FW: AndroForte® 5 PBS listing amendment 3rd response to your Letter, awaiting reply [SEC=OFFICIAL]

s22 @health.gov.au>
Fri 11/24/2023 5:14 PM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>

1 attachments (596 KB)
Letter to Lawley Pharm Expression of Interest AndroForte 5 PBS expansion.pdf;

Hey s22

I/we have sent an apologetic holding response back to below. We had started discussion about next steps (trying to find info on whether the sponsor is to bring a proposal to PBAC or whether we will put something together). Can we pick that up again next week sometime?

Have a great weekend

s22

From: PBAC <PBAC@health.gov.au>
Sent: Friday, 24 November 2023 4:57 PM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>
Subject: FW: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL] 3rd response to your Letter, awaiting reply

Hi team,

Looks like quarantine picked this one up, I just released it and this could be why we didn't get a response.

Cheers,
s22

My mottos:
If you do good, know for whom you are doing it, and your kindness will have its effect. (Sirach 12:1)
Without counsel plans fail, but with many advisers they succeed. (Prov 15:22)
Team work makes the dream work (1 Cor 12:25-26)

I am a supporter of the following communites/initiatives:

CaLD CULTURALLY & LINGUISTICALLY DIVERSE
NATIONAL ABORIGINAL & TORRES STRAIT ISLANDER STAFF NETWORK
DISABILITY & CARERS NETWORK

From: Michael Buckley s47F @lawleypharm.com.au>
Sent: Friday, 24 November 2023 2:29 PM
To: pbspricing <pbspricing@health.gov.au>
Cc: PBAC <PBAC@health.gov.au>
Subject: FW: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL] 3rd response to your Letter, awaiting reply

Dear PBS Pricing

Due to the absence of a response from PBAC@health.gov.au and no published telephone number available are you able to assist please?

Kind regards

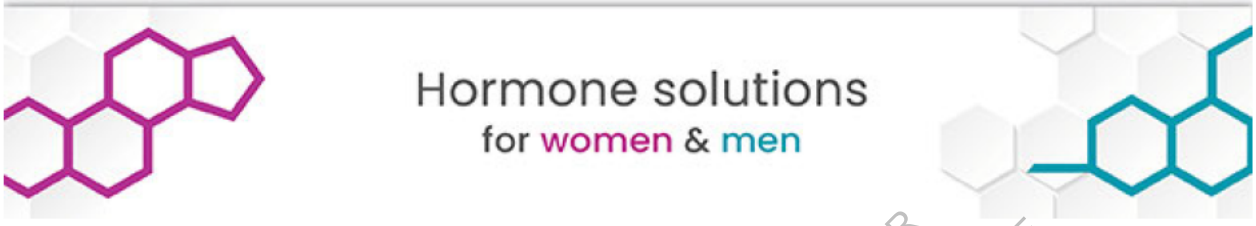
Michael Buckley

LAWLEY

Michael Buckley | Medical Director
M: s47F | E: s47F @lawleypharm.com.au

2/15A Harrogate Street, West Leederville, WA Australia 6007 | PO Box 1146, West Leederville, WA Australia 6901
P: +61 8 9388 0096 | Toll Free Phone: 1800 627 506

www.lawleypharm.com.au info@lawleypharm.com.au



From: Michael Buckley
Sent: Friday, November 24, 2023 9:12 AM
To: PBAC <PBAC@health.gov.au>
Cc: s47F @lawleypharm.com.au>
Subject: FW: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL] 3rd response to your Letter, awaiting reply

Dear PBAC

On 13th October you sent me a letter requesting a response from LAWLEY.
My response was sent the same day and re-sent 31st October as PBAC has not been acknowledged or responded.
Would you please confirm receipt of the email sent 13th Oct 2023? Scroll down on this email to view.

Yours sincerely

Michael Buckley

LAWLEY

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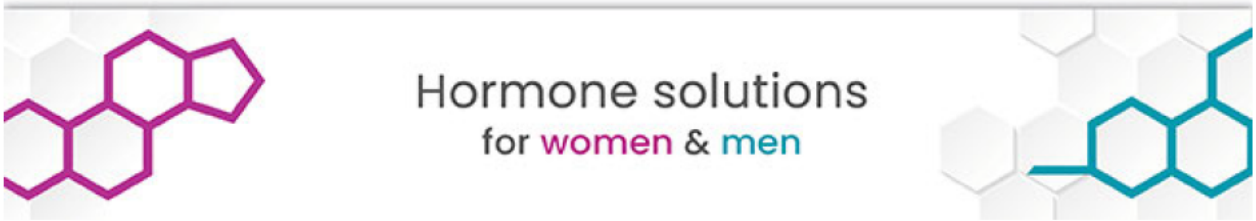

From: Michael Buckley
Sent: Tuesday, October 31, 2023 11:54 AM
To: PBAC <PBAC@health.gov.au>; s47F @lawleypharm.com.au>
Subject: FW: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL]

Dear PBAC

Would you please confirm receipt of the email sent 13th Oct 2023?

Lawley is keen to engage in order to assist those disadvantaged patients.

Yours sincerely

Michael Buckley

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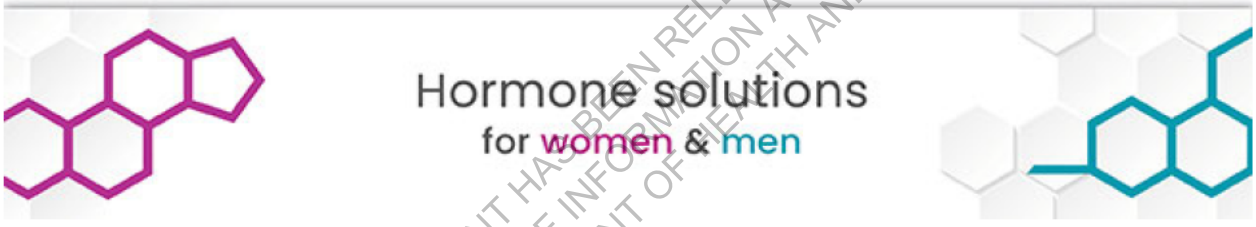

From: Michael Buckley
Sent: Friday, October 13, 2023 1:41 PM
To: 'PBAC@health.gov.au' <PBAC@health.gov.au>
Cc: s47F @lawleypharm.com.au>
Subject: FW: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL]

Dear s22 and PBAC Secretariat

Thank you for this email and attached correspondence.

Lawley would be pleased to explore this matter further at your soonest convenience.

I look forward to hearing from you with next steps.

Yours sincerely

Michael Buckley

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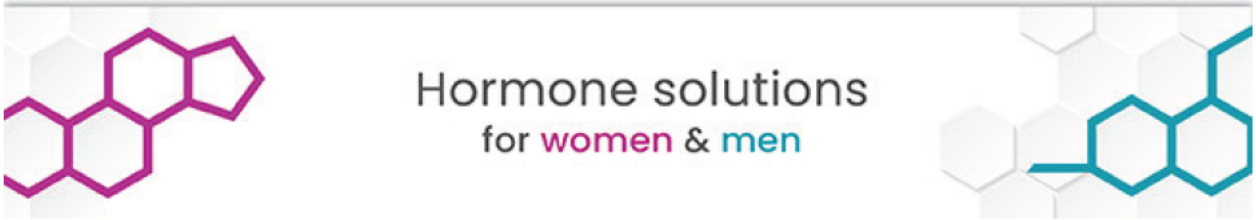

From: PBAC <PBAC@health.gov.au>
Sent: Fr day, October 13, 2023 1:26 PM
To: Michael Buckley <s47F @lawleypharm.com.au>
Cc: PBAC <PBAC@health.gov.au>
Subject: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL]

Dear Michael,

Please find attached a letter on behalf of the Pharmaceutical Benefits Advisory Committee (PBAC) Executive seeking your interest in making amendments to the Pharmaceutical Benefits Scheme (PBS) listing for AndroForte 5.

Kind regards,
s22

PBAC Secretariat

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: PBAC@health.gov.au
GPO Box 9848, Canberra ACT 2601 (MDP 910)

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

FW: AndroForte® 5 PBS listing amendment 3rd response to your Letter, awaiting reply - proposed meeting dates [SEC=OFFICIAL]

PBAC <PBAC@health.gov.au>
Wed 1/10/2024 4:51 PM
To s22 @health.gov.au> s22 @health.gov.au>
Cc s22 @Health.gov.au>
Hi s22 ,

Just FYI - Lawley has accepted our offer for a meeting on 31/1.

Kind regards
s22

From: Michael Buckley s47F @lawleypharm.com.au>
Sent: Wednesday, 10 January 2024 1:05 PM
To: PBAC <PBAC@health.gov.au>
Cc: s47F @lawleypharm.com.au>; s47F s47F @lawleypharm.com.au>; s47F @commercialeyes.com.au> s47F s47F commercialeyes.com.au>
Subject: RE: AndroForte® 5 PBS listing amendment 3rd response to your Letter, awaiting reply [SEC=OFFICIAL] - proposed meeting dates

Dear PBAC

Thank you for your email with the proposed meeting dates.

May we please meet Wednesday 31st Jan 2024 at 10am.

Lawley representatives joining the meeting will be:

Michael Buckley – Lawley (Medical Director / CEO)
s47F – Lawley (Finance)
s47F – Lawley (Finance)
s47F – Lawley (Admin)
s47F (Commercial Eyes)
s47F Commercial Eyes)

All have been cc'd into this reply for email addresses.

Yours sincerely

Michael

LAWLEY

Michael Buckley | Medical Director
M: s47F | E: s47F @lawleypharm.com.au

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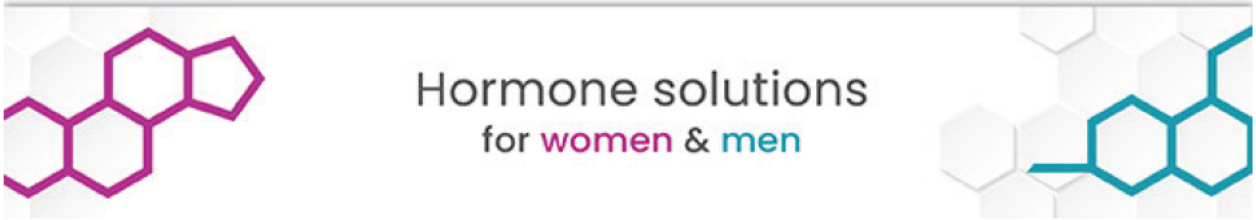

From: PBAC <PBAC@health.gov.au>
Sent: Monday, January 8, 2024 1:36 PM
To: PBAC <PBAC@health.gov.au>; Michael Buckley s47F @lawleypharm.com.au>
Cc: s47F @lawleypharm.com.au>
Subject: RE: AndroForte® 5 PBS listing amendment 3rd response to your Letter, awaiting reply [SEC=OFFICIAL]

Some people who received this message don't often get email from pbac@health.gov.au. Learn why this is important

Dear Michael,

We would like to arrange a meeting with your company, to discuss the next steps for exploring potential changes to the PBS listing for Androforte®5. Please let us know your availability for a 1-hour meeting between the following times, at the end of January:

- Tuesday, 30 January from 2 – 4 pm
- Wednesday, 31 January from 10 am – 12 pm

Please provide the names and email addresses of any additional representatives from your company that you would like to include in the meeting.

Kind regards,

PBAC Secretariat

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: PBAC@health.gov.au
GPO Box 9848, Canberra ACT 2601 (MDP 910)

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From: PBAC <PBAC@health.gov.au>
Sent: Fr day, 24 November 2023 5:11 PM
To: 'Michael Buckley' s47F @lawleypharm.com.au>
Cc: s47F @lawleypharm.com.au>
Subject: RE: AndroForte® 5 PBS listing amendment 3rd response to your Letter, awaiting reply [SEC=OFFICIAL]

Dear Michael,

Thank you for your email. I apologise for the delay in responding. We have received your response. We will contact you with further information regarding next steps for exploring this matter further.

Kind regards,

PBAC Secretariat

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Technology Assessment & Access Division | Health Resourcing Group
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From: Michael Buckley s47F @lawleypharm.com.au>
Sent: Friday, 24 November 2023 12:12 PM
To: PBAC <PBAC@health.gov.au>
Cc: s47F @lawleypharm.com.au>
Subject: FW: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL] 3rd response to your Letter, awaiting reply

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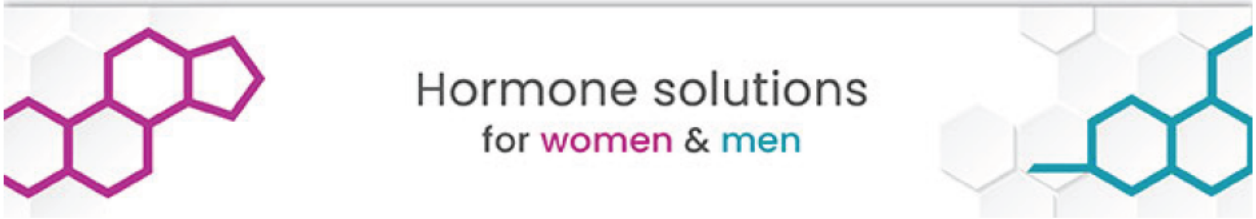

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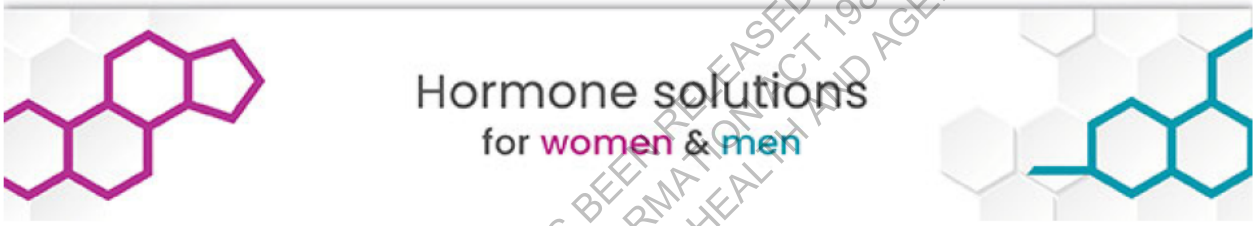

From: Michael Buckley
Sent: Friday, October 13, 2023 1:41 PM
To: 'PBAC@health.gov.au' <PBAC@health.gov.au>
Cc: s47F @lawleypharm.com.au>
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Dear s22 and PBAC Secretariat

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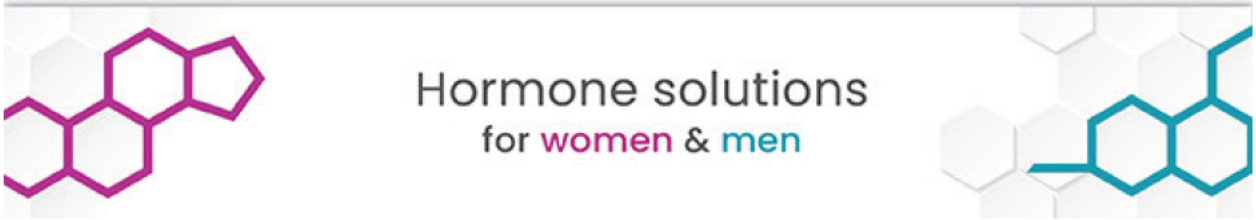

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To: Michael Buckley s47F @lawleypharm.com.au>
Cc: PBAC <PBAC@health.gov.au>
Subject: AndroForte® 5 PBS listing amendment [SEC=OFFICIAL]

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Kind regards,
s22

PBAC Secretariat

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Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
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Change in patient numbers for Androforte 5 [SEC=OFFICIAL:Sensitive]

s22 @health.gov.au>
Thu 1/4/2024 1:37 PM
To s22 @health.gov.au>
Cc s22 @health.gov.au>

2 attachments (302 KB)
testosterone cream utilisation .xlsx; RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL];

Hi s22

I know you are busy acting for Nikolai. As discussed the other day, I will be preparing some briefing points for a meeting with Lawley Pharma about next steps for a submission to amend the PBS listing for Androforte (due to barriers to access for trans and gender diverse patients because of the criteria – *must be applied to the scrotum area'*).

s22 has kindly put together utilisation data for Androforte 5, including number of patients who have increased quantity of medicine/number of repeats, and gender (attached email). Please note, information not to be disseminated - low patient number cells in the data don't appear to have been suppressed. The data itself would not be provided as part of any briefing document.

There does not appear to be a large population that has been excluded (but that is not unexpected). Utilisation (in the chart in the email below) has steadily increased since the 1 July 2021 change, which could be due to a number of reasons (patient switching from other topical products?? Population growth/changing population demographics??).

The number of patients who have identified as female gender has reduced from peak numbers in 2020 & 2021, but has remained relatively stable in 2022/2023 (table below – 2016 excluded due to low numbers).

Prev	Init	Year	Sex
28	25	2017	F
480	310	2017	M
135	114	2018	F
904	577	2018	M
201	128	2019	F
914	305	2019	M
218	114	2020	F
907	229	2020	M
228	105	2021	F
1032	346	2021	M
141	68	2022	F
1193	396	2022	M
144	64	2023	F
1502	561	2023	M

The number of patients who have received more than 1 pack of Androforte 5 has either remained stable or gradually increased. Patient's with more than 1 repeat has steadily increased. To me this could indicated that these patient groups may be applying Androforte to the upper body (dosing for the upper body is still permitted in the TGA approved PI, and is a higher dose compared to scrotal application).

It is very difficult to estimate the size of the trans and gender diverse patient population that was receiving treatment with Androforte (pre 1 July 2021). In terms of estimating any financial impact to the PBS, should PBAC recommend amending the clinical criteria *'must be applied to the scrotum area'*, is it fair to assume that the trans and gender diverse population that was accessing Androforte pre the 1 July 2021 listing changes, is still accessing treatment using the current PBS listing (i.e has not been excluded to a large extent by the 1 July 2021 change)?

I would appreciate your thoughts.

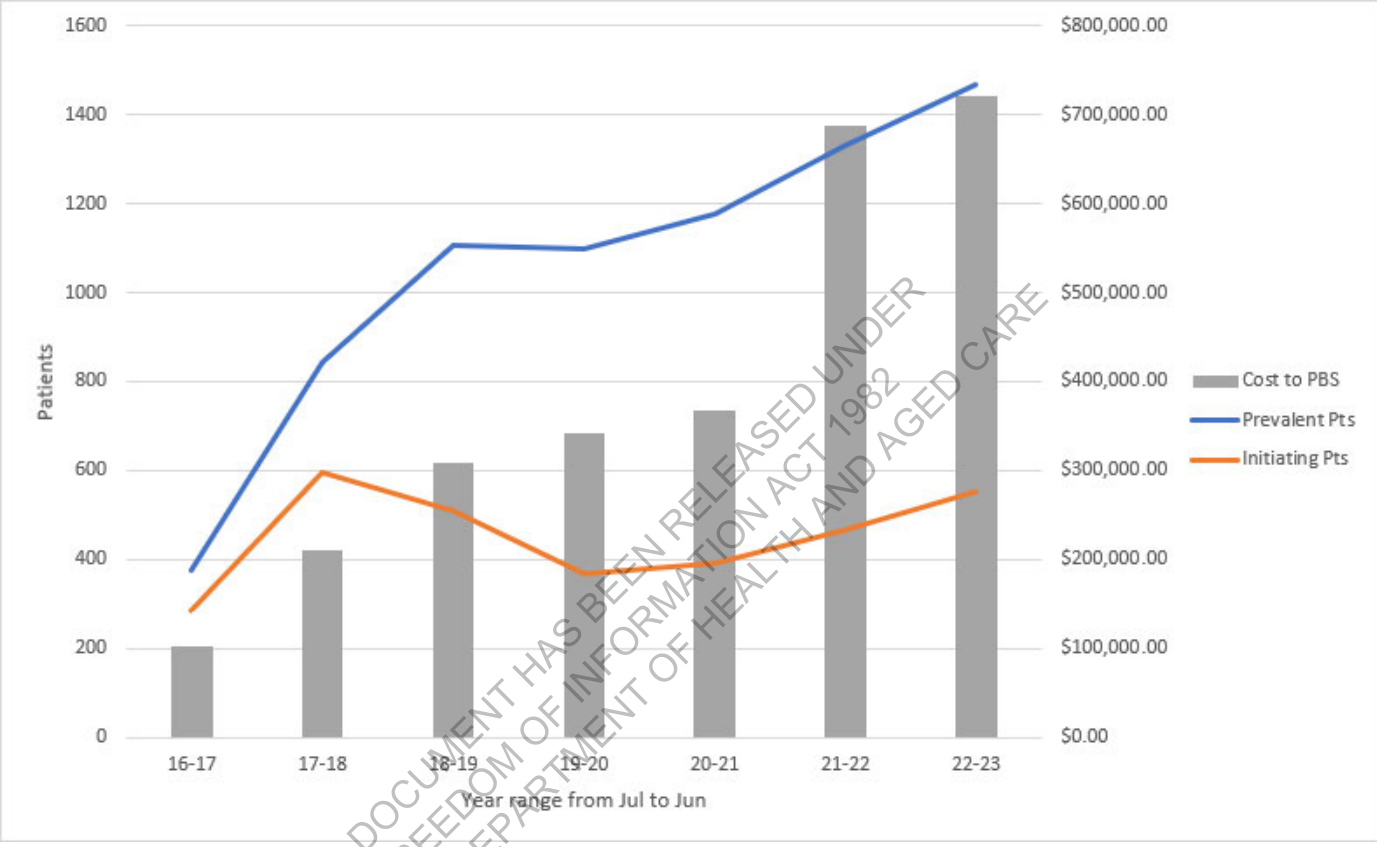
Kind regards
s22

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 11:46 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

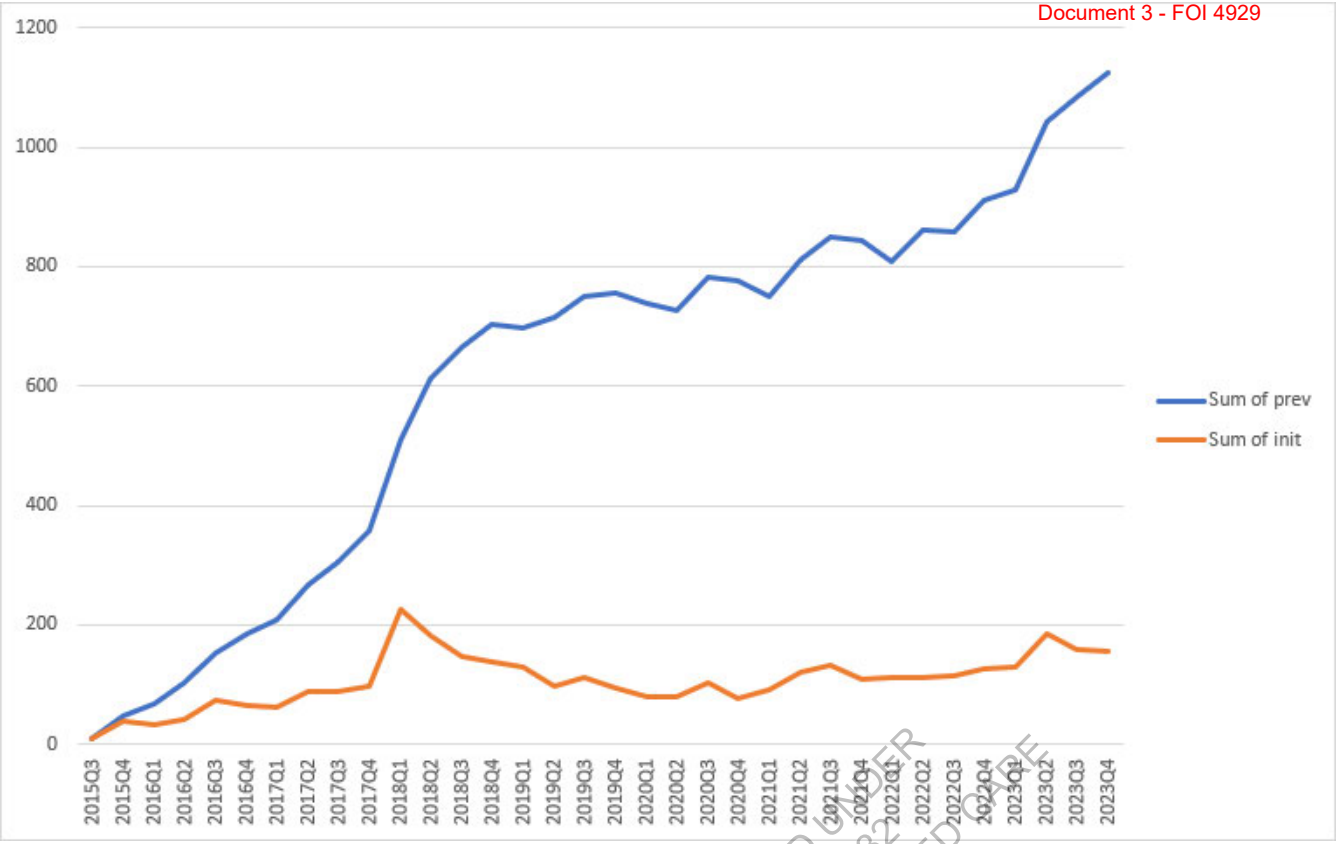
Hi s22

The graph below shows utilisation of item code 10378F and has been split into years ranging from July to June of the next year to coincide with the day that the listing change was implemented.

From the graph you can see that the number of patients initiating in 2021-22 is very similar to the numbers from 2019-20 and 2020-21 indicating that there doesn't seem to be large population that is avoiding use.



If anything, it appears that the restriction change has caused the number of patients initiating on testosterone cream to increase steadily. It's unclear why there's such a big increase in 2018Q1 and Q2. There was a restriction change in 01Jun2017 which allowed prescribing by paediatricians and it may be due to that.



The graphs along with the actual data can be found in the attached spreadsheet.

Please let us know if you'd like more information!

Thanks,
s22

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 9:12 AM
To: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Thank you, that would be great

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 9:05 AM
To: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Morning s22

Happy to get this analysis ready.

Thanks,
s22

From: s22 @health.gov.au>
Sent: Tuesday, 2 January 2024 5:26 PM
To: s22 @health.gov.au>
Subject: FW: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Hi s22

Do you have time to look at s22 request this week?

I'm happy to look at this if you need to prioritise other tasks.

Thanks,
s22

From: s22 @health.gov.au>
Sent: Tuesday, 2 January 2024 5:10 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Hi s22

Happy new year!

I'm putting together some briefing points for a meeting with Lawley Pharma, to discuss potential changes to the Androforte PBS listing that may help address the unintended barriers to some populations where scrotal application is infeasible or considered inappropriate.

For background – The PBAC considered an application from Lawley in March 2021 and recommended the following changes to the PBS listing for Androforte 5 (PBS item code 10378F)

- Addition of clinical criteria - *The treatment must be applied to the scrotum area*.
- Number of repeats reduced from 6 to 1.

These changes were done on the basis that scrotal application requires a low volume of drug, and sponsor had requested a corresponding higher price per pack. Changes were implemented on 1 July 2021.

I'm trying to workout how the estimates would change if we were to amend the listing to say - *The treatment must be applied to the scrotum area, where appropriate* (wording yet to be determined).

Would your team be able to put together a comparison of annual number patients who were prescribed Androforte 5 before and after the 1 July 2021 change to see what the impact on patient numbers was?

Noting that the number of repeats changed from 6 to 1 (because of the smaller application volume required for scrotal application), could you have a look at the number of requests for increased quantity/repeats (assuming that non-scrotal application would be at a high dosing volume)?

Would it be feasible to have this before senate estimates? Let me know what timing is feasible for your team.

Happy to discuss.

Thanks heaps.
s22

s22
Assistant Director
PBAC Assessment Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E s22 health.gov.au
Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

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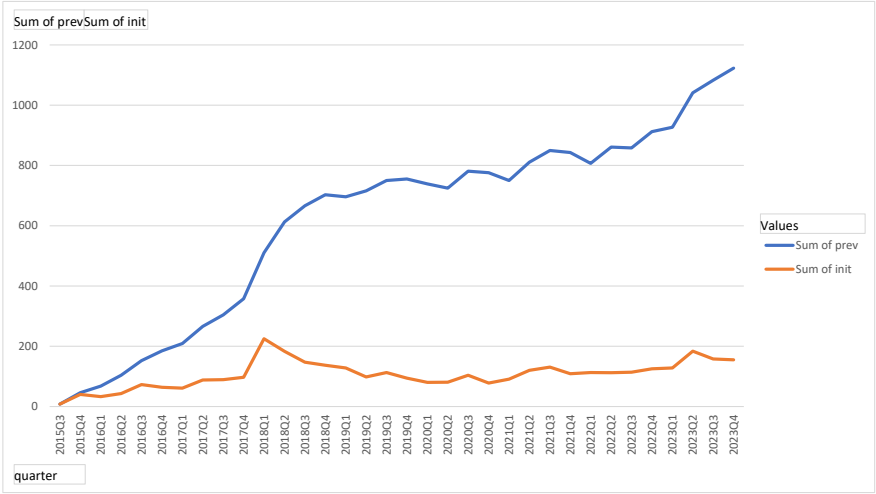
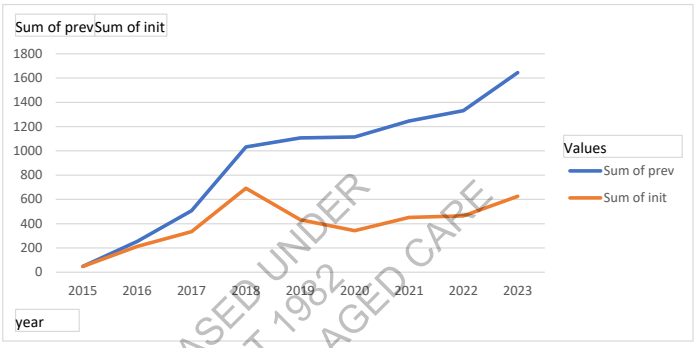
prev	init	rx	cost	quarter
8	8	12	751.08	2015Q3
46	40	93	6230.11	2015Q4
68	33	130	7934.11	2016Q1
104	43	218	12238.45	2016Q2
152	73	316	18455.32	2016Q3
185	64	404	24157.18	2016Q4
209	61	445	25446.86	2017Q1
266	88	585	33789.86	2017Q2
304	89	648	37459.4	2017Q3
358	97	718	43364.5	2017Q4
510	225	1019	56419.65	2018Q1
613	183	1366	73570.66	2018Q2
666	147	1464	73727.54	2018Q3
703	137	1598	83987.65	2018Q4
696	128	1527	74712.11	2019Q1
716	98	1581	76597.99	2019Q2
750	113	1697	83330.92	2019Q3
755	94	1732	92226.82	2019Q4
739	80	1670	84087.85	2020Q1
725	81	1565	81453.07	2020Q2
781	104	1725	94495.44	2020Q3
776	78	1749	100719.6	2020Q4
750	91	1582	82097.44	2021Q1
811	120	1703	89696.49	2021Q2
850	131	1788	182727.6	2021Q3
843	109	1716	184995.6	2021Q4
807	113	1558	156486.7	2022Q1
861	112	1599	162408.9	2022Q2
858	114	1632	170191.8	2022Q3
912	125	1778	185600.4	2022Q4
927	128	1600	168611.5	2023Q1
1041	184	1817	196193.1	2023Q2
1083	158	1861	200634.4	2023Q3
1123	155	2054	226386.8	2023Q4

Row Labels	Sum of prev	Sum of init
2015Q3	8	8
2015Q4	46	40
2016Q1	68	33
2016Q2	104	43
2016Q3	152	73
2016Q4	185	64
2023Q1	927	128
2023Q2	1041	184
2023Q3	1083	158
2023Q4	1123	155
Grand Total	**20996**	**3604**



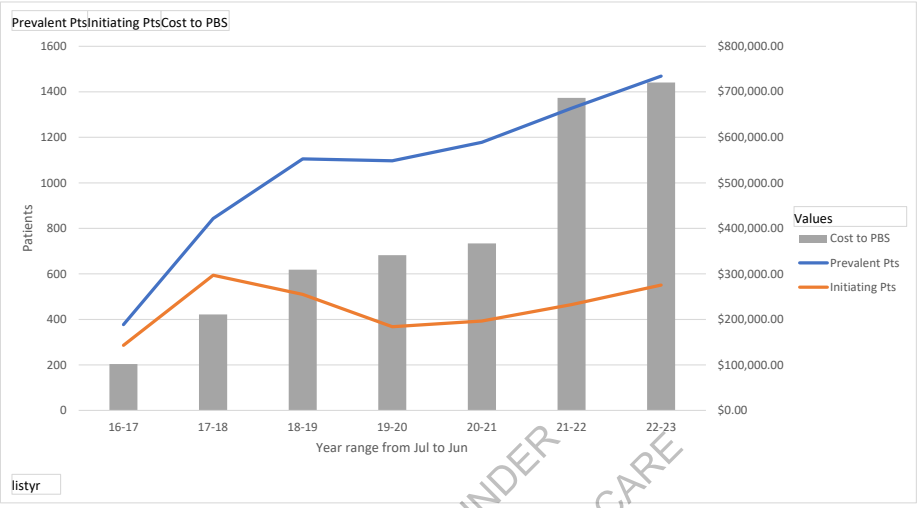
prev	init	rx	cost	year
48	48	105	6981.19	2015
253	213	1068	62785.06	2016
507	335	2396	140060.6	2017
1033	692	5447	287705.5	2018
1106	433	6537	326867.8	2019
1114	343	6709	360756	2020
1246	451	6789	539517.2	2021
1332	464	6567	674687.7	2022
1645	625	7332	791825.8	2023

Row Labels	Sum of prev	Sum of init
2015	48	48
2016	253	213
2017	507	335
2018	1033	692
2019	1106	433
2020	1114	343
2021	1246	451
2022	1332	464
2023	1645	625
Grand Total	**8284**	**3604**



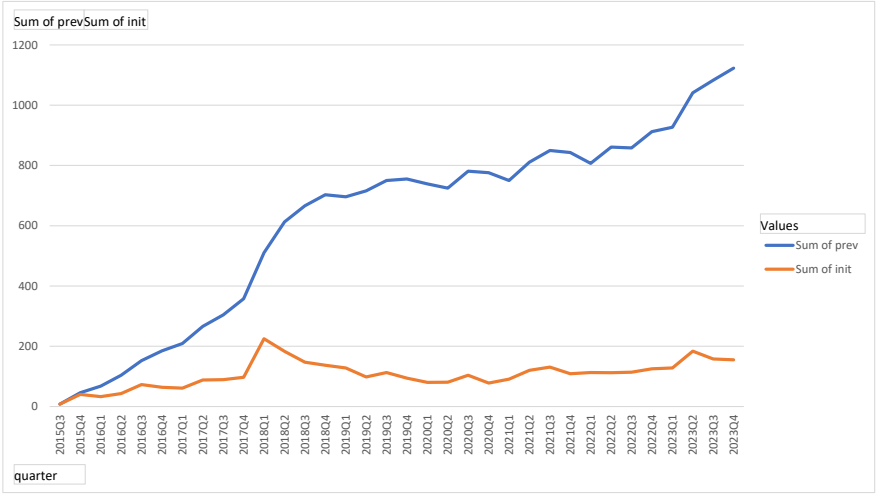
prev	init	rx	cost	listyr
377	286	1750	$101,849	16-17
843	594	3751	$210,814	17-18
1105	510	6170	$309,025	18-19
1097	368	6664	$341,099	19-20
1178	393	6759	$367,009	20-21
1328	465	6661	$686,619	21-22
1469	551	6827	$720,597	22-23

Row Labels	Prevalent Pts	Initiating Pts	Cost to PBS
16-17	377	286	101849.22
17-18	843	594	210814.21
18-19	1105	510	309025.29
19-20	1097	368	341098.66
20-21	1178	393	367009
21-22	1328	465	686618.82
22-23	1469	551	720596.76
Grand Total	**7397**	**3167**	**2737011.96**



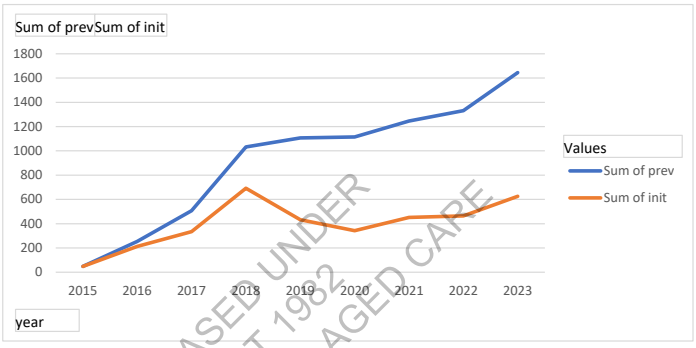
prev	init	rx	cost	quarter
8	8	12	751.08	2015Q3
46	40	93	6230.11	2015Q4
68	33	130	7934.11	2016Q1
104	43	218	12238.45	2016Q2
152	73	316	18455.32	2016Q3
185	64	404	24157.18	2016Q4
209	61	445	25446.86	2017Q1
266	88	585	33789.86	2017Q2
304	89	648	37459.4	2017Q3
358	97	718	43364.5	2017Q4
510	225	1019	56419.65	2018Q1
613	183	1366	73570.66	2018Q2
666	147	1464	73727.54	2018Q3
703	137	1598	83987.65	2018Q4
696	128	1527	74712.11	2019Q1
716	98	1581	76597.99	2019Q2
750	113	1697	83330.92	2019Q3
755	94	1732	92226.82	2019Q4
739	80	1670	84087.85	2020Q1
725	81	1565	81453.07	2020Q2
781	104	1725	94495.44	2020Q3
776	78	1749	100719.6	2020Q4
750	91	1582	82097.44	2021Q1
811	120	1703	89696.49	2021Q2
850	131	1788	182727.6	2021Q3
843	109	1716	184995.6	2021Q4
807	113	1558	156486.7	2022Q1
861	112	1599	162408.9	2022Q2
858	114	1632	170191.8	2022Q3
912	125	1778	185600.4	2022Q4
927	128	1600	168611.5	2023Q1
1041	184	1817	196193.1	2023Q2
1083	158	1861	200634.4	2023Q3
1123	155	2054	226386.8	2023Q4

Row Labels	Sum of prev	Sum of init
2015Q3	8	8
2015Q4	46	40
2016Q1	68	33
2016Q2	104	43
2016Q3	152	73
2016Q4	185	64
2023Q1	927	128
2023Q2	1041	184
2023Q3	1083	158
2023Q4	1123	155
Grand Total	**20996**	**3604**



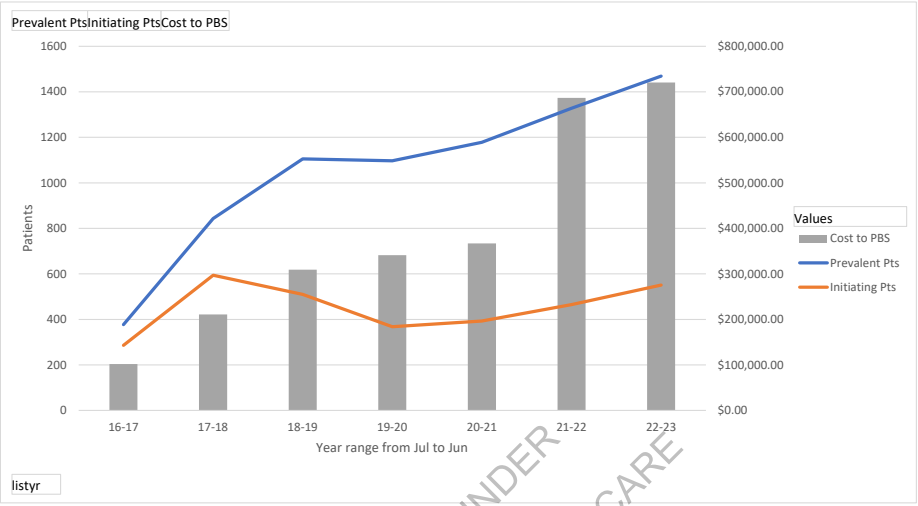
prev	init	rx	cost	year
48	48	105	6981.19	2015
253	213	1068	62785.06	2016
507	335	2396	140060.6	2017
1033	692	5447	287705.5	2018
1106	433	6537	326867.8	2019
1114	343	6709	360756	2020
1246	451	6789	539517.2	2021
1332	464	6567	674687.7	2022
1645	625	7332	791825.8	2023

Row Labels	Sum of prev	Sum of init
2015	48	48
2016	253	213
2017	507	335
2018	1033	692
2019	1106	433
2020	1114	343
2021	1246	451
2022	1332	464
2023	1645	625
Grand Total	**8284**	**3604**



prev	init	rx	cost	listyr
377	286	1750	$101,849	16-17
843	594	3751	$210,814	17-18
1105	510	6170	$309,025	18-19
1097	368	6664	$341,099	19-20
1178	393	6759	$367,009	20-21
1328	465	6661	$686,619	21-22
1469	551	6827	$720,597	22-23

Row Labels	Prevalent Pts	Initiating Pts	Cost to PBS
16-17	377	286	101849.22
17-18	843	594	210814.21
18-19	1105	510	309025.29
19-20	1097	368	341098.66
20-21	1178	393	367009
21-22	1328	465	686618.82
22-23	1469	551	720596.76
Grand Total	**7397**	**3167**	**2737011.96**



prev	quarter	PBS_QTY
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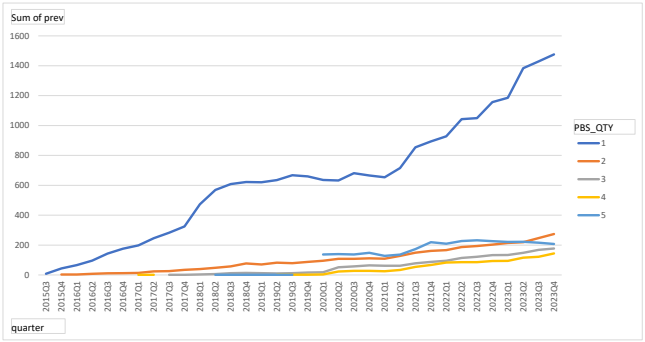
3	2015Q4	2
66	2016Q1	1
3	2016Q1	2
96	2016Q2	1
8	2016Q2	2
143	2016Q3	1
11	2016Q3	2
176	2016Q4	1
12	2016Q4	2
198	2017Q1	1
14	2017Q1	2
1	2017Q1	4
246	2017Q2	1
24	2017Q2	2
1	2017Q2	4
283	2017Q3	1
26	2017Q3	2
1	2017Q3	3
325	2017Q4	1
34	2017Q4	2
1	2017Q4	3
1	2017Q4	4
473	2018Q1	1
39	2018Q1	2
3	2018Q1	3
569	2018Q2	1
48	2018Q2	2
6	2018Q2	3
1	2018Q2	5
608	2018Q3	1
57	2018Q3	2
12	2018Q3	3
1	2018Q3	5
622	2018Q4	1
77	2018Q4	2
14	2018Q4	3
1	2018Q4	5
620	2019Q1	1
70	2019Q1	2
12	2019Q1	3
1	2019Q1	5
635	2019Q2	1
82	2019Q2	2
10	2019Q2	3
1	2019Q2	4
1	2019Q2	5
667	2019Q3	1
79	2019Q3	2
12	2019Q3	3
2	2019Q3	4
1	2019Q3	5
660	2019Q4	1
87	2019Q4	2
16	2019Q4	3
2	2019Q4	4
636	2020Q1	1
95	2020Q1	2
18	2020Q1	3
3	2020Q1	4
1	2020Q1	5
628	2020Q2	1
96	2020Q2	2
15	2020Q2	3
2	2020Q2	4
2	2020Q2	5
674	2020Q3	1
99	2020Q3	2
18	2020Q3	3
1	2020Q3	4
659	2020Q4	1
100	2020Q4	2
23	2020Q4	3
2	2020Q4	4
2	2020Q4	5
642	2021Q1	1
94	2021Q1	2
18	2021Q1	3
2	2021Q1	4
698	2021Q2	1
108	2021Q2	2
15	2021Q2	3
2	2021Q2	4
1	2021Q2	5
718	2021Q3	1
131	2021Q3	2
17	2021Q3	3
2	2021Q3	4
698	2021Q4	1
139	2021Q4	2
18	2021Q4	3
2	2021Q4	4
672	2022Q1	1
135	2022Q1	2
12	2022Q1	3
1	2022Q1	4
1	2022Q1	5
723	2022Q2	1
136	2022Q2	2
18	2022Q2	3
1	2022Q2	4
1	2022Q2	5
715	2022Q3	1
137	2022Q3	2
17	2022Q3	3
1	2022Q3	4
2	2022Q3	5
766	2022Q4	1
141	2022Q4	2
14	2022Q4	3
781	2023Q1	1
140	2023Q1	2
17	2023Q1	3
900	2023Q2	1
138	2023Q2	2
12	2023Q2	3
1	2023Q2	5
1	2023Q2	50
927	2023Q3	1
153	2023Q3	2
17	2023Q3	3
958	2023Q4	1
161	2023Q4	2
20	2023Q4	3
1	2023Q4	5

Sum of prev	Column Labels					
Row Labels	**1**	**2**	**3**	**4**	**5**	**Grand Total**
2015Q3	8					8
2015Q4	44	3				47
2016Q1	66	3				69
2016Q2	96	8				104
2016Q3	143	11				154
2016Q4	176	12				188
2017Q1	198	14		1		213
2017Q2	246	24		1		271
2017Q3	283	26	1			310
2017Q4	325	34	1	1		361
2018Q1	473	39	3			515
2018Q2	569	48	6		1	624
2018Q3	608	57	12		1	678
2018Q4	622	77	14		1	714
2019Q1	620	70	12		1	703
2019Q2	635	82	10	1	1	729
2019Q3	667	79	12	2	1	761
2019Q4	660	87	16	2		765
2020Q1	636	95	18	3	137	889
2020Q2	632	108	51	23	140	954
2020Q3	681	108	57	27	137	1010
2020Q4	666	111	64	27	148	1016
2021Q1	654	109	62	25	128	978
2021Q2	715	128	62	33	136	1074
2021Q3	854	149	78	54	173	1308
2021Q4	894	161	87	67	219	1428
2022Q1	928	166	95	83	209	1481
2022Q2	1043	187	114	86	227	1657
2022Q3	1050	194	122	86	232	1684
2022Q4	1157	203	133	93	226	1812
2023Q1	1186	214	134	94	221	1849
2023Q2	1384	219	148	116	222	2089
2023Q3	1429	247	168	122	216	2182
2023Q4	1476	274	177	144	207	2278
Grand Total	**21824**	**3347**	**1657**	**1091**	**2984**	**30903**



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552	2020Q1	6
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3	2020Q2	0
4	2020Q2	1
12	2020Q2	2
36	2020Q2	3
21	2020Q2	4
138	2020Q2	5
540	2020Q2	6
1	2020Q2	7
4	2020Q3	0
7	2020Q3	1
9	2020Q3	2
39	2020Q3	3
26	2020Q3	4
137	2020Q3	5
574	2020Q3	6
1	2020Q3	7
2	2020Q4	0
7	2020Q4	1
11	2020Q4	2
41	2020Q4	3
25	2020Q4	4
146	2020Q4	5
574	2020Q4	6
1	2020Q4	7
6	2021Q1	0
12	2021Q1	1
15	2021Q1	2
44	2021Q1	3
23	2021Q1	4
128	2021Q1	5
540	2021Q1	6
1	2021Q1	7
4	2021Q2	0
17	2021Q2	1
20	2021Q2	2
47	2021Q2	3
31	2021Q2	4
135	2021Q2	5
596	2021Q2	6
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61	2021Q3	3
52	2021Q3	4
173	2021Q3	5
476	2021Q3	6
1	2021Q3	7
16	2021Q4	0
196	2021Q4	1
22	2021Q4	2
69	2021Q4	3
65	2021Q4	4
219	2021Q4	5
330	2021Q4	6
1	2021Q4	7
8	2022Q1	0
256	2022Q1	1
31	2022Q1	2
83	2022Q1	3
82	2022Q1	4
208	2022Q1	5
202	2022Q1	6
1	2022Q1	7
9	2022Q2	0
320	2022Q2	1
51	2022Q2	2
96	2022Q2	3
85	2022Q2	4
226	2022Q2	5
134	2022Q2	6
2	2022Q2	7
8	2022Q3	0
335	2022Q3	1
57	2022Q3	2
105	2022Q3	3
85	2022Q3	4
230	2022Q3	5
82	2022Q3	6
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6	2022Q4	0
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119	2022Q4	3
93	2022Q4	4
226	2022Q4	5
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117	2023Q1	3
94	2023Q1	4
221	2023Q1	5
54	2023Q1	6
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11	2023Q2	0
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136	2023Q2	3
116	2023Q2	4
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1	2023Q2	7
12	2023Q3	0
502	2023Q3	1
94	2023Q3	2
151	2023Q3	3
122	2023Q3	4
216	2023Q3	5
37	2023Q3	6
1	2023Q3	7
15	2023Q4	0
518	2023Q4	1
113	2023Q4	2
157	2023Q4	3
144	2023Q4	4
206	2023Q4	5
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1	2024Q1	2

1	2024Q1	3
3	2024Q1	4
2	2024Q1	5

prev	quarter	RPT_ORDR_NMBR
1	2015Q3	5
7	2015Q3	6
2	2015Q4	1
1	2015Q4	2
1	2015Q4	3
11	2015Q4	5
32	2015Q4	6
1	2016Q1	0
2	2016Q1	1
1	2016Q1	4
12	2016Q1	5
55	2016Q1	6
1	2016Q2	0
2	2016Q2	1
3	2016Q2	2
5	2016Q2	3
1	2016Q2	4
19	2016Q2	5
76	2016Q2	6
3	2016Q3	0
7	2016Q3	2
7	2016Q3	3
3	2016Q3	4
33	2016Q3	5
104	2016Q3	6
1	2016Q4	0
4	2016Q4	1
7	2016Q4	2
6	2016Q4	3
4	2016Q4	4
30	2016Q4	5
140	2016Q4	6
2	2017Q1	0
3	2017Q1	1
4	2017Q1	2
10	2017Q1	3
6	2017Q1	4
40	2017Q1	5
150	2017Q1	6
3	2017Q2	0
2	2017Q2	1
7	2017Q2	2
14	2017Q2	3
10	2017Q2	4
60	2017Q2	5
188	2017Q2	6
4	2017Q3	0
4	2017Q3	1
4	2017Q3	2
15	2017Q3	3
7	2017Q3	4
52	2017Q3	5
232	2017Q3	6
4	2017Q4	0
4	2017Q4	1
10	2017Q4	2
17	2017Q4	3
9	2017Q4	4
55	2017Q4	5
264	2017Q4	6
3	2018Q1	0
6	2018Q1	1
8	2018Q1	2
26	2018Q1	3
14	2018Q1	4
74	2018Q1	5
385	2018Q1	6
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467	2018Q2	6
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19	2018Q4	2
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22	2018Q4	4
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527	2018Q4	6
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1	2018Q4	8
7	2019Q1	0
9	2019Q1	1
14	2019Q1	2
31	2019Q1	3
21	2019Q1	4
95	2019Q1	5
533	2019Q1	6
2	2019Q1	7
5	2019Q2	0
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15	2019Q2	2
21	2019Q2	3
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110	2019Q2	5
555	2019Q2	6
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9	2019Q4	2
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31	2019Q4	4
125	2019Q4	5
570	2019Q4	6
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5	2020Q1	0
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7	2020Q1	2
32	2020Q1	3
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9	2020Q3	2
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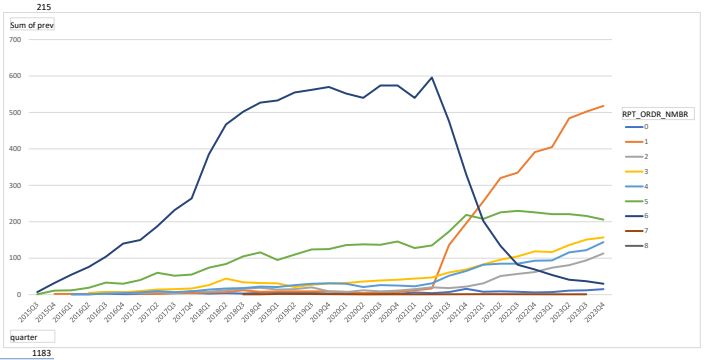
26	2020Q3	4
137	2020Q3	5
574	2020Q3	6
1	2020Q3	7
2	2020Q4	0
7	2020Q4	1
11	2020Q4	2
41	2020Q4	3

Sum of prev	Column Labels								
Row Labels	0	1	2	3	4	5	6	7	8 Grand Total
2015Q3						1	7		8
2015Q4		2	1	1		11	32		47
2016Q1	1	2			1	12	55		71
2016Q2	1	2	3	5	1	19	76		107
2016Q3	3		7	7	3	33	104		157
2016Q4	1	4	7	6	4	30	140		192
2017Q1	2	3	4	10	6	40	150		215
2017Q2	3	2	7	14	10	60	188		284
2017Q3	4	4	4	15	7	52	232		322
2017Q4	4	4	10	17	9	55	264		363
2018Q1	3	6	8	26	14	74	385		516
2018Q2	4	7	12	44	17	84	467		635
2018Q3	3	12	16	34	18	105	502	1	691
2018Q4	5	8	19	32	22	116	527	1	1 731
2019Q1	7	9	14	31	21	95	533	2	712
2019Q2	5	9	15	21	26	110	555	2	743
2019Q3	5	9	20	27	30	124	562	2	779
2019Q4	3	9	9	31	31	125	570	1	779
2020Q1	5	8	7	32	30	136	552	1	771
2020Q2	3	4	12	36	21	138	540	1	755
2020Q3	4	7	9	39	26	137	574	1	797
2020Q4	2	7	11	41	25	146	574	1	807
2021Q1	6	12	15	44	23	128	540	1	769
2021Q2	4	17	20	47	31	135	596	1	851
2021Q3	7	136	18	61	52	173	476	1	924
2021Q4	16	196	22	69	65	219	330	1	918
2022Q1	8	256	31	83	82	208	202	1	871
2022Q2	9	320	51	96	85	226	134	2	923
2022Q3	8	335	57	105	85	230	82	1	903
2022Q4	6	391	62	119	93	226	69	1	967
2023Q1	7	405	74	117	94	221	54	1	973
2023Q2	11	484	81	136	116	221	41	1	1091
2023Q3	12	502	94	151	122	216	37	1	1135
2023Q4	15	518	113	157	144	206	30		1183
Grand Total	177	3690	833	1654	1314	4112	10180	25	1 21986



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574	2020Q4	6
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6	2021Q1	0
12	2021Q1	1
15	2021Q1	2
44	2021Q1	3
23	2021Q1	4
128	2021Q1	5
540	2021Q1	6
1	2021Q1	7
4	2021Q2	0
17	2021Q2	1
20	2021Q2	2
47	2021Q2	3
31	2021Q2	4
135	2021Q2	5
596	2021Q2	6
1	2021Q2	7
7	2021Q3	0
136	2021Q3	1
18	2021Q3	2
61	2021Q3	3
52	2021Q3	4
173	2021Q3	5
476	2021Q3	6
1	2021Q3	7
16	2021Q4	0
196	2021Q4	1
22	2021Q4	2
69	2021Q4	3
65	2021Q4	4
219	2021Q4	5
330	2021Q4	6
1	2021Q4	7
8	2022Q1	0
256	2022Q1	1
31	2022Q1	2
83	2022Q1	3
82	2022Q1	4
208	2022Q1	5
202	2022Q1	6
1	2022Q1	7
9	2022Q2	0
320	2022Q2	1
51	2022Q2	2
96	2022Q2	3
85	2022Q2	4
226	2022Q2	5
134	2022Q2	6
2	2022Q2	7
8	2022Q3	0
335	2022Q3	1
57	2022Q3	2
105	2022Q3	3
85	2022Q3	4
230	2022Q3	5
82	2022Q3	6
1	2022Q3	7
6	2022Q4	0
391	2022Q4	1
62	2022Q4	2
119	2022Q4	3
93	2022Q4	4
226	2022Q4	5
69	2022Q4	6
1	2022Q4	7
7	2023Q1	0
405	2023Q1	1
74	2023Q1	2
117	2023Q1	3
94	2023Q1	4
221	2023Q1	5
54	2023Q1	6
1	2023Q1	7
11	2023Q2	0
484	2023Q2	1
81	2023Q2	2
136	2023Q2	3
116	2023Q2	4
221	2023Q2	5
41	2023Q2	6
1	2023Q2	7
12	2023Q3	0
502	2023Q3	1
94	2023Q3	2
151	2023Q3	3
122	2023Q3	4
216	2023Q3	5
37	2023Q3	6
1	2023Q3	7
15	2023Q4	0
518	2023Q4	1
113	2023Q4	2
157	2023Q4	3
144	2023Q4	4
206	2023Q4	5
30	2023Q4	6
1	2024Q1	0
13	2024Q1	1
1	2024Q1	2
1	2024Q1	3
3	2024Q1	4
2	2024Q1	5

prev	init	year	PTNT_SEX_CD
48	48	2015	M
s47F			
250	210	2016	M
28	25	2017	F
480	310	2017	M
s47F			
135	114	2018	F
904	577	2018	M
201	128	2019	F
914	305	2019	M
218	114	2020	F
907	229	2020	M
228	105	2021	F
1032	346	2021	M
141	68	2022	F
1193	396	2022	M
144	64	2023	F
1502	561	2023	M

RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

s22 @health.gov.au>

Wed 1/3/2024 3:40 PM

To s22 @health.gov.au>
Cc s22 @health.gov.au>

1 attachments (88 KB)

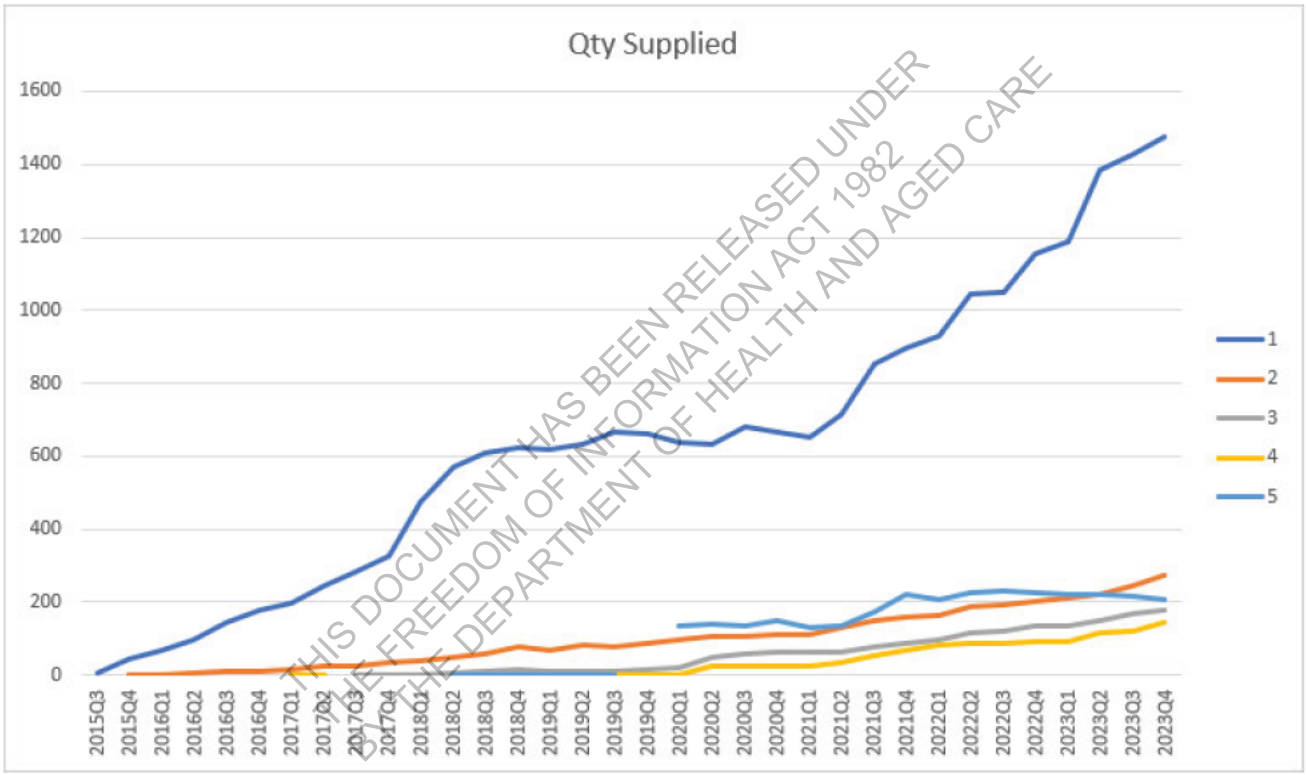
testosterone cream utilisation .xlsx;

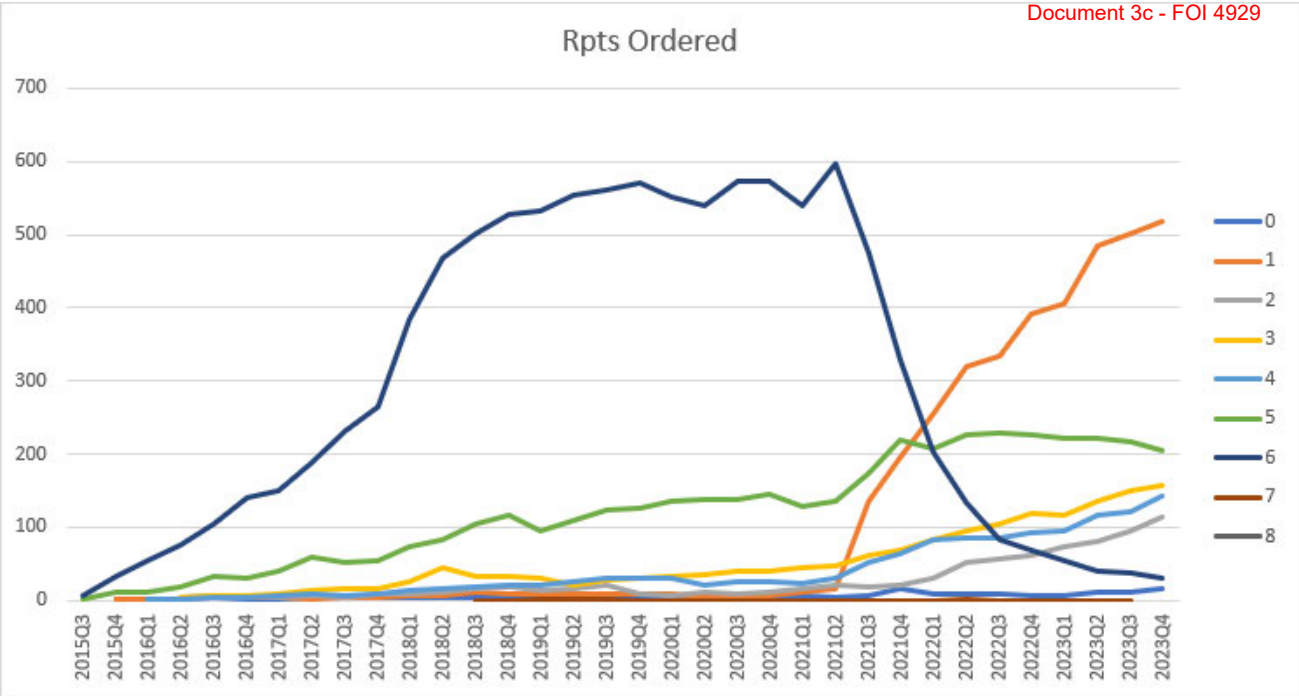
Hi s22

Below are two graphs showing the number of distinct patients in each group of either quantity supplied or repeats ordered per quarter.

Looks like the quantities have increased steadily but nothing super strange after the restriction changed.

The number of repeats is likely what's changed the most with patients on more than one repeat order scripts steadily increasing.





Please note that these counts cannot be summed, i.e. you cannot add the number of pts in 2021Q1 + 2022Q2 as there will be double counting.

As with before the actual values can be seen in the attached spreadsheet. I've also included a tab called gender which is a breakdown of males and females per year which s22 thought might be interesting as well.

Thanks,
s22

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 2:23 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Hi s22 ,

Would you have access to data on number of patients that were prescribed/supplied an increased quantity (or increased repeats) for Androforte 5. This information would also be useful.

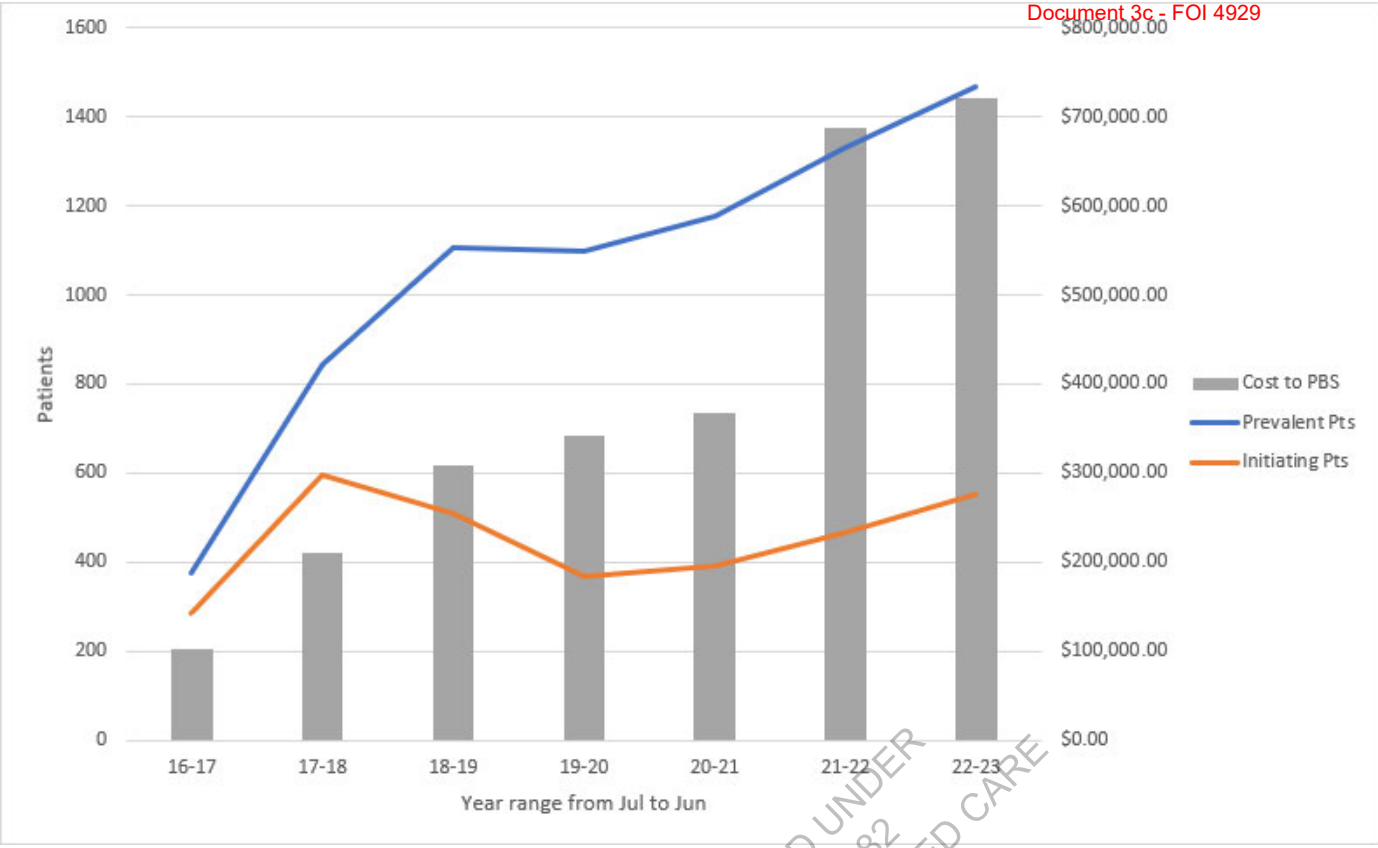
Kind regards
s22

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 11:46 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

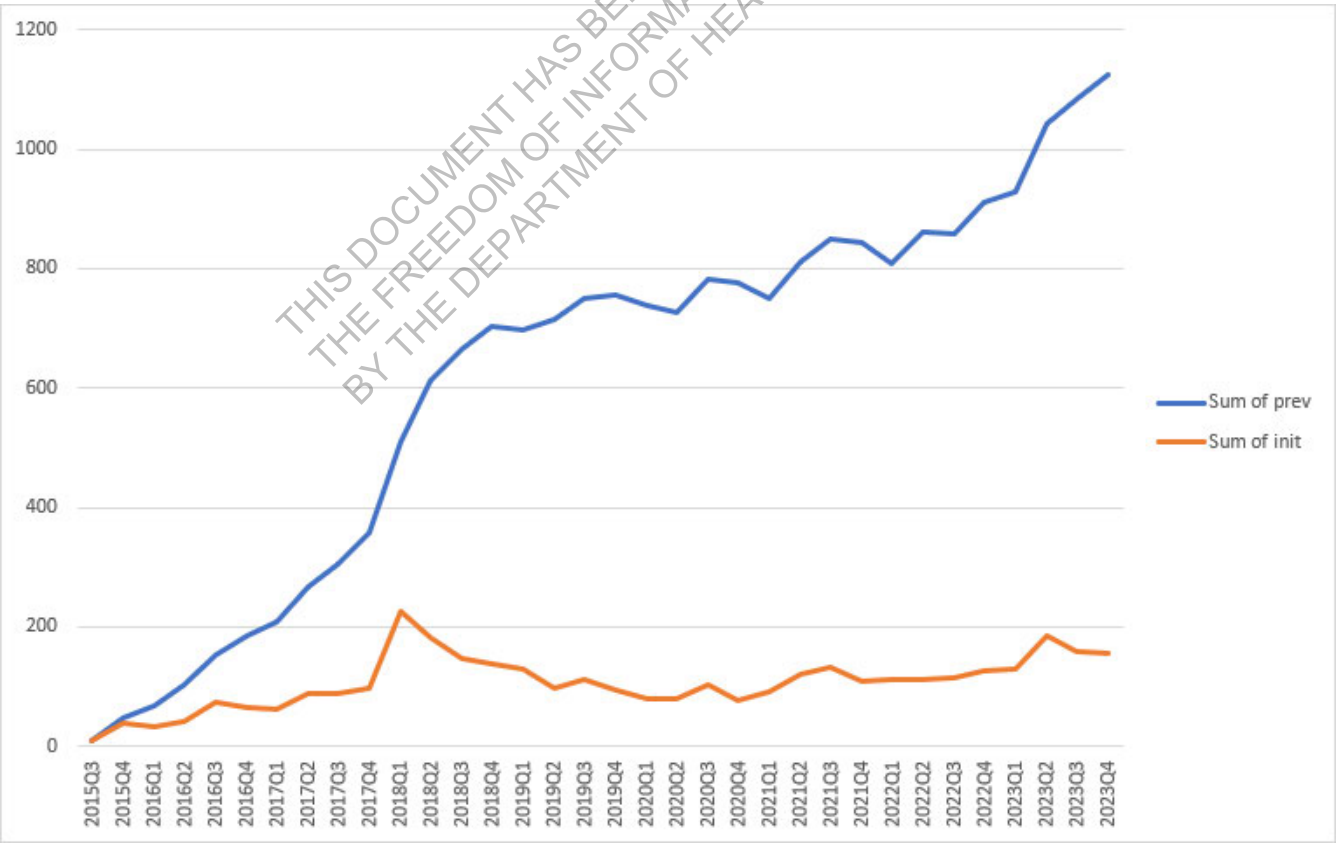
Hi s22

The graph below shows utilisation of item code 10378F and has been split into years ranging from July to June of the next year to coincide with the day that the listing change was implemented.

From the graph you can see that the number of patients initiating in 2021-22 is very similar to the numbers from 2019-20 and 2020-21 indicating that there doesn't seem to be large population that is avoiding use.



If anything, it appears that the restriction change has caused the number of patients initiating on testosterone cream to increase steadily. It's unclear why there's such a big increase in 2018Q1 and Q2. There was a restriction change in 01Jun2017 which allowed prescribing by paediatricians and it may be due to that.



The graphs along with the actual data can be found in the attached spreadsheet.

Please let us know if you'd like more information!

Thanks,

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 9:12 AM
To: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Thank you, that would be great

From: s22 @health.gov.au>
Sent: Wednesday, 3 January 2024 9:05 AM
To: s22 @health.gov.au>
Subject: RE: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Morning s22

Happy to get this analysis ready.

Thanks,
s22

From: s22 @health.gov.au>
Sent: Tuesday, 2 January 2024 5:26 PM
To: s22 @health.gov.au>
Subject: FW: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Hi s22

Do you have time to look at s22 request this week?

I'm happy to look at this if you need to prioritise other tasks.

Thanks,
s22

From: s22 @health.gov.au>
Sent: Tuesday, 2 January 2024 5:10 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: Change in patient numbers for Androforte 5 [SEC=OFFICIAL]

Hi s22

Happy new year!

I'm putting together some briefing points for a meeting with Lawley Pharma, to discuss potential changes to the Androforte PBS listing that may help address the unintended barriers to some populations where scrotal application is infeasible or considered inappropriate.

For background – The PBAC considered an application from Lawley in March 2021 and recommended the following changes to the PBS listing for Androforte 5 (PBS item code 10378F)

- Addition of clinical criteria - *The treatment must be applied to the scrotum area*.
- Number of repeats reduced from 6 to 1.

These changes were done on the basis that scrotal application requires a low volume of drug, and sponsor had requested a corresponding higher price per pack. Changes were implemented on 1 July 2021.

I'm trying to workout how the estimates would change if we were to amend the listing to say - *The treatment must be applied to the scrotum area, where appropriate* (wording yet to be determined).

Would your team be able to put together a comparison of annual number patients who were prescribed Androforte 5 before and after the 1 July 2021 change to see what the impact on patient numbers was?

Noting that the number of repeats changed from 6 to 1 (because of the smaller application volume required for scrotal application), could you have a look at the number of requests for increased quantity/repeats (assuming that non-scrotal

application would be at a high dosing volume)?

Would it be feasible to have this before senate estimates? Let me know what timing is feasible for your team.

Happy to discuss.

Thanks heaps.

s22

s22
Assistant Director
PBAC Assessment Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

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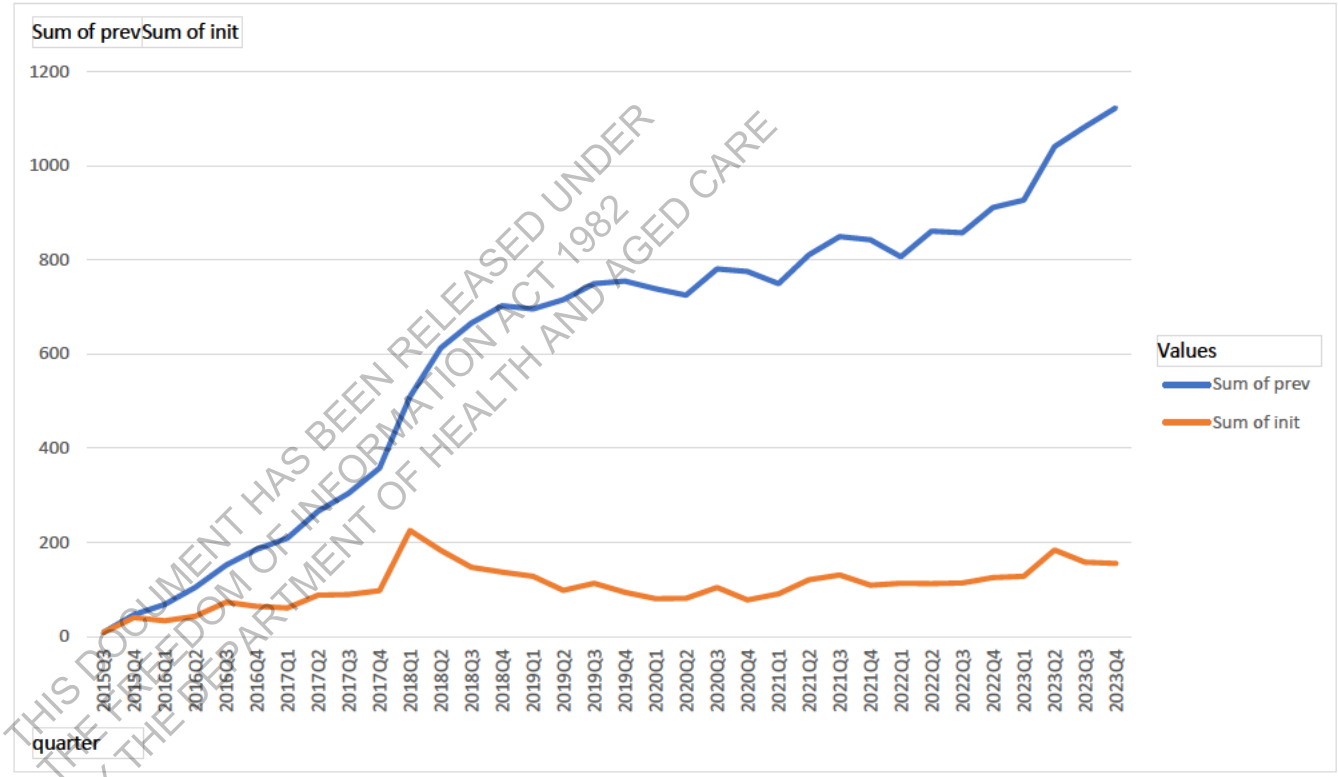
prev	init	rx	cost	quarter
8	8	12	751.08	2015Q3
46	40	93	6230.11	2015Q4
68	33	130	7934.11	2016Q1
104	43	218	12238.45	2016Q2
152	73	316	18455.32	2016Q3
185	64	404	24157.18	2016Q4
209	61	445	25446.86	2017Q1
266	88	585	33789.86	2017Q2
304	89	648	37459.4	2017Q3
358	97	718	43364.5	2017Q4
510	225	1019	56419.65	2018Q1
613	183	1366	73570.66	2018Q2
666	147	1464	73727.54	2018Q3
703	137	1598	83987.65	2018Q4
696	128	1527	74712.11	2019Q1
716	98	1581	76597.99	2019Q2
750	113	1697	83330.92	2019Q3
755	94	1732	92226.82	2019Q4
739	80	1670	84087.85	2020Q1
725	81	1565	81453.07	2020Q2
781	104	1725	94495.44	2020Q3
776	78	1749	100719.6	2020Q4
750	91	1582	82097.44	2021Q1
811	120	1703	89696.49	2021Q2
850	131	1788	182727.6	2021Q3
843	109	1716	184995.6	2021Q4
807	113	1558	156486.7	2022Q1
861	112	1599	162408.9	2022Q2
858	114	1632	170191.8	2022Q3
912	125	1778	185600.4	2022Q4
927	128	1600	168611.5	2023Q1
1041	184	1817	196193.1	2023Q2
1083	158	1861	200634.4	2023Q3
1123	155	2054	226386.8	2023Q4

Row Labels	Sum of prev	Sum of init
2015Q3	8	8
2015Q4	46	40
2016Q1	68	33
2016Q2	104	43
2016Q3	152	73
2016Q4	185	64
2023Q1	927	128
2023Q2	1041	184
2023Q3	1083	158
2023Q4	1123	155
Grand Total	**20996**	**3604**



s22

From: PBAC <PBAC@health.gov.au>
Sent: Monday, 5 July 2021 3:37 PM
To: s47F
Cc: Michael Buckley; s47F
Subject: RE: AndroForte 5 -PBS restriction request for further clarification [SEC=OFFICIAL]

Dear s47F

Thank you for reaching out on behalf of Lawley Pharmaceutical concerning this matter. As you are aware, this week is the July PBAC meeting and the PBAC Secretariat has no capacity to have a meeting to discuss this matter.

The restriction wording implemented on 1 July 2021 was consistent with the PBAC recommendation at the March 2021 PBAC meeting to amend the administrative advice for the restriction to specify scrotal application and that the maximum number of repeats be reduced to 1. This outcome was accepted by Lawley Pharmaceutical. Any further changes to this restriction wording will require a PBAC submission as changes to the wording will have clinical and financial implications that will require evaluation.

The intent to apply (ITA) deadline for the November 2021 PBAC meeting has now passed. The next available PBAC meeting is March 2022, for which the ITA deadline is 6 October 2021. ITA and submission due dates for PBAC meetings are available in the PBS calendar.

Kind regards,

s22

PBAC Assessment

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
E: PBAC@health.gov.au
GPO Box 9848, Canberra ACT 2601 (MDP 910)

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From: s47F @commercialeyes.com.au>
Sent: Monday, 5 July 2021 10:12 AM
To: PBAC <PBAC@health.gov.au>; PBS <PBS@health.gov.au>
Cc: Michael Buckley s47F @lawleypharm.com.au>; s47F @commercialeyes.com.au>
Subject: AndroForte 5 -PBS restriction request for further clarification
Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear PBAC Secretariat and Department of Health,

We are reaching out on behalf of Lawley Pharmaceutical (Michael Buckley – Medical Director cc'd in the email) regarding the PBS clinical criteria changes that occurred on 1 July 2021 for its product AndroForte 5.

The new PBS restrictions has an updated clinical criteria of " the treatment must be applied to the scrotum area". An unintended consequence of this restriction is that a proportion of patients (females) are now no longer eligible to receive PBS funded AndroForte 5. It is noted that on 1 October 2015, the restrictions were changed and the population criteria of "patient must be male" was removed thereby allowing for use of testosterone products by females on the PBS. In the February 2020 DUSC review, it was noted that approximately 2.5% of the people on testosterone were female.

Lawley pharmaceuticals would like to work with the department of health to ensure that the treatment of these patients is managed appropriately on the PBS and would like to set up a meeting with the department later this week (proposes a time on Wednesday 7th July in the afternoon) to discuss how these patients can access AndroForte 5 and to ensure their treatment is appropriately managed as they were eligible to accessing the product on the PBS prior to the 1 July 2021 restriction changes.

Thanks

s47F

commercial eyes pty ltd

Level 11, 500 Collins Street
MELBOURNE VIC 3000
P +61 3 9251 0777
F +61 3 9427 7600
E s47F @commercialeyes.com.au
www.commercialeyes.com.au

FW: Due 12pm Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

s22 @Health.gov.au>
Tue 9/26/2023 3:21 PM
To: s22 @health.gov.au>
Hi s22

Please see below some info I sent to s22 a little while ago about items regarding Androforte taken to the PBAC Executive meeting. It was last considered at the January 2023 meeting (minutes saved at *I:\Staging\PEB - Common\PBAC Meeting March 2023\PBAC Exec Meeting 1 - 24 Jan 2023*), where the Executive noted a letter from the Endocrine Society of Australia regarding a request for testosterone restriction changes, and considered that the sponsor should be contacted to confirm they would agree to the expanded listing before this change could be investigated further. The action from this item was 'PBAC Secretariat to contact sponsor to see whether it would support the amendment of the listing. PBAC Secretariat to respond to the ESA to advise of the PBAC Executive's consideration and that the sponsor has been contacted.' Draft letters to both ESA and the sponsor of Androforte (Lawley Pharmaceuticals) are saved at *I:\Staging\PEB - Common\PBAC Executive and Minors\Exec Team\Letters and Corro\2022.07 Exec Meeting 1 - ESA letter re testosterone clinical criteria*, but I don't believe they have been sent.

There was also an item about the letter from ESA regarding testosterone clinical criteria at the August 2022 PBAC Executive meeting, with the minutes saved at *I:\Staging\PEB - Common\PBAC Meeting November 2022\PBAC Exec Meeting 1 - 23 Aug 2022*.

Hope this helps. Many thanks,
s22

From: s22
Sent: Friday, 1 September 2023 4:40 PM
To: s22 @health.gov.au>
Subject: RE: Due 12pm Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Hi s22

I've just been doing some searching. It looks like at the August 22 Exec meeting, the Exec considered a request from ESA regarding testosterone clinical criteria, and the action was 'PBAC Secretariat to investigate the previous PBAC recommendations for testosterone and provide this for consideration of the Executive at a future meeting.' (see I:\Staging\PEB - Common\PBAC Meeting November 2022\PBAC Exec Meeting 1 - 23 Aug 2022)

In January 2023 the Exec again considered an ESA request for testosterone restriction changes with the action being 'PBAC Secretariat to contact sponsor to see whether it would support the amendment of the listing. PBAC Secretariat to respond to the ESA to advise of the PBAC Executive's consideration and that the sponsor has been contacted.' (see I:\Staging\PEB - Common\PBAC Meeting March 2023\PBAC Exec Meeting 1 - 24 Jan 2023). It looks like letters were drafted following the meeting, but it doesn't look like these were sent (I'm just confirming this with s22 and will let you know if there is anything different for this.

Hope this helps!

Many thanks,
s22

From: s22 @health.gov.au>
Sent: Friday, 1 September 2023 4:17 PM

To: s22 @Health.gov.au>
Subject: RE: Due 12pm Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Hi s22 t looks like there has been no further change on Androforte 5 since May 2023 – see last 4 dotpoints of p2 PMR's FAS brief. It would be great if you can please take a look to see if there's been anything since then (only if that was Exec Team's responsibility- this task may have been handed over to PRAIS/PMR?)

Thanks
s22

s22 (she/her)
s22
PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
PO Box 9848, Canberra ACT 2601, Australia
Location: Melbourne office

Part-time: Monday, Tuesday and Friday

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From: s22
Sent: Friday, 1 September 2023 3:29 PM
To: s22 @Health.gov.au>
Subject: FW: Due 12pm Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Hi s22

Thanks so much for taking a look- as discussed, just wanted to check if there has been any progress on Androforte 5 (highlighted in s22 email below.

Thanks
s22

s22 (she/her)
s22
PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
PO Box 9848, Canberra ACT 2601, Australia
Location: Melbourne office

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From: s47E(d) @health.gov.au>
Sent: Friday, 1 September 2023 12:42 PM
To: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s47E(d) @health.gov.au>
Subject: Due 12pm Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Hi All,

Can you please review the Below request and provide any input by 12pm Monday 4/9 for MBDHD to use in their response. MBD have copied in some previous input from us below as a starting point.

Thanks
s22

From: s47E(d) @health.gov.au>
Sent: Friday, 1 September 2023 12:31 PM
To: s47E(d) @health.gov.au>
Cc: s47E(d) @health.gov.au>
Subject: FW: Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Hi s22

For input by **COB Monday 4 September,** please see the request from MBD below – previous input has been provided for update if that helps?

Thanks very much

s22

---

s22 – Technology Assessment and Access Division |
Divisional Parliamentary Coordinator | Australian Government Department of Health and Aged Care

☏ (02) 6289-s22 / ✉ s47E(d) @health.gov.au

From: s47E(d) @health.gov.au>
Sent: Friday, 1 September 2023 11:27 AM
To: s47E(d) @health.gov.au>
Cc: s47E(d) @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s47E(d) @health.gov.au>
Subject: Request for TAAD input by 4 September FW: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Good morning

Following on from the below email from Assistant Minister Kearney's office, we would be grateful for input from TAAD for this MIR in relation to current access to PBS benefits for puberty blockers and hormones for patients undergoing gender affirmation, and relevant current PBAC applications by COB Monday 4 September.

Initially I have brought this information together from previous input provided by TAAD:

PBS benefits for puberty blockers and hormones for patients undergoing gender affirmation

- Gonadotropin releasing hormone (GnRH) analogues (sometimes referred to as 'puberty blockers') are only available on the PBS for the treatment of certain cancers and precocious puberty (early puberty) under certain circumstances. These medicines include goserelin 3.6 mg, 10.8 mg implant (Zoladex Implant®), leuprorelin acetate 7.5 mg, 22.5 mg, 30 mg, 45 mg modified release injection (Lucrin Depot® and Eligard®), triptorelin 3.75, 11.25 mg, 22.5 mg injection (Diphereline®) and triptorelin acetate 100 microgram/mL injection (Decapeptyl®).
- GnRH analogues (puberty blockers) could be used '"off label" for patients undergoing gender affirmation.
- The only product indicated for children is LUCRIN Depot Paediatric 30 mg PDS, its product information states: "LUCRIN Depot Paediatric 30 mg PDS Injection must only be prescribed after initial assessment by a paediatric endocrinologist, who is experienced in the diagnosis and management of CPP and with the ongoing supervision of such a specialist." This is indicated for suppression of precocious puberty.
- Doctors may use medications off label where they are satisfied that the benefits outweigh the risks for the patient. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-01299-3&d=20230601172310101
- A range of medicines used in gender-affirming hormone therapy are available on the PBS and can be accessed by transgender patients. Estrogen containing products are available in many cases as unrestricted benefits while testosterone containing products are mainly available as Authority Required listings.

PBAC applications currently under consideration relevant to gender affirmation

-

- At its March 2021 meeting, the pharmaceutical company (sponsor) of Androforte 5 (a testosterone cream formulation) requested a change in the number of repeats for the currently listed testosterone cream. The PBAC recommended amending the listing of AndroForte 5 to reduce the number of repeats from six to one and recommended an increase to the unit price which should not result in additional cost to the PBS. The PBAC's recommendation was based on the TGA approval for scrotal application that reduces the dose from 100 mg to 25 mg daily, and increases the number of treatments per tube from 25 to 100. The sponsor of AndroForte 5 accepted the PBAC recommendations with the addition of the PBS restriction criteria 'The treatment must be applied to the scrotum area'. This has been the subject of several correspondences from transgender and LGBTI organisations, claiming it creates a barrier to transgender patients receiving therapy. The Department, following advice from the PBAC Executive on the matter, is working with the sponsor on a proposed amendment to the restriction to address this.

-

Kind regards

s22
Medical Specialist Services Section
MBS Policy and Specialist Services Program
Medicare Benefits and Digital Health Division
P: (02) 6289 s22

From: s47E(d)
Sent: Thursday, 31 August 2023 12:35 PM
To: s47E(d) @health.gov.au>
Cc: s47E(d) @Health.gov.au>; s47E(d)

s47E(d) @health.gov.au>
Subject: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Hi all

A MIR has been logged under **MB23-002766** and assigned to **MBD** in PDMS.

Due to MO **08/09/2023.**

Thank you kindly

s22
Ministerial Coordination Officer
Ministerial and Parliamentary Services Branch (MPS)

People, Communication and Parliamentary Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
MPS Hotline: 02 6289 s22 | E: s47E(d)
Location: Sirius Building s22

PO Box 9848, Canberra ACT 2601, Australia

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We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47E(d) @Health.gov.au>
Sent: Thursday, 31 August 2023 11:39 AM
To: s47E(d) @health.gov.au>
Cc: s47E(d) @Health.gov.au>
Subject: MB23-002766 - MIR - PBS & MBS gender affirming healthcare - due 8 September 2023 [SEC=OFFICIAL]

Minister's Office	**Assistant Minister Kearney**
Request	MIR
Additional products	☐ Talking points ☐ Q&As ☐ Standard words ☐ Other _____
Subject	PBS & MBS gender affirming healthcare
Further details	MIR to cover the existing coverage of gender-affirming healthcare under both PBS and MBS across the continuum of care (from assessment, puberty blockers, hormones to surgical intervention). Should include any stipulations on the provision of that care, including age restrictions, and any current or expected applications to PBAC or MSAC in this area. Exploration of the division of responsibility between commonwealth and state and territory jurisdictions would be helpful as well please. Please cc MBO.

Requesting adviser	s47F
Attachments	No
Time frame	☒ Standard (5 days for MIR, 10 days for Info brief) ☐ Urgent *Due date:* 8/09/2023 5:00 PM *Reason for urgency:* Needed for a stakeholder meeting wc 11 September 2023.
Information will be provided externally	No
Relevant Division(s)	MBD with input from TAAD
DLO comments	The office received MB23-002109 (MIR – gender affirming care through Medicare) in July. Happy for this new request to build on MB23-002109. MPS – please link the two.

From: s47F @Health.gov.au>
Sent: Thursday, 31 August 2023 11:17 AM
To: s47E(d) @Health.gov.au>
Cc: s47E(d) @Health.gov.au>
Subject: Brief request - PBS & MBS gender affirming healthcare [SEC=OFFICIAL]

Hey s22

Just looking to request a MIR. I'd like it due COB 8 Sept please.

It was suggested by Tania that this request go to Penny's team rather than Tania's. It needs to cover the existing coverage of gender-affirming healthcare under PBS and MBS across the continuum of care (ie. from assessment, puberty blockers, hormones through to surgical intervention), any stipulations on the provision of that care (age restrictions etc), and any current or expected applications to PBAC or MSAC in this area. Exploration of the division of responsibility between commonwealth and state and territory jurisdictions would be helpful as well please.

Brief should be copied to MBO as well please.

Thanks!

s47F

s47F (He/Him)
Office of the Hon Ged Kearney MP
Assistant Minister for Health and Aged Care
E: s47F @health.gov.au
P: s47F
M: s47F
Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

[SEC=OFFICIAL]

RE: FW: due 12pm 10/01 : MEDIA: PBS testosterone, media inquiry - DUE 12 noon Wednesday 10 January [SEC=OFFICIAL]

PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Wed 1/10/2024 11:35 AM
To s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc s22 @health.gov.au>;PBAC <PBAC@health.gov.au>

Hi s22

The input is cleared (thanks s22 and s22

Can you please amend the format of the question/response; and include the "internal use background".

Thanks
N

Natasha Ploenges
(Ms/She/Her)
Assistant Secretary
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care

Diversity Champion - Cultural and Linguistic Diversity

T: 02 6289 s22 | E: Natasha.Ploenges@health.gov.au
Location: Sirius s22
PO Box 9848, Canberra ACT 2601, Australia

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CULTURALLY & LINGUISTICALLY DIVERSE

From: s22 @health.gov.au>
Sent: Wednesday, 10 January 2024 10:03 AM
To: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Cc: s22 @health.gov.au>; s47E(d) @health.gov.au>; PBAC <PBAC@health.gov.au>
Subject: FW: FW: due 12pm 10/01 : MEDIA: PBS testosterone, media inquiry - DUE 12 noon Wednesday 10 January [SEC=OFFICIAL]
Importance: High

Hi N, updated as requested – thanks s22 for updating.

A September 2023 briefing to Assistant Minister Kearney refers to a PBS restriction requiring a testosterone product to be "applied to the scrotum area". This led to complaints from transgender groups.

Questions

1. Has this restriction been altered or removed?

***Response**: At its March 2021 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended changes to the Pharmaceutical Benefits Scheme (PBS) listing for AndroForte 5 (testosterone 5% cream), including addition of the criterion "The treatment must be applied to the scrotum area". The PBS listing for this product was amended on 1 July 2021 to incorporate these recommendations. No changes to this PBS listing have occurred since this date. Details of the PBAC's consideration can be found in the Public Summary Document which is available on the PBS website at: www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2021-03/testosterone-transdermal-cream-50-mg-per-ml-50-ml-androfo.*

2. If so, what are the reasons for doing so?

***Response**: The Department of Health and Aged Care is liaising with Lawley Pharmaceuticals, the pharmaceutical company responsible for the supply of AndroForte 5, regarding any unintended barriers to patient access created by the current PBS restriction criteria. The Australian Government relies on advice from the independent expert PBAC in relation to changes to PBS listings.*

s22 *[She/Her]*
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

This email comes to you from Ngunnawal Country
PO Box 9848, Canberra ACT 2601, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

---------- Forwarded message ----------

From: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Date: 9 January 2024 at 5:07:19 pm AEDT
Subject: FW: due 12pm 10/01 : MEDIA: PBS testosterone, media inquiry - DUE 12 noon Wednesday 10 January [SEC=OFFICIAL]
To: s22 @health.gov.au>
Cc: s47E(d) @health.gov.au>

Hi s22

For completeness, please add the product and pharma company, and any relevant PBAC/PBS links.

Thanks
N

Natasha Ploenges
(Ms/She/Her)
Assistant Secretary
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care

Diversity Champion - Cultural and Linguistic Diversity

T: 02 6289 s22 | E: Natasha.Ploenges@health.gov.au
Location: Sirius s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47E(d) @health.gov.au>
Sent: Monday, 8 January 2024 4:29 PM
To: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Cc: s47E(d) @health.gov.au>
Subject: due 12pm 10/01 : MEDIA: PBS testosterone, media inquiry - DUE 12 noon Wednesday 10 January [SEC=OFFICIAL]

Hi Natasha,

See below response from s22 for clearance by **12pm 10/01/24**

For N:
As the request does not name the particular product we chose not to disclose the product name and sponsor. However, the detail is provided in the background information should you wish to include it.

Thanks s22 for drafting!
Cheers
s22

A September 2023 briefing to Assistant Minister Kearney refers to a PBS restriction requiring a testosterone product to be "applied to the scrotum area". This led to complaints from transgender groups.

Questions

1. Has this restriction been altered or removed?

***Response**: No changes have been made to the Pharmaceutical Benefits Scheme (PBS) listing for this product since the change to add the criterion "The treatment must be applied to the scrotum area" on 1 July 2021.*

2. If so, what are the reasons for doing so?

***Response**: The Department of Health and Aged Care is liaising with the relevant pharmaceutical company regarding any unintended barriers to patient access created by the current PBS restriction criteria. The Australian Government relies on advice from the independent expert Pharmaceutical Benefits Advisory Committee in relation to changes to PBS listings.*

FOR INTERNAL USE ONLY - Background information –

- At the March 2021 meeting of the PBAC, Lawley Pharmaceuticals Pty Ltd, the sponsor of AndroForte 5 (a testosterone cream formulation), requested a change in the number of repeats for the currently listed testosterone cream.
- The PBAC recommended amending the listing of AndroForte 5 to reduce the number of repeats from six to one and recommended an increase to the unit price which should not result in additional cost to the PBS. The PBAC's recommendation was based on the TGA approval for scrotal application that reduces the dose from 100 mg to 25 mg daily, and increases the number of treatments per tube from 25 to 100.
- The sponsor of AndroForte 5 accepted the PBAC recommendations with the addition of the PBS restriction criteria '*The treatment must be applied to the scrotum area*'.
- The PBAC Executive consider a letter from the Endocrine Society of Australia at its August 2022 meeting, asking for an amendment to the above wording, to ensure trans and gender diverse individuals and those with disabilities - where scrotal application is either not possible or inappropriate - are still able to use this preparation by application to the body. This letter was considered again at the PBAC Executive meeting in January 2023. The PBAC Executive supported amendments to the wording in principle, following an agreement being reached with the relevant company.
- On 13 October 2023, the PBAC Secretariat wrote to Lawley Pharmaceuticals seeking the company's interest in making changes to the current PBS listing for AndroForte 5.
- On 23 October 2023 Lawley Pharmaceutical replied, indicating that the company was willing to explore this matter further.
- The PBAC Secretariat is developing the next steps and plans to meet with Lawley Pharmaceuticals in the coming weeks.

Thanks
s22

From: s47E(d) @health.gov.au>
Sent: Monday, 8 January 2024 10:09 AM
To: s47E(d) @health.gov.au>
Cc: s47E(d) @health.gov.au>
Subject: Response request: MEDIA: PBS testosterone, media inquiry - DUE 12 noon Wednesday 10 January [SEC=OFFICIAL]

Hello, we have received the following Media request – is OHTA able to assist? AS cleared input due 12 noon Wednesday 10 January.

Question

I am a journalist writing about the debate over youth gender clinics. My reporting appears here -- - https://www.genderclinicnews.com/

I have a question arising from this FOI material --- https://www.health.gov.au/resources/foi-disclosure-log/foi-4713-release-documents

I have copied in departmental media.

A September 2023 briefing to Assistant Minister Kearney refers to a PBS restriction requiring a testosterone product to be "applied to the scrotum area". This led to complaints from transgender groups.

Thanks
s22

s22
TAAD Executive/PMO Section

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
Location: s22 Sirius Building
PO Box 9848, Canberra ACT 2601, Australia

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---

From: News <news@health.gov.au>
Sent: Monday, 8 January 2024 9:41 AM
To: s47E(d) @health.gov.au>
Cc: News <news@health.gov.au>
Subject: MEDIA: PBS testosterone, media inquiry [SEC=OFFICIAL]

Hi TAAD team,

Please see enquiry below, is this one you are able to assist with? Deadline COB Wednesday but happy to be flexible. Let me know if there are any issues.

Thanks,

s22
Media Unit

Australian Government, Department of Health and Aged Care
T: 02 6289 s22 | s22 E: news@health.gov.au

Unless stated otherwise, this information is provided on a background basis and should not be attributed.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Gender Clinic News | Bernard Lane <genderclinics@gmail.com>
Sent: Monday, 8 January 2024 8:00 AM
To: minister.kearney.media@aph.gov.au; News <news@health.gov.au>
Subject: PBS testosterone, media inquiry

Hello,

I am a journalist writing about the debate over youth gender clinics. My reporting appears here --- https://www.genderclinicnews.com/

I have a question arising from this FOI material --- https://www.health.gov.au/resources/foi-disclosure-log/foi-4713-release-documents

I have copied in departmental media.

A September 2023 briefing to Assistant Minister Kearney refers to a PBS restriction requiring a testosterone product to be "applied to the scrotum area". This led to complaints from transgender groups.

Questions

1. Has this restriction been altered or removed?

2. If so, what are the reasons for doing so?

Deadline close of business Tuesday.

Regards,

Bernard Lane

Gender Clinic News | Independent newsletter
genderclinicnews.com

Sydney, Australia **Phone** 0424 263 733
International +61 424 263 733
On **Signal** for encrypted messages

Twitter @Bernard_Lane

[SEC=OFFICIAL]

PBAC Executive Meeting Minutes

Tuesday 23 August 2022, 2pm – 4pm
November 2022 Cycle – Meeting 1

Attendees: Andrew Wilson, Jo Watson, Chris Etherton-Beer and Kirsten Howard

Department of Health/Secretariat attendees:

s22

s22

Natasha Ploenges

s22

Nikolai Tsyganov

s22

1 Welcome & confirmation of COIs

1.1 The PBAC Chair welcomed the attendees and noted there were no conflicts of interest declared.

s22

3 For discussion/advice

s22

s22

s22

[redacted]

3.3 Endocrine Society of Australia (ESA) letter regarding testosterone clinical criteria

The Executive noted the request from the ESA to amend the clinical criteria of testosterone on the PBS. The Executive were supportive in principle of the proposed changes but asked the Department to investigate the history of the listing and previous considerations by the PBAC to ensure the proposed amendment would align with the original intent of the recommendation.

ACTION: PBAC Secretariat to investigate the previous PBAC recommendations for testosterone and provide this for consideration of the Executive at a future meeting.

s22

[redacted]

s22

s22

Item PBAC Executive Meeting Minutes

Tuesday 24 January 2023, 2pm – 4pm
March 2023 Cycle – Meeting 1

Attendees: Andrew Wilson, Jo Watson, Christopher Etherton-Beer, Kirsten Howard

Department of Health/Secretariat attendees:

s22 s22 s22

Natasha Ploenges

1 Welcome & confirmation of COIs

1.1 The PBAC Chair welcomed the attendees and noted there were no conflicts of interest declared.

s22

3 For discussion

s22

s22

s22

s22

s22

s22


THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH AND AGED CARE

3.5 **Endocrine Society of Australia (ESA) request for testosterone restriction changes**

The Executive noted the letter from the ESA, last considered at its August 2022 meeting. The Executive reiterated that they were supportive in principle of the proposed changes and acknowledged that the clinical criteria may present unintended barriers to some populations where scrotal application is infeasible or considered inappropriate.

The Executive noted that the March 2021 PBAC recommendation to approve a price for testosterone cream due to the addition of scrotal application clinical criteria may have pricing implications should the amendment proceed.

The Executive considered that the sponsor should be contacted to confirm they would agree to the expanded listing before this change could be investigated further.

ACTION: PBAC Secretariat to contact sponsor to see whether it would support the amendment of the listing.
PBAC Secretariat to respond to the ESA to advise of the PBAC Executive's consideration and that the sponsor has been contacted.

s22

s22

s22

s22

Endocrine Society of Australia

6th July, 2022

To: Professor Andrew Wilson
Chair PBAC

Email: a.wilson@sydney.edu.au

Dear Professor Wilson

Testosterone replacement therapy is the cornerstone of management in male hypogonadism and masculinising gender affirming hormone therapy. Commonly used preparations in Australia include intramuscular testosterone undecanoate, transdermal gels and transdermal cream.

Most testosterone prescriptions in Australia are for cisgender men without disability, where scrotal application of the transdermal cream preparation is possible and highly effective. However, we are writing to request the PBAC review the current PBS requirements for prescription of testosterone 5% (50 mg/mL), 50 mL cream (trade name Androforte5), as all indications now have an additional clinical criterion "the treatment must be applied to the scrotum area".

We ask for an amendment to these criteria, such as: "where possible, the treatment must be applied to the scrotum area". This would ensure trans individuals and those with disabilities - where scrotal application is either not possible or inappropriate - are still able to use this preparation by application to the body.

Denying access to testosterone cream for these patient groups otherwise disadvantages many who often already come from marginalised communities where healthcare access and outcomes are not equitable.

1. Trans and gender diverse individuals on masculinising gender affirming hormone therapy

Trans individuals have a gender identity that differs from their sex assigned at birth and many have hormone therapy to affirm their gender identity. An estimated 1% of our population are trans and gender diverse (1); approximately 50% of these are transmasculine. Trans patients prescribed testosterone do not have a scrotum, so under current PBS criteria they are now excluded from using testosterone 5% cream.

PBS criteria for testosterone prescribing have been amended in recent years in an effort to reduce the misuse and potential harm from inappropriate testosterone prescribing. An additional important and welcome change by the PBAC from 1 October 2015 was the removal of the sex specific population criterion "the patient must be male" as this was found to be contrary to the

Address for correspondence: 145 Macquarie Street, Sydney, NSW 2000
Telephone: 02 9256 5405 Facsimile: 02 9251 8174 Email:s47F **@endocrinesociety.org.au**
Website: http://www.endocrinesociety.org.au/
Secretariat: s47F
ACN – 006 631 125
ABN – 80 006 631 125

intent of amendments to the Sex Discrimination Act 1984. We believe the requirement for testosterone 5% cream to be applied via the scrotum, effectively undoes the October 2015 PBAC amendment for this preparation.

Although testosterone undecanoate and testosterone gels remain options available to trans patients, testosterone cream provides an important option to which there should be equitable access. In particular, we note:

- Smoking, overweight and obesity affects around half of trans patients (3), which increase the risk of a raised haematocrit, making options for transdermal preparations very important
- Almost 10% of patients seen at the Monash Health Gender Endocrinology Clinic have autism spectrum disorder (ASD) (3), and high rates of ASD are well described in trans patients (4). People with ASD often struggle with the texture of gel preparations and intramuscular testosterone undecanoate often cannot be used either due to significant needle phobia and/or raised haematocrit. By excluding the option of testosterone 5% cream, they are finding a significant limitation on options for treatment

In one Australian series ~10% (72 patients out of 702) were prescribed testosterone cream (2). Notably, doses (and therefore cost) in trans patients can be lower than are used in cis men (2).

2. Patients where scrotal application may not be possible or be inappropriate

Patients with a physical or intellectual disability where carers need to assist with medication administration, including application of testosterone cream, should not be required to use testosterone 5% cream via scrotal application. For example, for patients with Prader Willi Syndrome and associated hypogonadism and intellectual disability (5), their carers (often parents), are typically responsible for medication administration. Scrotal application of medications in such circumstances is of course inappropriate and would be contrary to the intentions of the Disability Discrimination Act 1992. As with trans patients, some patients with disabilities have comorbidities or care requirements which preclude safe/ optimal use of other testosterone preparations, making access to testosterone 5% cream important for clinical care.

Overall

We fully support and actively prescribe scrotal application of testosterone 5% cream wherever possible. However, we are applying for PBAC review of the criteria for scrotal application, to ensure equitable access to all people requiring testosterone therapy - regardless of their birth assigned sex or any disability.

Thank you for your review and consideration

References

1. Cheung AS, Wynne K, Erasmus J, Murray S, Zajac JD. Position statement on the hormonal management of adult transgender and gender diverse individuals. Med J Aust. 2019.
2. Nolan BJ, Zwickl S, Locke P, Simpson S, Li L, Zajac JD, et al. Prescription Patterns and Testosterone Concentrations Achieved With AndroForte 5% Testosterone Cream in Transgender and Gender Diverse Individuals. J Sex Med. 2022;19(6):1049-54.
3. Endall R, Herath M, Upreti R, Watts A, Catford S. Gender affirming care at a Victorian tertiary centre. ESA-SRB-ANZBMS; 2021.

4. Warrier V, Greenberg DM, Weir E, Buckingham C, Smith P, Lai MC, et al. Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals. Nat Commun. 2020;11(1):3959.
5. Napolitano L, Barone B, Morra S, Celentano G, La Rocca R, Capece M, et al. Hypogonadism in Patients with Prader Willi Syndrome: A Narrative Review. Int J Mol Sci. 2021;22(4).

With kind regards

s47F

A/Professor Ann McCormack MBBS, FRACP, PhD
Co-Chair, Medical Affairs Committee, Endocrine Society of Australia

s22

From: s22 @health.gov.au>
Sent: Thursday, 16 February 2023 5:15 PM
To: hta; s22 ; s47E(d)
s22
Cc: s22
Subject: RE: Letter from s47F [SEC=OFFICIAL]

Hi s22
I don't see the need to go back to the applicant before we have had a discussion – it would be better to do in one go.
In addition to the policy/medical considerations for each proposal, the request needs to be considered in the context of the potential for the adverse consequences of identifying, or targeting of individuals having any of these services, or the practitioners providing them, as is occurring in America and the UK by those with vehemently negative views on gender affirmation interventions.

Cheers
s22

From: hta <hta@health.gov.au>
Sent: Thursday, 16 February 2023 10:52 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Cc: hta <hta@health.gov.au>
Subject: RE: Letter from s47F [SEC=OFFICIAL]

Dear all

I would like to follow-up on this matter, requesting that we have an internal meeting to discuss the briefing paper and go over all policy and MSAC considerations before meeting with the applicant. As the proposal crosses into PBAC territory with the mention of clarifying PBS eligibility for people to access testosterone for gender affirmation, I have included s22 from the PBAC team in this email as well.

Before I set up an internal meeting, has the briefing paper raised any questions that we should seek answers to from the applicant?

Regards

s22
MSAC pre-assessment Section
Office of Health Technology and Assessment
Technology Assessment & Access Division | Health Resourcing Group
T: 02 6289 s22 | E: s22 @health.gov.au

From: s47G @plasticsurgery.org.au>
Sent: Monday, 6 February 2023 2:12 PM
To: hta <hta@health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>;

s47E(d) @health.gov.au>; s47F @plasticsurgery.org.au>; s47G
s47G @plasticsurgery.org.au>
Subject: RE: Letter from s47F [SEC=OFFICIAL]

Dear s22 ,

Please find attached our briefing paper for pre-MSAC submission meeting consideration.

We also wanted to see whether it was possible to request that the pre-submission meeting be held in person?

We look forward to your response.

s47F
Australian Society of Plastic Surgeons
I work on Thursdays 9am-5pm and Fridays half day only.

T: +61 2 9437 9200
E: s47G @plasticsurgery.org.au
A: Suite G01, Ground Floor, 69 Christie Street, St Leonards, NSW 2065
W: www.plasticsurgery.org.au

Follow us

We acknowledge the Aboriginal people as the First Australians and pay respect to Elders past and present.

We are pleased to be able to assist you on this occasion. Positive feedback really helps to encourage the public to visit our website and use our content to educate themselves before beginning their plastic surgery journey. If you wouldn't mind leaving a review, it would be much appreciated." Google Review

From: hta <hta@health.gov.au>
Sent: Wednesday, January 4, 2023 4:34 PM
To: s47G
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; hta <hta@health.gov.au>; s47E(d) @health.gov.au>; s47F @plasticsurgery.org.au>; s47G
s47G @plasticsurgery.org.au>
Subject: RE: Letter from s47F [SEC=OFFICIAL]

Dear s47F

I am following up with you regarding the letter sent to s22 before the Christmas shutdown about a potential application to MSAC. Prior to meeting to discuss a potential application, the best way to obtain accurate and comprehensive advice about your proposal is to submit a short (one to two-page) briefing paper. The briefing paper is an effective way of having all relevant information in one document, and assists us in identifying the most relevant policy and funding area in the Department that can provide further advice. Your briefing paper can be in dot-point form, including details such as:

- Name of the new technology/service;
- Patients who would benefit from the technology/service
- Would there be any restrictions based on patient age, clinical features, or proposed frequency of use?
- Practitioners who would be providing the technology/service;

- Name of relevant professional medical college/society that will need to advise on (or provide a 'statement of clinical relevance' for) the proposed technology service;
- Practitioners who would be referring patients for the technology/service (e.g. GPs, specialists, social workers etc);
- Other practitioners who may be affected;
- What technologies/services are currently being provided to the patient group (i.e. what existing services would the new technology/service replace)?
- What are the anticipated improvements in health outcomes for the patient group, if this new technology/service was recommended for funding?
- Whether the technology/service will be provided to outpatients and/or to admitted hospital or day-procedure patients (via your initial proposal, and also if the health venue/patient location is likely to change in the future);
- How is the technology/service funded at present? (e.g. research funding; State-based funding; self-funded by patients; no funding or payments);
- If the new technology/service is a type of screening, why would it be suited to MBS funding, as opposed to a dedicated screening program? Have you researched and approached other funding sources?
- Current status of TGA registration of the product, device or medicine (if relevant);
- Current status of clinical trials (or other evidence);
- Cost/price of the technology/service (including professional service component, as well as separate cost of a product, appliance or device used during the service);
- Likely cost for Government (taxpayer);
- Potential out-of-pocket costs for patients; and
- Whether the technology/service involves a device/product that will need approval through another committee/process (e.g. PLAC or PBAC).

Once received, we will review the brief, and provide a more targeted response, including the possibility of a pre-application teleconference.

Regards

s22
MSAC pre-assessment Section
Office of Health Technology and Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s47G @plasticsurgery.org.au>
Sent: Friday, 23 December 2022 8:25 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>

Cc: s47F @plasticsurgery.org.au>; s47G @plasticsurgery.org.au>
Subject: Letter from s47F

Dear s22

I trust this email finds you well.

Please find attached a letter from s47F We look forward to your reply.

Have a good Christmas and Happy New Year.

s47F
Australian Society of Plastic Surgeons
I work on Thursdays 9am-5pm and Fridays half day only.

T: +61 2 9437 9200
E: s47G @plasticsurgery.org.au
A: Suite G01, Ground Floor, 69 Christie Street, St Leonards, NSW 2065
W: www.plasticsurgery.org.au

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We acknowledge the Aboriginal people as the First Australians and pay respect to Elders past and present.

Australian Society of Plastic Surgeons

Briefing Paper for Pre-MSAC Application Consideration
Items for Assessment and Treatment Related to Gender Incongruence
06.02.2023

- **Name of the new technology/service:**

Patient consultations and medical interventions relating to gender affirmation.

The term gender incongruence refers to people whose gender identity is consistently incongruent with their presumed or experienced gender. Gender affirmation involves social, medical and/or legal steps that are pursued by people with gender incongruence to affirm their gender. Gender affirming medical interventions have proven benefits for mental health in those with gender incongruence. The steps taken as part of the gender affirmation process will vary depending on each person's personal preferences and may involve any combination of social, medical and legal components.

The Australian Society of Plastics Surgeons (ASPS) will be the lead organisation for a forthcoming MSAC Application requesting funding for a range of medical interventions purposes of gender affirmation. For the purposes of developing this application ASPS initiated a Collaborative Group, with a range of relevant stakeholders, including those with a lived experience of being transgender and representatives of AusPATH - Australian Professional Association for Trans Health, Trans Health Research Group of the University of Melbourne and ACON - Aids Council of New South Wales

There are a range of medical interventions associated with gender affirmation. The medical interventions used will differ depending on a person's personal choice as to which medical affirmation interventions are right for them. As such, it is not considered informative to describe the service(s) associated with the forthcoming MSAC Application beyond the high-level description of 'patient consultations and medical interventions relating to gender affirmation.'

To facilitate access to the range of services associated with medical gender affirmation a series of MBS services will be proposed in a forthcoming MSAC Application, including:

MBS items for patient consultations: It is foreshadowed that patient consultation items will facilitate a multidisciplinary approach to care where this is required. Healthcare professionals anticipated to access patient consultation items include general practitioners, plastic surgeons, oral and maxillofacial surgeons, ear nose and throat surgeons, endocrinologists, urologists, gynaecologists, sexual health practitioners, psychologists and psychiatrists.

People will not require consultations with all of these practitioner types, rather the extent of interaction with various specialty practitioners will depend on the medical gender affirmation steps chosen by each person.

MBS item for hormonal treatment initiation and monitoring: Some people will choose to take hormonal treatment as part of their medical gender affirmation. Undertaking a comprehensive medical history, having a detail discussion facilitating informed consent to initiate hormonal treatment, and monitoring people to review the clinical effects of hormonal treatment are all pivotal for the safe use of hormonal treatment.

Australian Society of Plastic Surgeons

New MBS items for patient consultations associated with hormonal treatment initiation and monitoring will be proposed. It is anticipated that these MBS items will be used by general practitioners, endocrinologists and sexual health physicians prescribing hormone therapy for the purposes of gender affirmation.

MBS items for gender affirming surgeries: To ensure access to the range of gender affirming surgical procedures a range of new MBS items will be sought. A summary of the gender affirmation surgical categories and associated procedures for which MBS items will be sought is provided below.

- Gender affirming "top" surgery
  - Sub-total bilateral mastectomy for gender affirmation
  - Two stage bilateral female breast construction for gender affirmation
  - Single stage bilateral female breast construction for gender affirmation
  - Revision gender affirmation breast surgery

- Gender affirming "bottom" surgery
  - Bilateral orchidectomy for gender affirmation
  - Construction of a neo-phallus for gender affirmation (free flap)
  - Construction of a neo-phallus for gender affirmation single stage or first of two stages (local flap / prosthetic)
  - Second stage procedure for construction of a neo-phallus for gender affirmation
  - Construction of a neo-vagina for gender affirmation (free flap)
  - Construction of a neo-vagina for gender affirmation single stage or first of two stages (local flap)
  - Neurovascular island flap for genital sensation in gender affirmation

- Facial feminisation/masculinisation and voice surgery
  - Autologous facial feminisation/masculinisation surgery
  - Alloplastic facial feminisation/masculinisation surgery

- Laryngoplasty for gender affirmation

Healthcare professionals anticipated to access MBS items associated with gender affirmation surgery are plastic surgeons, oral and maxillofacial surgeons, urologists, and ear nose and throat surgeons.

- **Patients who would benefit from the technology/service**

People experiencing persistent gender incongruence electing to pursue medical interventions as part of their gender affirmation process.

- **Would there be any restrictions based on patient age, clinical features, or proposed frequency of use?**

Restrictions on being able to access medical interventions relating to gender affirmation based on patient age or clinical features are not being requested.

Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents (Telfer et al., 2020) outline that:

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> "Current law requires the adolescent's clinicians to ascertain whether or not an adolescent's parents or legal guardians' consent to the proposed treatment before an adolescent can access either pubertal suppression or hormone treatment. Where there is no dispute between the parents, the adolescent or the medical practitioner, the clinician may proceed on the basis of the adolescent's consent, where competent to consent, or parental consent, where the adolescent is not competent to consent. Where there is a dispute as to either competence, diagnosis or treatment, court authorisation prior to commencement of treatment is required."

There are circumstances in which people under the age of 18 years would legally seek access to medical interventions associated with gender affirmation. For this reason, the applicant is not proposing restrictions based on patients age.

In broader clinical practice most people accessing surgical procedures gender affirmation would be aged 16 year and over.

- **Practitioners who would be providing the technology/service;**

MBS items for patient consultations: General practitioners, plastic surgeons, oral and maxillofacial surgeons, ear nose and throat surgeons, endocrinologists, urologists, gynaecologists, sexual health practitioners, psychologists and psychiatrists.

MBS item for hormonal treatment imitation and monitoring: General practitioners, endocrinologists and sexual health physicians administering gender affirming hormone therapy.

MBS items for gender affirming surgeries: Plastic surgeons, oral and maxillofacial surgeons, and ear nose and throat surgeons.

- **Name of relevant professional medical college/society that will need to advise on (or provide a 'statement of clinical relevance' for) the proposed technology service;**

Australian Society of Plastic Surgeons, Royal Australian College of General Practitioners, Royal Australian College of Surgeons. Royal Australasian College of Psychiatrists, Australasian Chapter of Sexual Health Medicine (within Royal Australasian College of Physicians), Endocrine Society of Australia, Australian Professional Association for Trans Health, Royal Australian and New Zealand College of Obstetricians and Gynaecologists. ACON – (Aids Council of New South Wales).

- **Practitioners who would be referring patients for the technology/service (e.g. GPs, specialists, social workers etc);**

The requirement for referral to medical interventions will depend on the expertise of the persons managing clinician, as well as the type of medical intervention(s) used by the person for their gender affirmation.

General practitioners may refer patients to psychiatrists, psychologists, endocrinologists, or sexual health practitioners as part of the initiation of hormonal treatment. However, referrals to these specialties is not required where the general practitioner can safely initiate and monitor hormonal treatment.

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Patient referrals to a plastic surgeon, oral and maxillofacial surgeon, or ear nose and throat surgeon for gender affirming surgeries would be from a general practitioner, endocrinologist, or sexual health practitioner.

- **Other practitioners who may be affected;**

Anaesthetists, surgical assistants and nurses would be involved in episodes of care where a person undergoes a surgical procedure for gender affirmation.

- **What technologies/services are currently being provided to the patient group (i.e. what existing services would the new technology/service replace)?**

Item numbers on the MBS are currently being multipurposed for gender affirming treatments (see Attachment 1). The items are often not "a good fit" and cause anxiety to doctors using them as to whether they are using the appropriate MBS item. It also results in wide variation of items being used, which is not consistent with the aims of the MBS Review.

The lack of MBS items accurately describing the consultations and surgical procedures associated with medical gender affirmation results in confusion for patients and clinicians as to what MBS items may be used for gender affirmation, which also results in a lack of clarity in financial aspects of service provision.

Because there are no specific items for gender affirming surgical or medical care, many people do not know that they can access treatment and either remain untreated or seek treatment overseas. This is an effective denial of access to services for many people with gender incongruence who wish to receive medical interventions for gender confirmation.

In addition, the lack of MBS items specific gender affirmation means that there is no way of monitoring or evaluating activity in this area.

We propose the MBS should have a separate table for medical interventions associated with gender incongruence and gender affirmation treatment.

Requested discussion with Department of Health:

Is it reasonable to request the creation of a new 'Group' of professional attendance MBS items within 'Category 1: Professional Attendances' of the MBS?

The creation of a 'Group AXX: Gender Affirmation Attendances' would include MBS items for patient consultations claimable by multidisciplinary healthcare professionals involved in providing care to people seeking medical gender affirmation services. That, is general practitioners, plastic surgeons, oral and maxillofacial surgeons, ear nose and throat surgeons, endocrinologists, urologists, gynaecologists, sexual health practitioners, psychologists and psychiatrists.

Is it reasonable to request the creation of a new 'Subgroup' of therapeutic procedures under 'Category 3: Therapeutic Procedures, Group T8 Surgical Operations' of the MBS? It is proposed that creation of a 'Subgroup XX: Gender Affirmation Surgery' would include MBS items describing "top surgeries", "bottom surgeries", facial surgeries, voice surgeries and laryngoplasty procedures performed for the purposes of gender affirmation.

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If the creation of a new 'Group' for gender affirming professional attendances and 'Subgroup' for gender affirming surgery is not reasonable, could the Department please advise on the appropriate mechanism to have medical interventions for gender affirmation included in the MBS.

- **What are the anticipated improvements in health outcomes for the patient group, if this new technology/service was recommended for funding?**

Medical interventions associated with gender affirmation are unique in that they represent medical support provided to people who should not be considered as having a mental or physical illness or "diagnosis". As such, the application of a quantitative framework for the measurement of "improvement in health outcomes" that would be applied for health interventions with a primary purpose of diagnosing, preventing or treating a mental or physical illness is poorly placed to assess the benefits of medical interventions for gender affirmation.

Notwithstanding the challenges with adopting a quantitative evaluation framework assessing 'improvements in health outcomes', some people with gender incongruence may benefit from improvements in health-related quality of life and wellbeing or experience a reduction in levels of depression or suicide ideation following gender affirming treatments.

Importantly, some people will pursue gender affirmation treatment without concomitant issues relating to quality-of-life or feelings of depression. Thus, restricting access to gender affirmation treatment through the MBS to only those patients assessed has having a specific 'diagnosis' beyond gender incongruence is not considered medically appropriate and is not being requested.

- **Whether the technology/service will be provided to outpatients and/or to admitted hospital or day-procedure patients (via your initial proposal, and also if the health venue/patient location is likely to change in the future);**

Medical consultations associated with gender affirmation treatment would be provided to patients in an outpatient setting within general practitioner or specialist practices.

Most surgical procedures associated with gender confirmation require admission to hospital and overnight stay. Some minor surgeries would be day surgery procedures performed at a hospital or specialty clinic with the appropriate resources to undertake the surgery.

- **How is the technology/service funded at present? (e.g. research funding; State-based funding; self-funded by patients; no funding or payments);**

There is no universal funding program for the range of medical interventions associated with gender affirmation.

Some patient consultations would be funded through MBS items for attendances with general practitioners, specialists, sexual health medicine practitioners and psychiatrists.

The current funding arrangements for surgical procedures is highly fragmented. Some procedures may be claimed through existing MBS items (which are not fit-for-purpose) or self-funded, including self-funding treatment overseas.

There are various State-based funding programs, however none of these are for the full range of medical interventions associated with medical gender affirmation. NSW announced a package in 2022 to support

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mental health services, counselling and group support programs for trans and gender diverse groups. SA Health / SA Government is currently considering a state-wide service in the public sector.

- **If the new technology/service is a type of screening, why would it be suited to MBS funding, as opposed to a dedicated screening program? Have you researched and approached other funding sources?**

Not applicable.

- **Current status of TGA registration of the product, device or medicine (if relevant)**

Hormone treatments

Hormone treatments may be used by some people for the purposes of gender affirmation. Hormonal treatment with estradiol or testosterone will feminise or masculinise physical characteristics, thereby helping to reduce dysphoria and improving psychological and social functioning.

Feminising hormones: People who are presumed male at birth and desire feminisation use estradiol and anti-androgen therapies (such as spironolactone or cyproterone acetate). Estradiol therapy can be administered transdermally or orally. Typical full doses are oral estradiol or estradiol valerate 2–10mg daily and transdermal estradiol patches 100–200 µg/24 hours changed twice weekly.

An overview of the TGA-approved indication and PBS listings for estradiol and anti-androgen therapies is provided at Attachment 1. This shows that feminising hormones and anti-androgens are available through the PBS as unrestricted General Schedule listings. Thus, while use of feminising hormones and anti-androgens may technically be 'off label', there is no restriction on clinicians being able to prescribe these through current PBS listings.

Masculinising hormones: People who are presumed female at birth and desire masculinisation use testosterone therapy. Standard replacement doses of testosterone (similar to hypogonadal men – either intramuscular testosterone injections or transdermal testosterone gels/cream) are recommended to initiate and maintain masculinisation.

An overview of the TGA-approved indication and PBS listings for testosterone treatments are provided at Attachment 1. The PBS listings for testosterone are 'Authority Required' listings. As such, clinicians must contact Services Australia or the Department of Veterans Affairs and obtain approval before a prescription for PBS-listed testosterone treatment can be written.

The PBS restriction criteria for androgen deficiency is considered to apply if gender markers are male or female. For people requiring masculinising hormone therapy for gender affirmation, clinicians will use the authority indication "androgen deficiency due to an established testicular disorder", that is transgender men are men without testicular production of testosterone to establish eligibility to access testosterone through the PBS. Upon inquiries by clinicians to the Department of Human Services (who handle operational matters relating to the PBS), this arrangement has been approved as a reasonable way to facilitate prescribing testosterone for gender affirmation.

Notwithstanding the current 'work around' facilitating testosterone use for gender affirmation, the current PBS restrictions and authority indications for testosterone are not 'a good fit'. The existing arrangements causes anxiety to doctors as to whether they are using the appropriate PBS codes. The existing arrangements also result in some doctors not using authority PBS prescriptions for testosterone

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which results in confusion by patients and lack of clarity in financial aspects of the use of testosterone for their gender affirmation.

Because there are no specific items for gender affirmation, many doctors and people seeking medical interventions for gender affirmation do not know that they can access PBS-subsidised treatment and remain untreated or self-fund hormone treatment. This is an effective denial of access to services for much of those affected by gender incongruence.

In addition, the lack of specific PBS items for gender affirming hormonal treatment means that there is no way of monitoring or evaluating activity in this area.

Breast implants

Some people will seek to have breast implants used part of gender affirming surgeries. When used, these breast implants will be TGA registered and participants entered into the Australian Breast Device Registry.

- **Current status of clinical trials (or other evidence);**

Transgender people as a whole face significant marginalisation worldwide, including in healthcare. Difficulty accessing basic medical as well as gender affirming care are frequently reported (Safer et al., 2016). Even when being able to access gender affirming care, there remains low quality evidence to guide the medical treatment of transgender people overall and health provider knowledge of trans health remains frequently suboptimal (Ortiz-Martínez & Ríos-González, 2017; Safer, 2021).

Healthcare avoidance because of fear of misgendering, discrimination and mistreatment are extremely common which contributes to poor health. Moreover, the experiences of widespread social stressors (social isolation, violence and hate crimes, unemployment) resulting in economic and legal marginalisation leads to minority stress, in turn exacerbating poor physical and mental health outcomes (Bockting, Miner, Swinburne Romine, Hamilton, & Coleman, 2013; Meyer, 2003; Scandurra, Amodeo, Valerio, Bochicchio, & Frost, 2017).

It is not surprising that transgender people have an elevated risk of many chronic health conditions compared to their cisgender counterparts including chronic obstructive pulmonary disease, depression, hepatitis, HIV, schizophrenia, substance use disorders as well as obesity and other liver conditions (Dragon, Guerino, Ewald, & Laffan, 2017; L. Hughes, Shireman, & Hughto, 2021).

More than 60% of transgender people report a history of diagnosed depression or anxiety (Bretherton et al., 2021) and over 40% have attempted suicide (Budhwani et al., 2018; Chen et al., 2019; Marshall, Claes, Bouman, Witcomb, & Arcelus, 2016; Zwickl, Wong, et al., 2021). Mental health burden has been exacerbated by the COVID-19 pandemic. (Zwickl, Angus, et al., 2021) Rates of death by suicide are over two-fold greater than cisgender populations (Boyer et al., 2021) and significant disparities exist for all-cause mortality, especially among transgender people presumed male at birth (with feminine or non-binary identities) and transgender people of colour (L. D. Hughes et al., 2022a, 2022b; Wiepjes et al., 2020). The health inequity faced by transgender people in Australia and globally is a major public health concern.

Australian research is in progress

Research on the effects and adverse effects of gender affirming hormone therapy (GAHT) is evolving. Much of our understanding of the effects and adverse effects of GAHT has been gained from well-characterised retrospective analyses and observational cohort studies from North America, Europe.

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Australia is rapidly expanding their research in transgender health, with recent NHMRC grants (Investigator and Clinical Trials and Cohort Studies) in the field being award to the Trans Health Research group at The University of Melbourne and the Murdoch Children's Research Institute, both of whom are leading much of the research globally in adult and paediatric transgender health respectively.

The Trans Health Research group are one of the only groups globally undertaking prospective clinical trials to evaluate gender affirming hormone treatments. They have led the authorship of national guidelines on hormone treatment endorsed by AusPATH, RACP and ESA (Cheung, Wynne, Erasmus, Murray, & Zajac, 2019; M. M. Telfer, Tollit, Pace, & Pang, 2018), as well as established a large cohort of Australian trans individuals (n=2000+) engaged in the longitudinal observational research project TRANSform (adult) and TRANS20 (adolescent).

There are studies on healthcare delivery within Australia for the transgender population that indicate gaps in current clinical service provision are in dire need of address and that better coordination is required to ensure timely gender affirming care. (Solanki et al, 2020. Erasmus, J. 2020)

GENDER-Q is a patient-reported outcome measure (PROM) for adolescents and adults receiving gender affirming treatment. The development and protocol for the refinement of GENDER-Q is described by (Klassen et al., 2018). As one of the final steps of the development of this definitive PROM for transgender health care, international field tests are being performed of a provisional version. Australia is participating in this field test, with applicants of this MSAC application being involved. Data from the Australian cohort will be made available by the Canadian parent institution to inform this application.

A systematic review of published literature reporting qualitative and quantitative outcomes for patients receiving medical interventions for gender affirmation has been initiated. The findings of this systematic review are also planned to form part of the assessment report considered by MSAC.

- **Cost/price of the technology/service (including professional service component, as well as separate cost of a product, appliance or device used during the service);**

Costings will be developed in line with comparable MBS items for comprehensive/complex patient consultations and surgical procedures with comparable complexity as the procedures associated with gender affirmation treatment.

Requested discussion with Department of Health:

Could the Department please provide advice as to how appropriate fees for new MBS are determined by MSAC.

Specifically, what cost inputs and data sources are used by MSAC/Department of Health when establishing an MBS fee? These inputs will be used to inform the development of appropriate MBS fees for patient consultations and medical interventions relating to gender affirmation.

- **Likely cost for Government (taxpayer);**

It is challenging to provide a robust estimate of the likely cost to the taxpayer due to the poor transparency of the current uptake of gender affirmation services. This is partially a result of the current lack of a universal funding program for medical procedures for gender affirmation, thus normal data collection allowing for the assessment of the use and/or demand for services is lacking.

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Providing a robust estimate of the likely cost to government is also difficult given that the number and complexity of gender affirming medical procedures will vary on a person-by-person basis. Some people may only access professional attendance items and hormonal treatment, in which case the incremental cost to government is likely to be very low as these services are already being (partially) provided through current MBS and PBS items, albeit with access being suboptimal due to the poor fit of these existing items.

Other people will access professional attendances, hormonal treatment and a range of gender affirming surgeries which are not facilitated through existing MBS items. The cost of providing medical interventions for gender affirmation will be higher for these people compared with people who do not access surgical procedures, or who pursue less comprehensive surgeries.

Notwithstanding the issue above, it is estimated that transgender or gender diverse people represent 0.1-2% of the population (Goodman et al., 2019). Given the low proportion of the population that are transgender or gender diverse, and that not all of these people will seek medical interventions for gender affirmation, the overall cost to taxpayers is expected to be modest.

It is also important to consider that there are expected to be financial and societal costs too as a result of continuing not to fund gender affirming services. These costs are related to the treatment of mental illness experienced by gender incongruent people who are unable to access medical interventions for gender affirmation despite their wishes to do so, as well as the reduced capacity to contribute fully in society.

Requested discussion with Department of Health:

It will be challenging to establish a robust estimate of the likely costs for Government in the forthcoming MSAC Application and assessment report. Advice is sought on potential funding arrangements which would enable people to access medical interventions for gender affirmation while also allowing for data collection on the number of people accessing treatment, as well as the scope of interventions being provided.

It is noted that several services which have been recommended for funding by MSAC have been the basis of the 'Predicted versus Actual Utilisation Monitoring Process', usually undertaken 24 months after MBS listing. Would a funding proposal providing estimates of the likely costs for Government based on the best inputs currently available with a commitment to participate in the 'Predicted versus Actual Utilisation Monitoring Process' and use real-world data be beneficial? Under this arrangement all parties could re-visit the estimated costs to government and refine funding arrangements (if warranted) through a mutually-agreed process at a specific time point after establishing funding.

- **Potential out-of-pocket costs for patients; and**

This will be variable depending on the scope of medical interventions for gender affirmation pursued by each patient, as well as the MBS fees supported by MSAC.

- **Whether the technology/service involves a device/product that will need approval through another committee/process (e.g. PLAC or PBAC).**

The potential to prepare a parallel application to the PBAC to clarify PBS eligibility for people to access testosterone for gender affirmation is being explored.

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If pursued, it is anticipated that a minor amendment to the clinical criteria for existing PBS restrictions for the indication of androgen deficiency. The amendment based on PBS codes 11740X, 8619P and 8830R being considered is provided in red text below

Androgen deficiency

Clinical criteria:
Patient must have an established pituitary or testicular disorder or gender incongruence.

Requested discussion with Department of Health:

Advice on the appropriate mechanism to engage with the PBAC regarding the potential to amend current PBS restrictions for testosterone is sought. Would this need to be via a separate submission/assessment report to the PBAC or could this be incorporated into the MSAC Application and assessment report and considered by the PBAC in parallel?

It is noted that applications to the PBAC incur fees for PBAC evaluation services ranging from $32,050 - $219,990. It is also noted that fee waivers can be applied for if the application involves the public interest or would otherwise be financially unviable to pursue. Advice is sought on the process for seeking a fee waiver ahead of making a final decision regarding whether to pursue the potential parallel application to the PBAC as part of the broader funding application for medical interventions relating to gender affirmation.

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Attachment 1:

An overview of surgical procedures associated with gender affirmation is provided in Table 1. When broadly comparable surgical procedures are listed on the MBS the item number and MBS item descriptor is provided for reference.

Table 1: Compilation of existing MBS item numbers for gender affirming surgeries

Procedure/MBS item	Item descriptor
Top surgery	
45240 (x2)	DIRECT, INDIRECT OR LOCAL FLAP, revision of, by liposuction, not being a service to which item 45239, 45497, 45498 or 45499 applies (Anaes.)
31519	BREAST, total mastectomy (H) (Anaes.) (Assist.)
45451 (x2)	FREE GRAFTING (full thickness), to 1 defect, excluding grafts for male pattern baldness (Anaes.) (Assist.)
31524 (x2)	BREAST, subcutaneous mastectomy (H) (Anaes.) (Assist.)
45545	NIPPLE OR AREOLA or both, reconstruction of, by any surgical technique (Anaes.) (Assist.)
45523	Bilateral reduction mammaplasty.
Breast augmentation: Not MBS available for gender affirmation	
45524	Mammaplasty, augmentation (unilateral) in the context of: (a) breast cancer; or (b) developmental abnormality of the breast, if there is a difference in breast volume, as demonstrated by an appropriate volumetric measurement technique, of at least: (i) 20% in normally shaped breasts; or (ii) 10% in tubular breasts or in breasts with abnormally high inframammary folds. Applicable only once per occasion on which the service is provided (Anaes.) (Assist.)
45527	Breast reconstruction (unilateral), following mastectomy, using a permanent prosthesis (Anaes.) (Assist.)
45528	Mammaplasty, augmentation, bilateral (other than a service to which item 45527 applies), if: (a) reconstructive surgery is indicated because of: (i) developmental malformation of breast tissue (excluding hypomastia); or (ii) disease of or trauma to the breast (other than trauma resulting from previous elective cosmetic surgery); or (iii) amastia secondary to a congenital endocrine disorder; and (b) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.) (Assist.)
Facial surgery: Not MBS available for gender affirmation	
Browplasty (brow lift): 42872	EYEBROW, elevation of, by skin excision, to correct for a reduced field of vision caused by paretic, involutional, or traumatic eyebrow descent/ptosis to a position below the superior orbital rim (Anaes.)
Forehead reduction and hairline lowering	No comparable MBS item
Scalp advancement	No comparable MBS item
Rhinoplasty: 45632	Rhinoplasty, partial, involving correction of one or both lateral cartilages, one or both alar cartilages or one or both lateral cartilages and alar cartilages, if: (a) the indication for surgery is:

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Procedure/MBS item	Item descriptor
	(i) airway obstruction and the patient has a self reported NOSE Scale score of greater than 45; or (ii) significant acquired, congenital or developmental deformity; and (b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.)
Rhinoplasty: 45635	Rhinoplasty, partial, involving correction of bony vault only, if: (a) the indication for surgery is: (i) airway obstruction and the patient has a self-reported NOSE Scale score of greater than 45; or (ii) significant acquired, congenital or developmental deformity; and (b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.)
Rhinoplasty: 45641	Rhinoplasty, total, including correction of all bony and cartilaginous elements of the external nose, with or without autogenous cartilage or bone graft from a local site (nasal), if: (a) the indication for surgery is: (i) airway obstruction and the patient has a self-reported NOSE Scale score of greater than 45; or (ii) significant acquired, congenital or developmental deformity; and (b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.)
Rhinoplasty: 45644	Rhinoplasty, total, including correction of all bony and cartilaginous elements of the external nose involving autogenous bone or cartilage graft obtained from distant donor site, including obtaining of graft, if: (a) the indication for surgery is: (i) airway obstruction and the patient has a self-reported NOSE Scale score of greater than 45; or (ii) significant acquired, congenital or developmental deformity; and (b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.) (Assist.)
Rhinoplasty: 45650	Rhinoplasty, revision of, if: (a) the indication for surgery is: (i) airway obstruction and the patient has a self-reported NOSE Scale score of greater than 45; o(ii) significant acquired, congenital or developmental deformity; and (b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.)
Chondrolaryngoplasty (tracheal shave): 38453	TRACHEAL excision and repair without cardiopulmonary bypass (Anaes.) (Assist.)
Cheek enhancement	No comparable MBS item
Lip lift and reshaping: 45665	LIP, EYELID OR EAR, FULL THICKNESS WEDGE EXCISION OF, with repair by direct sutures (Anaes.)
Lip lift and reshaping: 45671	LIP OR EYELID RECONSTRUCTION using full thickness flap (Abbe or similar), first stage (Anaes.) (Assist.)
Lip lift and reshaping: 45674	LIP OR EYELID RECONSTRUCTION using full thickness flap (Abbe or similar), second stage (Assist.)
Genioplasty 45761	GENIOPLASTY, including transposition of nerves and vessels and bone grafts taken from the same site (Anaes.) (Assist.)
Genital reconfiguration surgery	

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Procedure/MBS item	Item descriptor
Vaginoplasty	
45563	NEUROVASCULAR ISLAND FLAP, including direct repair of secondary cutaneous defect if performed, excluding flap for male pattern baldness (Anaes.) (Assist.)
37405	PENIS, complete or radical amputation of (Anaes.) (Assist.)
37342	URETHROPLASTY single stage operation (Anaes.) (Assist.)
30641 (x2)	Orchidectomy, simple or subcapsular, unilateral with or without insertion of testicular prosthesis (H) (Anaes.) (Assist.)
45206 (x2)	Single stage local flap if indicated to repair one defect, on eyelid, nose, lip, ear, neck, hand, thumb, finger or genitals and excluding H-flap or double advancement flap not in association with any of items 31356 to 31376 (Anaes.)
37438	Scrotum, partial excision of, for histologically proven malignancy or infection (Anaes.) (Assist.)
35565	VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus (Anaes.) (Assist.)
45451	FREE GRAFTING (full thickness), to 1 defect, excluding grafts for male pattern baldness (Anaes.) (Assist.)
Vulvoplasty	
45563	NEUROVASCULAR ISLAND FLAP, including direct repair of secondary cutaneous defect if performed, excluding flap for male pattern baldness (Anaes.) (Assist.)
37405	PENIS, complete or radical amputation of (Anaes.) (Assist.)
37342	URETHROPLASTY single stage operation (Anaes.) (Assist.)
30642 (x2)	Orchidectomy, radical, including spermatic cord, unilateral, for tumour, inguinal approach, with insertion of testicular prosthesis, other than a service associated with a service to which item 30631, 30635, 30641, 30643, 30644 or 45051 applies (Anaes.) (Assist.)
45206 (x2)	Single stage local flap if indicated to repair one defect, on eyelid, nose, lip, ear, neck, hand, thumb, finger or genitals and excluding H-flap or double advancement flap not in association with any of items 31356 to 31376 (Anaes.)
37438	Scrotum, partial excision of, for histologically proven malignancy or infection (Anaes.) (Assist.)
Phalloplasty	
Radial forearm free-flap technique	No comparable MBS item
Anterior lateral thigh technique	No comparable MBS item
Metoidioplasty	No comparable MBS item
Testicular Prosthesis 30630	Insertion of testicular prosthesis, at least 6 months following orchidectomy
Hysterectomy	
35750	Hysterectomy, laparoscopic assisted vaginal, by any approach, including any endometrial sampling, with or without removal of the tubes or ovarian cystectomy or removal of the ovaries and tubes due to other pathology, not being a service associated with a service to which item 35595 or 35673 applies. (H) (Anaes.) (Assist.)
35751	Hysterectomy, laparoscopic, by any approach, including any endometrial sampling, with or without removal of the tubes, not being a service associated with a service to which item 35595 applies (H) (Anaes.) (Assist.)
35753	Hysterectomy, complex laparoscopic, by any approach, including endometrial sampling, with either or both of the following procedures: (a) unilateral or bilateral salpingo-oophorectomy (excluding salpingectomy); (b) excision of moderate endometriosis or ovarian cyst; including any associated laparoscopy, not being a service associated with a service to which item 35595 applies (H) (Anaes.) (Assist.)

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Procedure/MBS item	Item descriptor
35754	Hysterectomy, complex laparoscopic, by any approach, that concurrently requires either extensive retroperitoneal dissection or complex side wall dissection, or both, with any of the following procedures (if performed): (a) endometrial sampling; (b) unilateral or bilateral salpingectomy, oophorectomy or salpingo-oophorectomy; (c) excision of ovarian cyst; (d) any other associated laparoscopy; not being a service associated with a service to which item 35595 or 35641 applies (H) (Anaes.) (Assist.)
35756	Hysterectomy, laparoscopic, by any approach, if the procedure is completed by open hysterectomy for control of bleeding or extensive pathology, including any associated laparoscopy, not being a service associated with a service to which item 35595 or 35641 applies (H) (Anaes.) (Assist.)
Orchidectomy	
30641	Orchidectomy, simple or subcapsular, unilateral with or without insertion of testicular prosthesis (H) (Anaes.) (Assist.)
30642	Orchidectomy, radical, including spermatic cord, unilateral, for tumour, inguinal approach, with insertion of testicular prosthesis, other than a service associated with a service to which item 30631, 30635, 30641, 30643, 30644 or 45051 applies (Anaes.) (Assist.)
Vocal surgery	
41879	LARYNGOPLASTY or TRACHEOPLASTY, including tracheostomy (Anaes.) (Assist.)
41864	MICROLARYNGOSCOPY WITH REMOVAL OF TUMOUR (Anaes.) (Assist.)

An overview of the TGA-approval and PBS-listing status for hormonal treatments is provided in Table 2. When broadly comparable surgical procedures are listed on the MBS the item number and MBS item descriptor is provided for reference.

Table 2: Compilation of existing TGA-approved hormonal treatments used for gender affirmation

PBS code	Brand(s)	PBS restriction	TGA indication
Masculinising hormones (Testosterone)			
10378F	AndroForte 5	Authority Required Androgen deficiency Clinical criteria: Patient must have an established pituitary or testicular disorder. Treatment criteria: Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. Androgen deficiency is defined as: (i)	For use as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests
10380H	Testogel		
8830R	Testogel		
11740X	Testavan		
8619P	Androderm		For testosterone replacement therapy for confirmed testosterone deficiency in males
10205D	Reandron		Testosterone replacement in primary and secondary male hypogonadism

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PBS code	Brand(s)	PBS restriction	TGA indication
		testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated. The name of the specialist must be included in the authority application.	
Not PBS listed	Sustanon	NA	Androgen replacement therapy for confirmed testosterone deficiency in males
Not PBS listed	Primoteston	NA	
Feminising hormones			
Estrogen (estradiol)			
1663M (1 mg), 1664N (2 mg)	Progynova	None (unrestricted General Schedule listing)	Short term treatment of climacteric complaints after the cessation of monthly bleeding, or deficiency symptoms after oophorectomy or radiological castration for non-carcinomatous diseases, such as hot flushes, outbreaks of sweat, sleep disturbances, depressive moods, irritability, headaches, dizziness
8761D (25 ug), 8125P (50 ug), 8486P (75 ug), 8126Q (100 ug)	Climara		Short term treatment of signs and symptoms of estrogen deficiency due to the menopause, whether natural or surgically induced Prevention of postmenopausal bone mineral density loss. When prescribed solely for the prevention of postmenopausal bone mineral density loss, therapy should only be prescribed for women who are at high risk of osteoporosis and future fracture and who, are intolerant of, or contraindicated for non-estrogen products approved for prevention of osteoporosis
8311K (25 ug), 8140K (50 ug), 8312L (100 ug)	Estraderm MX		
8761D (25 ug), 8762E (37.5 ug), 8763F (50 ug), 8764G (75	Estradot		Short term treatment of symptoms of estrogen deficiency due to the menopause, whether natural or surgically induced

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PBS code	Brand(s)	PBS restriction	TGA indication
ug), 8765H (100 ug)			
8286D	Sandrena		Short term treatment of climacteric symptoms after natural or surgical menopause
8274L	Zumenon		Symptomatic treatment of estrogen deficiency due to natural or surgical menopause in hysterectomised post menopausal women
Anti-androgens			
2339D (25 mg), 2340E (100 mg)	Spironlactone Viatris, Aldactone, Spiractin	None (unrestricted General Schedule listing)	Treatment of females with hirsutism, an androgen related increase in facial and body hair
1269T (50 mg), 1270W (50 mg), 8019C (100 mg)	Anterone, APO-Cyproterone, Cyprone, Cyproterone Sandoz, GenRx Cyproterone, Pharmacor, Androcur	1269T: Authority Required (STREAMLINED) Moderate to severe androgenisation Clinical criteria: The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation Population criteria: Patient must be female Clinical criteria: Patient must not be pregnant 1270W and 8019C: None (unrestricted General Schedule listing)	Inoperable prostatic carcinoma -To suppress 'flare' with initial luteinising hormone releasing hormone (LHRH) analogue therapy -In long-term palliative treatment where LHRH analogues or surgery are ineffective, not tolerated, contraindicated or where oral therapy is preferred -In the treatment of hot flushes in patients treated with LHRH analogues or who have had orchidectomy

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s22

From: s22 @health.gov.au>
Sent: Thursday, 9 March 2023 11:23 AM
To: s22
Cc: s22
Subject: Jan Exec action item - testosterone cream [SEC=OFFICIAL]

Hi s22

We have drafted the letters to the ESA who wrote in about Androforte cream and to the sponsor regarding the potential change to restrictions following the Jan Exec meeting. This is not overly urgent so can potentially wait until you are back from leave. Letters and original correspondence are in the following folder:

\\central.health\DFSApps\ServerApps\Staging\PEB - Common\PBAC Executive and Minors\Exec Team\Letters and Corro\2022.07 Exec Meeting 1 - ESA letter re testosterone clinical criteria

Kind Regards,

s22
B Med Sci, M Pharm

Assistant Director – PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care

T: 02 6289 s22 | E: s22 @health.gov.au

Location: Sirius Building
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

s22

From: s22 @health.gov.au>
Sent: Thursday, 25 May 2023 4:32 PM
To: s22
Cc: s22 ; LUCCHESE, Renaye; s22 ; PLOENGES, Natasha; s22 s22
Subject: RE: PBS Medicines for LGBTI - FAS brief for senate estimates [SEC=OFFICIAL]
Attachments: FAS Briefs - May 2023 - Budget Senate Estimates - PBS medicines for trans and gender diverse patients. PRAIS input. docx.docx

Hi s22

I have made a number of suggested changes/edits in track alongside s22 . Happy to discuss these with yourself and s22

Kind regards,

s22

From: s22 @Health.gov.au>
Sent: Thursday, 25 May 2023 1:38 PM
To: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; LUCCHESE, Renaye <Renaye.Lucchese@health.gov.au>; s22 @health.gov.au>; PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: PBS Medicines for LGBTI - FAS brief for senate estimates [SEC=OFFICIAL]

Hi s22

Please see the Brief attached including PRAIS input. I have added cleared wording from previous correspondences that we received in that regard. This includes the previous PBAC recommendations for changes in testosterone restrictions that you can use as required.

I would like to note that some prescribers are still confused about which indication to use to access testosterone for their transgender patients. We have received multiple correspondences around that issue. However, there are published advice from the RACGP journal and MJA position statement that suggests that the "Androgen deficiency" indication is the most appropriate to use to access testosterone through the PBS for both male and female patients.
RACGP - Hormone therapy for trans and gender diverse patients in the general practice setting
Position statement on the hormonal management of adult transgender and gender diverse individuals | The Medical Journal of Australia (mja.com.au)
However from a PBS perspective, we do not specifically state that transgender patients can use the "Androgen deficiency" indication as it's not stated in the eligibility criteria, the clinical decision is up to the prescriber.

Also, the PBAC Assessment Team is putting together a paper on the issue around the clinical criterion *"the treatment must be applied to the scrotum area"* for the use of AndroForte 5® cream in transgender patients. We do not currently have a timeframe on this but PBAC Assessment is aware that we have been receiving many enquiries from GPs and Services Australia on this matter.

Please let me know if you require any further information.

Kind regards,
s22

s22 B.Pharm, BCGP

PBS Restrictions And Implementation Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
T: 02 6289s22 | E: s22 @Health.gov.au
Australian Government, Department of Health and Aged Care
GPO Box 9848, Canberra ACT 2601, Australia

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From: s22 @Health.gov.au>
Sent: Wednesday, 24 May 2023 4:47 PM
To: s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 @Health.gov.au>; s22 s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; LUCCHESE, Renaye <Renaye.Lucchese@health.gov.au>; s22 @health.gov.au>; PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FW: PBS Medicines for LGBTI - FAS brief for senate estimates [SEC=OFFICIAL]

Good afternoon,

PMR have prepared the attached brief as mentioned below, and are circulating for any input/comment in case we have missed anything that others are aware of or have previously done in this space. We would appreciate any input/comments back by 2pm Thursday 25 May (tomorrow).

Kind regards,

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Genomic and Health Technology Assessment Policy Branch
Australian Government Department of Health and Aged Care
☎ (02) 6289 s22 | s22 @health.gov.au
Location: Sirius Building
GPO Box 9848, Canberra ACT 2601, Australia
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---

From: s22 @health.gov.au>
Sent: Tuesday, 23 May 2023 1:38 PM
To: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22

s22 @health.gov.au>; LUCCHESE, Renaye <Renaye.Lucchese@health.gov.au>; PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: PBS Medicines for LGBTI - FAS brief for senate estimates [SEC=OFFICIAL]

Hi All

Confirming that PMR will pull together a list of medicines and will seek input form PBAC Assessment, PRAIS and PBS listings on recent PBAC consideration, restriction changes and any other issues we may have missed.

We could also share with Health Equity Branch in PHD to see if they have any input.

s22

From: s22
Sent: Tuesday, 23 May 2023 11:56 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; LUCCHESE, Renaye <Renaye.Lucchese@health.gov.au>; PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Subject: RE: PBS Medicines for LGBTI - FAS brief for senate estimates [SEC=OFFICIAL]

Thanks s22 I have discussed with s22 in s22 team, I think we have a plan but will confirm shortly.

Renaye and Natasha, copying you in for visibility.

s22

From: s22 @health.gov.au>
Sent: Tuesday, 23 May 2023 11:22 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: PBS Medicines for LGBTI - FAS brief for senate estimates [SEC=OFFICIAL]

s22

s22 has asked me to find a pharmacist who can do a Senate estimates brief on access to PBS medicines for LGBTI patients please

I found this article on NPS – but there may be something more recent.

Prescribing for transgender patients - Australian Prescriber (nps.org.au)

We need to identify which of the treatments recommended for use by transgender individuals are PBS listed, and if they are unrestricted benefits, or have a restriction that allows/does not allow us in transgender patients.

If there are medicines that are not available on PBS, we should look at whether they have a TGA indication for use in transgender people. If not, we should note this, and say use if off-label and not subsidised on PBS.

Timing is next 3 days.

Do either of you have someone with capacity to undertake this please

s22

s22 **PSM**
Office of Health Technology Assessment
Australian Government Department of Health and Ageing
M: s22 E: s22 @health.gov.au

s22

From: s22 @health.gov.au>
Sent: Wednesday, 27 September 2023 11:02 AM
To: s22 s47E(d)
Cc: s22
Subject: FW: For revision - FAS brief - PBS medicines for trans and gender diverse [SEC=OFFICIAL]
Attachments: Updated s22 NP edits 23Sep23 OHTA - PBS medicines for trans and gender diverse patients - FAS Briefs October 2023.DOCX

Hi s22

I have finalised this version with a further small update and put s22 as contact as I will be away during Estimates. Natasha had a comment for you about the title I have left in but this is otherwise cleared for FAS.

Kind regards,

s22

From: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Sent: Tuesday, 26 September 2023 5:44 AM
To: s22 @health.gov.au>; s47E(d) @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
Subject: RE: For revision - FAS brief - PBS medicines for trans and gender diverse [SEC=OFFICIAL]

Hi s22

Thanks for your email – I had cleared the brief, once it was revised.

Re my query on timing – I anticipate that the FAS would want to know about timing.

Thanks
N

Natasha Ploenges
(Ms/She/Her)
Assistant Secretary
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: Natasha.Ploenges@health.gov.au
Location: Sirius s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Monday, 25 September 2023 1:55 PM
To: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>; s47E(d) @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
Subject: RE: For revision - FAS brief - PBS medicines for trans and gender diverse [SEC=OFFICIAL]

Thanks Natasha, I have accepted your changes and addressed all but the comment directed to s22 and the other one you had about timing in the following paragraph about changes to the AndroForte 5 cream PBS listing criteria:

- The Department, following advice from the PBAC Executive on the matter, will work with the sponsor on a proposed amendment to the restriction to address this.

I'm proposing to keep the wording as is, we don't have any specific timing for this project at this stage as we've had to commit our resources to other priorities since this advice was received from the Exec. We are hoping to be able to progress this work in the coming months now we have a few people back on board.

Kind regards,

s22

From: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Sent: Saturday, 23 September 2023 5:13 PM
To: s47E(d) @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: For revision - FAS brief - PBS medicines for trans and gender diverse [SEC=OFFICIAL]

Hi

Thanks for the brief.

My edits/comments are attached. Cleared, once revised.

Thanks
N

Natasha Ploenges
(Ms/She/Her)
Assistant Secretary
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: Natasha.Ploenges@health.gov.au
Location: Sirius s22

PO Box 9848, Canberra ACT 2601, Australia

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From: s22 @health.gov.au>
Sent: Wednesday, 20 September 2023 4:01 PM
To: PLOENGES, Natasha <Natasha.Ploenges@health.gov.au>
Cc: s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: For clearance - FAS brief - PBS medicines for trans and gender diverse [SEC=OFFICIAL]

Hi Natasha,

Please find attached the updated FAS brief for PBS medicines for trans and gender diverse patients based on the May brief. PRAIS has reviewed and provided input.

s22 – draft brief is located at D23-3355791 in TRIM if needed.

Kind Regards,

s22
B Med Sci, M Pharm

A/g Director – PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care

T: 02 6289 s22 | E: s22 @health.gov.au

Location: Sirius Building
GPO Box 9848, Canberra ACT 2601, Australia

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s22

From: s22 @health.gov.au>
Sent: Wednesday, 11 October 2023 3:15 PM
To: s22
Subject: RE: Letter to sponsor - AndroForte 5 PBS listing amendments [SEC=OFFICIAL]
Attachments: Letter to Lawley Pharm - Expression of Interest - AndroForte 5 - PBS expansion.pdf; Letter to Lawley Pharm - Expression of Interest - AndroForte 5 - PBS expansion.docx

Please send PDF

(only minor changes)

Thanks

s22 *[She/Her]*
Director – PBAC Assessment Section
Office of Health Technology Assessment

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M: s22 | E: s22 @health.gov.au

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From: s22 @health.gov.au>
Sent: Thursday, 5 October 2023 12:35 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: Letter to sponsor - AndroForte 5 PBS listing amendments [SEC=OFFICIAL]

Hi s22

I've found a draft letter to Lawley Pharma to seek interest in changing the wording of the AndroForte 5 listing (regarding scrotal application). I've made a few changes. I couldn't find specific reference to DUSC analysis in the PBAC exec minutes. I wasn't at the latest meeting for this, and it was in the initial draft letter so have left it in.

The aim is to get this send out to the sponsor before Senate Estimates.

Happy to make changes.

Kind regards
s22

s22
Assistant Director
PBS Restrictions and Implementation Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health Technology Assessment
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E s22 @health.gov.au
Location: Sirius Building s22

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

Pharmaceutical Benefits Advisory Committee

Reply to: PBAC@health.gov.au

Michael Buckley
Medical Director
Lawley Pharmaceuticals Pty Ltd
PO Box 1146
WEST LEEDERVILLE WA 6901
s47F @lawleypharm.com.au

Dear Mr Buckley

I am writing to you on behalf of the Pharmaceutical Benefits Advisory Committee (PBAC) Executive to ascertain your interest in amending the Pharmaceutical Benefits Scheme (PBS) listing of AndroForte® 5 (item code 10378F) to allow for non-scrotal application.

The PBAC Secretariat has received stakeholder correspondence raising concerns that the clinical criterion '*The treatment must be applied to the scrotum area'* presents a barrier to those where chest application is still most appropriate. The PBAC Executive supports amendments to this wording in principle, following an agreement being reached with your company. Any proposed changes would still require consideration by the full PBAC.

The PBAC Secretariat understands that the March 2021 consideration resulted in a price increase for AndroForte® 5. If the wording in the listing is amended, the PBAC Executive advised that a DUSC review should be undertaken 24 months following the change, to analyse utilisation.

Should you be interested in exploring this matter further, please advise the PBAC Secretariat at PBAC@health.gov.au at your earliest convenience.

Yours sincerely

s47F

s22
Director
PBAC Assessment Section
Department of Health and Aged Care
11 October 2023

RE: Testosterone for transgender men [SEC=OFFICIAL]

s22 @health.gov.au>

Mon 10/05/2021 21:52

To:PBAC <PBAC@health.gov.au>
Cc:s22 @health.gov.au>;s22 @health.gov.au>s22 s22 @health.gov.au>

2 attachments (313 KB)
MC21-000059 - s47F MC21-000059.docx;

Hi s22

I've attached corro and response from earlier this year that might assist in responding.

Cheers

s22
Director – PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health
T: 02 6289 s22 | M: s22
E: s22 @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: PBAC <PBAC@health.gov.au>
Sent: Wednesday, 5 May 2021 12:44 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FW: Testosterone for transgender men [SEC=OFFICIAL]

Hi s22

This is the email that s22 mentioned at our team meeting.
If you have any example response, feel free to share it with us!

Many thanks,

s22
PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: 02 6289 s22 | E: s22 @health.gov.au
Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

From: s47F
Sent: Monday, 3 May 2021 3:30 PM
To: PBAC <PBAC@health.gov.au>
Subject: Testosterone for transgender men

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear PBAC Secretary,

s47F

I am writing to hope to speak with you regarding options and potential steps required to enable access to testosterone for transgender men. There is currently no specific indication for testosterone treatment for transgender men on PBS, and they require specialist approval by an endocrinologist/sexual health physician etc as per the guidelines for hypogonadal men. Whilst these men can still access testosterone, there are additional health care costs which can be a barrier to care for some individuals.

I am hoping to speak with you regarding the steps required to apply for "Gender affirmation" as a PBS indication.

Many thanks for your assistance.

Kind regards,
s47F

s47F | **Endocrinologist | PhD Candidate** s47F
s47F
s47F
T: s47F **E:** s47F

s22

From: Minister Hunt <Minister.Hunt@health.gov.au>
Sent: Saturday, 26 December 2020 3:32 PM
To: s47E(d)
Subject: MC21-000059 - s47F

Categories: s22

MC21-000059

D response – TAAD

s22
Departmental Liaison Officer

Office of the Hon Greg Hunt MP | Minister for Health and Aged Care
☏: 02 6277 s22 | s22
s47E(d) @health.gov.au
Suite M1.41, PO Box 6022, Parliament House, Canberra ACT 2600, Australia

From: s47F @gmail.com>
Sent: Wednesday, 16 December 2020 10:16 AM
To: Minister Hunt <Minister.Hunt@health.gov.au>
Cc: Tanya.Plibersek.MP@aph.gov.au; Chris.Bowen.MP@aph.gov.au
Subject: PBS issue

Dear Minister Hunt,

I'm writing to raise an issue of access on the Pharmaceutical Benefits Scheme.

I'm working as a GP in Newtown and I reside within the City of Sydney Council area.
This year I've started practicing gender-affirming medicine with a focus on prescribing hormone replacement therapy (HRT) for trans and gender diverse people.

Oestradiol tablets and patches are a general benefit listing available to those seeking feminising HRT. However those seeking masculinising HRT with testosterone require specialist physician approval to access their therapy on the PBS. This is often a cumbersome and expensive extra step (especially outside metropolitan areas) when this treatment is able to be safely prescribed and monitored in general practice.

I appreciate the significant difference in the absolute cost of these medicines. I also realise that cismen with androgen deficiency also require specialist approval for testosterone replacement. However the frameworks for managing androgen deficiency in cismen and transmen are fundamentally different given the latter are prescribed HRT and monitored under an informed consent model of care.

So while the ideal solution would be to make testosterone replacement a general PBS listing for cismen and transmen, currently I am focused on reconciling the problematic ethics of inequitable access to HRT between transmen and transwomen. To that end I'm writing in the hope that you will consider either

- adding an authority listing for masculinising HRT for transmen and non binary people that does not require specialist physician approval or
- making topical and injectable testosterone preparations a general PBS listing for initiation and continuation in general practice.

Thanks for your consideration of this issue.

Regards,
s47F

Australian Government
Department of Health

Ref No: MC21-000059

s47F

Dear s47F

Thank you for your correspondence of 16 December 2020 to the Minister for Health and Aged Care, the Hon Greg Hunt MP, regarding access to hormone replacement therapy through the Pharmaceutical Benefits Scheme (PBS). The Minister has asked me to reply.

The Australian Government receives advice on PBS listings from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, about the listing of medicines on the PBS. The Government cannot list a new medicine on the PBS, or change the restriction for an existing listing, unless the PBAC makes a recommendation in favour of doing so. As you would be aware, there is no provision for the subsidised supply of a PBS-listed item outside the terms of restrictions. In addition, no exceptions are permitted to be made for individual patients, even in particular cases where the medicine might be beneficial or recommended on clinical grounds.

There are no specific listings of hormones on the PBS for transgender hormone therapy. However, as you noted, estradiol has an unrestricted PBS listing. PBS listings reflect the requests put to, and evidence that has been considered by, the PBAC to date. In the case of testosterone, some restriction changes have been made in response to concerns raised with the Committee.

In April 2015, a number of restriction changes were made to testosterone listings for the treatment of androgen deficiency, following an analysis of testosterone use by the Drug Utilisation Sub-Committee (DUSC) and recommendations of the PBAC. The DUSC analysis found that testosterone use had increased markedly over the preceding five years and considered that while some use might be attributed to unmet clinical need, a proportion of use might not be within the intended PBS restriction. This was in the context of safety concerns with testosterone, including possible increased cardiovascular risk in older men. One of the restriction changes was that patients must be treated by a; specialist, paediatric endocrinologist, specialist paediatrician, specialist general paediatrician, specialist endocrinologist, specialist urologist, or a GP in consultation with one of the listed specialists.

The National LGBTI Health Alliance provided a submission to the PBAC to consider at its July 2015 meeting, which requested changes to the restrictions for testosterone. This resulted in a stakeholder meeting between the PBAC and the National LGBTI Health Alliance in November 2015 where the Alliance discussed their concerns regarding the restriction changes to testosterone, particularly regarding prescribing having to be initiated at a specialist level. At its November 2015 meeting, the PBAC noted that the negative impacts on

GPO Box 9848 Canberra ACT 2601
Telephone: (02) 6289 1555

trans people and people with intersex variations were unintended consequences of the restriction amendments. The Committee considered that it is important to balance facilitated access for this vulnerable patient group with the safety concerns that had driven the restriction amendments.

The National LGBTI Health Alliance submission also led to a PBAC recommendation to amend the restriction wording for testosterone to remove the population criterion 'patient must be male'. The PBAC considered this clinical criterion was an unintentional barrier to some trans people and people with intersex variations receiving PBS-subsidised testosterone replacement therapy. While the rate of females (individuals with a recorded sex of female in their Medicare enrolment file) accessing subsidised testosterone remains small, it has increased each year since this restriction change in 2015.

Details of the PBAC considerations are available at: www.pbs.gov.au using the search terms 'testosterone PBAC'. Details of the DUSC considerations are available at: www.pbs.gov.au using the search term 'testosterone DUSC'.

While most PBAC submissions are lodged by pharmaceutical companies, nothing prevents other stakeholders from lodging submissions. You may wish to contact the National LGBTI Health Alliance to ask if they intend to apply or can assist you with applying to the PBAC regarding your requested restriction changes. National LGBTI Health Alliance can be contacted at info@lgbtiqhealth.org.au or by phone at 02 7209 6301.

Thank you for raising these concerns.

Yours sincerely

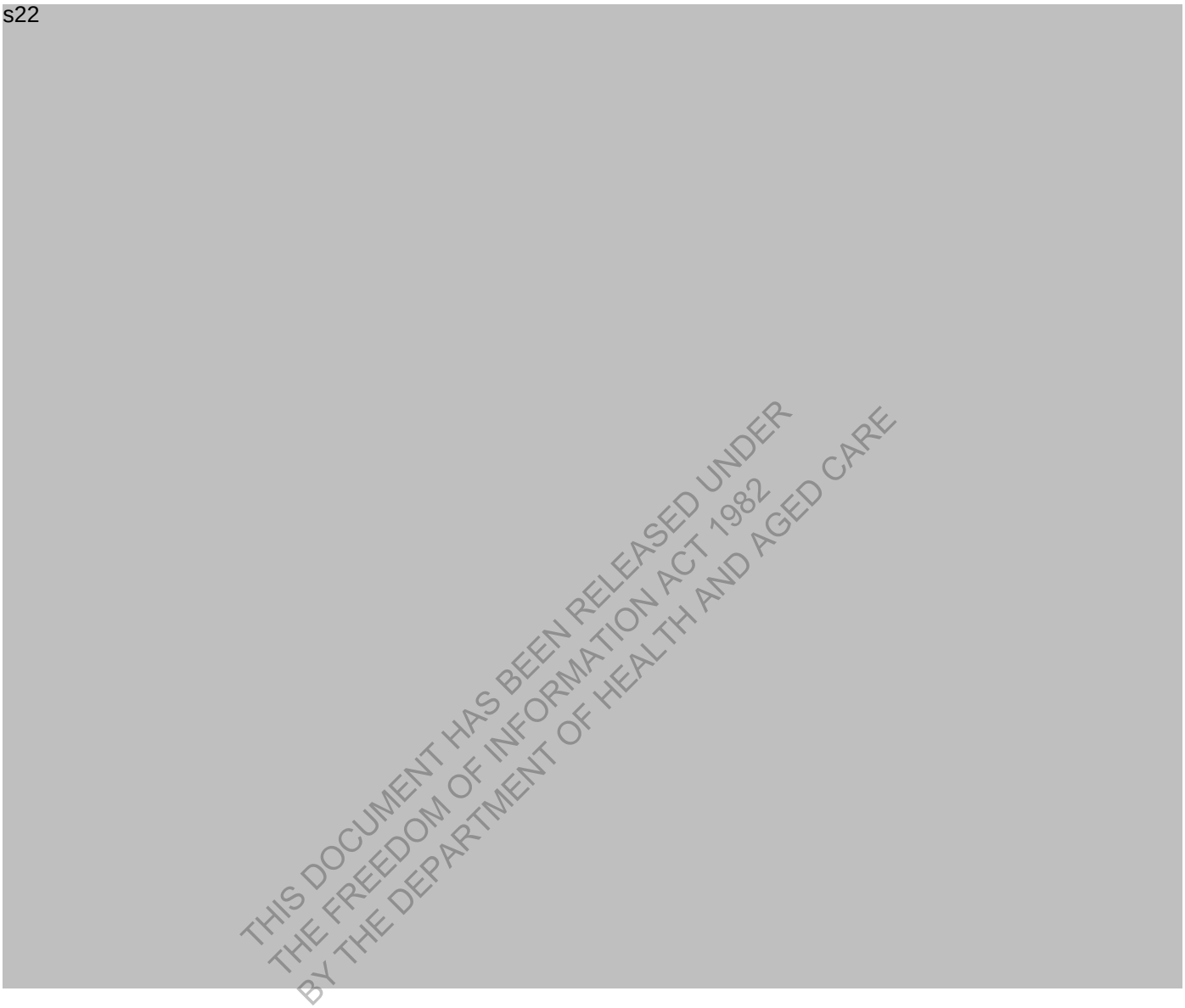
s47F

Natasha Ryan
Assistant Secretary
Office of Health Technology Assessment
28 January 2021

KEEP WITH FILE COPY

s22

s22



RE: Testosterone for transgender men [SEC=OFFICIAL]

s22 @health.gov.au>
Fri 14/05/2021 15:38
To s22 @health.gov.au>
Cc: s22 @health.gov.au>

Hey s22

From what I gathered from s47F s47F and is seeking to enable access to testosterone for transgender men (a term used to describe a person who identifies with the male gender and was assigned a female sex at birth), stating that while these individuals can still access testosterone, there are additional health care costs which can be a barrier to care for some of these individuals. s47F has requested (directly and indirectly):

- (indirectly) The TGA to register gender affirmation as an indication for testosterone products that are already indicated for androgen deficiency/hypogonadism.
- (directly) The PBAC to recommend adding gender affirmation as an indication to its PBS listed testosterone products.
- (indirectly) The Department to review the PBS clinical criteria that all patients diagnosed with male androgen deficiency must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists in order to receive PBS subsidised testosterone, asserting that this creates a barrier to care for some individuals.

s22 response (thanks for drafting s22) has addressed the MBS component of seeing a specialist and advised him of a way to apply for having the diagnosis of gender affirmation as a medical service on the MBS. Her response has also addressed what the PBAC have done to facilitate the use of PBS subsidised testosterone in genders other than male (which may encompass transgender men who still have female as their gender on their Medicare profile, noting that Services Australia only records males and females on their system), and has also provided a means by which he can make a submission to the PBAC if he so chooses.

I have added one extra part about PBS listed indications having to be TGA registered first should he decide to go ahead and make a submission to add gender affirmation as an indication on the PBS.

My changes are in red.

Cheers,
s22

Personal motto: Team work makes the dream work

From: PBAC <PBAC@health.gov.au>
Sent: Friday, 14 May 2021 1:14 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: Testosterone for transgender men [SEC=OFFICIAL]

Hi s22

I've drafted my response to s47F below. His request isn't directly related to access to testosterone, it is rather the additional health care cost which can cause barriers to some patient and how to have a new indication be considered to be listed on the PBS.

Also thank you for letting me know about s22 reply. I've inserted some of MSAC standard responses into the draft below in blank font.

I found this one a bit odd to write to. I don't know if I have answered s47F query but thought to send it off to you to see what you think.

Thanks,
s22

Dear s47F

Thank you for your email in regards to subsidised access to testosterone for transgender patients on the PBS.

The Australian Government is committed to ensuring that all Australians are able to access timely and affordable, high quality health care by providing Medicare benefits for services listed on the Medicare Benefits Schedule (MBS), subsidising a comprehensive range of medicines through the PBS, and providing free hospital services for public patients in public hospitals.

The Medical Services Advisory Committee (MSAC) is an independent scientific committee, comprising individuals with expertise in clinical medicine, health economics and consumer matters. MSAC evaluates medical services, health technologies and health programs proposed for public funding, in order to advise the Minister for Health on whether a medical service, health technology or program should be publicly funded via the MBS or other programmes, including the circumstances in which it should be funded. MSAC assesses applications made for public funding on their comparative safety, clinical effectiveness, cost effectiveness and total cost/financial impact, using best available evidence.

Applications in seeking funding and subsidy of new medical service, health technology or program can be made to the Department by the medical profession and medical industry. To apply for public funding a completed application form should be provided to the medical services Health Technology Assessment (HTA) Team in the Department of Health. The Department assess the information provided and determines the application's suitability to proceed through the MSAC process.

The Government also receives advice on PBS listings from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, about the listing of medicines on the PBS. The Government cannot list a new medicine on the PBS, or change the restriction for an existing listing, unless the PBAC makes a recommendation in favour of doing so. As you would be aware, there is no provision for the subsidised supply of a PBS-listed item outside the terms of restrictions. In addition, no exceptions are permitted to be made for individual patients, even in particular cases where the medicine might be beneficial or recommended on clinical grounds.

There are no specific listings of hormones on the PBS for transgender hormone therapy. PBS listings reflect the requests put to, and evidence that has been considered by, the PBAC to date. In the case of testosterone, some restriction changes have been made in response to concerns raised with the Committee.

The National LGBTI Health Alliance provided a submission to the PBAC to consider at its July 2015 meeting, which requested changes to the restrictions for testosterone. The National LGBTI Health Alliance submission led to a PBAC recommendation to amend the restriction wording for testosterone to remove the population criterion 'patient must be male'. The PBAC considered this clinical criterion was an unintentional barrier to some trans people and people with intersex variations receiving PBS-subsidised testosterone replacement therapy. While the rate of females (individuals with a recorded sex of female in their Medicare enrolment file, noting that the Medicare personal records system only allows gender to be recorded as male or female) accessing subsidised testosterone remains small, it has increased each year since this restriction change in 2015.

While most PBAC submissions are lodged by pharmaceutical companies, nothing prevents other stakeholders from lodging submissions. You may wish to contact the National LGBTI Health Alliance to ask if they intend to

apply or can assist you with applying to the PBAC regarding your requested restriction changes. The National LGBTI Health Alliance can be contacted at info@lgbtiqhealth.org.au or by phone at 02 7209 6301.

Please note that medicines are not generally made available on the PBS to treat conditions for which they have not been approved by the Therapeutic Goods Administration (TGA), Australia's regulator of medicines and other therapeutic goods. To date gender affirmation has not been approved by the TGA as an indication for testosterone.

For further information on the MSAC process and how to apply for public funding, please visit www.msac.gov.au/internet/msac/publishing.nsf/Content/how-to-apply-for-public-funding
The HTA Team in the Department of Health can also be contacted directly to provide assistance by email at: hta@health.gov.au.

Thank you for writing on this matter.

Kind regards

From: s47F
Sent: Monday, 3 May 2021 3:30 PM
To: PBAC <PBAC@health.gov.au>
Subject: Testosterone for transgender men

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear PBAC Secretary,

My name is s47F
s47F

I am writing to hope to speak with you regarding options and potential steps required to enable access to testosterone for transgender men. There is currently no specific indication for testosterone treatment for transgender men on PBS, and they require specialist approval by an endocrinologist/sexual health physician etc as per the guidelines for hypogonadal men. Whilst these men can still access testosterone, there are additional health care costs which can be a barrier to care for some individuals.

I am hoping to speak with you regarding the steps required to apply for "Gender affirmation" as a PBS indication.

Many thanks for your assistance.

Kind regards,
s47F

s47F **Endocrinologist | PhD Candidate** s47F
s47F
s47F
T: s47F **E:** s47F

Australian Society *of* Plastic Surgeons

Friday, 7 January 2022

Mr Greg Hunt MP
Minister for Health
PO Box 6022
House of Representatives, Parliament House
Canberra ACT 2600
Email: Greg.Hunt.MP@aph.gov.au; Minister.Hunt@health.gov.au

Dear Minister Hunt,

Regarding health services for medical gender affirming treatments

There are currently inadequate health services for the treatment and support of people experiencing gender incongruence with approximately 60% of trans Australians describing difficulty accessing hormonal treatment or accessing gender-affirming surgery.[1] We know that being unable to access such surgery leads to a higher risk of suicide.[2]

Being transgender, both binary and non-binary, is not a health problem in itself, though people with lived experience of being transgender have an incongruence between the gender presumed for them at birth and their self-determined gender, and may often experience dysphoria. This incongruence may affect their health and quality of life and may require a variety of gender affirming treatments which may include medications, surgery and other health services.

One of the primary barriers to a person affirming their gender is that access to surgery and other medical gender affirmations such as hormone therapy is limited and in some cases entirely inaccessible. Whilst there are some interventions publically available to those seeking gender affirming treatments, there is no consistency in access for all gender affirming treatment options. Additionally, the financial barriers as a result of a lack of public health coverage means that gender affirming treatments are largely unaffordable to many trans people.

Evidence for demand and support for surgical services to be publically funded has been recently illustrated by a petition to parliament which generated some 148,182 signatures and which currently sits in your Office for consideration awaiting a response.[3] At this stage we are unaware of any existing or historic applications to have pharmaceutical benefits applied to gender affirming

[1] Bretherton et al. "The Health and Well-Being of Transgender Australians: A National Community Survey", *LGBT Health* 2021 https://doi.org/10.1089/lgbt.2020.0178.
[2] Zwickl et al. "Factors associated with suicide attempts among Australian transgender adults", *BMC Psychiatry* 2021, https://doi.org/10.1186/s12888-021-03084-7.
[3] Parliamentary Petition EN3307 - *Gender affirming surgery should be covered by Medicare.* Link: https://www.aph.gov.au/e-petitions/petition/EN3307.

Australian Society of Plastic Surgeons

treatments through PBAC or surgical treatments through MSAC, though welcome any information you may have with regards to this.

As a group, we are cognisent that the processes for developing community access to hormones on the PBS (via PBAC) and surgery on the MBS (via MSAC) are complex and usually designed for single item interventions, often sponsored by pharmaceutical companies or device manufacturers (i.e. commercial entities). We see a problem in submitting multiple PBAC applications and multiple MSAC applications independently and without significant collaboration. The financial and logistic challenges associated with this approach mean that this is not a realistic approach for a group of member organisations, with no professional in house health technology assessment ('HTA') expertise. In addition, the conceptual problem from a Department of Health perspective is that if each application is separate, we need to find evidence of clinical effectiveness, safety and cost effectiveness for each individual intervention or drug, which is exceptionally difficult to do when all of these treatments are interrelated.

Our vision is that there should be a suite of surgical MBS item numbers and PBS drugs provided as a holistic care package for trans people who seek gender affirming treatment. Our societies are prepared to work together to form a collaboration or alliance to achieve this vision. ASPS will act as the contact organisation for conveniences' sake, but recognises the other organisations as equal partners. Please also note that the co-authors of this letter intend to approach and collaborate with all relevant stakeholders should such a package be developed. We expect this would include the following groups and organisations in addition to the letters' authors: surgical specialties performing gender affirming surgeries (plastic and reconstructive, urology, gynaecology, maxillofacial specialists and so forth); endocrinologists through the Endocrine Society of Australia; consumer groups such as ACON, and GP representatives either as part of the RACGP or in a different capacity.

We would like you, along with the Department of Health to consider whether the Department could financially and logistically support a process to develop and assess such a package. Although there may not be precedence for this, we feel that community sentiment on this issue is very strong and clear, and the time to act is now.

Yours Sincerely,

s47F

Australian Society of Plastic Surgery (ASPS)

s47F

Australian Professional Association for Transgender Health (AusPATH)

s47F

Trans Health Research group, The University of Melbourne

Australian Society of Plastic Surgeons

aus PATH

TRANS HEALTH RESEARCH

Australian Society of Plastic Surgeons

References

Ingrid Bretherton, Emily Thrower, Sav Zwickl, Alex Wong, Daria Chetcuti, Mathis Grossmann, Jeffrey, D. Zajac, and Ada S. Cheung, "The Health and Well-Being of Transgender Australians: A National Community Survey" in *LGBT Health*, Vol 8, No 1 (2021), pp 42-49. [Available at https://doi.org/10.1089/lgbt.2020.0178].

Sav Zwickl, Alex Fang Qi Wong, Eden Dowers, Shalem Yiner-Lee Leemaqz, Ingrid Bretherton, Teddy Cook, Jeffrey D. Zajac, Paul S. F. Yip and Ada S. Cheung, "Factors associated with suicide attempts among Australian transgender adults" in *BMC Psychiatry*, 21:81 (2021). [Available at https://doi.org/10.1186/s12888-021-03084-7].

The Hon Greg Hunt MP
Minister for Health and Aged Care

Ref No: MC22-000501

s47F
Australian Society of Plastic Surgery
s47F

s47F
Australian Professional Association for Transgender Health
s47F

s47F
Trans Health Research Group
The University of Melbourne
s47F

28 MAR 2022

Dear s47F

I refer to your correspondence concerning health services for medical gender affirming treatments. I regret the delay in responding.

I appreciate the many challenges faced by transgender people and those who experience gender dysphoria. The Australian Government is committed to supporting all Australians to access timely and affordable, high-quality health care by providing medical benefits (rebates) for services listed on the Medicare Benefits Schedule (MBS), subsidised medicines via the Pharmaceutical Benefits Scheme (PBS), and free hospital services for public patients in public hospitals.

Further to your correspondence, I understand the Australian Society of Plastic Surgeons has recently met with my Department through the Continuous Improvement Committee (CIC) and raised proposals for how a suite of surgical MBS items and PBS medications could be made available to support people undergoing gender affirming treatment, and how best to take this work forward. My Department will refer this matter to the Medical Services Advisory Committee Executive for preliminary advice on potential mechanisms for considering these issues, noting there may not be a single pathway for consideration given the complexity of the issues. Please continue to liaise with Dr John Primrose, Principal Medical Advisor and Chair of the CIC.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt

FAS Brief – May 2023
Budget Senate Estimates

Title: PBS MEDICINES FOR TRANS AND GENDER DIVERSE PATIENTS

Overview/key points

- A range of medicines used in gender-affirming hormone therapy are available on the PBS, in many cases as unrestricted benefits, and can be accessed by transgender patients. PBS and non-PBS medicines available in Australia for gender affirming hormone therapy are outlined in **Attachment 1**.
- Many of these medicines have been included in the list of medicines recommended by PBAC in Dec 2022, as suitable for listing with increased maximum dispensing quantities. This proposal will give clinicians the choice to prescribe a 60-day quantity per dispensing where a patient has established chronic and stable use of a medicine, and where the prescriber considers it clinically appropriate to do so.
- Gonadotropin releasing hormone (GnRH) analogues (sometimes referred to as 'puberty blockers') are only available on the PBS for the treatment of certain cancers and precocious puberty. When used for gender affirming hormone therapy these medicines are supplied on private prescriptions.
- In 2022 the Australian Professional Association for Trans Health (AusPATH) published consensus guidelines for clinicians with trans and non-binary patients, titled *Australian Informed Consent Standards of Care for Gender Affirming Hormone Therapy*.
- The goal of gender-affirming hormone therapy is to align physical appearance with gender identity to reduce distress and improve wellbeing. Treatments are generally described as *feminising* and *masculinising* to describe their effects on the body, rather than to describe the genders of people using them.
- AusPATH recommends that prescribing of a gender-affirming hormone therapy starts with a low dose to minimise side effects, then titrated upward over time to target hormone levels in the reference range of the affirmed gender.
- Gender-affirming hormone therapy is usually lifelong, although some patients may choose to cease hormones once the desired changes have occurred.

Key sensitivities

- Due to increasing PBS utilisation rates and the potential misuse of testosterone, testosterone containing medicines are listed as Authority Required. However, the PBS restriction for testosterone medicines for '*androgen deficiency due to an established pituitary or testicular disorder'* is gender agnostic and can be accessed by patients undergoing gender affirming hormone treatment.
- A stakeholder meeting was held with the National LGBTI Health Alliance in November 2015 to inform restriction arrangements for testosterone use in transgender patients.
- Changes to the PBS restrictions for testosterone medicines were recommended in 2015 to remove the criterion '*patient must be male'* and in 2016 to allow prescribing for '*established pituitary disorders*', following requests to the PBAC from stakeholders.
- The Drug Utilisation Sub-Committee (DUSC)'s most recent review of the use of testosterone was undertaken in 2020 and found that usage had increased in patients with female gender markers following the restriction changes (particularly in the 15-19 years cohort).
- At the March 2021 meeting, the sponsor of Androforte 5 (a testosterone cream formulation) requested a change in the number of repeats for the currently listed testosterone cream.
- The PBAC recommended amending the listing of AndroForte 5 to reduce the number of repeats from six to one and recommended an increase to the unit price which should not result in additional cost to the PBS. The PBAC's recommendation was based on the TGA approval for scrotal application that reduces the dose from 100 mg to 25 mg daily, and increases the number of treatments per tube from 25 to 100.
- The sponsor of AndroForte 5 accepted the PBAC recommendations with the addition of the PBS restriction criteria '*The treatment must be applied to the scrotum area*'. This has been the subject of several correspondences from trans and LGBTI organisations, claiming it creates a barrier to trans-patients receiving therapy.
- The Department, following advice from the PBAC Executive on the matter is working with the sponsor on a proposed amendment to the restriction to address this.

Attachments:

A) List of medicines (PBS and non-PBS) that may be used in gender affirming hormone therapy

Contact Officer:	s22	Work Phone: (02) 6289 s22	Mobile: s22
Cleared by Assistant Secretary:	Renaye Lucchese	Work Phone: (02) 6289 s22	Mobile: s22

Attachment A

Medicines for trans and gender diverse patients

Feminising agents[1,2]

Medicine	TGA indication	PBS listing	Comments	60-day MDQ medicine?
Estradiol valerate 1 mg tablet *Progynova®*	Short term treatment of climacteric complaints after the cessation of monthly bleeding, or deficiency symptoms after oophorectomy or radiological castration for non-carcinomatous diseases.	Unrestricted		Yes
Estradiol 2 mg tablet *Zumenon®*	Symptomatic treatment of oestrogen deficiency due to natural or surgical menopause in hysterectomised post-menopausal women.	Unrestricted		Yes
estradiol 0.1% (1 mg/g) gel, *Sandrena®*	Short-term treatment of climacteric symptoms after natural or surgical menopause.	Unrestricted		Yes
estradiol 25,50,75,100 microgram/24 hours patches, *Climara®*	For short term treatment of signs and symptoms of oestrogen deficiency due to the menopause, whether natural or surgically induced. Prevention of post-menopausal bone mineral density loss.	Unrestricted		Yes
estradiol 25, 50,100 microgram/24 hours patches, *Estraderm®*	Short-term treatment of signs and symptoms of oestrogen deficiency due to menopause, whether natural or surgically induced.	Unrestricted		Yes
estradiol 25, 37.5, 50, 75, 100 microgram/24 hours patches, *Estradot®*	Short term treatment of symptoms of oestrogen deficiency due to the menopause, whether natural or surgically induced.	Unrestricted		Yes
estradiol 1 and 2 mg tablets, *Estrofem®*	Short term symptomatic treatment of oestrogen deficiency due to natural or surgical menopause in hysterectomised postmenopausal women.	No		No
Estradiol implant (compounded)	Compounded formulations of estrogen implants are not approved by Australia's Therapeutic Goods Administration and are therefore not subject to the regulatory conditions of approved pharmaceutical products.	No	Estradiol pellets are available as either 50mg or 100mg pellets, with between. Pellets are replaced every 6-24 months, depending on the response of the individual.[1]	No

Medicine	TGA indication	PBS listing	Comments	60-day MDQ medicine?
Spironolactone 25 and 100 mg tablets, 100 *Aldactone® Spiractin®*	Hirsutism in Females.	Unrestricted		Yes
Cyproterone acetate 50 mg and 100 mg tablets, 20 *Androcur® and generic brands*	WOMEN: Moderately severe to severe signs of androgenization. MEN: Reduction of drive in sexual deviations.	Unrestricted Cyproterone acetate 50 mg tablet, 20 – Authority Required for Moderate to severe androgenisation. Patient must be female.		Yes
Progesterone 100 mg and 200 mg capsules, 30 *Prometrium®*	Treatment of menstrual irregularities, - In women Hormone replacement therapy,- adjunctive use with an oestrogen in postmenopausal women with an intact uterus.	No		No

[1] *https://www.transhub.org.au/clinicians/feminising-hormones*

[2] https://auspath.org.au/wp-content/uploads/2021/06/AJGP-07-2020-Focus-Cundill-Hormone-Therapy-WEB.pdf

Masculinising agents[3,4]

Medicine	TGA indication	PBS listing	Comments	60-day MDQ medicine?
Testosterone undecanoate 1 g/4 mL modified release injection, *Reandron 1000®*	Testosterone replacement in primary and secondary male hypogonadism.	Authority Required: Androgen deficiency, micropenis, pubertal induction, constitutional delay of growth or puberty		No
Testosteron enanthate Depot 250mg/1mL Injection Syringe *Primoteston®*	Androgen replacement therapy for confirmed testosterone deficiency in males.	No		No
Testosterone esters 250mg/1mL vial *Sustanon®*	Androgen replacement therapy for confirmed testosterone deficiency in males.	No		No
Testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations *Testogel®*	Testosterone replacement therapy for male hypogonadism.	Authority Required: Androgen deficiency, micropenis, pubertal induction, constitutional delay of growth or puberty		Yes
Testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets *Testogel®*	Testosterone replacement therapy for male hypogonadism	Authority Required: Androgen deficiency, micropenis, pubertal induction, constitutional delay of growth or puberty		Yes
Testosterone 2% (23 mg/actuation) gel, 56 actuations *Testavan®*	Testosterone replacement therapy for adult male hypogonadism	Authority Required: Androgen deficiency, micropenis, pubertal induction, constitutional delay of growth or puberty		Yes
Testosterone 5% (50 mg/mL) cream, 50 mL *AndroForte 5®*	Testosterone replacement therapy for adult male hypogonadism	Authority Required: Androgen deficiency, micropenis, pubertal induction, constitutional delay of growth or puberty	Restriction criteria includes the term 'Treatment must be applied to the scrotum area' which is seen by some stakeholders as a barrier to transgender patients accessing the medicine.	Yes
Testosterone 24.3 mg per patch transdermal delivery system sachet *Androderm®*	Testosterone replacement therapy for confirmed testosterone deficiency in males.	No		No

[3]https://www.transhub.org.au/clinicians/masculinising-hormones
[4]https://auspath.org.au/wp-content/uploads/2021/06/AJGP-07-2020-Focus-Cundill-Hormone-Therapy-WEB.pdf

Puberty Blockers[5]

Medicine	TGA indication	PBS listing	Comments	MDQ medicine?
goserelin 3.6 mg and 10.8 mg implant, *Zoladex Implant*®	Prostate cancer, cancer, endometriosis, uterine fibroids, endometrial thinning, assisted reproduction.	Restricted Benefit: Carcinoma of the prostate, endometriosis, breast cancer, anticipated premature ovarian failure.	GnRH analogues are not listed on the PBS for puberty suppression related to gender affirmation hormone therapy.	No
leuprorelin acetate 7.5 mg, 22.5 mg, 30 mg, 45 mg modified release injection *Lucrin Depot*® *Eligard*®	Palliative treatment of metastatic or locally extensive prostatic cancer.	Restricted Benefit: Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate	As above.	No
triptorelin 3.75 11.25 mg, 22.5 mg injection, *Diphereline*® triptorelin acetate 100 microgram/mL injection, *Decapeptyl*®	Treatment of hormone-dependent locally advanced or metastatic prostate cancer. Treatment of children 2 years and older with central precocious puberty (CPP).	Restricted Benefit: Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate. Central precocious puberty.	As above.	No

[5]https://www.transhub.org.au/puberty-blockers

s22

From: s22
Sent: Tuesday, 22 November 2022 3:04 PM
To: s22
Cc: s22
Subject: FW: FOR URGENT ADVICE: s22 - Testosterone cream for transgender patient [SEC=OFFICIAL]

Hi s22

The PBAC Executive considered correspondence earlier this year which requested that the criterion be amended. The Department is now putting together a paper which we are aiming to have considered by the PBAC in early 2023.

Thanks,

s22

Assistant Director
PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

Part-time: Tues-Fri

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 @health.gov.au>
Sent: Tuesday, 22 November 2022 1:34 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: FOR URGENT ADVICE: s22 - Testosterone cream for transgender patient [SEC=OFFICIAL]

Hi s22

Would your team be able to respond to this one?

Thanks
s22

s22

PBAC Assessment Section
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
Location: Melbourne office – s22

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 @Health.gov.au>
Sent: Tuesday, 22 November 2022 11:51 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>
Subject: FW: FOR URGENT ADVICE: s22 - Testosterone cream for transgender patient [SEC=OFFICIAL]

Hi s22 and s22

We are managing LAP escalations from SA around the use of AndroForte cream in transgender patients without a scrotum (see email trail).

Would you be able to let me know if PBAC Exec has provided further advice on the issue around the clinical criterion *"the treatment must be applied to the scrotum area"*. If advice is yet to be provided, does the PBAC Exec intend on addressing this in the near future?

Further details here: https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2021-03/files/testosterone-psd-mar-2021.pdf

Many thanks,
s22

s22
Assistant Director | **PBS Restrictions & Implementation Section**

Office of Health and Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T: s22 | E s22 @health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

CULTURALLY & LINGUISTICALLY DIVERSE

From: s22 @health.gov.au>
Sent: Tuesday, 22 November 2022 11:32 AM
To: s22 @Health.gov.au>
Cc: s22 @Health.gov.au>
Subject: RE: FOR URGENT ADVICE: s22 - Testosterone cream for transgender patient [SEC=OFFICIAL]

Hi s22

Yes I agree with your conclusion, it seems reasonable to approve – but as was stated in the email trail, there is a specific criterion issue here, so is there any plan to take this to PBAC Exec?

Kind regards
s22

s22

Medical Adviser, Technology Assessment and Access Division

Australian Government Department of Health & Aged Care

E: s22 @health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @Health.gov.au>
Sent: Tuesday, 22 November 2022 11:23 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>
Subject: FW: FOR URGENT ADVICE: s22 - Testosterone cream for transgender patient [SEC=OFFICIAL]
Importance: High

Hi s22

We require some advice for this one – see email trail below for details.

s47F

The intent of the inclusion of this clinical criterion was to emphasise the recent TGA approved application site that has a better absorption rate compared to the previous TGA approved application site of the chest. Hence a much lesser amount of cream would be required when it is applied on the scrotum, and in turn a lesser number of repeats are required (the number of repeats used to be 5 and is now 1). Further details here: https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2021-03/files/testosterone-psd-mar-2021.pdf

We have had similar requests previously which were also approved (see attached).

Based on the above, my thoughts are it is reasonable to approve the request. Would you also support approval for this request?

Kind regards,
s22

s22
Assistant Director | **PBS Restrictions & Implementation Section**

Office of Health and Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T: 02 s22 | E s22 @health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

From: s22 @servicesaustralia.gov.au>
Sent: Thursday, 17 November 2022 12:05 PM
To: PBAC <PBAC@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @servicesaustralia.gov.au>; s22 @servicesaustralia.gov.au>; s47E(d) @servicesaustralia.gov.au>
Subject: FOR URGENT ADVICE: LAP202211171 - Testosterone cream for transgender patient [SEC=OFFICIAL]
Importance: High

Good Morning,

We have received an urgent online/telephone request with testosterone (AndroForte 5) for androgen deficiency (secondary to established testicular disorder), where the transgender patient is unable to meet the following restriction criteria.

Clinical criteria:

The treatment must be applied to the scrotum area.

s47F

We have previously been advised that these cases should continue to be escalated on an individual basis until further advice is sought from the PBAC Executives. Could you please advise if you would support an approval of this application for authority to prescribe AndroForte 5 based on the information provided? Please find attached the de-identified information from the prescriber for your reference.

Could we please also follow up if there has been any progress and advice from PBAC Executives on this matter?

Your advice again is greatly appreciated.

Kind Regards,
s22

s22
Programme Officer
Phone s22
PBS Authorities, Systems and Reform.
Pharmaceutical Benefits Branch
HEALTH PROGRAMMES | HEALTH AND AGED CARE
SERVICES AUSTRALIA
servicesaustralia.gov.au
Services Australia

☎ s22
✉ s22 @servicesaustralia.gov.au
servicesaustralia.gov.au

s22

From: s22
Sent: Tuesday, 22 November 2022 1:40 PM
To: s22
Subject: RE: FOR URGENT ADVICE: s22 - Testosterone cream for transgender patient [SEC=OFFICIAL]

Hi s22

s22 and s22 were putting a paper together on this issue after the Exec considered some corro earlier this year but the paper hasn't gone back to the Exec or PBAC (no timeframe at this stage but the earliest it would be considered by PBAC would be March 23).

Happy to assist with response if helpful.

Kind regards,

s22

s22 duplicate of document 20

s22 duplicate of document 20

s22 duplicate of document 20

s22 duplicate of document 20

s22 duplicate of document 20

s22

From: PBAC
Sent: Thursday, 14 July 2022 12:44 PM
To: Andrew Wilson
Cc: s22
Subject: RE: Non-scrotal testosterone application of Androforte cream [SEC=OFFICIAL]

Thanks Andrew, we've added to the agenda.

Kind regards,

s22

From: Andrew Wilson s47F
Sent: Wednesday, 6 July 2022 3:57 PM
To: PBAC <PBAC@health.gov.au>
Subject: Fwd: Non-scrotal testosterone application of Androforte cream

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Pls record and add to next Executive
Aw
Professor Andrew Wilson

Begin forwarded message:

> **From:** s47F
> **Date:** 6 July 2022 at 3:15:28 pm AEST
> **To:** Andrew Wilson s47F
> **Cc:** s47F
> endocrinesociety.org.au>
> **Subject: Non-scrotal testosterone application of Androforte cream**
>
> Dear Professor Wilson
>
> Please see attached letter sent on behalf of Endocrine Society of Australia.
>
> Kind regards
> s47
>
> s47F MBBS (Hons 1) PhD FRACP
>
> Staff Specialist | Department of Endocrinology
> St Vincent's Hospital
>
> Conjoint Associate Professor |
> Faculty of Medicine, UNSW

Group Leader | Hormones and Cancer
Garvan Institute of Medical Research

President-Elect, Endocrine Society of Australia

A Gender Agenda
PO Box 4010 Ainslie ACT 2602
www.genderrights.org.au

10th June 2015

Re: Recent restrictions on GP's perscribing testosterone

To Whom It May Concern,

A Gender Agenda writes to you in support of the submission presented by the National LGBTI Health Alliance.We as a member organisation are also concerned for the welfare of the affected populations of men of trans experience, people with non-binary genders and people with intersex characteristics who need access to testosterone on the PBS for androgen deficiency. The service delays which result from the recent restrictions on GPs prescribing testosterone will contribute to poorer health outcomes for these members of our community. The disruption to continuity of care provided by a GP will also negatively impact health outcomes.

If you have any questions regarding our support for the National LGBTI Health Alliance submission please do not hesitate to contact me.

Best Wishes,
s47F

A Gender Agenda
s47F
(02) 6162 1924.

Public Health Association
AUSTRALIA

Pharmaceutical Benefits Advisory Committee
Email: CommentsPBAC@health.gov.au
CC: Adriana.Platona@health.gov.au; s22 @health.gov.au; s22 @health.gov.au;
s47F ;

10 June 2015

Dear Colleagues

I am writing to provide the Public Health Association of Australia's (PHAA) support for the National LGBTI Health Alliance's submission re recent changes to GP testosterone prescribing.

PHAA is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes. PHAA has a vision for a healthy region, a healthy nation and healthy people living in a healthy society and a sustaining environment based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level.

The National LGBTI Health Alliance (the Alliance) is proposing an amendment to the revised PBS restrictions on GP prescribing of testosterone for androgen deficiency to enable continued access by transgender and intersex patients.

Specifically, that an exemption be added to restore GP testosterone prescribing without consultation with a (non-GP) specialist when treating androgen deficiency in:

- patients who cannot produce testosterone within the normal male range due to absent or non-functioning testes;
- patients undergoing gender affirmation; and
- patients with intersex characteristics who give informed consent on their own behalf.

Further, PHAA supports the Alliance's additional proposals to ensure PBS compliance with federal anti-discrimination legislation.

PHAA is concerned that the recent changes to GP testosterone prescribing have had the unintended consequence of inhibiting access for transgender and intersex patients. It would seem that these communities have not been well served by consultation processes and that the resultant changes have led to some harmful outcomes that must now be addressed as a matter of priority.

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 **F** (02) 6282 5438 **E** phaa@phaa.net.au **W** www.phaa.net.au

We trust that PHAA's statement of support for the Alliance's submission to PBAC is useful in informing the Committee's consideration of the proposed amendment to the revised PBS restrictions on GP testosterone prescribing.

Please do not hesitate to contact me should you have any queries or require additional information in relation to this submission.

Yours sincerely

s47F

Melanie Walker
Acting Chief Executive Officer
Public Health Association of Australia

National LGBTI Health Alliance
lesbian, gay, bisexual, transgender, and intersex people and other sexuality and gender diverse (LGBTI) people and communities
PO Box 51 Newtown NSW 2042
(02) 8568 1120
Executive Director: Rebecca Reynolds

Minor Submission to the Pharmaceutical Benefits Advisory Committee July 2015 Meeting

Part A: Proposed amendment to revised PBS restrictions on GP testosterone prescribing

The National LGBTI Health Alliance proposes an amendment to the revised PBS restrictions on GP prescribing of **testosterone for androgen deficiency** to enable access by transgender and intersex patients. We note the endorsement of this submission by Associate Professor Ruth McNair, Director and GP of Northside Clinic (Appendix A on pg. 6 of this document).

Proposed amendment:

That an exemption be added to restore GP **testosterone** prescribing without consultation with a (non-GP) specialist when treating **androgen decifiency** in:

a) patients who cannot produce testosterone within the normal male range due to absent or non-functioning testes;
b) patients undergoing gender affirmation;
c) patients with intersex characteristics who give informed consent on their own behalf.

(Part a. includes trans patients and patients with intersex characteristics with a current testosterone prescription who are thus unable to document low testosterone despite requiring ongoing, lifelong administration of testosterone. Part a. also includes patients who require discretion in their medical record. Part c. excludes involuntary and coerced treatment of patients with intersex variations.)

GP consultation with a (non-GP) specialist for populations a, b, and c (above) should only be required where BOTH of the following two criteria are met:

a) routine monitoring or indicated assessment identifies a medical need beyond the individual GPs scope of practice and experience, as determined on a case-by-case basis; and
b) the consultation is with a specialist endocrinologist with specific expertise in testosterone therapy for the specific patient population (e.g., an endocrinologist with specific expertise in testosterone therapy for trans men will be consulted in the case of a trans man patient).

GPs working with patient populations a, b, and c, will not be required to consult with a urologist or member of the Australasian Chapter of Sexual Health Medicine when prescribing testosterone.

Rationale:

- Lifelong testosterone administration is medically necessary for trans patients who seek this medication as part of medical gender affirmation (i.e., the consensual process of affirming one's gender through medical intervention)[3,5,6,7,13].

- In addition to medical concerns, restricted access to testosterone results in harmful mental health outcomes for trans patients[15,19].

- People with intersex characteristics in Australia are often subjected to involuntary and coerced medical interventions intended to 'normalise' their bodies (as documented in the Senate Report on the Involuntary or coerced sterilisation of intersex people in Australia[1]) by specialist

endocrinologists, urologists, and sexual health physicians. For many people with intersex characteristics, their GP is the only medical provider with whom they feel safe from abuse.

- These non-consensual and medically unnecessary interventions continue to include inappropriate testosterone prescribing on the PBS by endocrinologists (often paediatric endocrinologists), urologists, and sexual health physicians. Intersex patients often report lack of safety, discomfort, distrust, and avoidance of care with these specialists[1]. Thus the requirement to consult with these specialists does not prevent medically unnecessary testosterone prescribing and has a disproportionately negative effect on people with intersex variations.

- Australia medical curricula—including specialist training for endocrinologists, urologists, and sexual health physicians—do not routinely cover testosterone therapy for trans patients or respectful and consensual care of patients with intersex variations. Thus many of these specialists have insufficient knowledge and experience with the medical needs of these populations and do not add value to GP prescribing (see provider testimony in Appendix A).

- Many trans patients who are prescribed testosterone on a long-term basis do not require the involvement of a (non-GP) specialist (see Appendix A). As one Australian urological trainee stated: 'Most urologists I know do not have much experience with testosterone prescribing. If someone has an orchiectomy, the GP deals with prescribing testosterone if needed. Testosterone is not indicated for most urological conditions, and GPs and endocrinologists typically handle those issues. This policy is really poorly thought out.'

- The (non-GP) specialist consultation requirement for GPs treating trans patients and patients with intersex characteristics when prescribing testosterone will further exacerbate existing health disparities and access shortages faced by trans people (including brotherboys, a term for Aboriginal/Indigenous and Torres Strait Islander people assigned 'female' who live part or all of their lives as men or as brotherboys), and people with intersex characteristics in rural and remote communities, particularly those in underserved Aboriginal/Indigenous and Torres Strait Islander communities[9,16] and those living in rural, regional, and remote communities[11].

- Based on the numerous complaints we have received, the restriction on GP testosterone prescribing has had an immediate and profoundly harmful effect on those communities in which (non-GP) specialists with basic competency with trans patients and patients with intersex variations are unavailable or difficult to access.

- An Australian study of 4,596 specialist doctors found that only 19% provided outreach, of which only 16% involved remote outreach[17]. In some as of Australia, people must travel for many hours in order to access basic GP services. As a result of these severe workforce shortages, GPs who provide services in rural and remote communities must often provide care that is more commonly provided by non-GP specialists in well-resourced urban areas (e.g., the phenomenon of rural GP surgeons[2,8])[4,9,10,12,14,16,17,20]. In this climate, the new restrictions on GP testosterone prescribing have exacerbated existing health disparities faced by trans patients and patients with intersex variations.

- The wait times for an appointment with an endocrinologist in some regions can be up to 12 months long, particularly for an endocrinologist with adequate knowledge and experience treating trans patients and/or patients with intersex variations.

- The added travel time and financial expense can also be a formidable hurdle for those in rural, regional, and remote areas and those with limited income and limited access to transportation to the nearest specialist, often many hours away. We have received numerous complaints about unnecessary expenses and lost wages due to the new GP testosterone prescribing restrictions.

Part B: PBS compliance with federal anti-discrimination legislation

Proposed amendments:

We propose removal of the requirement for patients prescribed testosterone to be listed as "male".

We also propose to:

a) restrict testosterone prescribing on the PBS by endocrinologists, urologists, and sexual health physicians for patients with intersex characteristics to only those patients who have given informed consent on their own behalf, including paediatric puberty induction and micropenis; and

b) permit testosterone prescribing on the PBS for puberty induction and micropenis for patients with intersex variations who are over 18 and can give informed consent on their own behalf.

Rationale:

- From 1 August 2013, the *Sex Discrimination Act 1984*[18] has included amendments that prohibit both direct and indirect discrimination on the basis of sexual orientation, relationship status, gender identity, and intersex status in Commonwealth activities.

- According to the *Act,* indirect discrimination is a situation in which a policy is the same for everyone but places a particular group at a disadvantage; the intent to discriminate is not necessary for a policy to constitute indirect discrimination. This includes access to healthcare services and being disproportionately subjected to involuntary and coerced healthcare.

- This important legislation contributes toward an inclusive framework for the implementation of Australian equality values in the delivery of Commonwealth services. The Medicare Benefits Schedule (MBS) has been amended to remove gender-specific MBS item codes to ensure compliance with this legislation. We advise a similar change to PBS prescribing requirements.

Conclusion

As Australia's national experts on LGBTI health policy, we appreciate this opportunity to address the severe and ongoing harm that has been caused by the recent changes to GP testosterone prescribing. We encourage you to contact the Alliance's s47F , with any questions. He can be reached by email at s47F @lgbtihealth.org.au or by phone at s47F .

Yours sincerely

s47F

Rebecca Reynolds
EXECUTIVE DIRECTOR

SEE REFERENCES OVERLEAF

REFERENCES

1. Australian Senate. (2013). Involuntary or coerced sterilisation of intersex people in Australia. Community Affairs Reference Committee, Senate, Parliament of Australia, Canberra. (Available from: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Involuntary_Sterilisation/Sec_Report/~/media/Committees/Senate/committee/clac_ctte/involuntary_sterilisation/second_report/report.ashx)

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5. Colizzi, M., Costa, R., & Todarello, O. (2014). Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: Results from a longitudinal study. *Psychoneuroendocrinology*, *39*, 65-73.

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Appendix A: A GP perspective on testosterone prescribing for trans men

I am a GP working in a clinic with a high proportion of transgender clients including trans men. We prescribe testosterone as a lifelong and essential hormone for trans men who have undergone full assessment by mental health experts and satisfied the internationally agreed criteria for gender dysphoria. These men attend our clinic for holistic care as well as their hormone therapy, and benefit from developing a long term and trusting relationship with a GP. Many of them have had difficult experiences in the health care system in the past, including discrimination, and ignorance about their trans status, so engaging them in the primary care system is very important.

As a GP expert in trans care, I do not need endocrine specialist involvement to provide excellent care for trans men. There is a growing body of trans-skilled GPs in Australia, most of whom are members of ANZPATH. This organisation provides us with regular up-skilling and peer support.

More importantly, I feel that it is inappropriate that trans men be required to see a specialist to initiate testosterone treatment. It adds considerable expense, and often long waiting times before they can be seen. It has the potential to undermine the trust that we are building. Further, the majority of endocrinologists are not expert in hormonal therapy for trans people, and so are not adding anything to patient care.

I am pleased to endorse the National LGBTI Health Alliance application for testosterone in various forms to be formally listed on the PBS as a medication for trans and intersex men, without the need for specialist review or intervention.

s47F

August 2022

Monday, 27 June 2022
10:05 AM

Item	Action	Which team is responsible?	In progress (notes)	Completed
s22				
3.3 ESA letter testosterone	PBAC Secretariat to investigate the previous PBAC recommendation for testosterone, and any implications that may arise from amendment of the restriction. PRAIS to advise on appropriate wording for the restriction and action the administrative change should the listing still align with the intent of the recommendation.	Exec	In progress	
s22				

s22

s22

From: s22
Sent: Tuesday, 24 January 2023 4:07 PM
To: s22
Subject: my exec notes in case useful [SEC=OFFICIAL]

Agree with your approach per chat s22
Here are my notes in case useful.

s22

s22

3.5 testosterone
Difficulty - current price reflects lower dose scrotal application
sponsor hasn't been involved to date, unsure if they would be amenable to a lower/weighted price
10% leakage was noted as potential but not permitted in the restriction
Mind to change
Sec write to sponsor (+ESA?)

s22

s22

Director – PBAC Assessment Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | M: s22
E: s22 @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

s22

s22

Dear PBAC Secretary,

s47F

I am writing to hope to speak with you regarding options and potential steps required to enable access to testosterone for transgender men. There is currently no specific indication for testosterone treatment for transgender men on PBS, and they require specialist approval by an endocrinologist/sexual health physician etc as per the guidelines for hypogonadal men. Whilst these men can still access testosterone, there are additional health care costs which can be a barrier to care for some individuals.

I am hoping to speak with you regarding the steps required to apply for “Gender affirmation” as a PBS indication.

Many thanks for your assistance.

Kind regards,
s47F

s47F | Endocrinologist | PhD Candidate s47F
s47F
s47F
T: s47F E: s47F

Dear s47F

Thank you for your correspondence regarding Pharmaceutical Benefits Advisory Committee (PBAC) consideration of gender affirming hormone treatments. We apologise for the delay in response – we are implementing new processes to ensure correspondences like yours will be responded to in a timely manner.

The Australian Government receives advice on Pharmaceutical Benefit Scheme (PBS) listings from the PBAC, an independent, expert advisory body, about the listing of medicines on the PBS. The Government cannot list a new medicine on the PBS, or change the restriction for an existing listing, unless the PBAC makes a recommendation in favour of doing so. There is no provision for the subsidised supply of a PBS-listed item outside the terms of restrictions. In addition, no exceptions are permitted to be made for individual patients, even in particular cases where the medicine might be beneficial or recommended on clinical grounds.

There are no specific listings of hormones on the PBS for gender affirming hormone therapy. The current PBS listings reflect the requests put to, and evidence that has been considered by, the PBAC to date. In the case of testosterone, some restriction changes have been made in response to concerns raised with the Committee.

In April 2015, a number of restriction changes were made to testosterone listings for the treatment of androgen deficiency, following an analysis of testosterone use by the Drug Utilisation Sub-Committee (DUSC) and recommendations of the PBAC. The DUSC analysis found that testosterone use had increased markedly over the preceding five years and considered that while some use might be attributed to unmet clinical need, a proportion of use might not be within the intended PBS restriction. This was in the context of safety concerns with testosterone, including possible increased cardiovascular risk in older men. One of the restriction changes was that patients must be treated by a; specialist, paediatric endocrinologist, specialist paediatrician, specialist general paediatrician, specialist endocrinologist, specialist urologist, or a GP in consultation with one of the listed specialists.

The National LGBTI Health Alliance provided a submission to the PBAC to consider at its July 2015 meeting, which requested changes to the restrictions for testosterone. This resulted in a stakeholder meeting between the PBAC and the National LGBTI Health Alliance in November 2015 where the Alliance discussed their concerns regarding the restriction changes to testosterone, particularly

regarding prescribing having to be initiated at a specialist level. At its November 2015 meeting, the PBAC noted that the negative impacts on trans people and people with intersex variations were unintended consequences of the restriction amendments. The Committee considered that it is important to balance facilitated access for this vulnerable patient group with the safety concerns that had driven the restriction amendments.

The National LGBTI Health Alliance submission also led to a PBAC recommendation to amend the restriction wording for testosterone to remove the population criterion 'patient must be male'. The PBAC considered this clinical criterion was an unintentional barrier to some trans people and people with intersex variations receiving PBS-subsidised testosterone replacement therapy. While the rate of females (individuals with a recorded sex of female in their Medicare enrolment file) accessing subsidised testosterone remains small, it has increased each year since this restriction change in 2015.

Details of the PBAC consideration is available at: www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2015-07/files/testosterone-psd-july-2015.pdf. Details of the DUSC considerations are available at: www.pbs.gov.au/info/industry/listing/participants/public-release-docs/testosterone/testosterone-utilisation-analysis-Oct-2012.

While most PBAC submissions are lodged by pharmaceutical companies, nothing prevents other stakeholders from lodging submissions. You may wish to contact the National LGBTI Health Alliance to ask if they intend to make any further applications to the PBAC regarding gender affirming hormone treatment. The National LGBTI Health Alliance can be contacted at info@lgbtiqhealth.org.au or by phone at 02 7209 6301.

Thank you for raising these concerns.

Thank you for writing on this matter.

Kind regards

Dear PBAC,

Are you able to provide me with any information as to whether PBAC has received any prior applications for **gender affirming** hormone treatments (e.g. testosterone)? If so, are you able to provide any documentation on the outcome and findings?

Kind regards

s47F

s47F (Tues AM/Fri 11am-2pm)

Australian Society of Plastic Surgeons

POINTS for discussion

- TYPE of application required
- If the application site criteria is amended, to allow application of androforte to other sites, this may affect the sponsors March 2021 Estimates, and the AEMP also needs to be reviewed.

The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC23-014763

Ms Susan Templeman MP
Chair
Standing Committee on Petitions
petitions.committee.reps@aph.gov.au

Dear Chair Susan

Thank you for your correspondence of 1 August 2023 regarding Petition EN5135, requesting that gender affirming care not be covered under Medicare.

The Australian Government is committed to supporting all Australians to access high quality health care by providing Medicare benefits (rebate) for services listed on the Medicare Benefits Schedule (MBS), subsidised pharmaceuticals available through the Pharmaceutical Benefits Scheme and free hospital services for public patients in public hospitals.

Currently some surgical procedures that may be performed in the gender affirmation process attract a Medicare rebate. The Government relies on the judgement of health practitioners in determining the appropriate care for patients and upholding the principle of clinical relevance when deciding whether a procedure is necessary for a particular patient.

I can advise that the Medical Services Advisory Committee (MSAC) has recently received an application for the public funding of patient consultations and surgical procedures for gender affirmation in adults with gender incongruence.

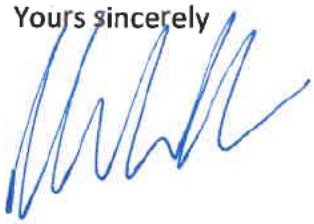
MSAC is an independent, expert advisory group which provides advice to the Government on whether a new medical service or technology should be publicly funded, based on an assessment of the comparative safety, clinical effectiveness, cost-effectiveness and total costs of services and/or procedures, using the best available evidence. The MSAC commonly assesses applications for new services seeking public funding on the MBS. Any person or organisation can submit an application to the MSAC for the consideration of public funding of a medical service.

The application will be considered following standard MSAC processes. The MSAC seeks feedback from relevant clinical and consumer organisations as part of the appraisal process for an application. Information about the MSAC consultation process can be found on the MSAC website at www.msac.gov.au/internet/msac/publishing.nsf/Content/MSAC-Consultation-Process.

The Government will consider the advice from MSAC on this issue when received.

Thank you for writing on this matter.

Yours sincerely



Mark Butler

27 / 09 / 2023