines considered in this analysis are:

- dexamfetamine
- methylphenidate (immediate release (IR) and modified release (MR) forms)
- atomoxetine
- lisdexamfetamine
- guanfacine

This analysis also examines the use of clonidine (which has a specific registered indication as a cardiovascular drug) as a treatment for ADHD.[1]

Background

Clinical situation

ADHD is characterised by a persistent pattern of inattentiveness, hyperactivity and/or impulsiveness that is associated with learning, behavioural and emotional impairment.

ADHD is a disorder that occurs across the lifespan, although it can present in different ways and in combination with different disorders at different ages. Little is known about the presentation of ADHD in older age. The symptoms of ADHD are present before the age of 12 years, but a diagnosis may not occur until later when functional impact may become more obvious as demands for independence increase.[3]

In 2013-2014, the prevalence of ADHD in Australian children and adolescents aged 4-17 was estimated to be 7.4%.[2] The prevalence of ADHD is higher in males than females at 10.4% compared to 4.3% of females having ADHD.[2] Many children with ADHD continue to have symptoms as adults.[2]

There are no Australian adult prevalence studies using the DSM-5 diagnostic criteria. The prevalence of adult ADHD in Australia is likely to be similar to that found internationally, which is between 2% and 6% of the population.[3]

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[1] Australian Medicines Handbook January 2021. Accessed 15 April 2021. https://amhonline.amh.net.au/chapters/cardiovascular-drugs/antihypertensives/other-antihypertensives/clonidine-cardiovascular

[2] Lawrence D, Johnson S, Hafekost J, Boterhoven De Haan K, Sawyer M, Ainsley J, Zubrick SR 2015. The Mental Health of Children and Adolescents. Report on the second Australian Child and Adolescent Survey of Mental Health and Wellbeing. Canberra: Department of Health

A high proportion of people with ADHD have co-occurring neurodevelopmental, mental health and medical conditions. ADHD can be diagnosed in the presence of other conditions. In children the most common co-occurring disorders are oppositional defiant disorder, language disorders, autism spectrum disorders and anxiety disorders, with depressive disorders and substance use disorders emerging in adolescence. Specific learning disorders also commonly occur in people with ADHD and involve difficulties in reading, written expression or mathematics. Among adults with ADHD, the most commonly co-occurring mental health disorders are depressive disorders, bipolar disorders, anxiety disorders, personality disorders and substance use disorders. Medical conditions, such as epilepsy, acquired brain injury, and foetal alcohol spectrum disorder can co-occur with ADHD. For people with ADHD and a co-occurring condition, the onset, duration and pattern of functional impact can help differentiate the effects of ADHD from those of the other condition, to help guide the treatment plan.[3]

The most current ADHD guidelines approved by the National Health and Medical Research Council (NHMRC), the Australian Evidence-Based Clinical Practice Guidelines for ADHD[3] (AADPA Guidelines) (2022) and Therapeutic Guidelines[4] from 2021 recommend an individualised multimodal treatment and support plan for the management of ADHD. Behavioural and educational interventions may be used as non-pharmacological management of ADHD symptoms, either alone or in combination with medicines. The AADPA Guidelines recommend that in young children (under 5), medication should be used cautiously, and monitored closely.

In Australia, psychostimulants are considered the first-line pharmacological treatment for ADHD.[2,3,5] Therapeutic Guidelines recommend that, with rare exceptions, stimulants (dexamfetamine, lisdexamfetamine and methylphenidate) should not be used in children aged younger than 6 years.[4] Atomoxetine, a non-stimulant drug, is approved for use in children (over six years old), adolescents and adults with ADHD where treatment with stimulants is not suitable or tolerated.[3,4] Guanfacine, a non-stimulant drug, is approved for children (over six years old) and adolescents (up to the age of 18).

PBS restrictions for subsidisation of ADHD treatments differ according to the age at which the person received the diagnosis. Guanfacine is subsidised only for those with a diagnosis between the ages of 6 and 17 years inclusive. Atomoxetine is subsidised only for those with a diagnosis between the ages of 6 and 18 years inclusive.

Dexamfetamine, lisdexamfetamine and methylphenidate are Schedule 8 medicines under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Schedule 8 medicines have a high potential for abuse and dependence. The prescribing and supply of Schedule 8 medications are tightly regulated, and regulations vary between each state and territory.

Most Australian states and territories restrict the prescribing of psychostimulants for the treatment of ADHD to specialist medical practitioners, including psychiatrists, neurologists and paediatricians. These specialist prescribers are generally required to obtain prior authorisation from the relevant state or territory regulatory body for each patient. Prescribing of

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[3] Australian Evidence Based Clinical Practice Guideline For Attention Deficit Hyperactivity Disorder (ADHD) 1st Edition 2022

[4] Attention deficit hyperactivity disorder. Therapeutic Guidelines Ltd (eTG March 2021 edition) [Internet]. Published March 2021. Accessed 26 July 2023. https://tgldcdp.tg.org.au/viewTopic?topicfile=attention-deficit-hyperactivity-disorder&guidelineName=Psychotropic&topicNavigation=navigateTopic

[5] Tonge, B. (2013). 'Principles for managing attention deficit hyperactivity disorder'. Australian Prescriber, 36:162-5.

psychostimulants to patients under the age of 2 years is generally prohibited, and there are additional regulatory requirements to prescribe psychostimulants to patients aged between 2 to 3 years old.

Due to all States and Territories having different laws about stimulant prescribing, State and territory government health webpages should be checked for the most up to date regulatory information regarding psychostimulant prescribing.[6]

Previous utilisation analysis undertaken by DUSC did not consider the use of buproprion, modafinil, or tricyclic antidepressants as these medicines are not specifically TGA-indicated or R/PBS-subsidised for the treatment of ADHD.

The utilisation of clonidine was included in the 2021 review, and has been included in this analysis as the mechanism of action is similar to guanfacine and it is frequently used for the management of ADHD.[7]

Pharmacology

The exact mechanism of action of ADHD medications is not fully established but is thought to be due to modification of dopaminergic and noradrenergic activity in the brain. Dexamfetamine, lisdexamfetamine and methylphenidate hydrochloride are central nervous system stimulants.[5,8,9] Lisdexamfetamine[10] is a prodrug of dexamfetamine and is broken down into active dexamfetamine after ingestion.[5] Atomoxetine is a selective noradrenaline reuptake inhibitor.[11] Guanfacine[6] is a selective alpha$_{2A}$-adrenergic receptor agonist and was Anatomical Therapeutic Chemical (ATC) classified as a cardiovascular drug similar to clonidine.[12]

[6] A consolidated ADHD stimulant prescribing regulation and authorities overview can be found at: https://aadpa.com.au/adhd-stimulant-prescribing-regulations-in-australia-new-zealand/ Last updated April 2023.
[7] Australian Medicines Handbook January 2021. Accessed 25 July 2023 at: https://amhonline.amh.net.au/chapters/cardiovascular-drugs/antihypertensives/other-antihypertensives/clonidine-cardiovascular
[8] Aspen Pharma Pty Ltd, Product Information: Aspen Dexamfetamine Tablets. Approved 14 October 1991. Most recent amendment 15 October 2021. Accessed on: 25 July 2023, at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2017-PI-01667-1
[9] NOVARTIS Pharmaceuticals Australia Pty Limited, Product Information: RITALIN® 10/RITALIN® LA (methylphenidate). Approved 02 August 1991. Most recent amendment 6 April 2022. Accessed on: 25 July 2023, at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-03175-3
[10] Takeda Pharmaceuticals Australia Pty Ltd, Product Information: VYVANSE (Lisdexamfetamine dimesilate)) tablets. Approved 22 July 2013. Most recent amendment 17 July 2023. Accessed on: 25 July 2023, at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-02051-1
[11] Eli Lilly Australia Pty Limited (2018), Product Information: STRATERA® (atomoxetine hydrochloride). Approved 27 January 2004. Most recent amendment 06 May 2020. Accessed on: 25 July 2023, at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-04269-3
[12] Clonidine product information. Accessed on: 25 July 2023, at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=clonidine

Therapeutic Goods Administration (TGA) approved indications and PBS restrictions

The TGA indications and PBS restricted uses of medicines used to manage ADHD is shown below. [13]

Drug	TGA indications	PBS restricted uses
Dexamfetamine	• Hyperkinetic behaviour disorders in children • Narcolepsy	• ADHD • Narcolepsy
Methylphenidate Immediate-Release (MPH-IR)	• ADHD • Narcolepsy	• ADHD
Methylphenidate Modified-Release (MPH-MR)	• ADHD	• ADHD in patients who require continuous coverage and has demonstrated a response to IR methylphenidate.
Atomoxetine	• ADHD as defined by the DSM-IV criteria for people aged ≥6 years.	• ADHD as defined by the DSM-5 criteria, diagnosed by a paediatrician or psychiatrist, in patients diagnosed between ages 6 to 18, who are contraindicated to or intolerant of stimulant treatment.
Guanfacine	• ADHD in children and adolescents aged 6-17 years old, as monotherapy (when stimulants or atomoxetine are not suitable, not tolerated or have been shown to be ineffective) or as adjunctive therapy to psychostimulants.	• ADHD as defined by the DSM-V criteria, diagnosed by a paediatrician or psychiatrist, in patients diagnosed between ages 6 to 17, who are contraindicated to or intolerant of stimulant treatment.
Lisdexamfetamine	• ADHD treatment commenced by specialist. • Moderate to severe Binge Eating Disorder in adults when non-pharmacological treatment is unsuccessful or unavailable. Must be commenced and managed by specialist.	• ADHD in patients who require continuous coverage over 12 hours.

TGA product information box warnings

Dexamfetamine, lisdexamfetamine and methylphenidate have box warnings concerning drug dependence. They should be used cautiously in people with a history of drug or alcohol dependence. Chronic abuse may lead to tolerance, psychological dependence and abnormal behaviour.[9,10,11] Supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

[13]Sources: Therapeutic Goods Administration Product Information pages, Australian Register of Therapeutic Goods. Accessed 25 July 2023.

Atomoxetine has a box warning to monitor peoples for suicidal thoughts and behaviours. Short-term placebo-controlled studies showed a positive signal for suicidal thoughts and behaviours in children aged 12 years and under.[11]

Dosage and administration

Treatment is usually commenced on dexamfetamine, lisdexamfetamine or the immediate release (IR) formulation of methylphenidate. Doses are started low and then up-titrated weekly to optimal doses.[3]

People taking methylphenidate IR may switch to long-acting methylphenidate once responsive and dose stabilised. Alternative treatments should be considered if the maximum stimulant dose has been reached and significant improvement in symptoms has not occurred after a month or unacceptable side effects have developed.[4]

There are no established guidelines for the length of time persons should be maintained on stimulants.

Full details on dosing and titration schedules can be found in the Product Information. The current Product Information (PI) and Consumer Medicine Information (CMI) are available from the TGA (Product Information) and the TGA (Consumer Medicines Information).

Date of listing on R/PBS

The dates of listing and changes to listing for these medicines are available in Appendix A.

Current R/PBS listing and restriction details are available from the PBS website.

Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC recommendations for all ADHD medicines listed prior to 2020 are provided in Appendix B. Most medicines have been recommended on a cost-minimisation basis to existing therapies.

Methylphenidate Modified Release

At the March 2022 meeting, the PBAC recommended expanding the General Schedule Authority Required listing of methylphenidate 10mg, 20mg, 30mg, 40mg and 60mg modified release capsules, Ritalin LA®, to include adults with a retrospective diagnosis of ADHD under the same population criteria as lisdexamfetamine.

Lisdexamfetamine

At the March 2020 meeting, the PBAC recommended expanding the listing of lisdexamfetamine to include treatment of people with ADHD who are diagnosed after the age of 18.

Previous reviews by the DUSC

DUSC reviewed this therapeutic area in October 2010, as part of the 24 month Predicted versus Actual (PvA) review of atomoxetine. DUSC noted that there was lower than expected utilisation of atomoxetine, which may have been influenced by the listing of the 12-hour MPH-MR (Concerta®) three months before the listing of atomoxetine and possible over-estimation of the number of people with the required contraindications to stimulants to meet the restriction.[14]

DUSC reviewed ADHD medicines in June 2012, with further analyses requested by DUSC considered in October 2012.[15] When considering all people treated with ADHD medicines, highest use was in children aged 10 years. DUSC noted that there was steady growth in the utilisation of ADHD medicines between January 2005 and October 2011. PBS benefits paid for ADHD medicines in November 2010–October 2011 totalled around $24.6 million, up 4.2% from the previous year. The highest cost medicine to the PBS was the 12-hour MPH-MR **(**Concerta®**)** at $11.2 million, followed by atomoxetine at $6.2 million, despite its low utilisation.[18]

The DUSC reviewed ADHD medicines in June 2015,[16] finding that there was steady growth in the utilisation of ADHD medicines between 2010 and 2014. Over 875,000 prescriptions were dispensed at a cost to the PBS of approximately $30 million in 2014, with methylphenidate being the most used medication. Rates of prescribing varied across states and territories, with rates of treatment in school-aged children being highest in the ACT, NSW and QLD. Rates of treatment in adults were highest in WA. The majority of prescriptions were written by a specialist, usually a paediatrician or psychiatrist as most Australian states and territories restrict the prescribing of methylphenidate and dexamfetamine for the treatment of ADHD to specialist medical prescribers.

The DUSC reviewed ADHD medicines in May 2018,[17] finding that over the five year period of 2013-2017 the number of people treated with R/PBS medicines for ADHD increased at a yearly average growth rate of 9.9%, with the number of prescriptions increasing at similar rates. Similar to the previous review, the most used medicine in terms of prevalent peoples was the modified-release formulation of methylphenidate. More males than females were treated, although the ratio is decreasing over time, and children aged 6-12 years old account for over 40% of R/PBS ADHD medicines supplied.

DUSC reviewed ADHD medicines, including guanfacine, in June 2021.[18] Key findings over the seven year period of 2014-2020 were:

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[14] Drug Utilisation Sub-Committee. DUSC Predicted versus Actual analysis of atomoxetine. Canberra: Australian Department of Health: 2010. Unpublished.
[15] Drug Utilisation Sub-Committee. DUSC Reviews of ADHD Drugs June and October 2012. Canberra: Australian Department of Health: 2010. Unpublished.
[16] Drug Utilisation Sub-Committee. ADHD Utilisation Analysis October 2015. Canberra: Australian Department of Health. Accessed on 25 July 2023, at: http://www.pbs.gov.au/pbs/industry/listing/participants/public-release-docs/2015-06/attention-deficit-hyperactivity-disorder-2015-06-prd
[17] Drug Utilisation Sub-Committee. ADHD Utilisation Analysis May 2018. Canberra: Australian Department of Health. Accessed on 25 July 2023, at: https://www.pbs.gov.au/pbs/industry/listing/participants/public-release-docs/2018-05/attention-deficit-hyperactivity-disorder
[18] https://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/2021-06/guanfacine-for-attention-deficit-hyperactivity-disorder-jun

- The number of prevalent patients treated with R/PBS medicines for ADHD has risen at a yearly average growth rate of 12.4%, however this rate did not give the full picture.
- From 2014-2017 the yearly average growth rate was 9.8%, whereas from 2018-2020 the yearly growth rate was 16%. The substantial increase since 2018 was likely to be due to the listing of guanfacine in September 2018.
- The number of prescriptions also increased at similar growth rates, from 2014-2017 the yearly average growth rate was 10.25%, whereas from 2018-2020 the yearly growth rate was 17.67%.
- The modified-release formulation of methylphenidate remains the most commonly used medicine.
- For all age groups more males than females were treated.
- Of all prevalent patients treated with R/PBS listed ADHD medicines, under 18 year olds accounted for 67% of patients.

Guanfacine:

- The listing of guanfacine in September 2018 contributed towards an increase in the use of ADHD medicines.
- The total number of guanfacine prescriptions supplied in Year 1 (74,725) was more than [redacted] the predicted number [redacted] with an even [redacted] in Year 2 [redacted] which was an increase of [redacted] over the predicted amount.
- The expected cost offset from substitution of other ADHD medicines to guanfacine has [redacted] realised.

Methods

PBS and RPBS (R/PBS) prescription data for PBS-listed ADHD medicines (dexamfetamine, methylphenidate, atomoxetine, lisdexamfetamine and guanfacine) and clonidine (Unrestricted PBS listing) were extracted from the supplied prescriptions database maintained by the Department of Health and Aged Care, processed by Services Australia for the period July 2013 to June 2023 inclusive, based on the date that the prescription was supplied. Unless indicated in specific tables, all data were extracted on 18th July 2023. Data for this period includes all R/PBS supplies regardless of whether a subsidy was paid; i.e. both over co-payment and under co-payment. As dexamfetamine is PBS-listed for both ADHD and narcolepsy, the prescription data for dexamfetamine was merged with the authority approvals database and limited by the ADHD authority restriction number to obtain only the supplies related to ADHD.

The R/PBS prescription data were used to determine the number of prescriptions supplied, R/PBS expenditure, age, gender, state/territory of residence and prescriber type. These prescription data were also used to count the number of patients, both incident (new to pharmacological treatment) and prevalent (number treated) in each time period. There were two types of initiations calculated, initiation to a particular medicine (see Figures 6a and b and 8a and b) and initiation to overall ADHD therapy (i.e. when the patient started their first ADHD medicine, see Figures 2, 3a, b and c, Table 3 and Figure 9). For initiation to overall ADHD therapy, Figure 2 and Table 9 simply report on the number of people that initiated ADHD therapy, whereas Figures 3a, b and c and 9 also report on the medicine on which a person initiated ADHD therapy. For both types of initiation (i.e. overall therapy or individual

medicine), the initiation date was defined as the date of supply of the first PBS or RPBS prescription of the ADHD medicine (since July 2013).

The number of prevalent people was determined by counting the number of people supplied at least one PBS prescription using person-specific numbers (non-identifying) in the data for the specified time periods.

Clonidine was included in the data extract to examine if it was being used to treat ADHD. While definitive results are difficult to establish due to clonidine's unrestricted listing (i.e. the indication for which it is prescribed is not specified), it is estimated that clonidine is being used as an ADHD medication across all age groups. There is a high level of confidence that clonidine is being prescribed for people ≤18 years old for ADHD, as this age group would not usually be prescribed clonidine for other diseases / disorders.

The patients per 1000 population rates for financial years were based on the ABS estimated residential population (ERP) at 31 December for the specific financial year. For example, the rate for 2022/23 was the number of patients in that year divided by the ERP as at 31 December 2022 (i.e. the mid-point of the financial year). ABS ERP data were sourced from .Stat Data Explorer (BETA) • Quarterly Population Estimates (ERP), by State/Territory, Sex and Age (abs.gov.au).

As these analyses use date of supply prescription data, there may be small differences compared with publicly available Services Australia Medicare date of processing data. These data only include subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included.

Results

Note, for all of the graphs, MPH-MR consists of both Concerta® and Ritalin LA®.

Analysis of drug utilisation

Overall utilisation

The number of R/PBS prescriptions for ADHD medications supplied per financial year since 2013-14 is shown in Figure 1a. Figure 1b and 1c show the total number of prescriptions supplied per financial year, to >18 year olds (Figure 1b) and ≤18 year olds (Figure 1c).

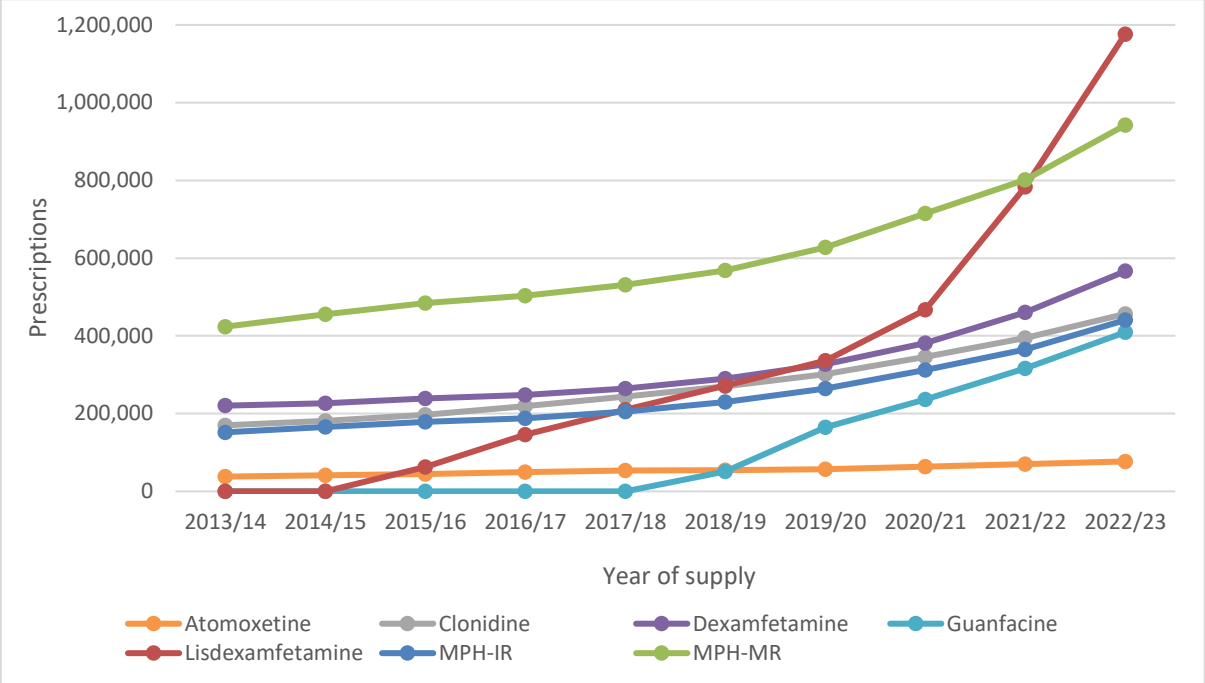

Figure 1a: Number of PBS/RPBS ADHD prescriptions supplied per financial year

Figure 1a shows an overall increase in the rate of growth in R/PBS ADHD prescriptions supplied during 2013-14 to 2022-23. The average annual growth rate since 2013-2014 is just under 18%, however as can be seen in Figure 1a and Table 1, the growth rate, particularly in lisdexamfetamine prescriptions, has greatly accelerated since the 2019-20 financial year. The growth rate over the four financial years, 2019-20 to 2022-23, is just over 25% per annum. This growth is due to an increased use of all ADHD medications, with the highest increases found in the prescribing of guanfacine (which was PBS listed on 1 September 2018), and lisdexamfetamine (which had restriction changes on 1 February 2021). Out of the ADHD medications, atomoxetine had the fewest prescriptions, and its rate of growth has been the slowest.

Figure 1a includes the prescription count of clonidine, which is prescribed for people with ADHD. However, the prescription count of clonidine includes prescriptions for non-ADHD related indications.

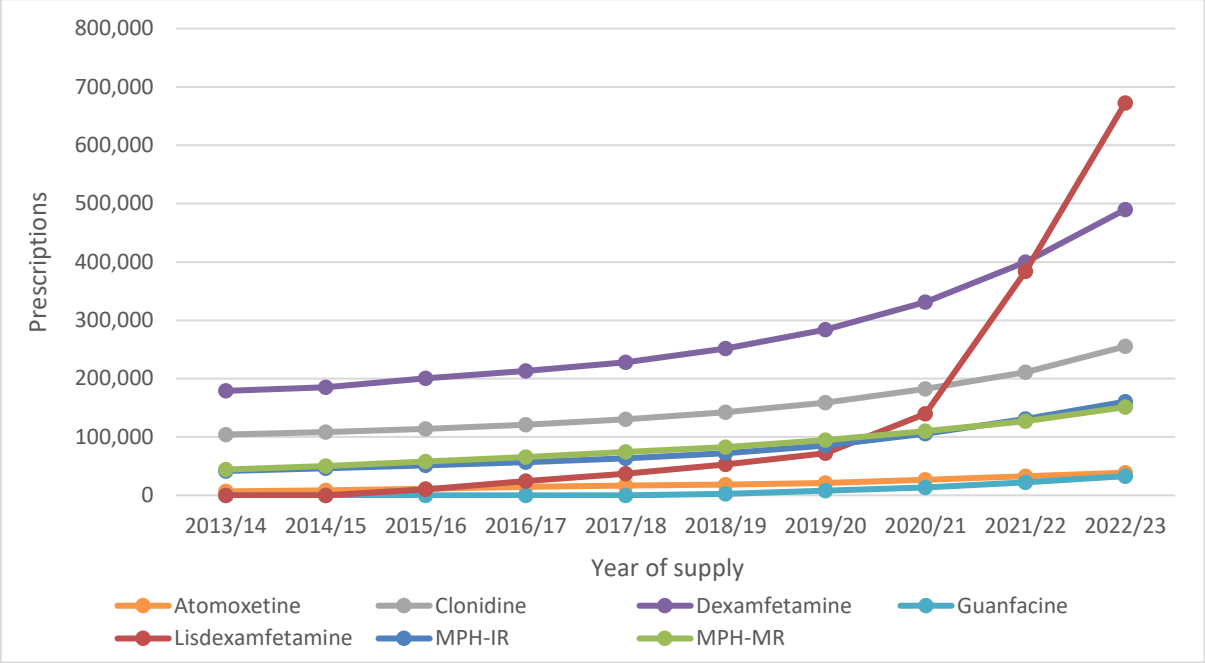

Figure 1b Number of PBS/RPBS ADHD prescriptions supplied to people >18 years old per financial year

The impact of the restriction change to lisdexamfetamine on 1 February 2021 can be clearly seen in Figure 1b, which shows the number of prescriptions supplied to the affected population (>18 year olds).

The 2020-21 financial year incorporates five months of the restriction change. A noticeable increase in the rate of prescribing is evident, however due to this data only including five months of the restriction change data, this rise is not nearly as great as that shown after the 2020-21 financial year which includes all months of restriction change.

Prior to the restriction change, in 2019-20, the rate of growth of lisdexamfetamine prescriptions was 18%. In 2020-21, the rate of growth was 64% and in 2021-22 the growth was 175%. This rate of growth reduced in 2022-23 to 75%, with 672,700 prescriptions of lisdexamfetamine supplied to people who were over the age of 18.

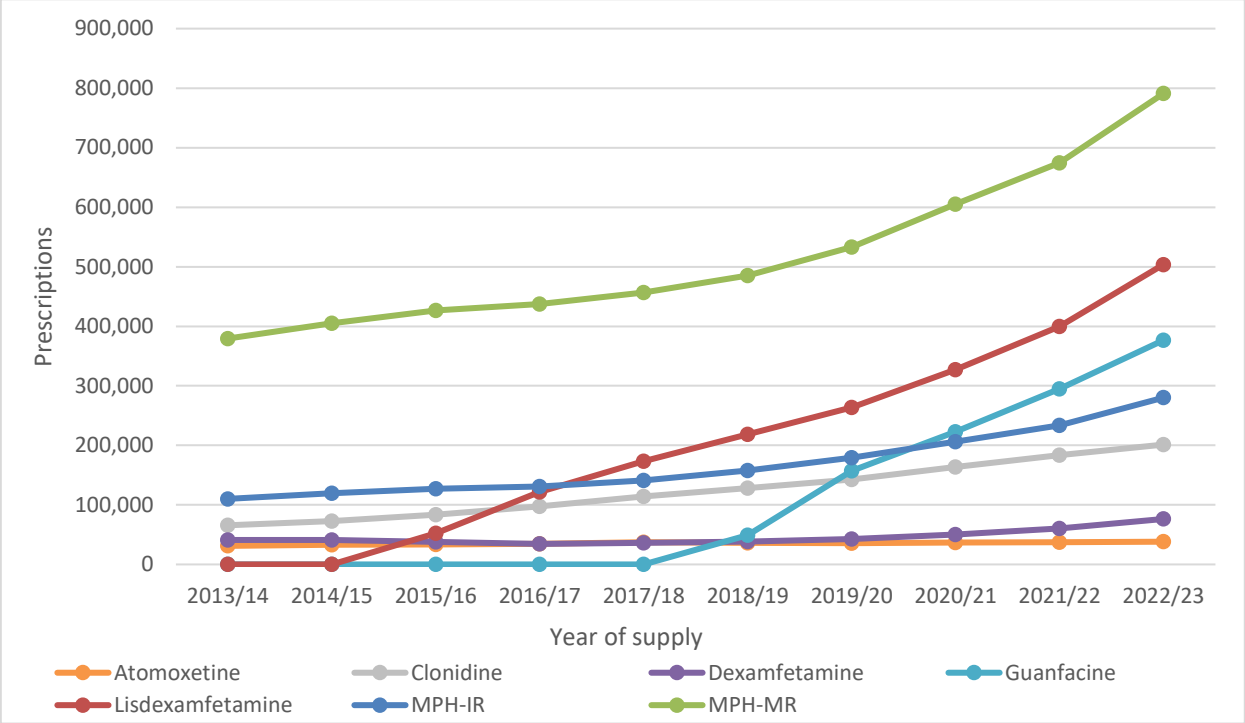

Figure 1c Number of PBS/RPBS ADHD prescriptions supplied to people ≤18 years old per financial year

Figure 1c shows the number of prescriptions supplied to ≤18 year olds. It is clear from the graph that all ADHD medications apart from atomoxetine have been prescribed at higher rates over time.

The listing of guanfacine in September 2018 does not appear to have reduced use of other ADHD medications in the 18 year old and under population.

Table 1 shows the ADHD drug prescription count by financial year.

Table 1: ADHD drug prescription count by financial year.

Drug Name / Prescription Count	2013 - 14	2014 - 15	2015 - 16	2016 - 17	2017 - 18	2018 - 19	2019 - 20	2020 - 21	2021 - 22	2022 - 23
MPH-MR	423,772	455,502	484,562	503,316	531,006	568,111	627,354	715,128	801,637	942,260
Lisdexamfetamine			62,490	146,266	210,318	271,989	335,809	466,775	783,443	1,176,452
Dexamfetamine	220,577	226,397	238,632	247,725	264,419	289,854	326,755	381,688	460,378	566,381
MPH-IR	151,956	165,733	178,526	187,614	204,821	229,910	264,222	312,093	364,582	440,693
Guanfacine						51,592	165,238	236,289	316,701	409,535
Atomoxetine	37,981	41,461	45,005	49,245	53,950	54,663	56,882	63,282	69,940	76,965
TOTAL	834,286	889,093	1,009,215	1,134,166	1,264,514	1,466,119	1,776,260	2,175,255	2,796,681	3,612,286
Growth from previous year (%)		6.6%	13.5%	12.4%	11.5%	15.9%	21.2%	22.5%	28.6%	29.2%

Patients initiating and prevalent to ADHD therapy

The total number of new patients starting ADHD medicines (initiating) and the number of patients treated with R/PBS-listed ADHD medicines each quarter (prevalent) are shown in Figure 2.

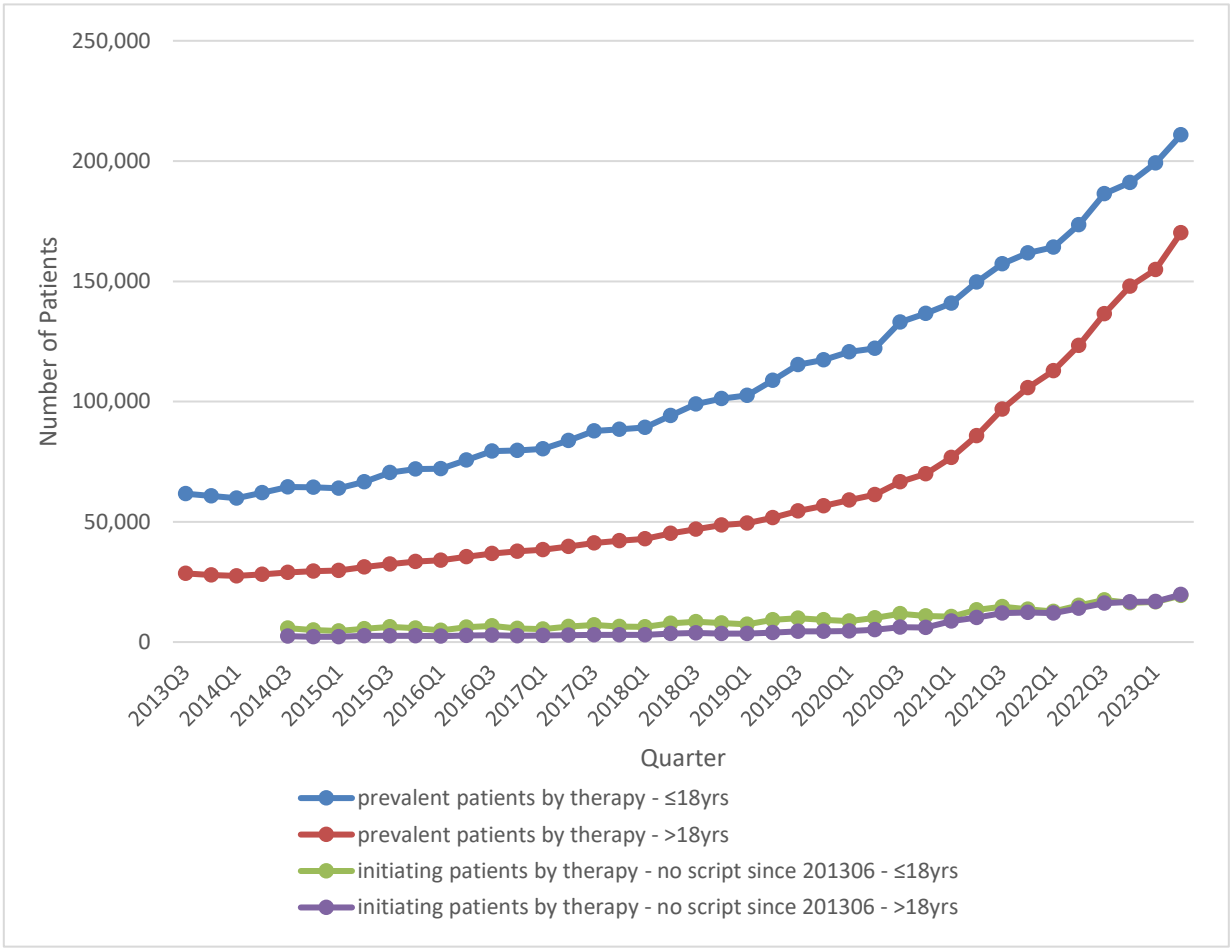

Figure 2: Prevalent and initiating people receiving ADHD therapy per quarter

The total number of people on ADHD medicines has increased over time. The growth rate of the prevalent population from 2013Q3 to 2023Q1 was 242% for ≤18 year olds, and 496% for >18 year olds. This much larger increase in prevalent adults coincides with the restriction change to lisdexamfetamine in February 2021.

There is a clear increase in adults (>18 year olds) initiating ADHD therapy since the lisdexamfetamine restriction change.

Figure 3a shows the number of initiating people per quarter by their first ever R/PBS-subsidised ADHD medicine supplied in 2014Q3 to 2023Q2.

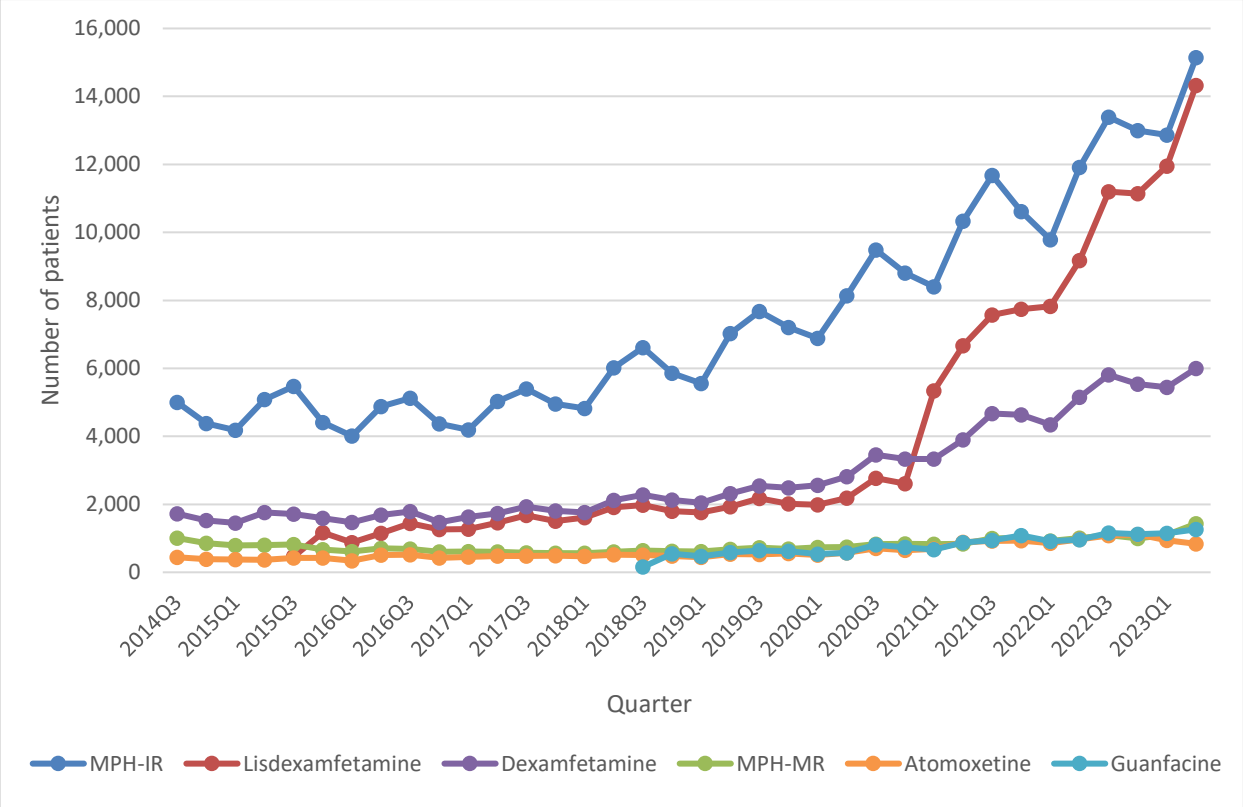

Figure 3a: Total number of people initiating ADHD therapy by initiating medicine (i.e. first ever prescription for an ADHD medicine, not including clonidine)

Prior to the lisdexamfetamine restriction change, the majority of initiating people (Figure 3a) commence R/PBS ADHD therapy with short-acting medicines, particularly short-acting methylphenidate (MPH-IR). However, there has been considerable uptake in lisdexamfetamine since its R/PBS listing in September 2015, and a large spike in uptake of lisdexamfetamine since the restriction change on 1 February 2021, which has resulted in lisdexamfetamine almost reaching parity with MPH-IR as the highest initiating ADHD medicine.

Guanfacine has marginally overtaken atomoxetine as the highest first initiated non-stimulant initial ADHD medication.

Use of atomoxetine is the lowest of all ADHD drug therapy by initiating population.

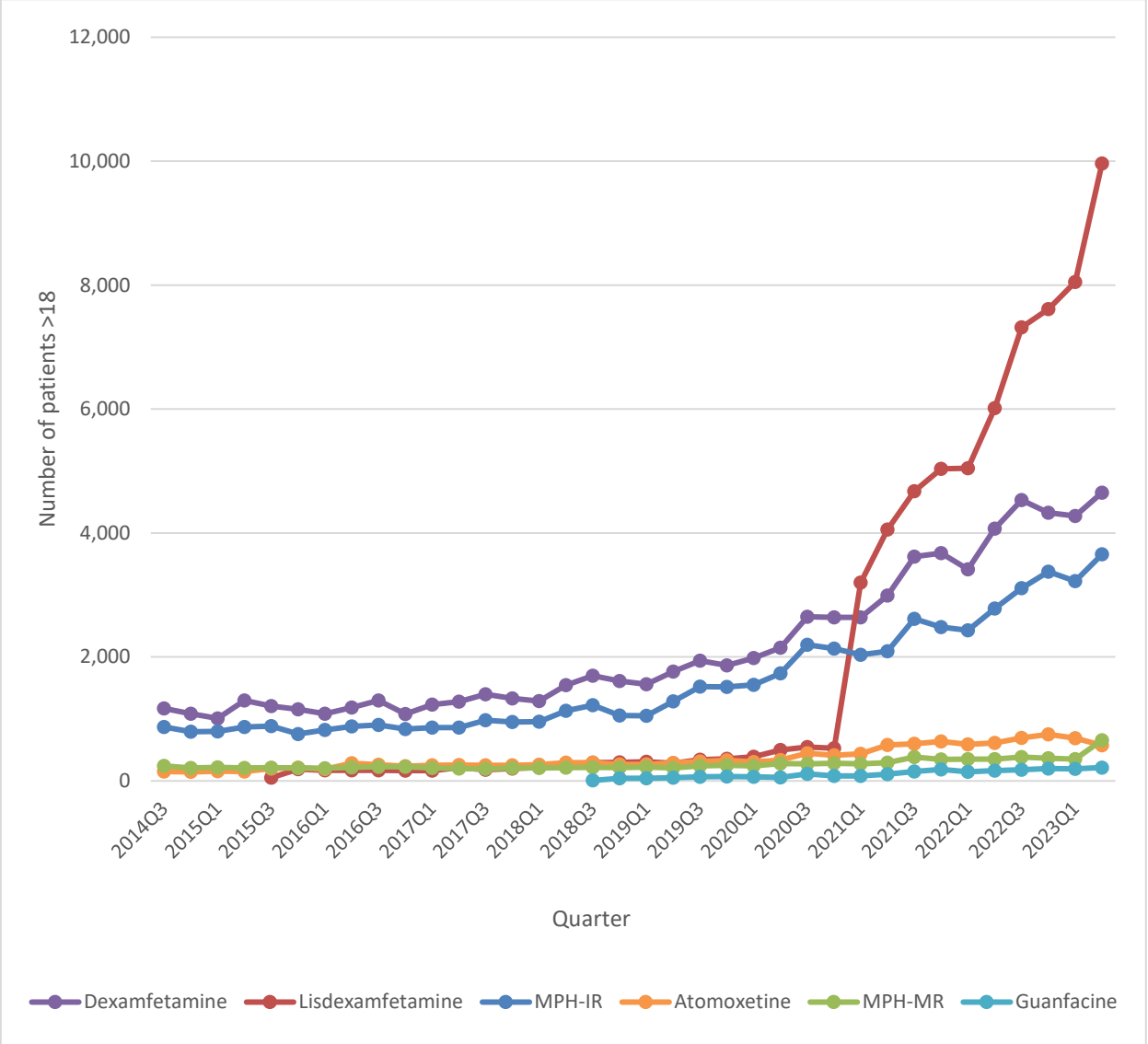

Figure 3b: Number of people >18 years old initiating ADHD therapy by initiating medicine (i.e. first ever prescription for an ADHD medicine, not including clonidine)

Since 2014Q3, adults initiating ADHD treatment on dexamfetamine, MPH-IR and lisdexamfetamine in the >18 year old population has increased. This increase was at a much slower rate until about 2019, when the growth of initiating people started to accelerate.

The change to the R/PBS lisdexamfetamine restriction on 1 February 2021 can clearly be seen to have impacted the use of ADHD therapy in initiating adults, with the amount of people increasing from 530 in 2020Q4 to 3,198 in 2021Q1 (which only included restriction change data from February). By the last quarter of data available (2023Q2), 9,962 adults diagnosed with ADHD initiated treatment on lisdexamfetamine.

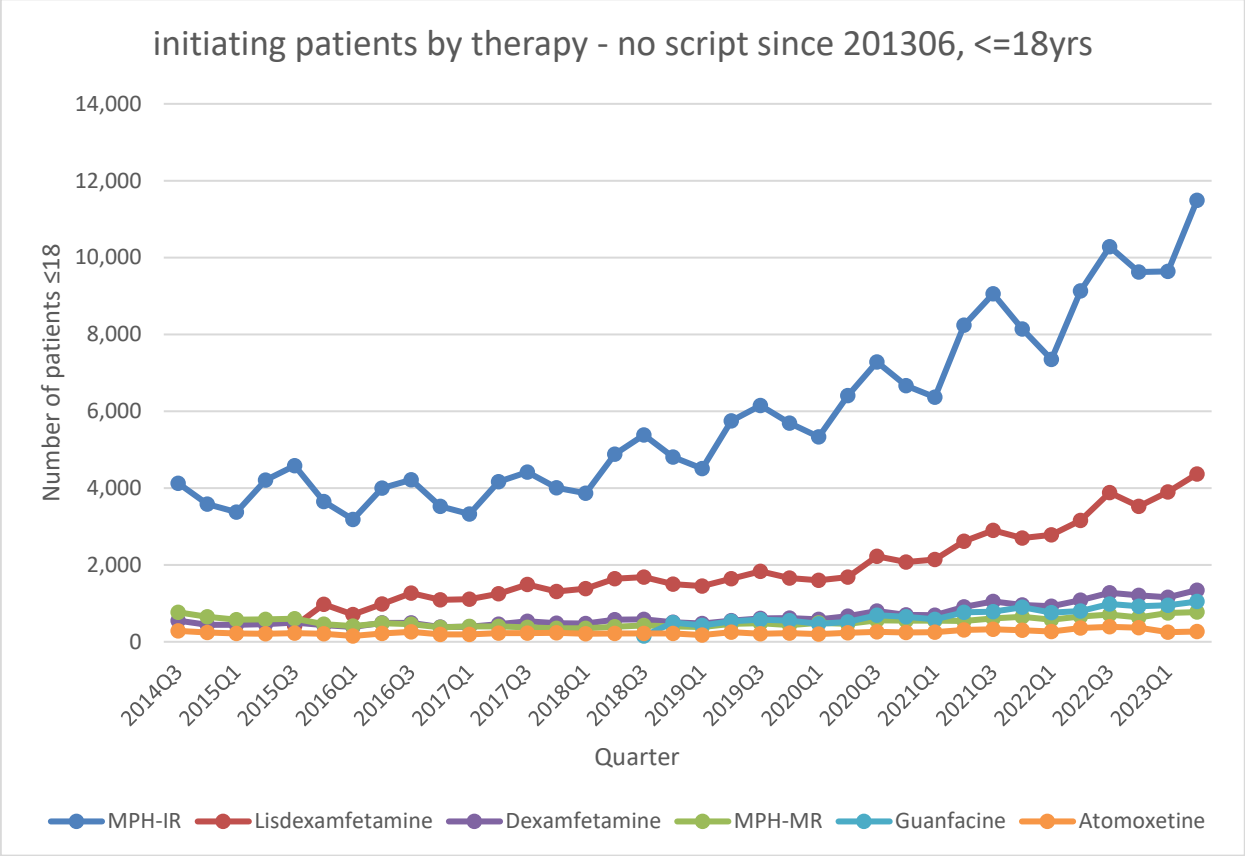

Figure 3c: Number of people ≤18 years old initiating ADHD therapy by initiating medicine (i.e. first ever prescription for an ADHD medicine, not including clonidine)

Since 2014Q3, initiating use of all ADHD medicines (apart from atomoxetine) in the ≤18 years old population has increased.

The majority of initiating people ≤18 years of age commence R/PBS therapy with short-acting methylphenidate (MPH-IR). There has been considerable uptake in lisdexamfetamine since its R/PBS listing in September 2015.

Guanfacine, which was listed on 1 September 2018, has overtaken atomoxetine as the first initiated non-stimulant initial ADHD medication.

Figure 4a depicts the total number of prevalent people per quarter for each ADHD medicine supplied from 2013Q3 to 2023Q2.

Figure 4b depicts the number of prevalent people >18 years old, per quarter for each ADHD medicine supplied from 2013Q3 to 2023Q2.

Figure 4c depicts the number of prevalent people ≤18 years old, per quarter for each ADHD medicine supplied from 2013Q3 to 2023Q2.

In figures 4a, 4b and 4c, a person may be supplied more than one ADHD medicine in the same quarter.

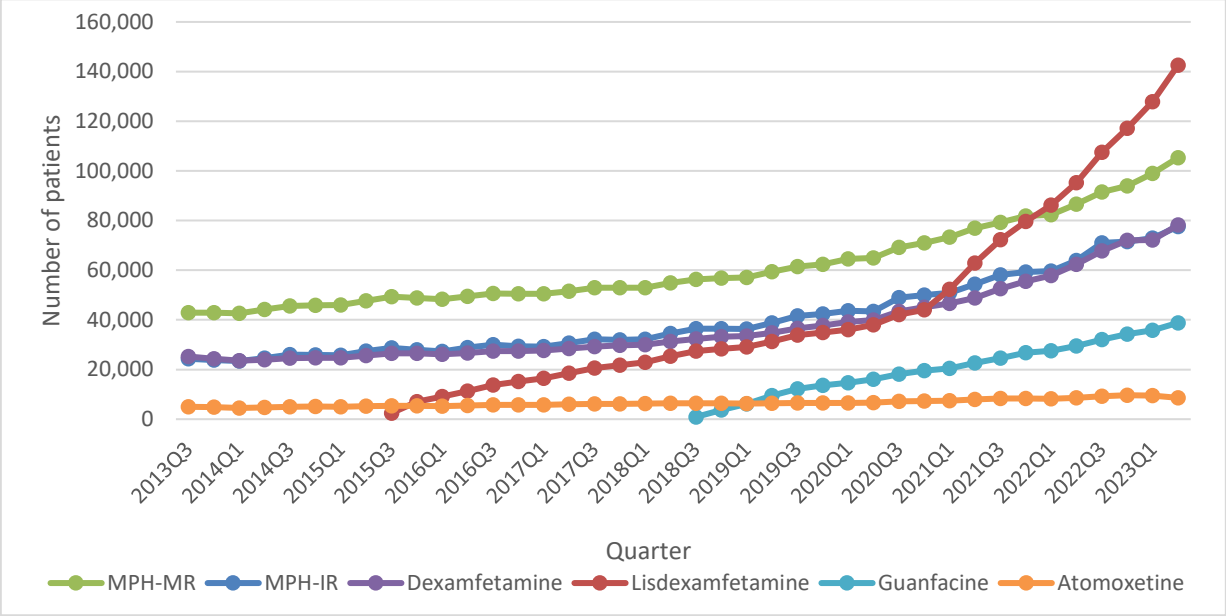

Figure 4a: Prevalent people treated with each ADHD medicine per quarter

When considering the number of prevalent people treated across all years (Figure 4a and Table 2a), long-acting methylphenidate was used by the most people until 2021Q4, when lisdexamfetamine became the most used medicine.

Atomoxetine is used in a small proportion of people and has shown very low growth, which is somewhat surprising considering the substantial uptake of guanfacine since its R/PBS listing in September 2018.

Overall, the data shows a steady increase in the number of ADHD patients, with a much higher increase starting from 2018-2019 (growth rate of 15%) and another increase from 2020-21 (growth rate of 23%). The growth rate of 2022-23 jumped further, to 28%.

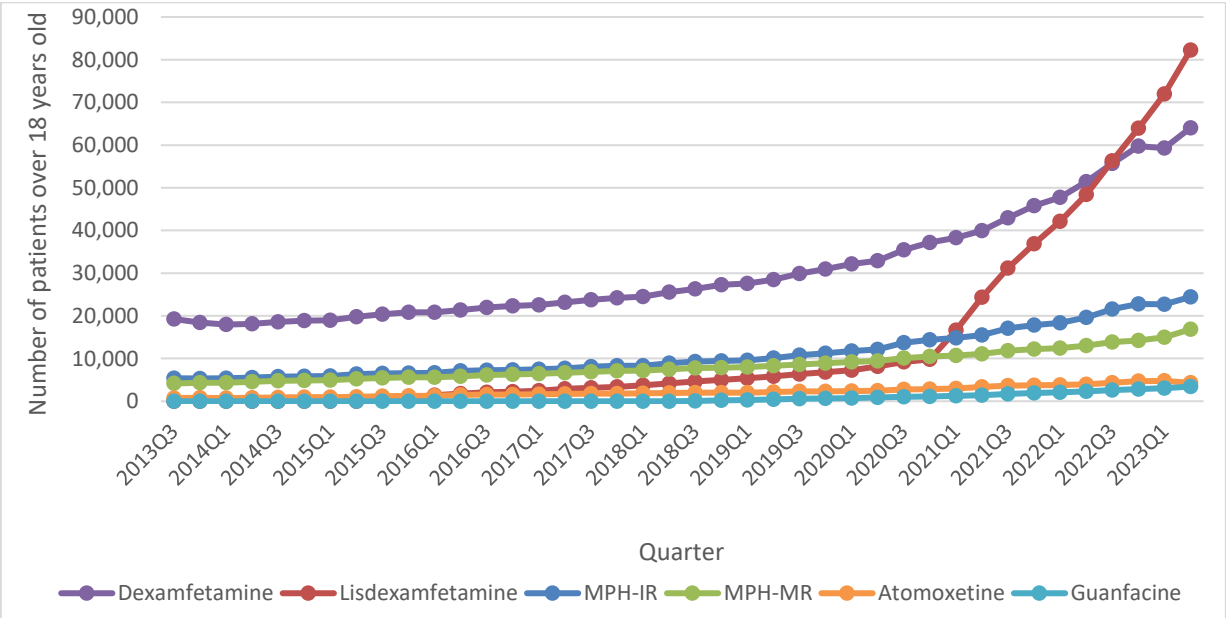

Figure 4b: Prevalent people >18 years old treated with each ADHD medicine per quarter

When considering the number of prevalent adults treated across all years (Figure 4b and Table 2b), dexamfetamine was the ADHD medicine used by the most people until 2022Q3, when lisdexamfetamine became the most used medicine. The impact of the restriction change for lisdexamfetamine (on 1 February 2021) is clear in this graph, with the number of people using lisdexamfetamine increasing as a rapid rate.

Overall, the data shows a steady increase in the number of ADHD patients, with much higher increases in the number of people using lisdexamfetamine since 2021Q1. The growth of lisdexamfetamine in the financial year 2019-20 was 36%, by 2020-21 (which incorporated five months of the restriction change) this had risen to 170%. The number of adults rose by a further 115% in 2021-22 and increased again, albeit at a smaller rate of growth, in 2022-23 by 68%.

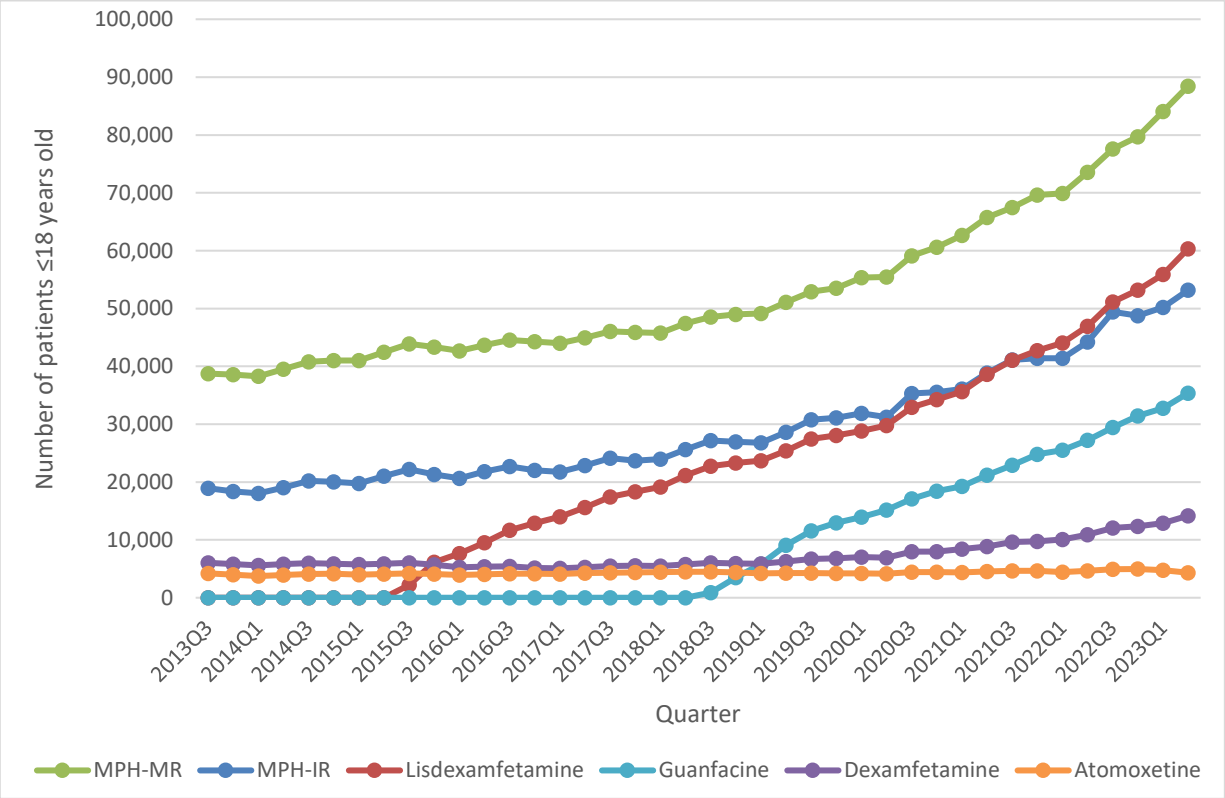

Figure 4c: Prevalent people ≤18 years old treated with each ADHD medicines per quarter

In the ≤18 year old prevalent population, (Figure 4c and Table 2c), the medicine used by the most people is the modified release form of methylphenidate.

The data shows a steady increase in the number of ADHD patients ≤18 years old. This increase appears to have risen in 2018-19, shortly after guanfacine was listed on the PBS.

Overall, the data shows a steady increase in the ADHD population, with a much higher increase starting from 2018-2019 (growth rate of 15%) and another increase in 2022-23 (growth rate of 20%).

Tables 2a, 2b and 2c show the number of prevalent people treated with each ADHD medicine per financial year. Table 2a is the overall number of prevalent people, while Table 2b and 2c are split in to >18 year old and ≤18 years old populations.

Table 2a: Prevalent patients treated with each ADHD medicines per financial year

Drug Name / Patient Count	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Lisdexamfetamine			14,652	25,342	33,877	42,042	50,942	78,179	122,023	179,090
MPH-IR	44,077	48,142	51,831	54,386	60,327	68,728	80,042	96,649	115,483	142,835
MPH-MR	56,617	60,811	64,999	66,901	70,643	76,691	85,002	97,515	112,184	133,991
Dexamfetamine	33,901	34,406	37,080	38,956	42,729	48,039	55,939	68,764	88,300	116,596
Guanfacine						11,492	21,938	29,796	38,921	50,583
Atomoxetine	7,375	7,864	8,658	9,498	10,301	10,582	11,044	12,748	14,657	16,412
Total	117,824	124,826	140,131	155,521	174,378	200,367	233,615	287,746	367,434	470,274
Growth		6%	12%	11%	12%	15%	17%	23%	28%	28%

*Therapy total is less than the sum of components as people are only counted once even if they are prevalent to more than one ADHD medication.

Table 2b: Prevalent patients >18 years old treated with each ADHD medicines per financial year

Drug Name / Patient Count	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Lisdexamfetamine			2,283	3,885	5,445	7,502	10,195	27,546	59,308	99,380
Dexamfetamine	24,565	24,816	27,322	29,739	32,740	37,018	43,068	52,881	68,584	91,003
MPH-IR	9,060	9,976	11,196	12,393	14,135	16,156	19,797	25,381	32,222	42,081
MPH-MR	5,787	6,545	7,510	8,466	9,425	10,635	12,010	14,072	16,745	21,265
Atomoxetine	1,287	1,625	2,293	2,863	3,246	3,593	4,140	5,364	6,947	8,333
Guanfacine						629	1,393	2,171	3,373	4,965
Total	37,645	39,500	45,034	50,676	57,072	65,786	78,085	104,358	149,770	209,564
Growth		5%	14%	13%	13%	15%	19%	34%	44%	40%

*Therapy total is less than the sum of components as people are only counted once even if they are prevalent to more than one ADHD medication.

Table 2c: Prevalent patients ≤18 years old treated with each ADHD medicines per financial year

Drug Name / Patient Count	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
MPH-MR	50,798	54,245	57,489	58,423	61,205	66,044	72,989	83,440	95,439	112,726
MPH-IR	34,991	38,135	40,625	41,985	46,180	52,569	60,242	71,262	83,261	100,754
Lisdexamfetamine			12,368	21,449	28,426	34,538	40,747	50,632	62,715	79,710
Guanfacine						10,862	20,544	27,625	35,548	45,618
Dexamfetamine	9,310	9,564	9,746	9,210	9,982	11,019	12,867	15,874	19,716	25,593
Atomoxetine	6,080	6,235	6,365	6,628	7,050	6,989	6,904	7,383	7,710	8,079
Total	80,098	85,254	95,075	104,811	117,273	134,566	155,521	183,370	217,664	260,710
Growth		6%	12%	10%	12%	15%	16%	18%	19%	20%

*Therapy total is less than the sum of components as people are only counted once even if they are prevalent to more than one ADHD medication.

Number of patients by age and gender

The number of peoples treated with R/PBS-listed medicines for ADHD, broken down by gender and more detailed age groups per financial year is shown in Figure 5 and Tables 3 and 4. The data is presented as the number of people initiating R/PBS ADHD therapy (Table 3) from 2014-15 to 2022-23 and prevalent people (Table 4) from 2013-14 to 2022-23 by age group and gender.

Figure 5 shows an increase in the number of prevalent ADHD patients by age group, gender and financial year, beginning in 2013-14.

Previously, 6-12 year olds were the largest age cohort (both initiating and prevalent). However, since around 2021-22 this changed, and the age group with the largest population is now the adult population (>18 year olds). This might be due to people moving through the age cohorts, however this pattern is also seen in initiating people, leaving the lisdexamfetamine restriction change (1 February 2021) as the most likely reason for this increase.

Of note, the growth in ADHD treatment for females (when compared to males) is much larger in some age groups, most noticeably the older age groups.

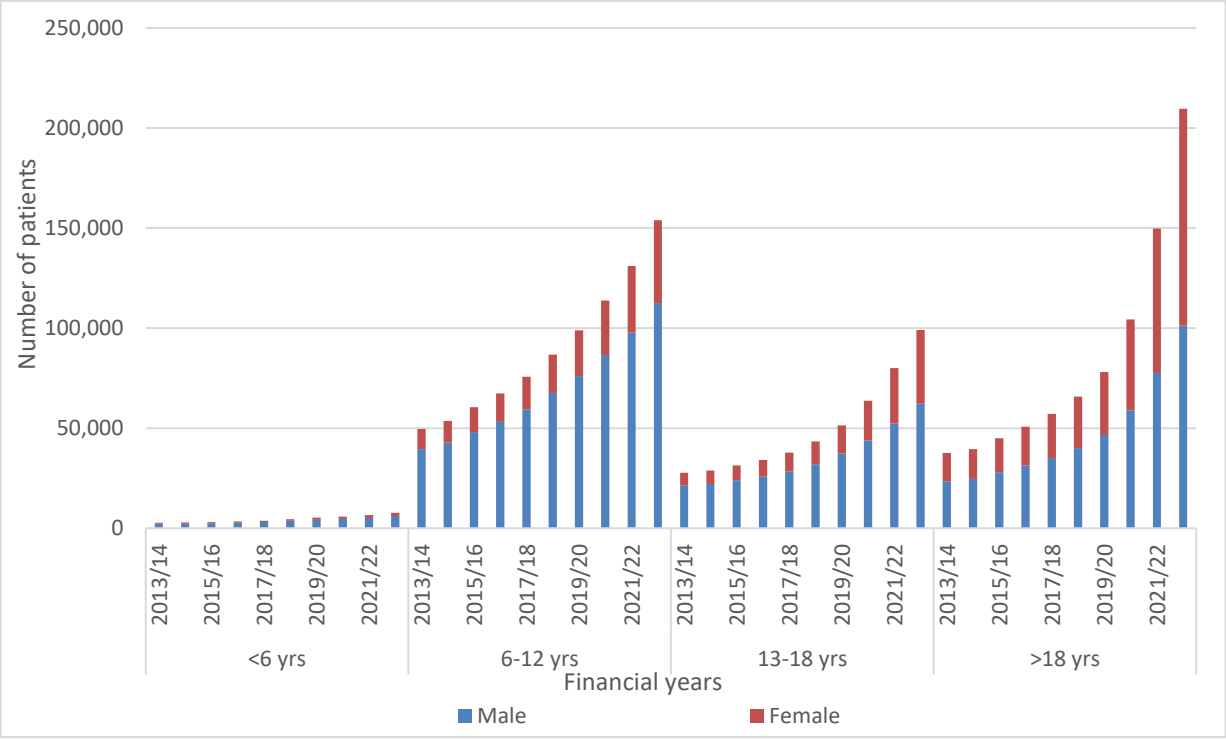

Figure 5: Prevalent people treated with R/PBS-listed ADHD medicines by age group and gender

Table 3 shows the number of people initiating ADHD therapy by age group and gender. From the 2020-21 financial year, females in the >18 year old population outnumbered males. From 2020-21, the amount of females treated for ADHD in the 13-18 year old population overtook the amount of males being treated in this age group.

Table 3. Number of people initiating R/PBS-listed ADHD medicine therapy by age group and gender per financial year

Patients Age	Gender	2014-15	2015-16	2016/17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23
<6 yrs	Male	1,568	1,784	1,854	2,197	2,628	2,981	3,273	3,542	4,444
	Female	402	483	457	496	630	762	866	1,060	1,241
6-12 yrs	Male	11,143	12,559	13,213	14,778	17,435	18,847	21,882	24,152	29,155
	Female	3,171	3,678	4,025	4,813	5,821	6,794	8,349	10,568	13,725
13-18 yrs	Male	3,007	3,039	3,058	3,288	3,993	4,897	6,136	7,845	9,912
	Female	1,435	1,541	1,575	1,866	2,479	3,417	6,160	9,058	11,270
>18 yrs	Male	5,814	6,342	6,592	7,359	8,495	10,300	15,231	21,664	28,446
	Female	3,569	3,944	4,344	4,979	6,062	8,102	15,876	28,718	40,911
Unknown		18	≤5	≤5	≤5		≤5	≤5		
Total new patients		**30,127**	**≤33,375**	**≤35,123**	**≤39,781**	**47,543**	**≤56,104**	**≤77,778**	**106,607**	**139,104**
% growth from previous year			11%	5%	13%	20%	18%	39%	37%	30%

Note: Unknown denotes age and gender not available in the data.

Table 4 shows the number of prevalent people treated with PBS listed ADHD therapy by age group and gender per financial year.

In the >18 year old population, for the first time, females overtook males in 2022-23. This is due to the increasing numbers of initiating females as shown in Table 3.

Table 4. Number of prevalent people treated with PBS-listed ADHD medicines by age group and gender per financial year

Patients Age	Gender	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
<6 yrs	Male	2,278	2,320	2,492	2,704	3,096	3,653	4,218	4,690	5,124	6,106
	Female	518	558	649	636	664	801	1,016	1,179	1,443	1,663
6-12 yrs	Male	39,517	42,733	47,984	53,171	59,315	67,485	76,047	86,544	97,718	112,437
	Female	10,133	10,884	12,495	14,136	16,386	19,313	22,784	27,193	33,292	41,494
13-18 yrs	Male	21,414	22,095	23,979	25,855	28,332	32,040	37,268	43,862	52,332	62,429
	Female	6,238	6,664	7,476	8,309	9,480	11,274	14,188	19,902	27,755	36,581
>18 yrs	Male	23,400	24,589	28,071	31,392	35,070	40,049	46,591	58,820	77,636	101,295
	Female	14,245	14,911	16,963	19,284	22,002	25,737	31,494	45,538	72,134	108,269
Unknown		81	72	22	34	33	15	9	18		
Grand Total		**117,824**	**124,826**	**140,131**	**155,521**	**174,378**	**200,367**	**233,615**	**287,746**	**367,434**	**470,274**
% growth from previous year			**6%**	**12%**	**11%**	**12%**	**15%**	**17%**	**23%**	**28%**	**28%**

Note: Unknown denotes age and gender not available in the data.

In 2019-20, for prevalent people:

- Children <6 years constituted 2% of all people treated with ADHD medicines
- Children aged 6-12 years old constituted 42% of all people treated with ADHD medicines
- Adolescents aged 13-18 years old constituted 22% of all people treated with ADHD medicines
- Adults (>18 years old) constituted 33% of all people treated with ADHD medicines

In 2022-23, for prevalent people:

- Children <6 years constituted 2% of all people treated with ADHD medicines
- Children aged 6-12 years old constituted 33% of all people treated with ADHD medicines
- Adolescents aged 13-18 years old constituted 21% of all people treated with ADHD medicines
- Adults (>18 years old) constituted 45% of all people treated with ADHD medicines

The above figures highlight the shift in patient demographics, where the adult population has become the highest treated population for ADHD medicines.

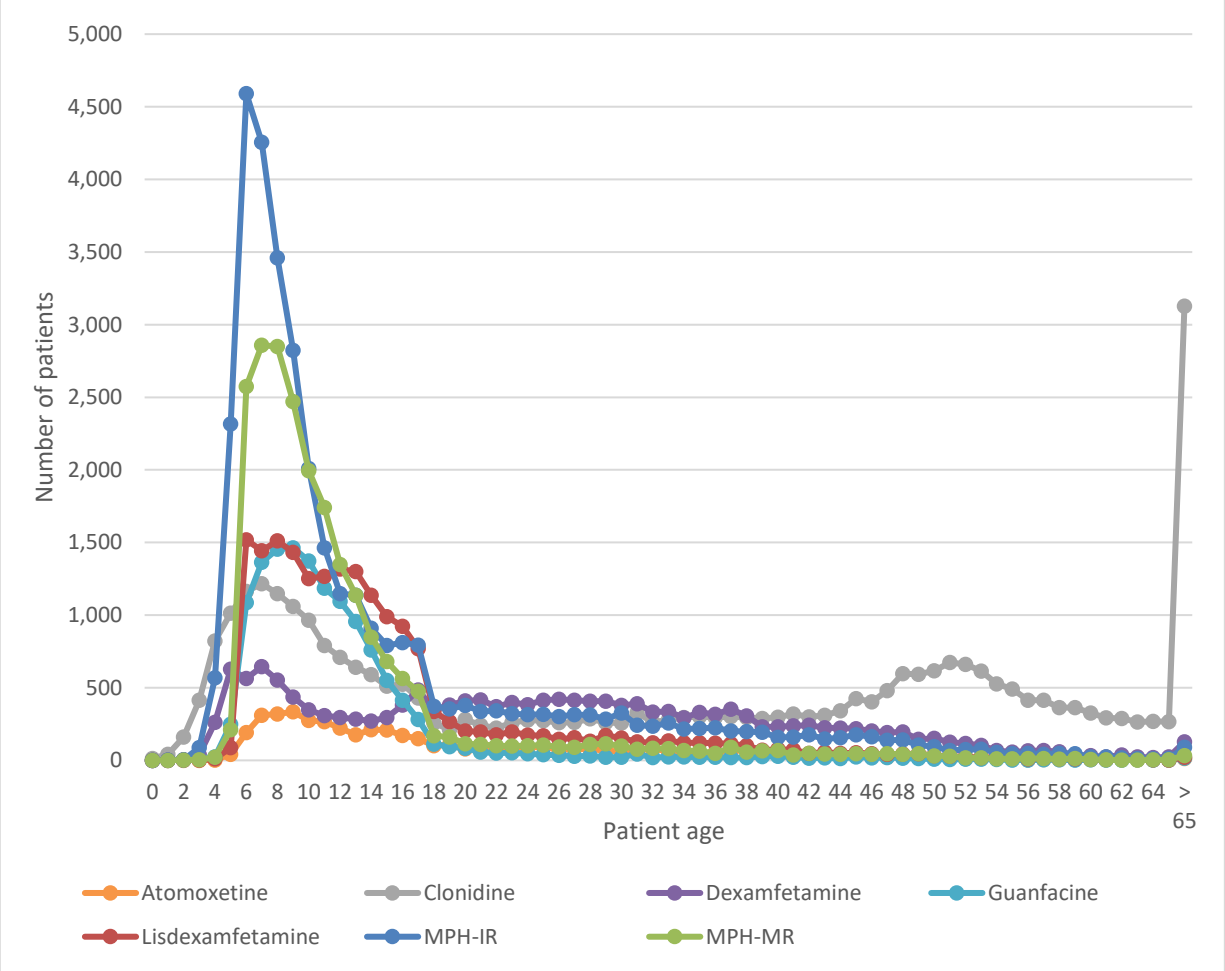

Figure 6a: Age distribution of people initiating an ADHD medicine or clonidine in financial year 2019-20

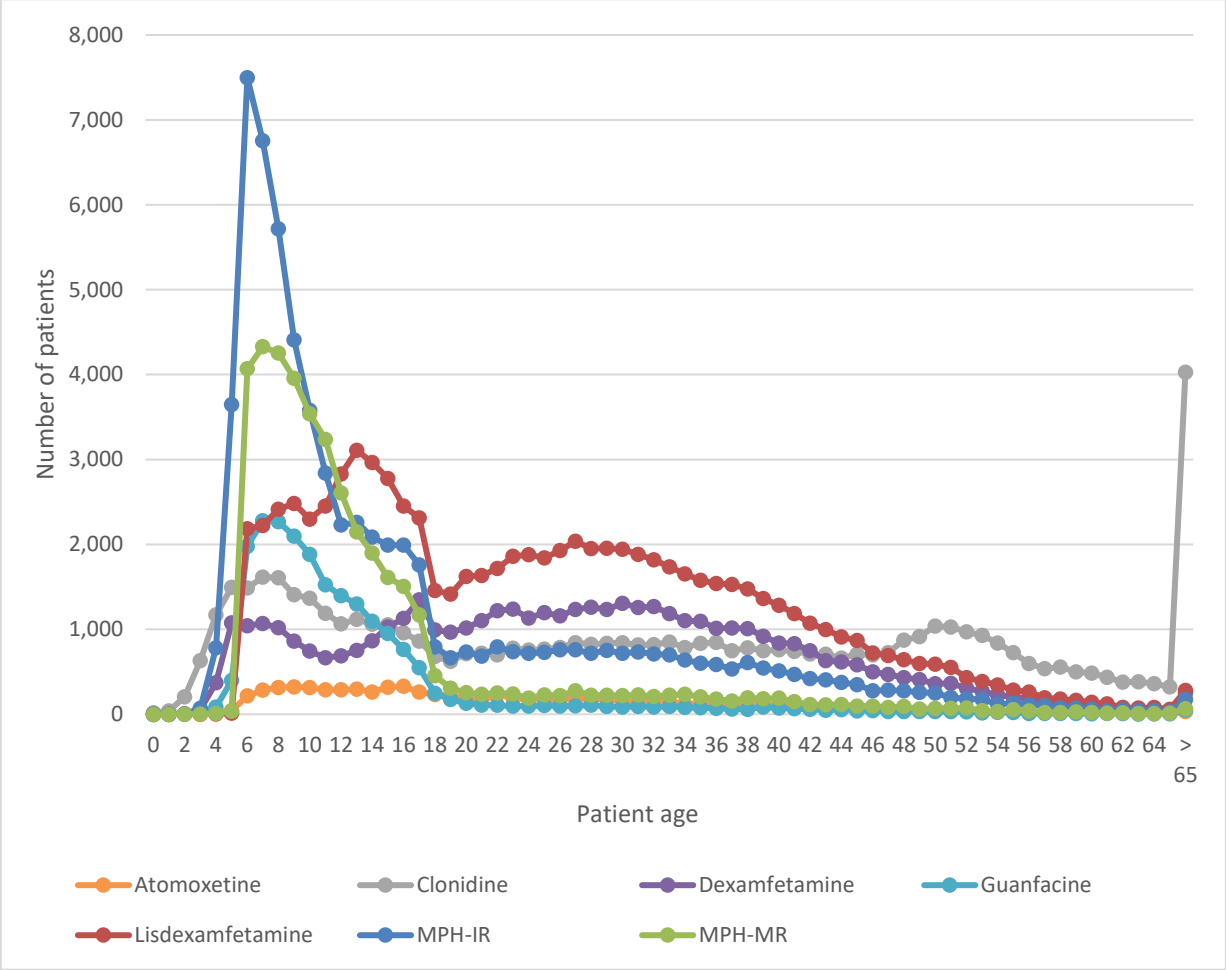

Figure 6b: Age distribution of people initiating an ADHD medicine or clonidine in financial year 2022-23

When comparing the two figures (6a and 6b) the rise in use of all ADHD medicines (apart from atomoxetine) from the 2019-20 financial year compared to the 2022-23 financial year is evident.

The distribution of initial prescribing for lisdexamfetamine has dramatically changed over the two year time periods in the graphs. There is increasing prescribing amongst 10 year olds, with the age of initial medicine prescription peaking in the 13 year old age group.

The overall initial prescribing of lisdexamfetamine is much higher in 2022-23 than in 2019-20 (prior to the restriction change), the distribution has also changed with a much higher amount of adults using lisdexamfetamine in 2022-23 compared to 2019-20.

The use of dexamfetamine has also increased in 2022-23 compared to 2019-20. Clonidine use remains consistent across the two time periods. There is a high level of confidence that clonidine is being prescribed for people ≤18 years old for ADHD, as this age group would not usually be prescribed clonidine for other diseases/disorders. The high use of clonidine in the above 44 year old and >65 year old populations is likely due to use for other non-ADHD related conditions, such as hypertension.

Figure 7a shows the age distribution for all people supplied an ADHD medicine in the 2019-20 financial year by medicine.

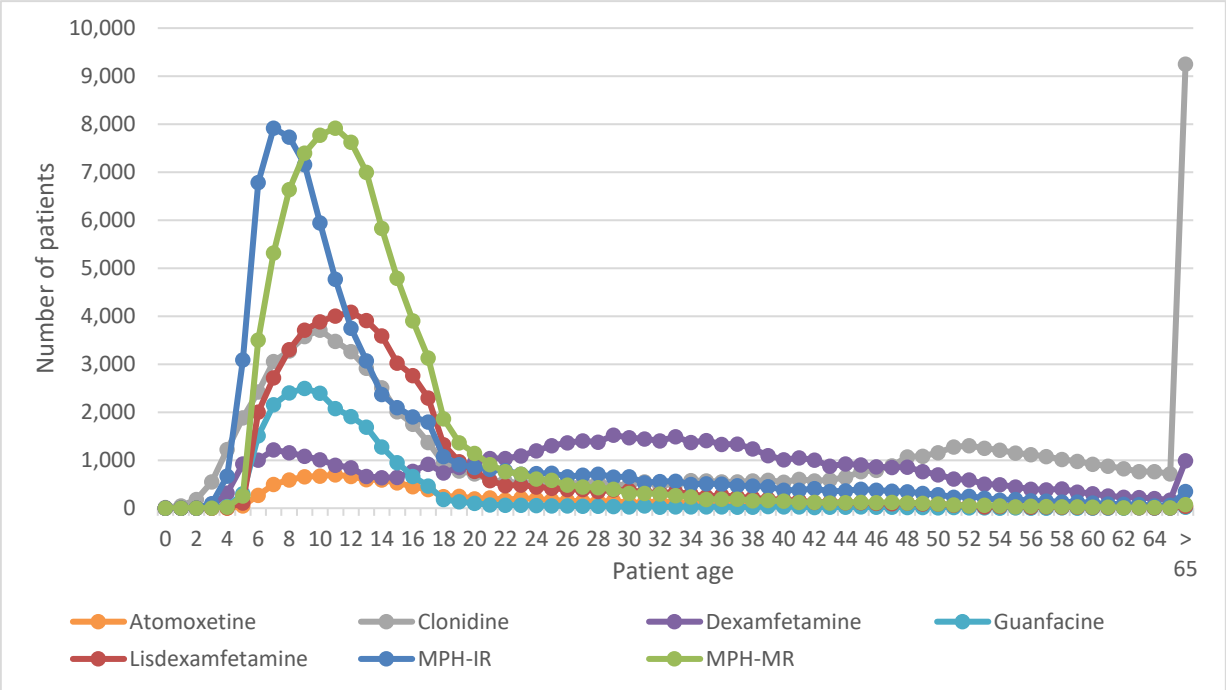

Figure 7a: Age distribution of prevalent people by ADHD medicine or clonidine in financial year 2019-2020

Figure 7b shows the age distribution for all people supplied an ADHD medicine in the 2022-23 financial year by medicine.

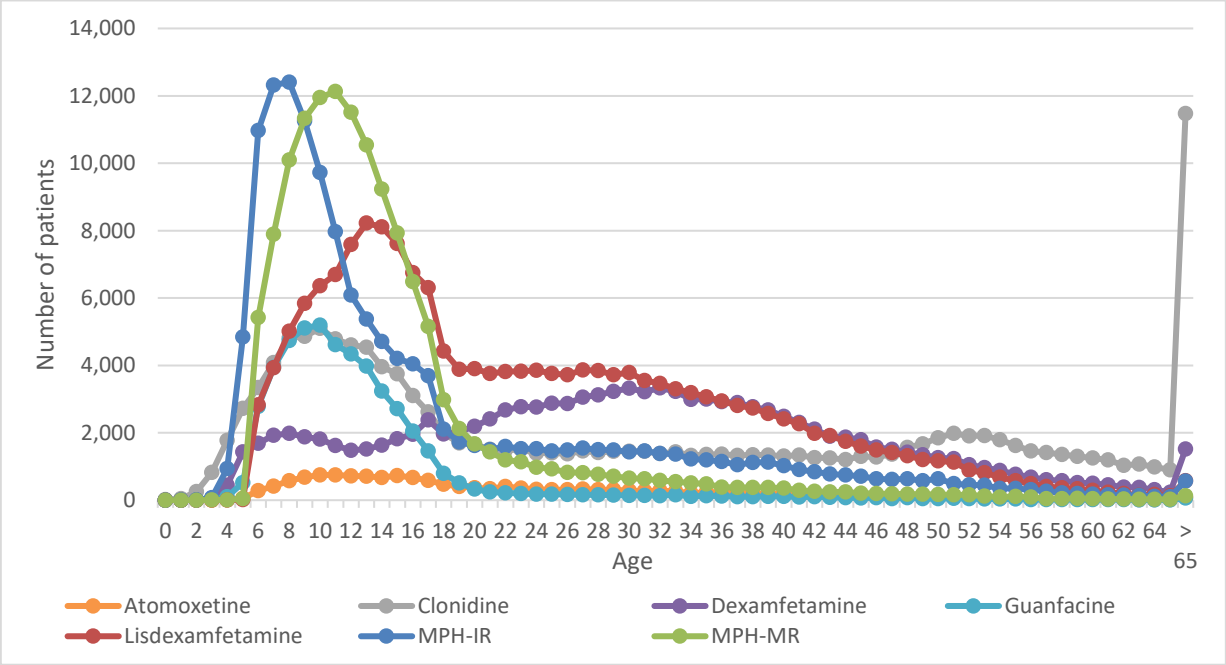

Figure 7b: Age distribution of prevalent people by ADHD medicine or clonidine in financial year 2022-2023

Similar to Figure 6a and 6b, the rise in use of all ADHD medicines (apart from atomoxetine) in prevalent people is clear.

While use of both forms of methylphenidate remains the highest in the younger age groups, lisdexamfetamine use has dramatically increased. Where lisdexamfetamine use previously tapered off after the age of 18 (Figure 7a), after the restriction change (1 February 2021) use has remained high in the adult population.

Similar to initiating people, clonidine use remains high in continuing people.

Prescribers

Each State and Territory law stipulates the conditions under which medical practitioners are able to prescribe ADHD medicines.[1]

Figure 8a shows the type of prescribers for the initiating prescription for each R/PBS ADHD medicine or clonidine supplied in 2019-20. Figure 8b shows the types of prescribers for the initiating prescription for each R/PBS ADHD medicine or clonidine supplied in the 2022-23 financial year.

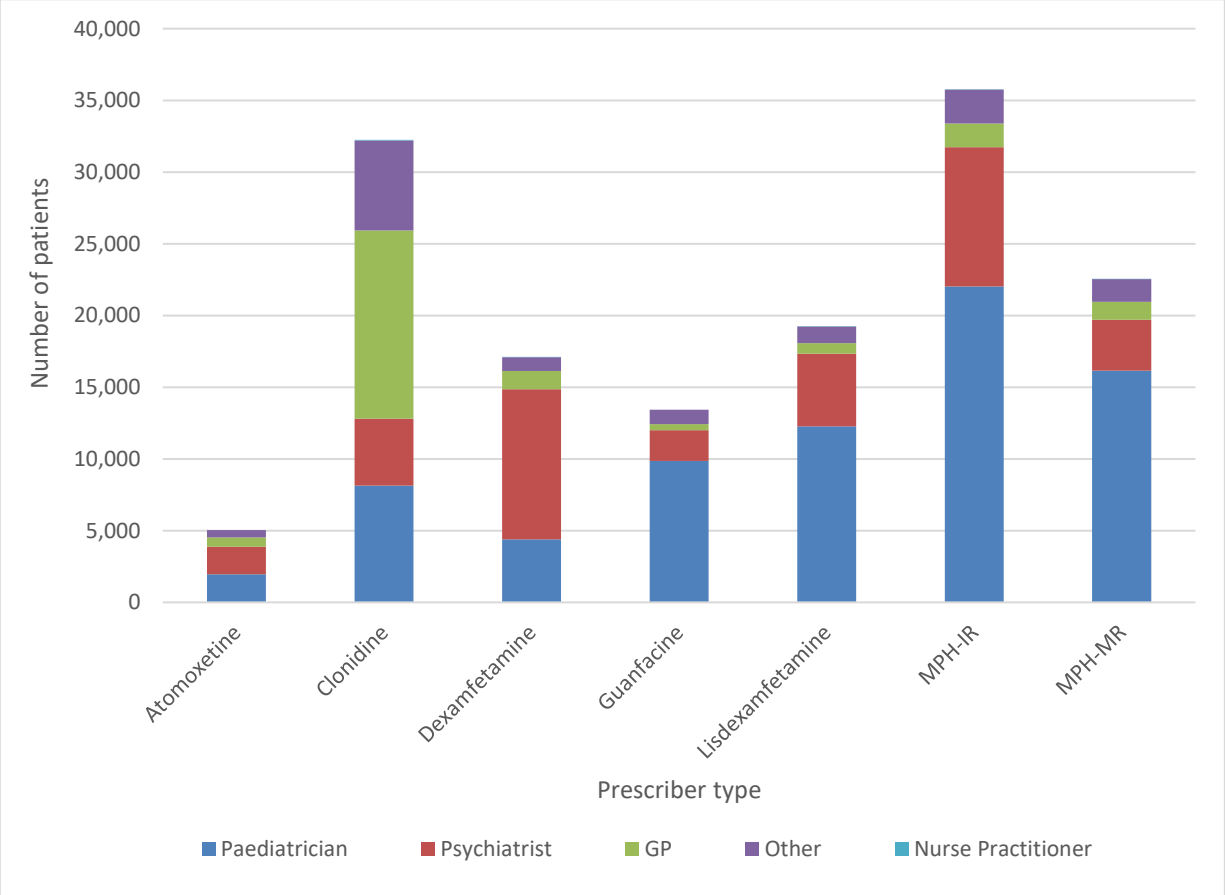

Figure 8a: Prescriber type for people initiating ADHD medicines or clonidine in financial year 2019-20

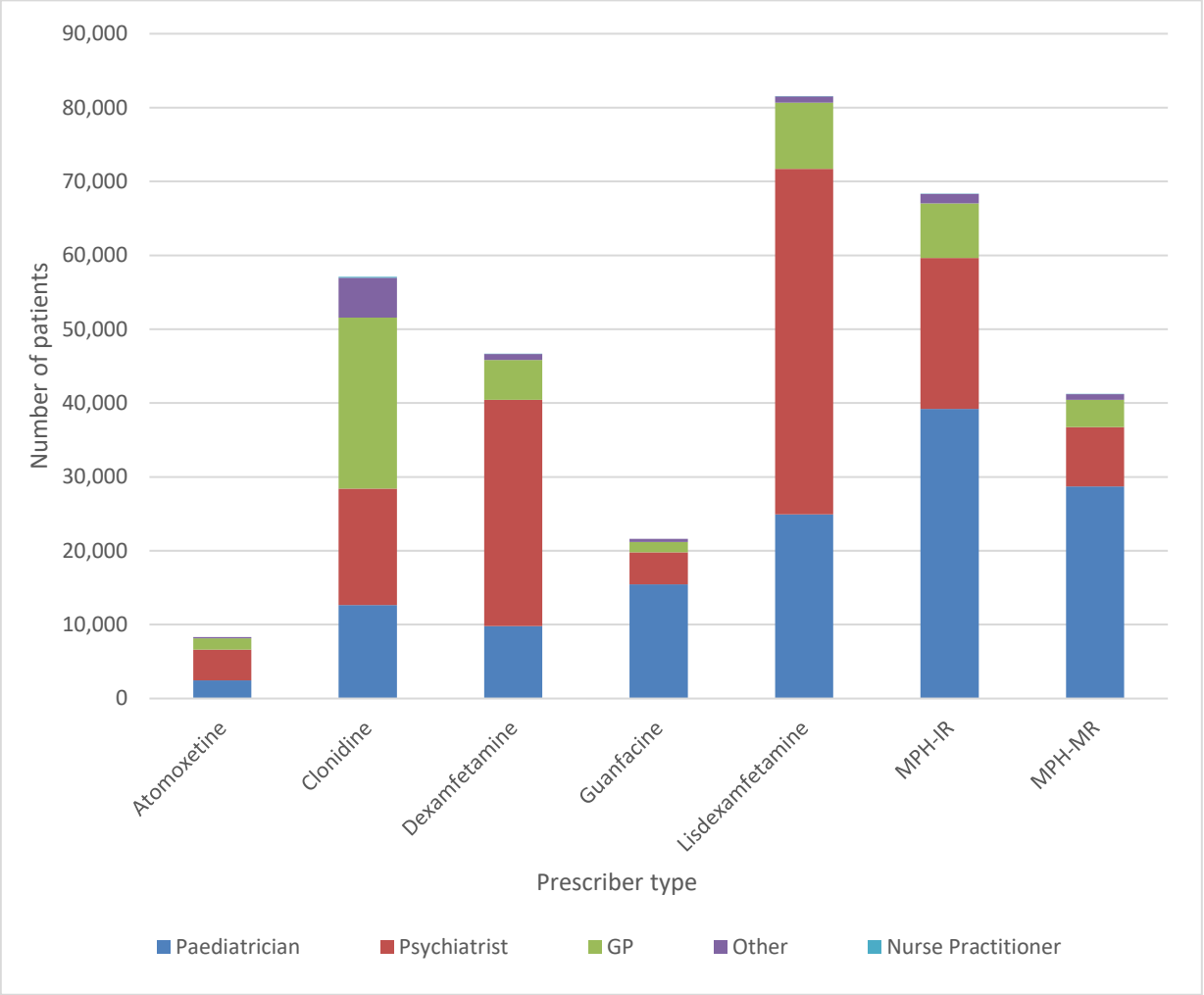

Figure 8b: Prescriber type for people initiating ADHD medicines or clonidine in financial year 2022-23

The initial prescriber for commencing an ADHD medicine is influenced by state and territory regulations and also by the age of the patient.

The change in prescriber type for lisdexamfetamine is interesting when comparing Figure 8a and 8b. Prior to the restriction change, lisdexamfetamine was usually prescribed by paediatricians (Figure 8a), however since the restriction change initiating use of lisdexamfetamine is more likely to be prescribed by psychiatrists (Figure 8b), due to their higher involvement with non-paediatric populations.

The initial prescribing of clonidine has also changed over the two different time periods. Use of clonidine has increased (in line with the increase of all ADHD medicines), however proportionally fewer general practitioners (GPs) are prescribing clonidine.

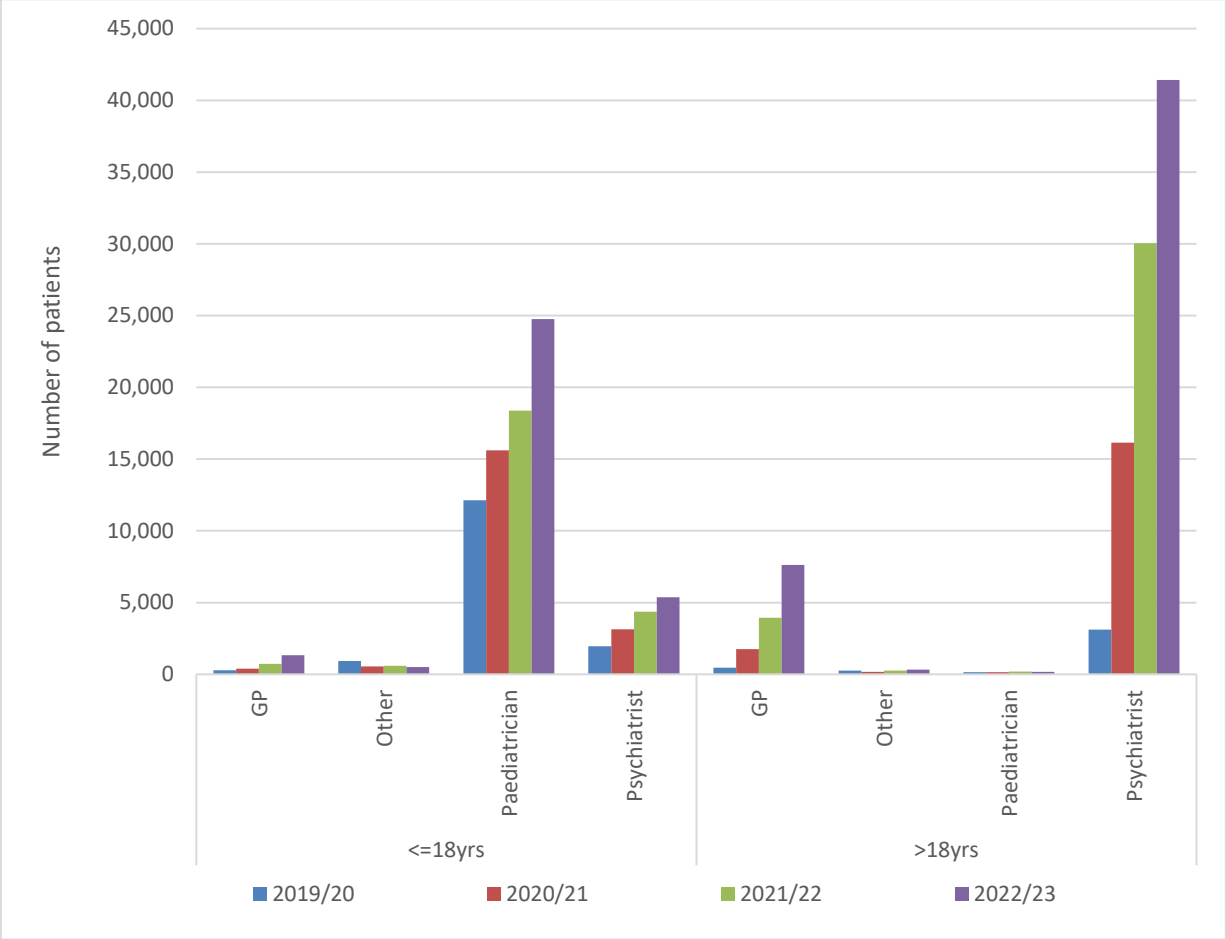

Figure 9: Prescriber type for ≤18 year old and >18 year olds initiating ADHD therapy on lisdexamfetamine by financial year

Figure 9 depicts the prescriber type for people initiating ADHD therapy on lisdexamfetamine by financial year.

Paediatricians are the most common prescriber type of the ≤18 year old population, while psychiatrists are the most common prescriber for the >18 year old population.

The figure shows that utilisation of lisdexamfetamine in the adult population has increased rapidly since the restriction change on 1 February 2021.

Utilisation by State/Territory

Figure 10 shows the number of people supplied ADHD medicines (excluding clonidine) per 1,000 population by therapy in the 2022-23 financial year, broken down by age and patient state/territory. Figure 10 does not double count patients who are on more than one ADHD medication.

Rates of prescribing vary across states and territories, reflecting the different jurisdictional laws about stimulant prescribing.

2022-23 financial year rates of treatment (Figure 10 and Table 5)

- Treatment in <6 year olds was highest in Tas and QLD and lowest in the NT
- Treatment in school-aged children (6-12 years old) was highest in Tas, and lowest in SA.
- Treatment for 13-18 year olds was highest in ACT and lowest in SA
- Treatment in adults (>18 years old) was highest in WA and the ACT, and lowest in Tas and the NT.

The adult rates of prescribing were significantly higher in WA and the ACT compared to the other States and the NT.

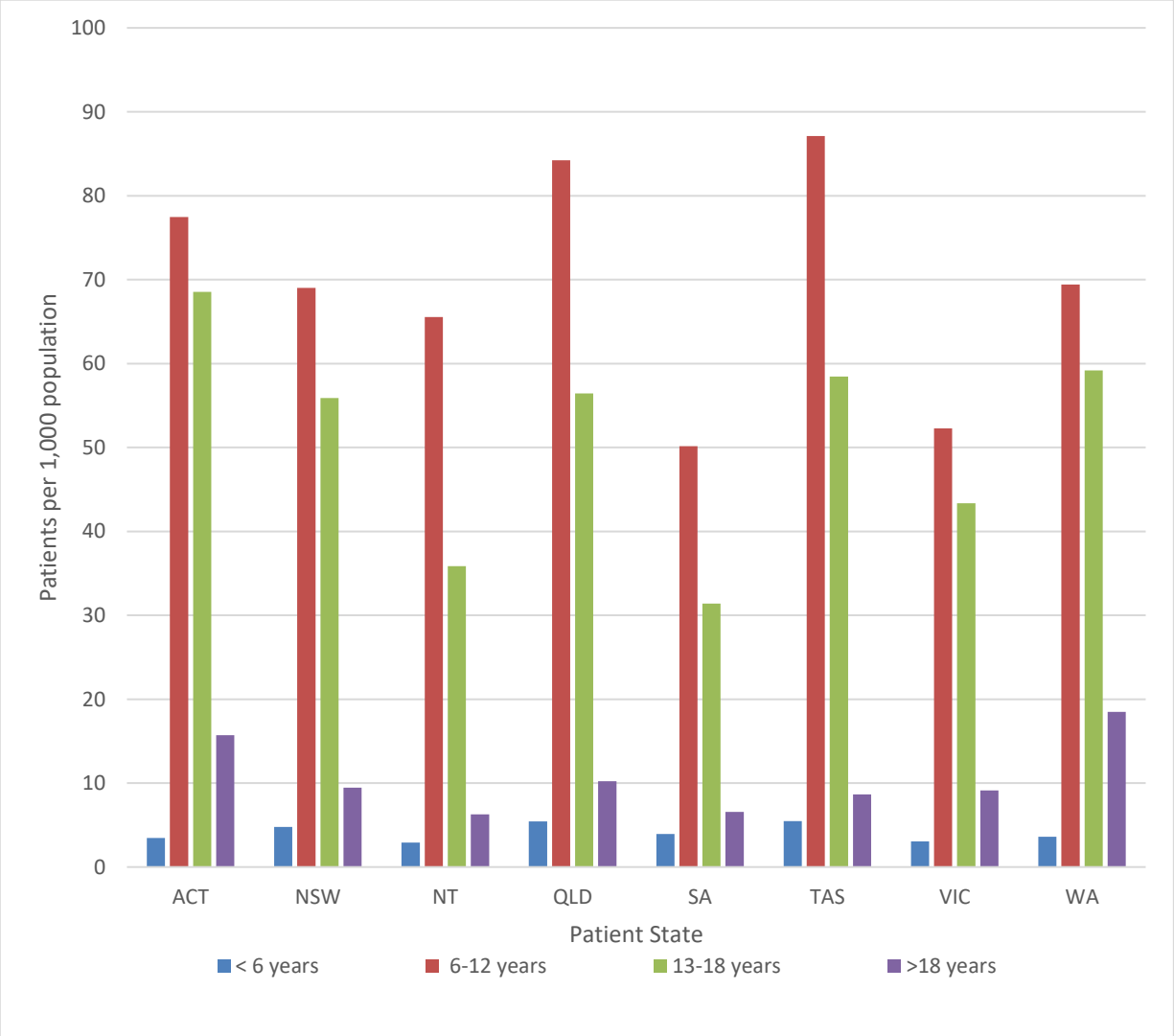

Figure 10: Number of people supplied an ADHD medicine (excluding clonidine) per 1000 population in the 2022-23 financial year by patient state/territory and age group (age group specific rate)

Table 5. Number of people supplied an ADHD medicine (excluding clonidine) per 1000 population by state/territory and age group in financial years

Age group	State / Territory	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
< 6 years	ACT	1.14	0.94	1.04	0.94	1.42	1.66	1.92	2.41	3.45
	NSW	1.97	2.09	2.07	2.31	2.66	3.24	3.65	3.93	4.76
	NT	1.23	1.53	1.30	1.69	2.71	2.93	3.20	2.96	2.91
	QLD	1.83	2.09	2.24	2.46	2.80	3.13	4.01	4.56	5.45
	SA	1.11	1.05	1.05	1.31	1.55	2.26	2.61	3.42	3.95
	TAS	1.92	1.87	2.43	3.32	3.48	4.08	5.10	5.94	5.47
	VIC	1.09	1.20	1.29	1.50	1.98	2.22	2.34	2.63	3.05
	WA	1.13	1.26	1.47	1.52	1.78	2.15	2.58	3.03	3.63
6-12 years	ACT	27.17	30.36	33.73	36.83	43.04	49.49	56.75	66.07	77.48
	NSW	31.22	33.97	35.74	38.49	42.41	47.04	53.58	59.56	69.00
	NT	17.02	21.13	26.61	34.35	39.00	47.06	55.85	61.20	65.53
	QLD	33.76	36.96	39.90	43.85	49.12	54.57	62.64	73.36	84.23
	SA	14.30	15.34	16.74	19.30	22.48	26.45	32.63	40.32	50.16
	TAS	26.66	28.82	32.30	36.72	42.65	51.31	59.94	72.29	87.11
	VIC	17.86	19.98	22.20	24.75	28.57	32.74	37.25	43.81	52.25
	WA	23.27	27.05	29.86	33.86	38.88	43.71	49.38	58.50	69.40
13-18 years	ACT	16.70	18.30	21.02	24.80	29.80	37.20	44.31	56.78	68.53
	NSW	22.07	23.84	24.96	26.93	29.87	34.46	40.95	48.14	55.90
	NT	8.84	9.96	10.80	11.84	16.25	17.67	21.97	27.94	35.87
	QLD	18.27	19.85	21.58	23.81	26.96	31.72	38.99	48.04	56.43
	SA	7.14	7.74	8.67	9.55	10.57	12.71	17.49	24.16	31.39
	TAS	17.46	18.94	21.09	23.25	25.86	30.64	37.87	47.78	58.45
	VIC	11.13	12.59	13.85	15.47	17.86	21.37	26.67	34.31	43.34
	WA	17.42	19.18	20.92	23.47	27.42	32.06	39.16	49.83	59.19
>18 years	ACT	2.73	2.96	3.31	3.75	4.42	5.62	7.65	11.32	15.71
	NSW	2.17	2.42	2.69	3.02	3.44	4.04	5.19	7.09	9.46
	NT	1.20	1.26	1.42	1.73	2.02	2.12	2.78	4.25	6.28
	QLD	2.01	2.33	2.63	2.95	3.28	3.79	5.11	7.47	10.24
	SA	1.26	1.37	1.56	1.70	1.87	2.20	2.83	4.29	6.58
	TAS	1.03	1.36	1.79	2.06	2.15	2.67	3.67	5.73	8.66
	VIC	1.32	1.51	1.70	1.93	2.30	2.81	4.07	6.27	9.14
	WA	5.56	6.15	6.54	6.97	7.71	8.55	10.80	14.50	18.49

Table 5 and Figure 11 show the increased use of ADHD medication since the 2014-15 financial year across all state and territories and age groups.

The rate of ADHD medicine supply has increased across every age group and state and territory except in the <6 year old age group in Tas and NT. Despite this decrease from the previous year, Tas continues to have the highest rate of ADHD medicine supply in this age group (5.47/1000 population), with QLD not too far behind (5.45/1000 population).

The rate of ADHD medicine supply in the 6-12 year age group was highest in Tas (87.11/1000 population), closely followed by QLD (84.23/1000 population), with SA having the lowest rate amongst this age group (50.16/1000 population).

The rate of ADHD medicine supply in adolescents (13-18 year olds) was highest in the ACT (68.53/1000 population) and lowest in SA (31.39/1000 population).

For adults, the rate of supply of ADHD medicine was much higher in WA (18.49/1000 population) than all other states and territories, which ranged from 6.28-15.71/1000 population. This was consistent with the findings in previous DUSC reports.

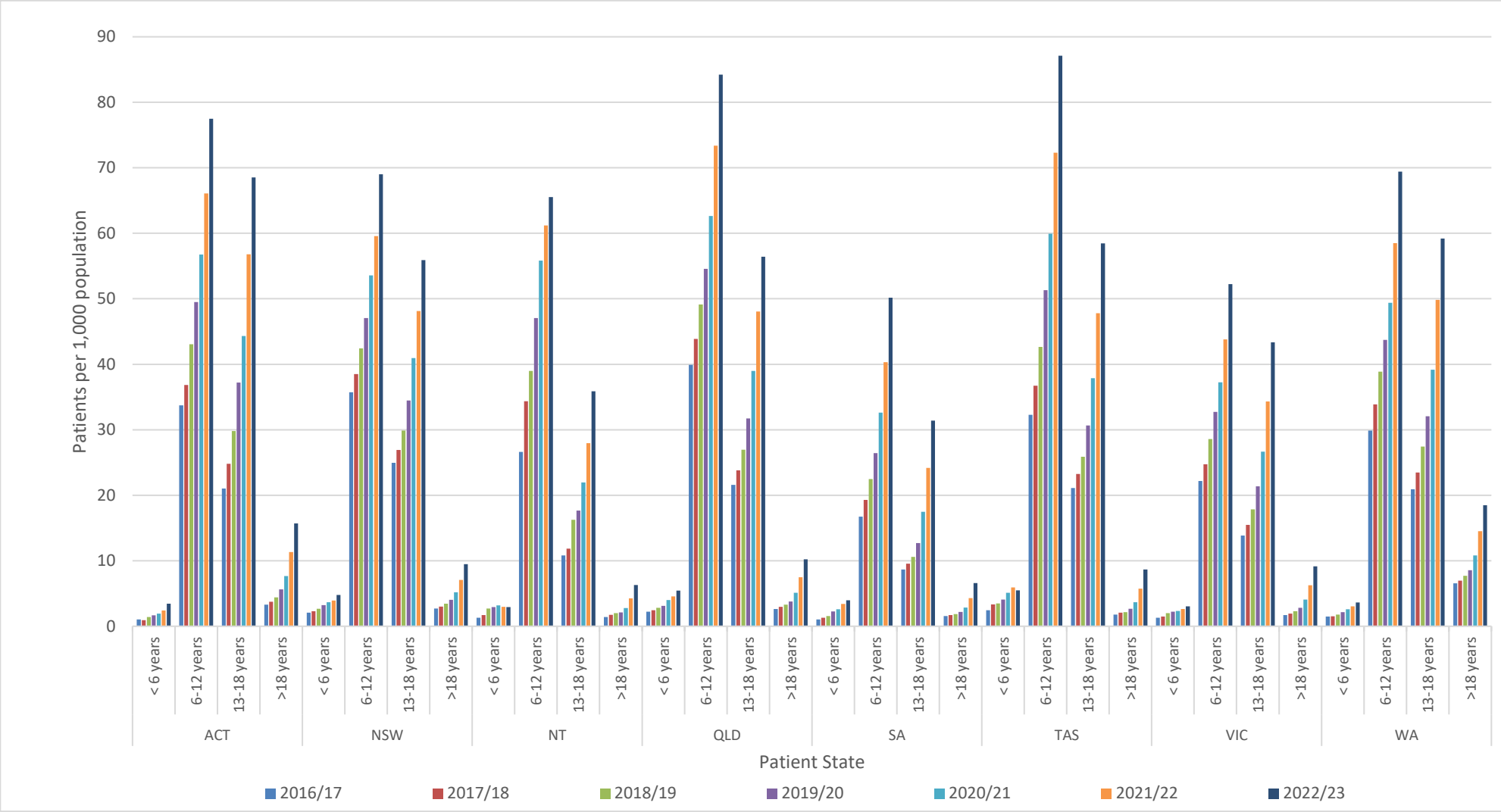

Figure 11: Number of people supplied an ADHD medicine (excluding clonidine) per 1000 population by state/territory and age group 2014-2020

Figures 12 depicts the number of people supplied ADHD medicines per 1,000 population in 2022-23 financial year for patients ≤18 years old. The figures are presented by medicine and patient state/territory and are adjusted to account for the population size and age distribution in each state/territory in 2022-23. The high use of clonidine indicates that an even greater proportion of young people are being treated for ADHD or side effects of ADHD medications, than what is currently recognised.

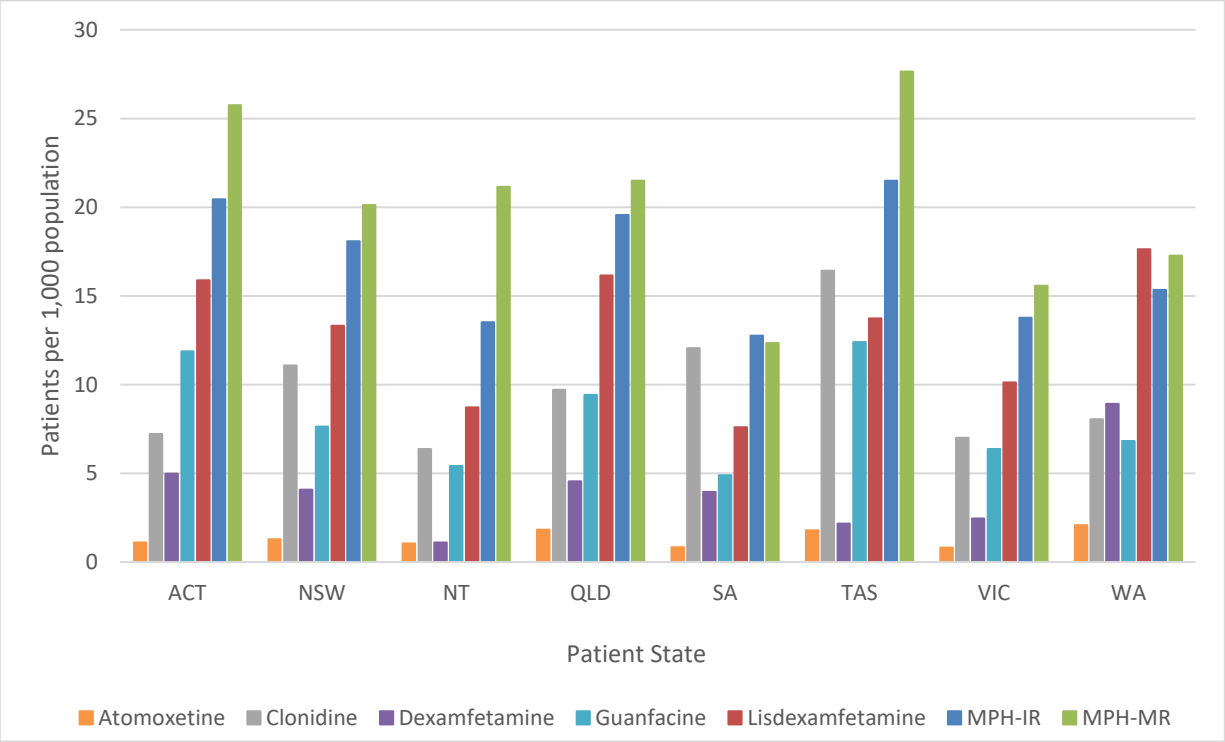

Figure 12: Number of people aged ≤18 years supplied an ADHD medicine or clonidine per 1,000 population in 2022-23 financial year by patient state/territory and medicine (age group specific rate)

The pattern of ADHD medicines use varied across the states and territories. In the >18 years old age group, the rate of people supplied dexamfetamine and lisdexamfetamine is much higher in WA compared to other states and territories.

Figure 13a depicts the number of people supplied ADHD medicines per 1,000 population in 2019-20 for >18 years old. The figures are presented by medicine and patient state/territory and are adjusted to account for the population size and age distribution in each state/territory. This graph shows the supply of medicines prior to the lisdexamfetamine restriction change.

Figures 13b depicts the number of people supplied ADHD medicines per 1,000 population in 2022-23 financial year for >18 years old. The figures are presented by medicine and patient state/territory and are adjusted to account for the population size and age distribution in each state/territory in 2022-23. This graph shows the supply of medicines after the lisdexamfetamine restriction change, where a clear picture of the increased use of lisdexamfetamine is evident.

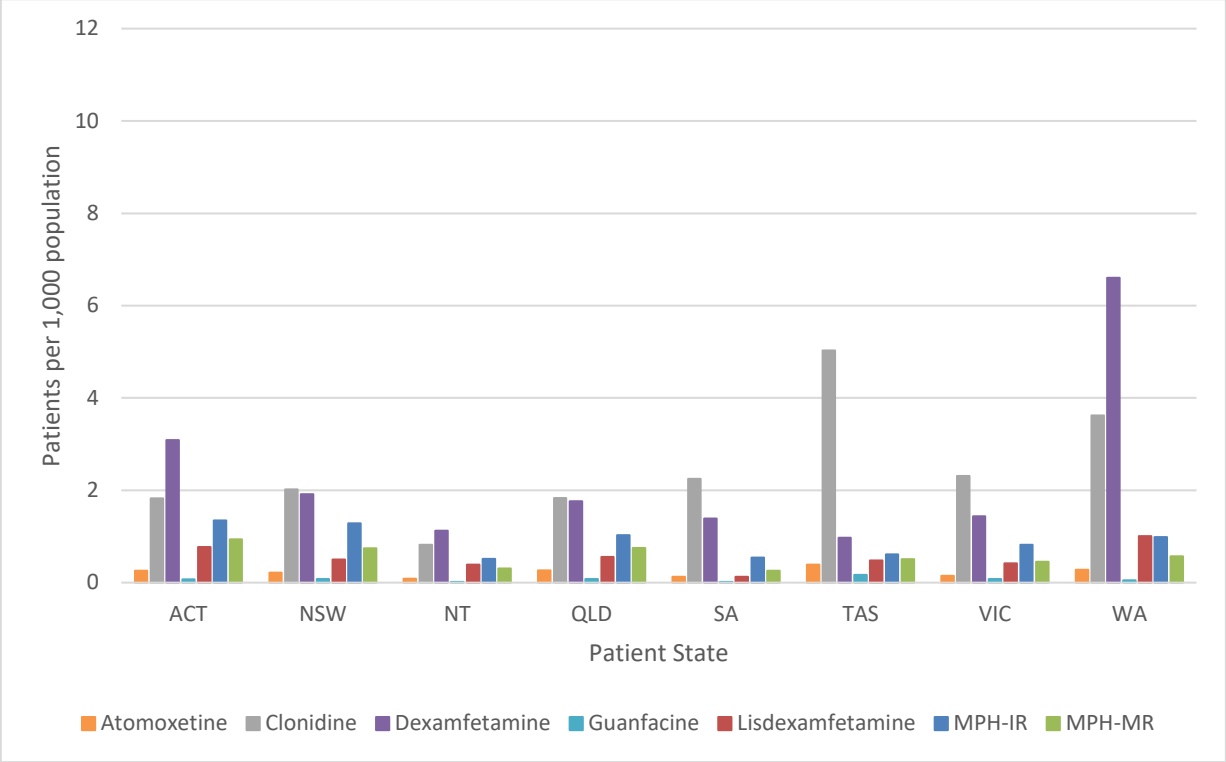

Figure 13a: Number of people aged >18 years supplied an ADHD medicine or clonidine per 1,000 population in 2019-20 by patient state/territory and medicine age (age group specific rate)

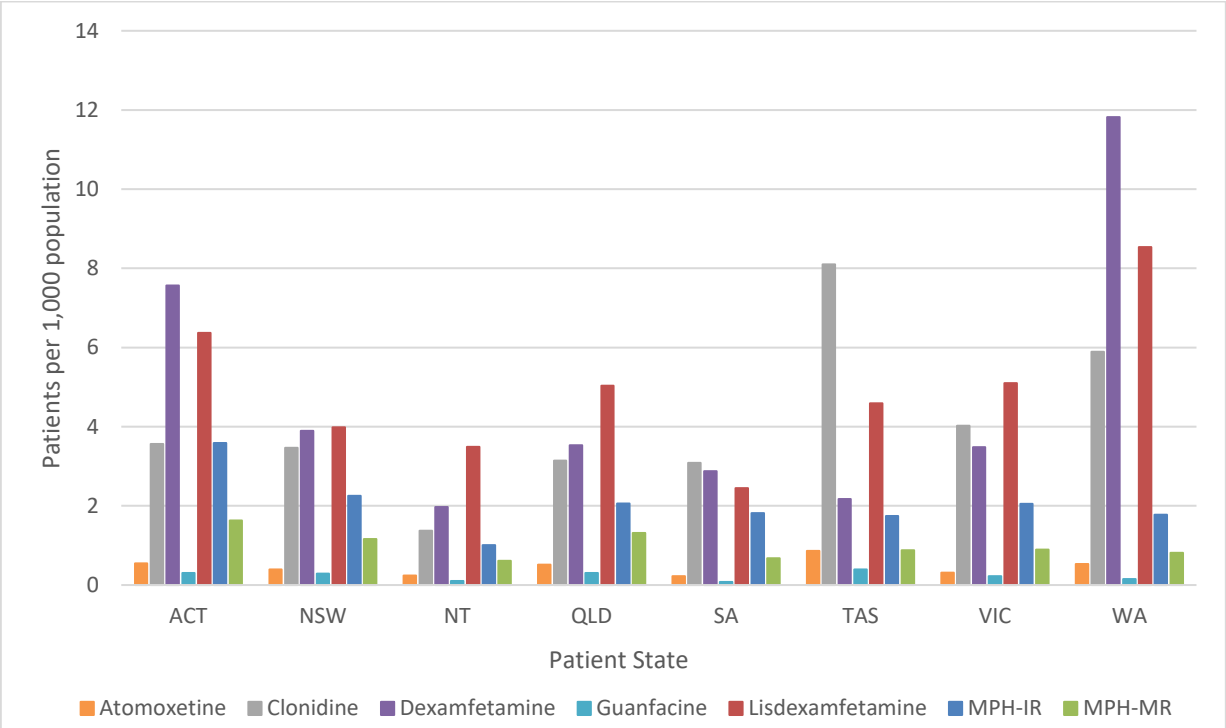

Figure 13b: Number of people aged >18 years supplied an ADHD medicine or clonidine per 1,000 population in 2022-23 by patient state/territory and medicine (age group specific rate)

Lisdexamfetamine predicted versus actual analysis

Approach taken to estimate utilisation

A market share analysis was used to inform the utilisation and financial estimates of the expanded listing of lisdexamfetamine, to include treatment of patients with ADHD who are diagnosed after the age of 18 years.

Commercial-in-confidence

[redacted]

Analysis of actual versus predicted utilisation

Table 6 presents the predicted versus actual utilisation of lisdexamfetamine. The actual figures are the script count for >18 years old initiating on lisdexamfetamine after 1 February 2021.

Table 6. Lisdexametamine: actual versus predicted utilisation

Parameter	Difference	Year 1 Feb 2021 – Jan 2022	Year 2 Feb 2022 – Jan2023
Number of scripts dispensed	Predicted (P)	[redacted]	[redacted]
	Actual (A)	176,953	422,576
	Difference (%) ((P-A)/P) x 100	[redacted]	[redacted]

In the first year of the lisdexamfetamine restriction change, the actual scripts dispensed were marginally [redacted] than the amount predicted. In the second year, the actual scripts dispensed were [redacted] the predicted amount.

End commercial-in-confidence

Discussion

This ADHD utilisation report examines the use of ADHD medications and includes a review of the potential utilisation of clonidine as a medication prescribed for ADHD. While definitive results are difficult to establish, it is estimated that clonidine is being used as an ADHD medication across all age groups. There is a high level of confidence that clonidine is being prescribed for people 18 years and under, as this age group would not usually be prescribed clonidine for other diseases/disorders. The inclusion of clonidine increases the number of people 18 years and under who are supplied ADHD medicines.

Overall, the utilisation of ADHD medicines listed on the R/PBS increased between the ten financial years, 2013-14 to 2022-23. This trend is consistent for prescriptions and patient data over this period.

In the previous review in June 2021[18], children aged 6-12 years old were the highest percentage (42%) of people treated with ADHD medicines in both initiating and prevalent populations. However, since that review and the lisdexamfetamine restriction change on 1 February 2021, the >18 year old group has become the highest percentage of people treated with ADHD medicines, in both initiating and prevalent populations.

Males are generally treated at higher rates than females. However, from the 2020-21 financial year, for the first time seen in DUSC analyses, initiating females in the 13-18 year old and >18 year old population outnumbered males. This trend has continued over the following two financial years. This strong uptake in the initiating female adult population has meant that in 2022-23, the >18 year old female prevalent population overtook the male population.

The rate of ADHD medicine supply per 1000 population shows that Tas has the highest rate of supply for <6 year olds (5.47) closely followed by QLD (5.45), while the NT has the lowest (2.91). Rates in the 6-12 year old group were highest in Tas (87.11) and QLD (84.23), while SA and Vic had much lower rates of 50.16 and 52.25 per 1000 population respectively. Rates in the 13-18 year old group were highest in the ACT (68.53) and lowest in SA (31.39). Rates in the >18 year old group were highest in WA (18.49) and lowest in the NT (6.28) and SA (6.58).

Whilst the overall number of people utilising ADHD medicines has increased year on year over this review period, the 1 February 2021 lisdexamfetamine restriction change has led to a higher rate of increase in the >18 year old population.

In the first year of the lisdexamfetamine restriction change, the actual scripts dispensed were [redacted] than the amount predicted. In the second year, the actual scripts dispensed were [redacted] the predicted amount.

DUSC consideration

DUSC noted:

- The utilisation of ADHD medicines has increased over the ten financial years of the reporting period (2013-14 to 2022-23).

- DUSC noted that adults were now the highest percentage of patients treated for ADHD, when previously 6-12 year olds were the largest cohort. DUSC commented that this shift was a result of the expanded listing of lisdexamfetamine.
- DUSC noted in Year 2 of the lisdexamfetamine extension, the number of lisdexamfetamine scripts was [redacted] the amount predicted.
- That for the first time since reporting on ADHD, use of ADHD medicines in females outnumbered males in some age groups.
- The increasing prevalence over time; growth rate of 242% in ≤18 year olds, and 496% in >18 year olds.
- The variation of use by state and territory. DUSC commented that this was due to different state and territory rules regarding prescription of ADHD medicines. DUSC commented that about 15-20 years ago Western Australia had a high use of ADHD medicines in under 18 year olds and that the shift in Western Australia could be due to people aging.
- That determining if clonidine is being used for ADHD is difficult, however for people under 18 years old it is more certain. DUSC noted that the Australian ADHD Professionals Association (AADPA) advised that clonidine is used to manage sleep disturbance and could be an adjunctive ADHD therapy.

DUSC commented that people can be represented more than once in the prevalent use figures (4a, 4b and 4c), noting that in overall use, most patients used a modified release of methylphenidate until 2021, when lisdexamfetamine became the most used medicine.

DUSC discussed responses from AADPA, the Australian Association of Psychologists and the sponsor regarding the review. DUSC noted AADPA's suggestion that the prevalence of ADHD medicine use in approaching prevalence of the condition in people under 18 years of age, and that the adult prescribing rate is still below prevalence estimates, which indicates that there is not an over-prescription of ADHD medicines. DUSC considered that not every person with ADHD would be treated with medication and for this reason prescription rates probably would not reach parity with prevalence rates.

DUSC discussed the rising use of telehealth as a means for people to obtain prescriptions.

DUSC discussed the issues with lifetime drug use, recognising the importance of holistic care and multimodal solutions.

DUSC discussed the illicit use of ADHD medicines noting that the National Drug and Alcohol Research Centre might have data on this, including how many people are diverting from illicit use into proper care.

DUSC actions

DUSC requested that the report be provided to the PBAC for consideration.

Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

Sponsors' comments

Takeda Pharmaceuticals Australia Pty. Ltd: The sponsor has no comment.

Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health and Aged Care has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up to date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

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Appendix A: Key R/PBS listing dates for ADHD medicines and changes to listing dates

Table A.1: Date of listing of PBS medicines used in the treatment of ADHD

Date	Drug name	Brand name	Strength	Item
Dec 1973	Dexamfetamine	-	5 mg	1165H
Aug 2005	Methylphenidate IR	Ritalin 10	10 mg	8839F
Dec 2005	Methylphenidate IR	Attenta*	10 mg	8829F
April 2007	Methylphenidate MR	Concerta	18 mg	2387P
			36 mg	2388Q
			54 mg	2432B
July 2007	Atomoxetine	Strattera	10 mg	9092M
			18 mg	9093N
			25 mg	9094P
			40 mg	9095Q
			60 mg	9096R
Aug 2007	Methylphenidate MR	Concerta	27 mg	2172H
April 2008	Methylphenidate MR	Ritalin LA	20 mg	2276T
			30 mg	2280B
			40 mg	2283E
Dec 2008	Atomoxetine	Strattera	80 mg	9289X
			100 mg	9290Y
Aug 2010	Methylphenidate MR	Ritalin LA	10 mg	3440C
Sep 2015	Lisdexamfetamine	Vyvanse	30 mg	10486X
			50 mg	10474G
			70 mg	10492F
Sep 2018	Guanfacine	Intuniv	1 mg	11452R
			2 mg	11451Q
			3 mg	11440D
			4 mg	11441E

Notes: * The Attenta® brand of methylphenidate IR was delisted in March 2009.

Table A.2. Changes to R/PBS restrictions of ADHD medicines

Date	Drug name	Change to the restriction/s
Aug 2007	Methylphenidate MR (Concerta®)	Replacement of "…child or adolescent aged 6 to 18 years inclusive" with "…patient aged 6 to 18 years inclusive".
Nov 2008	Atomoxetine (all items)	The restrictions were changed to remind prescribers that atomoxetine is not PBS subsidised for use with other ADHD medicines. "Initial treatment…" was replaced by "Initial sole PBS-subsidised treatment…", and "Continuing treatment…" was replaced by "Continuing sole PBS-subsidised treatment…". A note was also added, "No applications for increased maximum quantities and/or repeats will be authorised", as the listing of the 80 mg and 100 mg doses was considered to negate the need for increased maximum quantities.
Oct 2009	Methylphenidate (modified release) (all items)	The restrictions were modified to extend the listing to the treatment of patients aged over 18 years who were diagnosed between ages 6–18. "Treatment of attention deficit hyperactivity disorder (ADHD) in a patient between the ages of 6 and 18 years inclusive" was changed to "'Treatment of attention deficit hyperactivity disorder (ADHD) in a patient *diagnosed* between the ages of 6 and 18 years inclusive".
Aug 2014	Atomoxetine (all items)	The restriction was simplified and changed from Authority Required to Authority Required (STREAMLINED). The requirement for diagnosis using the DSM-IV criteria was updated to the DSM-V. The emphasis on "sole PBS-subsidised treatment" use was removed. References in the previous restriction to specific contraindications and adverse events were generally removed.
July 2016	Methylphenidate (modified release) (all items)	The restriction criteria remains the same but was contents were restructured to separately define population criteria and clinical criteria.
July 2016	Dexamfetamine 5mg, tablets	The restriction criteria remains the same but was contents were restructured to separately define the two criteria for prescribing.
July 2016	Atomoxetine (all items)	The restriction was modified to account for the new listing of lisdexamfetamine. The criteria was further limited by adding the requirement for contraindication to lisdexamfetamine before prescribing. "* Patient must have a contraindication to dexamphetamine, methylphenidate or *lisdexamfetamine* as specified in TGA-approved product information;"
Sept 2018	Atomoxetine (all items)	Change in the restriction from 'The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria…' to 'Treatment criteria: * Must be treated by a paediatrician or psychiatrist. Clinical criteria: * The condition must be or have been diagnosed according to the DSM-5 criteria…'
March 2019	Guanfacine (all items)	Addition of new listing for patients taking guanfacine simultaneously with maximum tolerated dose of other stimulants.
Feb 2021	Lisdexamfetamine	Restriction change to allow use in adults with ADHD persisting from childhood even if diagnosed after 18 years of age.
May 2023	Methylphenidate	Restriction change to allow use in adults with ADHD persisting from childhood even if diagnosed after 18 years of age.

Appendix B: PBAC recommendations for listing of ADHD medicines (Prior to 2020)

Copies of the PBAC Meeting Outcomes and Public Summary Documents are available on the PBAC Meetings website.

Guanfacine (Intuniv®)

At the Jully 2017, the PBAC recommended the listing of guanfacine on a cost-minimisation basis with atomoxetine for the treatment of patients diagnosed with ADHD between the ages of 6 and 17 years inclusive who are contraindicated or intolerant to stimulant therapy. The PBAC did not recommend the listing of guanfacine as monotherapy in patients who have failed to achieve an adequate response to stimulants as the evidence presented did not support a listing in that population.

The PBAC recommended that the indications for guanfacine should be the same as those of atomoxetine and that guanfacine should be a streamlined authority.

The PBAC advised that guanfacine should not be treated as interchangeable on an individual basis with any other drugs and that it is not suitable for prescribing by nurse practitioners.[19]

At the July 2018, the PBAC recommended the listing of guanfacine, as a General Schedule Authority Required (Streamlined) benefit, as add-on therapy in conjunction with optimised stimulant therapy, for ADHD in patients experiencing residual moderate to severe ADHD symptoms.

Methylphenidate IR

At the March 2005 meeting, the PBAC recommended listing on a cost-minimisation basis compared to dexamfetamine sulfate, with the equi-effective doses being methylphenidate hydrochloride 10 mg and dexamfetamine sulfate 5 mg.[20] The PBAC was concerned over the possible extent of use of the product and requested that the DUSC monitor this.

Methylphenidate MR (Concerta®)

At the November 2006 meeting the PBAC recommended listing of methylphenidate MR (Concerta®) as an authority required benefit on a cost effectiveness basis over methylphenidate IR. Although the extent of any clinical benefit over methylphenidate IR remained uncertain, the Committee agreed that the likely improvements in compliance and in ease of administration, particularly in relation to the removal of the need for a dose of medication at school, were sufficient to justify listing.[21]

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[19] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2017-07/files/guanfacine-hydrochloride-psd-%20july-2017.pdf

[20] Department of Health (2005), March 2005 PBAC Outcomes - Positive Recommendations. Accessed on: 27 February 2018, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2005-03/positive-recommendations

[21] Department of Health (2007), PBAC Meetings Public Summary Documents: Methylphenidate Hydrochloride, extended release tablets, 18 mg, 36 mg and 54 mg, Concerta November 2006. Accessed on: 27 February 2018, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2006-11/pbac-psd-methylphenidate-nov06

In July 2012 the PBAC rejected a submission to extend the listing to include patients diagnosed with ADHD after the age of 18 years, on the basis of uncertain efficacy and safety in the proposed population, and high and highly uncertain cost to the PBS.[22]

Methylphenidate MR (Ritalin LA®)

In November 2007, the PBAC recommended listing of methylphenidate hydrochloride modified release (Ritalin LA®) capsules on the PBS on a cost-minimisation basis compared with methylphenidate hydrochloride modified release tablets (Concerta®) at the same price per day, as reflected by the equi-effective doses.[23]

In March 2020, the PBAC recommended the listing of methylphenidate hydrochloride 60 mg modified release capsule Ritalin® LA 60 mg), under the same conditions as the currently listed Ritalin LA strengths (10 mg, 20 mg, 30 mg and 40 mg).[24]

Atomoxetine (Strattera®)

The PBAC recommended the listing of atomoxetine (Strattera®) 10 mg, 18mg, 25 mg, 40 mg and 60 mg in November 2006, on a cost-effectiveness basis over placebo. The PBAC considered that there was a clinical need for the product and that the proposed restriction targeted the appropriate population.[25]

In July 2008, the PBAC recommended the listing of two additional strengths of atomoxetine (Strattera®), 80 mg and 100 mg, but rejected a submission to extend the use of atomoxetine to patients diagnosed with ADHD as adults due to insufficient evidence of clinical and cost-effectiveness. The submission claimed that the new strengths were unlikely to increase atomoxetine use or cost to the PBS.[26]

In March 2014, the PBAC recommended that the current Authority required restriction for atomoxetine be changed to Authority Required (STREAMLINED).[27]

Lisdexamfetamine (Vyvanse®)

In July 2014, the PBAC considered the resubmission and recommended the listing of lisdexamfetamine (Vyvanse®) 30mg, 50mg, 70mg on a cost-minimisation basis compared with long-acting methylphenidate. The PBAC considered that the evidence in the submission

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[22] Department of Health (2012), PBAC Meetings Public Summary Documents: Methylphenidate hydrochloride, Tablets, 18 mg, 27 mg, 36 mg, and 54 mg,(extended release) Concerta® - July 2012 Accessed on: 27 February 2018, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2012-07/methylphenidate-hydrochloride

[23] Department of Health (2007), November 2007 PBAC Outcomes - Positive Recommendations. Accessed on: 27 February 2018, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2007-11/positive-recommendations

[24] https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/2020-03/methylphenidate-capsule-containing-methylphenidate

[25] Department of Health (2007), PBAC Meetings Public Summary Documents: Atomoxetine Hydrochloride, capsules, 10 mg, 18 mg, 25 mg, 40 mg and 60 mg, Strattera® November 2006. Accessed on: 15 April 2021, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2006-11/pbac-psd-atomoxetine-nov06
Department of Health (2008), PBAC Meeting Public Summary Documents: Atomoxetine hydrochloride, capsules, 80 mg and 100 mg,

[26] Strattera®, July 2008 Accessed on: 27 February 2018, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2008-07/pbac-psd-atomoxetine-hydrochloride-july08

[27] Department of Health (2014), March 2014 PBAC Outcomes - Positive Recommendations. Accessed on: 27 February 2018, at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/pbac-recommendations-march-2014

demonstrated non-inferiority to long-acting methylphenidate in terms of effectiveness, and inferiority to long-acting methylphenidate in terms of safety.

The resubmission presented cost minimisation analysis versus MPH-OROS in children aged 6 to 12, cost-utility analysis versus MPH-OROS in adolescents aged 13-17 and cost-utility analysis versus 'no pharmacological treatment' or 'placebo' as proxy for standard of care in patients who have failed MPH-OROS.

The PBAC recommended the proposed listing of LDX as an authority required benefit in patients diagnosed between the ages of 6 and 18 years (inclusive). For the restriction, PBAC considered that there should be no requirement for patients to demonstrate response to dexamfetamine, as use of dexamfetamine DEX does not give guidance of dose or tolerability of lisdexamfetamine.

The PBAC recommended that lisdexamfetamine should not be treated as interchangeable with any other drugs.[28]

In July 2019, the PBAC recommended the listing of three additional strengths of lisdexamfetamine (Vyvanse®), 20 mg, 40 mg and 60 mg.[29]

In March 2020, the PBAC recommended expanding the listing of lisdexamfetamine to include treatment of patients with ADHD who are diagnosed after the age of 18 years old.[30]

[28] Department of Health (2014), PBAC Meeting Public Summary Document: LISDEXAMFETAMINE DIMESILATE, capsules, 30 mg, 50 mg & 70 mg, Vyvanse®, Shire Australia Pty Ltd, July 2014. Accessed on: 16 April 2021, at: https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/2014-07/lisdexamfetamine-dimesilate-psd-07-2014

[29] https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/2019-07/lisdexamfetamine-capsule-containing-lisdexamfetamine-dimesi

[30] https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/2020-03/lisdexamfetamine-capsule-containing-lisdexamfetamine