Aide-Mémoire

Puberty Blockers Evidence Brief: Next steps post release

Date due to MO:	30 April 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024040460
To:	Hon Dr Shane Reti, Minister of Health		
Cc:			
Consulted:	Health New Zealand: ☒ Māori Health Authority: ☐		

Contact for telephone discussion

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Purpose:

In response to your request for additional information, this report provides additional information on what next steps may look like for:

- enhanced prescription monitoring or controls for puberty blockers (e.g. using special authority to improve data, etc)
- enhanced wraparound support for people being prescribed puberty blockers.

It also provides a summary table showing what other comparable countries have done on this issue (where known).

Comment: This Aide-Mémoire discloses all relevant information.

Dr Joe Bourne
Chief Medical Officer | Ngā Āpiha Hauora
Clinical, Community and Mental Health Directorate | Te Pou Whakakaha

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Context

1. The Ministry of Health will soon release its evidence brief on the impact of puberty blockers on gender dysphoric adolescents.

2. The Ministry's accompanying position statement on the *Use of Puberty Blockers for Gender-Affirming Care* sets out the following actions for the use of puberty blockers for gender-affirming care:

    - A clear direction that clinicians who initiate puberty blockers should be experienced in providing gender-affirming care and be part of an interprofessional team offering a full range of supports to young people presenting with gender related issues.
    - The Ministry will work with Health New Zealand – Te Whatu Ora to establish clinical governance structures across gender related services. Clinical governance will require enhanced monitoring of the range of services required including wraparound support, as well as the use of medicines.
    - Enhanced prescription monitoring.
    - The Ministry will continue to monitor international literature for emerging evidence on puberty blockers and gender-affirming care more generally.
    - New Zealand based research will be commissioned in the longer-term.

3. Following the publication of the position statement and evidence brief the Ministry will develop a detailed work programme to deliver the described actions. The work programme will include a timeline and resource requirements.

Enhanced prescription monitoring of puberty blockers

4. Prescribing data is available from Health New Zealand's Pharmaceutical Collection – a data warehouse that contains claim and payment information from pharmacists for subsidised dispensings. It is possible to get some insights into prescribing patterns through this data, but there are limitations as this is not the primary reason for its collection.

5. The Ministry has discussed with Pharmac the possibility of utilising the Special Authority process for enhanced monitoring of prescribers. Decisions regarding the introduction of a special authority are made by Pharmac. Health New Zealand manages Special Authority applications which is a funding tool, not a clinical one.

6. Pharmac has indicated that while this use does not align with their strategy regarding Special Authority, they are open to exploring it with the Ministry as an

option. If Special Authority is identified as an appropriate means to place additional restrictions on prescribing of puberty blockers, implementation will take at least eight weeks.

7. The use of Special Authority needs further exploration as would audit processes. There are some issues that need to be considered:

   - Identifying what criteria will be applied and whether any restriction is placed on the scope of the applying practitioner.
   - While Special Authority applicants can be limited to practitioners with a particular vocational scope of practice e.g. paediatrician/endocrinologist/general practitioner, it is not possible to identify a special interest. A private prescription would still be able to be written if the patient is self-funding.

8. The Ministry could also consider placing restrictions on prescribing the medicines used as puberty blockers (goserelin and leuprorelin), as provided for under the Medicines Act 1981, by granting provisional consent with conditions. This has been used in the past for other medicines e.g. clozapine. The provisional consent will apply to the entire medicine, meaning any conditions could be included for specific indications (uses).

9. s 9(2)(h)

10. The cross-agency work programme will explore these issues while also considering whether other enhanced monitoring options are available.

Availability of psychosocial wraparound support

11. The Ministry has connected with Health NZ to gain a more complete understanding of the services available to young people presenting with issues relating to their gender identity. There is currently no evidence that individual clinicians are prescribing outside of an interprofessional team, and the proposed enhanced monitoring will provide additional assurance.

12. Unlike the centralised services that have recently been disestablished in both England and Scotland, the New Zealand model is a distributed one. It ensures an individual is supported by an interprofessional team including medical specialists, general practitioners with a special interest, psychiatrists and psychologists, and locating services in districts to ensure appropriate access. This comprehensive model of care has already implemented in Auckland, and as a combined service across Canterbury and West Coast. Further services are being commissioned with resource from a Budget 22 allocation. This is an enhancement of existing services.

Comparable countries

13. The evidence brief includes a stocktake of legislative or governance changes relating to puberty blockers. It notes that prescription of puberty blockers is a complex issue and that some jurisdictions have recently made changes to prescribing practices and regulatory oversight. A table showing the approaches other comparable countries have taken on this issue (where known) is included on the following page.

14. We believe the approach New Zealand are taking is most closely comparable with Canada and Australia, with differences in Australia relating most substantially to medication funding pathways.

Schedule of comparable jurisdictions' approach to puberty blocker prescribing

Country	Approach	Comments
New Zealand	Access through clinical processes involving individuals and their families, as part of comprehensive gender-affirming care.	Once published the position statement sets out clearly the expectations of prescribers in this area, including the clinician is experienced in providing gender-affirming care and is part of an interdisciplinary team.
Australia	In most states and territories, the prescription of puberty blockers for people aged under 18 years requires consent from the young person, treating clinician and all parties who have parental responsibility.	Like New Zealand, prescribing is "off-label", however the medications are not funded through the Pharmaceutical Benefits Scheme. Prescription is most often through specialist services to enable access to heavily subsidised funding of the medicines through DoH investment. Services appear to be well funded, with some specialist services having a funded research arm attached to them.
Canada (most provinces)	Access through clinical processes involving individuals and their families, as part of comprehensive gender-affirming care.	Alberta is considering banning the use of puberty blockers for young people aged under 16 years.
England	In March 2024 NHS England published a clinical policy changing practice stating that prescription of puberty blockers is limited to those enrolled in a clinical trial.	The independent Cass report published April 2024 for NHS England raised gaps in interprofessional approaches and variability in service access by patients, making 32 recommendations specific to NHS England.
Scotland	In April 2024 NHS Greater Glasgow and Clyde and NHS Lothian issued a joint statement confirming a pause on new prescriptions for puberty hormone suppressants and cross sex hormone medication for young people with gender dysphoria.	The statement confirmed that referrals to paediatric endocrinology for the prescription of puberty-suppressing hormones have been paused, but anyone referred will be given "the psychological support they require" while care pathways are reviewed in line with the Cass Review findings. The statement also confirmed that young people currently receiving these medicines will not be affected by this pause.
The Netherlands	Access through clinical processes involving individuals and their families, as part of comprehensive gender-affirming care.	On February 15, 2024, the Dutch Parliament ordered that an investigation be conducted into the physical and mental health outcomes of children prescribed puberty blockers. (source article)
Finland	Prescription of puberty blockers is limited to those enrolled in a clinical trial.	Finland's Council for Choices in Health Care revised its guidelines in 2020 to prioritize psychosocial support over medical intervention but confirmed that initiation of hormonal interventions may be considered in

		a person before the age of 18 "if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria."
Norway	Prescription of puberty blockers is limited to those enrolled in a clinical trial.	In 2023 Norway's Healthcare Investigation Board (Ukom) recommendation to the Ministry of Health that puberty blockers and hormonal and surgical gender confirmation treatment for children and young people should be defined as experimental treatment. Explicit new guidance from the country has not yet been issued.
Sweden	Prescription of puberty blockers is limited to those enrolled in a clinical trial.	In 2022 Sweden's National Board of Health and Welfare said that the risks of puberty blockers and gender-affirming hormone treatments for persons younger than 18 years currently outweigh the potential benefits for the group as a whole. Treatment with hormones should continue to be given, but only within a research framework. Hormones can also be given to this age group in exceptional cases.
The United States	The US Food and Drug Administration (FDA) functions at the federal level to govern the prescription of puberty blockers for gender dysphoria. The FDA regulates pharmaceuticals but does not regulate the practice of medicine.	Many states are currently enacting new legislation addressing access to puberty blockers. E.g., the Wisconsin Assembly passed legislation in 2023 prohibiting gender transition medical intervention for individuals under 18 years of age.
France	Prescription continues to be possible with parental authorisation at any age.	France's National Academy of Medicine recommended in 2022 that the "greatest reserve" is required regarding the use of puberty blockers and/or transitioning hormones in children and adolescents. https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en