MSAC Application 1754

Surgical procedures for gender affirmation in adults with gender incongruence

Pre-PASC PICO Confirmation

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Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for gender affirmation surgical procedures in adults with gender incongruence

Component	Description
Population	s47C
Intervention	One or more gender affirming surgical procedure(s), including first and subsequent stages of a multistage procedure. Gender affirming chest surgery: 1. Feminising chest surgery by any method, including but not limited to insertion of prostheses, autologous fat graft or local flaps 2. Masculinising chest surgery with surgical repositioning of the nipple areolar complex 3. Bilateral simple mastectomy Genital reconfiguration surgery: 4. Penectomy 5. Bilateral orchidectomy 6. Bilateral orchidectomy with scrotectomy 7. Construction of labia +/- neo-vagina and inset of urethra by any method using penoscrotal skin 8. Construction of neo-vagina by skin grafting around a mould 9. Construction of neo-vagina using intestinal segment or peritoneal pull through technique 10. Subsequent stage of construction of neo-vagina surgery using local flaps or skin graft, where single stage surgery was not feasible 11. Hysterectomy with or without bilateral salpingo-oophoretomy 12. Construction of neo-phallus by any method using local skin flaps, first stage of a multi-staged procedure 13. Construction of neo-phallus by any method using local skin flaps, subsequent stage of a multi-staged procedure 14. Construction of neo-phallus using pedicled fascio-cutaneous regional flap (such as pedicled antero-lateral thigh flap) 15. Construction of neo-phallus by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap) 16. Construction of neo-urethra by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap) 17. Construction of neo-phallus by metoidioplasty (formation of penis from clitoral tissue) 18. Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) with vaginectomy 19. Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) without vaginectomy

Component	Description
	20. Neo-phallus, insertion of prosthesis to Gender affirming facial procedures: 21. Remodelling of the forehead and orbits using burring of frontal bone, including any associated advancement flap of scalp for alteration of hairline 22. Remodelling of the forehead and orbits using bone flap and remodelling of the frontal sinus, including any associated advancement flap of scalp for alteration of hairline 23. Bone genioplasty 24. One or more mandibular ostectomies (other than simple bone genioplasty) and mandibular reshaping if undertaken 25. Insertion of facial implants or bone grafts 26. Soft tissue surgery of the mid-face including skin advancement of local flaps to philtrim and lips and including fat grafting 27. Rhinoplasty Gender affirming voice surgery: 28. Chondrolaryngoplasty
Comparator/s	1. No gender affirming surgical procedures s47C 2. Gender affirming surgical procedures using current MBS items (for financial impact analysis only)
Outcomes	**Safety** • Surgery associated complications and adverse events **Effectiveness -** primary • Health-related quality of life (HRQoL) (as measures s47C • s47C **Effectiveness** - secondary • Functional outcomes of surgery (e.g. incidence of categories of urinary incontinence, sexual performance) • Patient satisfaction / regret with decision for surgery s47C

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Component	Description
	s47C **Health care resource use** Cost-effectiveness Net financial impact • MBS budget • If relevant, other Commonwealth health budgets (e.g. PBS) • If relevant, other health budgets (e.g. state government funding, private health insurers, patients out of pocket costs) **Other relevant issues** s47C • Implementation issues (e.g. workforce availability, s47C
Assessment questions	1. What is the safety, effectiveness and cost-effectiveness of gender affirmation surgery versus no surgery in adults with gender incongruence? 2. What is the financial impact of adding specific gender affirming surgical procedure items to the MBS s47C

MBS = Medical Benefits Services; PBS = Pharmaceutical Benefits Scheme

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Main issues for PASC consideration

Population:

- s47C

Intervention:

- s47C

Comparator:

- s47C

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Outcomes:

- s47C

Proposal for Public funding

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Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of a new suite of surgical procedures for gender affirmation in adults experiencing gender incongruence was received from the Australian Society of Plastic Surgeons Inc (ASPS) by the Department of Health and Aged Care (the Department).

In addition to a suite of items for gender affirming surgical procedures the Applicant proposed changes to consultation items on the MBS for health assessment and multidisciplinary care plans, that will enable improved access for people with gender incongruence s47C. The Department considers that existing items may be used for the services proposed by the Applicant. The Department considers the Applicants proposed changes to consultation and care plan items out of scope of this MSAC process and will progress these changes as part of broader MBS review work. The MSAC executive considered that a multi-disciplinary best practice model of care framework extending before and after surgery was needed and that improving existing services and developing a framework of support could be a potential alternative to developing new MBS items (MSAC executive teleconference, 26th May 2023).

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Together, the proposed changes aim to provide a multidisciplinary best model of care framework, giving improved treatment access and care for patients seeking medical or surgical interventions for gender affirmation, that extends before and after surgery.

Clinical claims

The Applicant's clinical claim (with a comparator of no surgery) is:

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The ~~Clinical~~ clinical claim with a secondary comparator (MBS funded non-gender affirmation surgical procedures) is:

*The use of MBS funded gender affirmation surgical procedures results in **non-inferior safety and non-inferior health outcomes** compared to gender affirmation surgical procedures using existing non-gender affirmation MBS items.*

It can be assumed that the safety and effectiveness of surgery using proposed or current MBS items would be the same, and this second comparison should be the focus of a financial impact analysis only. s47C

The clinical and economic assessment should focus on the comparison of proposed gender affirmation surgery compared with no surgery s47C

PICO criteria

Population

The population for this ~~new~~ application is s47C

Eligibility and diversity

Gender incongruence s47C. Among transgender and gender diverse people s47C trans) are those who experience gender incongruence ~~such that~~and will ~~they~~ seek medical and/or surgical intervention s47C The services sought will depend on an individual's personal choice, and may involve one or more surgical procedures, with or without hormone therapy. People with gender incongruence are at higher risk for gender dysphoria, psychological disorders such as depression or anxiety, and suicide ideation and suicide attempt,

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than other adults. It is proposed that by undergoing surgical procedures that align with a s4 -trans individual's experienced gender (gender affirming surgery), as a part of holistic multidisciplinary care, the risk of these outcomes may be reduced.

The World Health Organization (WHO) International Classification of Diseases – 11th edition (ICD-11) HA60 has moved gender incongruence out of the "Mental and behavioural disorders" chapter into a new "Conditions related to sexual health" chapter, and described Gender Incongruence of Adolescence and Adulthood[1]:

> *"Gender incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual's experienced gender and the assigned sex, which often leads to a desire to transition, in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning a diagnosis."*

The Applicant proposes that no other restrictions be placed on eligibility for gender affirming surgery (other than the diagnosis of gender incongruence), except for limiting the surgery to adults. No testing will be required to access the surgical procedures, and diagnosis should only require one practitioner to make the decision.

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The diagnosis would most often be currently made by a general practitioner. In a multidisciplinary care setting, diagnosis may be made by a sexual health practitioner, endocrinologist, or psychiatrist – depending on whom the individual may be consulting with.

The diagnosing clinician will need to rule out temporal gender incongruence which may occur as part of an acute psychotic episode, or cases where surgery is sought for reasons other than the alleviation of gender incongruence.

In the past, gender transition has been seen by the broader population as a binary concept (male-to-female or female-to-male). However, now there is recognition of gender incongruence in non-binary individuals, who are estimated to comprise 30% of the s4 trans population (Cheung et al. 2019). The surgical or medical interventions sought for transition are a very individual matter, stemming from their own experienced gender. It is preferred that surgical procedures are therefore referred to as gender affirmation surgery or treatment, rather than masculinising or feminising gender affirming surgery.

Care pathway and prognosis

Many s4 -trans people experience higher levels of stigma, discrimination, abuse and violence, than their non- s4 trans counterparts. As a result, they tend to live in poorer social and economic conditions and are often marginalised. In addition, s4 -trans people have poorer physical health and higher rates of

[1] World Health Organization ICD-11 for Gender Incongruence in adults: https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f90875286

[2] https://www.healthdirect.gov.au/gender-affirming-surgery

psychological conditions than other people (Coleman et al. 2022). People with gender incongruence are at risk of gender dysphoria, a state of acute distress associated with gender incongruence, that can vary temporally and with treatment. There is evidence to indicate that s4 -trans people avoid seeking medical care because of a fear of discrimination (Cheung et al. (2019).

Recently, an Australian study found that s4 -trans people have higher rates of depression (58% vs 8%) and anxiety (40% vs16%) compared to an age-matched Australian population (Cheung et al. 2018). Further recent Australian studies have found that s4 -trans people in Australia have high rates of suicide ideation (62%) and suicide attempt (10%) (Hill et al. 2023); that those who felt socially isolated due to their gender identity in the last 12 months were at higher risk of suicide ideation (No vs Yes: OR 2.0; 95% CI 1.6,2.5) (Hill et al. 2023); and s4 trans adults attempt suicide 10 times more often than the general Australian population (Zwickl et al. 2021). s47C

-Having publicly funded access to gender affirming surgery therefore may reduce distress.

An Australian position statement on hormonal management of s4 -trans adults was published in 2019 (Cheung et al. 2019) following the 2017 Australian Professional Association for Trans Health (AusPATH) conference, and reported that a patient-centred holistic approach is recommended for the assessment of people requesting treatment for gender incongruence. Attendance at a health clinic provides an opportunity for a routine health assessment, preventative screening, and a mental health review, conducted by an experienced clinician (general practitioner (GP), physician, psychiatrist, or psychologist). In the absence of a pathway to surgery with funding support, clinicians may choose to use MBS items meant for other conditions, s4 trans individuals may fund surgery themselves, or s4 -trans individuals may seek surgery in countries where it is cheaper than in Australia.

Australian demographics of gender incongruence

Health data on the s4 -trans population in Australia are scarce, however a proportion of 0.1-2% of the population was estimated by Goodman et al (Goodman et al. 2019) to be s4 -trans in a study of 17 western culture countries who use similar definitions. Using an estimate of 1.05% (the midpoint of these data according to (Cheung et al. 2018)) ~~of~~ and ~~the~~ ABS population data ~~for those aged between 18 and 50~~ s47 there are approximately 64,101 s47C and 64,044 s47C trans people s47C resumed female~~s~~ at birth (trans men and non-binary) in Australia in 2023. Not all people with gender incongruence desire to undergo gender affirmation surgery, so the size of the population needs to be estimated based on data on the proportion of s4 -trans people who have undergone surgery, or are interested in undergoing surgery for the purposes of gender affirmation.

An estimate of the number of surgeries that may be required can be made by applying data from a survey of the health and well-being of 928 Australian s4 -trans people 18 years and older that was published in 2020 (Bretherton et al. 2020). Bretherton et al reported on the proportion of the 923 respondents assigned male or female at birth s47C who:

- had undergone prior gender affirming surgery;
- wanted surgery in the future; and those who
- did not want surgery.

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At the time the survey was conducted (s47C to January 2018), of s47C h who responded to survey questions on surgery, 82% had either undergone prior genital reconfiguration surgery (the most common surgery amongst s47C ; 71/384, 18%) or wanted genital reconfiguration in the future (243/384, 64%). Of s47C female s47C who responded to the survey questions on surgery, 89% had either undergone prior mastectomy/chest surgery (the most common surgery in s47C 159/511, 31%) or wanted the surgery in the future (297/511, 58%).

Applying the surgery rates for the most common surgeries from the publication by Bretherton et al (2020) to the ABS data for 2023, it is estimated that of 64,101 s47C in 2023, 11,538 will have had prior genital reconfiguration surgery and 41,024 will want genital reconfiguration surgery in the future. Of 64,044 s47C in 2023, 19,853 will have undergone prior mastectomy/chest surgery and 37,146 want the surgery in the future. These data, along with data for other common surgeries, are summarised in Table 2.

Table 2 Estimate of gender affirming surgeries in the transgender and gender diverse population in Australia

Surgical procedure	Have had n (%)		Want someday n (%)		Don't want n (%)	
	Survey data[a]	Australia 2023[b]	Survey data	Australia 2023	Survey data	Australia 2023
s47C (total surveyed: N=403)						
Breast augmentation (N=362)[c]	32 (9)	5,769	196 (54)	34,615	134 (37)	23,717
Genital reconfiguration (N=384)	71 (18)	11,538	243 (64)	41,025	70 (18)	11,538
Facial feminisation (N=372)	23 (6)	3,846	235 (63)	40,383	114 (31)	19,871
Voice (N=348)	6 (2)	1,202	149 (43)	27,563	193 (55)	35,256
s47C (total surveyed: N=520)						
Chest surgery/mastectomy (N=511)[c]	159 (31)	19,853	297 (58)	37,146	55 (11)	7,044
Genital reconfiguration (N=481)	10 (2)	1,280	213 (44)	28,179	258 (54)	34,584
Voice (N=405)	1 (<1)	<640	15 (4)	2,561	389 (96)	61,482

Notes: a. Data is sourced from 923 s4 trans adults surveyed in (Bretherton et al. 2020)

b. Data is sourced from the rate of s4 -trans people in Australia reported by Cheung et al (2018) (median 1.05%) applied to the Australian Bureau for Statistics population data for 2023 for ages 18 to 50 years s4 -trans birth-assigned males: n = 64,101; TGD birth-assigned females: n = 64,044.

c. N = number of survey respondents to individual survey questions in (Bretherton et al. 2020)

In another Australian survey conducted in 2016 (Cheung et al. 2018) of 540 s4 trans adults, 10% had undergone feminising surgeries, and 21.1% had undergone prior masculinising surgery, a total of 31.1% of s4 trans individuals in all (see Table 5 for details of surgeries). These figures are likely to be under-estimates for current uptake, as a sharp increase in requirement for specialist s4 -gender affirming services has been reported. A 10-fold increase in the number of s4 trans people attending endocrine specialist clinics occurred between 2011 and 2016 according to the authors. A second source of data, SA Health Model of Care for Gender Diversity (SA Health 2023), also found the rate of services sought were increasing sharply, reporting that in 2021 there were 115 adults referred to the Northern Adelaide Local Health Network (NAHLN) alone for s47C -gender affirming services compared to 60 referrals in 2020, an increase of almost 100%. The SA report also noted that the current service provider (SHINE SA Hormone

Service) had closed books during 2021 due to lengthy waitlists, so the actual demand for services is likely to be even higher. An earlier survey of young Australian s4 -trans people (aged 14-25 years) reported that 6.3% s47C trans people up to 25 years of age had undergone prior gender affirming surgery, and a further 20.9% wanted surgery in the future (Strauss et al. 2017). From these data it was estimated that between 108 and 545 18- to 24-year-olds would be seeking gender affirmation surgery in SA in the future (after 2017) (SA Health 2023). However, the current annual demand in SA is unknown.

It is difficult to determine how many of the s4 trans population are likely to take up surgeries in the first year following an approval of MBS funding, as the proportion of individuals undergoing surgery *each year* has not been reported in the referenced studies. In addition, some items likely mastectomy, can already be accessed, but the number undergoing this procedure for gender incongruence in Australia cannot be determined from MBS statistics.

Impact of gender incongruence on mental health and measures of equity

The survey by Cheung et al (Cheung et al. 2018) analysed data from a Melbourne general practice clinic (Equinox Gender Diverse Health Centre) and endocrine specialist clinics. Referral from a GP is required to attend an endocrine specialist. The data of 283 s4 -trans adults attending endocrine clinics and 257 new s4 trans patients registered at the GP clinic were compared, and in some analyses clinic data were compared with general Australian population statistics. They provide a snapshot of the s4 trans population in Melbourne.

The median age of the 540 patients was 27 (range 16-72) years, and 23.8% of the whole group had experienced homelessness. Of those attending the endocrine clinics 31% lived in rural or remote areas. The level of education of the s4 trans group was overall higher than an Australian age-matched population (53.4% vs 38.5% holding a university degree). Despite the higher education level, 21.3% were unemployed – four times higher than the general unemployment rate in Australia. In addition, 36% of the group were smokers, three times higher than the age-matched Australian mean. While hazardous alcohol usage was higher in those attending endocrine clinics compared to those at the GP clinic, it was still lower than the general Australian population.

Of those seeking hormone therapy at an endocrine clinic, 88.3% were assessed by a psychiatrist or psychologist experienced in gender dysphoria prior to therapy. The prevalence of depression was 55.7%, and anxiety was 40.4%, both higher than the aged matched Australian population (7.9% and 16.3% respectively). A summary of prevalence of psychiatric conditions amongst the 540 s4 trans people compared to the general Australian population is given in Table 3.

Table 3 Prevalence of psychiatric conditions compared between s4 trans adults and the general Australian population (Cheung et al. 2018)

Condition	Australian population prevalence[a] (%)	Prevalence in 540 s4 -trans GP and endocrine clinic attendees n (%)
Major depression	7.9%[b]	301 (55.7%)
Anxiety	16.3%[b]	218 (40.4%)
Bipolar disorder	1.8-3.6%	18 (3.3%)
Post-traumatic stress disorder	6.4%	24 (4.4%)
Obsessive compulsive disorder	1.9%	11 (2.0%)
Borderline personality disorder	2.7%-6%	35 (6.5%)

Other personality disorders	<1.7%	8 (1.5%)
Eating disorders	0.8%-11.1%	16 (3.0%)
Autism spectrum disorder (ASD)	0.7%	26 (4.8%)
Attention deficit/hyperactivity syndrome (ADHD)	1.1%	23 (4.3%)

GP = general practitioner; s4 trans = transgender and gender diverse people

Notes: a. Australian population prevalence is based on a median age of 27 years.

b. Refers to prevalence rates for age group 25-34 years.

Applicant comments to PASC:

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[3] https://auspath.org.au/2011/09/01/world-professional-association-for-transgender-health-standards-of-care-version-7/

[4] Coleman, Eli, et al. "Standards of care for the health of transgender and gender diverse people, version 8." *International Journal of Transgender Health* 23.sup1 (2022): S1-S259.

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Intervention

The Application is requesting MBS listing for a suite of surgical procedures that are performed for gender affirmation. Adults with gender incongruence may require one or more surgical procedures, in addition to or without hormone therapy. The s47C aim of treatment is to alleviate gender incongruence, ~~and~~ reduce the risk of gender dysphoria or psychological distress, and to improve QoL by supporting the individual to live as their defined gender. s47C

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Gender affirming surgical procedures are intended as one component of helping people with gender incongruence s47C affirm ~~to~~ their defined gender s47C. Surgeries are often but not always used in conjunction with other components such as hormone therapy, social s47C and legal steps for affirmation.

The type and number of surgeries required for those with for gender incongruence will depend on the needs of each individual s47C

Gender affirming surgical procedures would be offered in a multidisciplinary health care s47 framework, providing the best available holistic care to individuals with gender incongruence. Services (which may include medical treatments, psychological care as well as surgical procedures) would be offered and conducted by clinicians with sensitivity and experience in treating s4 trans people. Surgeries conducted for gender affirmation include:

1. Gender affirming chest surgical procedures
2. Genital reconfiguration surgical procedures
3. Gender affirming facial surgical procedures
4. Gender affirming voice surgical procedures

An individual interested in gender affirmation help would need to visit a GP, where they may ask advice on intervention options. Some people may be interested in advice and support for social transition only and would not necessarily seek surgical or medical treatment. They should have a medical history taken, general health checks and receive an assessment for gender incongruence to identify the condition. If an individual is interested in medical or surgical treatment they should be referred to an appropriate specialist or transgender health clinic.

Health care professionals likely to be involved in gender affirmation surgery are plastic surgeons, oral and maxillofacial surgeons, urologists, and ear, nose and throat surgeons. A surgeon or service provider should be appropriately qualified and have experience and training in treating s4 trans people. They need to discuss the options and likely outcomes of surgery for the individual seeking it. Some surgeries are

irreversible, so the implications need to be carefully considered. In addition, reproductive outcomes may be impacted and if this is the case, a consultation should include a discussion of reproductive needs and alternative options. All risks and benefits of a surgical procedure should be discussed prior to decision making. These discussions would be based on the protocols establishing standard of care in Australia and articulated in the Royal Australasian College of Surgeons Professional Skills Curriculum.

Some gender affirmation procedures are staged surgeries that require more than one surgical stage (or revision) and anaesthesia. The additional stages are considered part of the single primary procedure.

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Currently there are MBS items that can be used to perform some s47C revision surgeries, however access criteria for some items are restricted, making them difficult to use for the purposes of gender affirming surgery.

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Specific surgical procedures within the scope of this application ~~included~~ are described in Table 4. All gender affirming surgical procedures listed that report the relevant outcomes in adults should be included in the literature review.

Table 4 Gender affirming surgical procedures[a]

Chest surgery
Feminising chest surgery, by any method, including but not limited to, insertion of prostheses, autologous fat graft or local flaps
Masculinising chest surgery with surgical repositioning of the nipple areolar complex
Bilateral simple mastectomy in the context of gender affirming surgery
Genital reconfiguration surgery
Penectomy
Bilateral orchidectomy
Bilateral orchidectomy with scrotectomy
Construction of labia +/- neo-vagina and inset of urethra by any method using penoscrotal skin
Construction of neo-vagina by skin grafting around a mould
Construction of neo-vagina by any method using intestinal segment or peritoneal pull through technique
Subsequent stage of construction of neo-vagina surgery using local skin flaps or skin graft, where single stage surgery was not feasible
Hysterectomy with or without salpingo-oophorectomy
Construction of neo-phallus by any method using local skin flaps, first stage of a multi-staged procedure
Construction of neo-phallus by any method using local skin flaps, subsequent stage of a multi-staged procedure
Construction of neo-phallus using pedicled fascio-cutaneous regional flap (such as pedicled antero-lateral thigh flap)
Construction of neo-phallus by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap)
Construction of neo-urethra by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap)
Construction of neo-phallus by metoidioplasty (formation of penis from clitoral tissue)
Construction of neo-urethra by metoidioplasty (formation of penis from clitoral tissue) with vaginectomy
Construction of neo-urethra by metoidioplasty (formation of penis from clitoral tissue) without vaginectomy
Neo-phallus, insertion of prosthesis to

Gender affirming facial surgery
Remodelling of forehead and orbits using burring of frontal bone, including any associated advancement flap of scalp or alteration of hairline
Remodelling of the forehead and orbits using bone flap and remodelling of the frontal sinus, including any associated advancement flap of scalp and alteration of hairline
Bone genioplasty
One or more mandibular ostectomies (other than simple bony genioplasty) and mandibular reshaping if undertaken
Insertion of facial implants or bone grafts
Soft tissue surgery of the mid-face including skin advancement or local flaps to philtrum or lips and including fat grafting
(Also to be considered): Rhinoplasty
Voice surgery
Chondrolaryngoplasty

Gender affirming ~~Surgeries~~ surgeries conducted in an Australian population were s47C reported in a retrospective study of 540 s4 trans adults. (Cheung et al. 2018). The most frequently performed surgeries were mastectomy which was conducted in 99 people (58.9% of surgeries) and genital reassignment (vaginoplasty and orchidectomy) which was conducted in 37 people (22.0% of surgeries). All surgeries are listed in Table 5. Of the 540 individuals, 457 (84.6%) were on hormone therapies. In total 168 individuals (31.1%) underwent surgeries. The rates of surgery identified in this study may not be reflected in the Australian s4 trans population overall if greater access is made available due to the introduction of specific MBS items, however additional data are difficult to source.

Table 5 Surgeries conducted in transgender and gender diverse adults in Melbourne (Cheung et al. 2018)

Patient group	Surgical procedure	N (% of patient group)
Trans female (n=196)	Genital reassignment (vaginoplasty and orchidectomy)	36 (18.4)
	Genital reassignment (orchidectomy only)	4 (2.0)
	Breast augmentation	6 (3.1)
	Feminising facial surgery	5 (2.6)
	Laryngeal shave	1 (0.5)
Trans male (n=238)	Hysterectomy	14 (5.9)
	Phalloplasty	1 (0.4)
	Mastectomy	88 (40.0)
Gender nonbinary (n=99)	Orchidectomy	1 (1.0)
	Mastectomy	11 (12.1)
	Laryngeal shave	1 (1.0)
Total (n=540)	-	168 (31.1)

Applicant comments to PASC:

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Comparator(s)

The primary comparator to be used for the review of clinical safety, effectiveness, and cost effectiveness of gender affirming surgical procedures proposed to be listed on the MBS is:

1. no gender affirming surgical procedures s47C

A secondary comparator s4 should be used for a financial impact analysis only (to determine the impact of cost shifting from current MBS items to proposed MBS items, including the impact of increased utilisation):

2. gender affirmation surgery using current MBS funded items.

The MSAC guidelines (2021) state that the comparator should be the current alternative health technologies for the condition in Australia, i.e., the treatments most likely to be replaced (or added to) in clinical practice. In current practice, it is estimated that 31% of s4 trans people have undergone gender affirming surgeries, but a larger proportion are interested in having surgical procedures at some point in the future (see Table 5). Gender affirming surgeries are currently paid for by the individuals (up to $50,000)[5] (either in Australia or overseas)[6], or (for a small proportion of cases) by accessing some existing MBS items not specifically listed for the indication of gender affirmation. The Applicant clarified that only a handful of healthcare providers use existing MBS items for gender affirmation surgery (given the non-specific nature of the items)[7]. Furthermore, the Applicant noted that recent MBS amendments may mean that gender incongruence now falls outside of the scope of a number of the MBS items that providers may previously have been using for these purposes. The majority of people interested in undergoing surgical gender affirmation are therefore currently not receiving surgery, so the most appropriate comparator is s47C gender affirming surgical procedures.

The application had initially proposed that the comparator should be surgery using existing MBS items (for those procedures that can be claimed) or paid for out-of-pocket. However, it was noted by the MSAC Executive that the current MBS items encompass a number of surgical procedures that are well-established in clinical practice which did not undergo an HTA assessment before MBS listing. The MSAC Executive therefore considered that the cost-effectiveness of the comparator would need to be

[5] MSAC executive teleconference 26th May 2023
[6] Considered to be out of scope as comparators (MSAC executive teleconference, 26th May 2023)
[7] Personal communication, pre-PASC teleconference between the Department, the Applicants, and the Assessment group, 10th October 2023)

established before the cost-effectiveness of the intervention could be assessed[8]. However, as noted above, the most appropriate comparator is s47C gender affirming surgical procedures. Further, as the surgical procedures are identical for the current practice items and new proposed items (only the MBS item used would differ), it is pragmatic for the s47C assessment report to compare the safety, effectiveness and cost-effectiveness of the intervention (i.e., all gender affirmation surgical procedures) against the comparator of s47C no gender affirming surgical procedures. The change in use of current MBS items may be taken into account for the financial analyses (i.e., gender affirming surgical procedures using current MBS items is included as a secondary comparator for financial impact analysis only).

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Non-surgical care

Alongside gender affirming surgery s47C the recommended standard of care for people with gender incongruence can include medical care (hormone therapy) and s47C It can be given in a transgender health clinic setting or overseen by a GP. A holistic health clinic may offer other services as well such as social services or counselling, and legal advice.

Apart from surgical intervention, hormone therapy is the main stay of interventions sought in people with gender incongruence who seek physical transition. Hormonal therapy is not within the scope of this application.

Hormone therapy carries risks and adverse effects and requires a health assessment and ongoing monitoring. The Australian position statement on hormonal management of s4 trans adults (Cheung et al. 2019) recommends individuals should be informed of the physical changes to expect, the probable time course of changes, and the irreversibility of some changes. Treatment is likely to impair fertility, so options such as sperm or oocyte cryopreservation should be considered prior to commencing hormone therapy. The position statement reports that clinical data on hormone therapy in the s4 trans population supports its safety only short-term, and clinical evidence relating to long-term treatment is not currently available. Using a harm minimisation approach, monitoring should be given in the short and longer term. Specific risks are associated with testosterone therapy, requiring monitoring for polycythaemia, dyslipidaemia, sleep apnoea, and acne, while specific risks for estradiol therapy require monitoring for cardiovascular disease, thromboembolic disease, hypertriglyceridaemia, prolactin elevation, gall bladder disease, and breast cancer. The position statement recommends screening for cancer based on the presence of organs in s4 trans individuals, not gender identity or hormonal therapy status (Cheung et al. 2019).

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[8] Although the MSAC guidelines (2021) state that *if the comparator is listed on the MBS it may be justifiable to assume the cost-effectiveness of the comparator, even if a formal cost-effectiveness analysis has not been performed*, this statement is assumed not to be relevant in this case, as the MBS items being used are not specific to gender affirmation surgery, and are assumed not to have been added to the MBS for that purpose.

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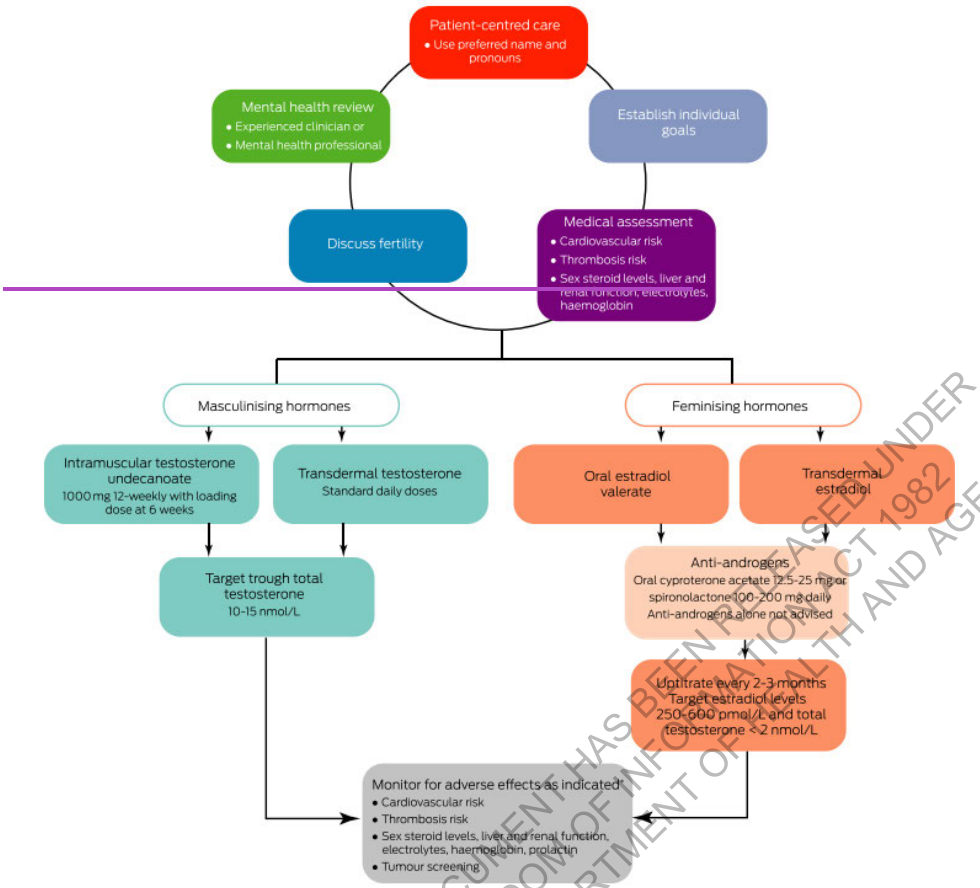

~~Figure 1 A suggested gender affirming hormone therapy algorithm (Cheung et al. 2019) (permission to reproduce this Figure has been requested from John Wiley and Sons)~~

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Outcomes

The assessment of the effectiveness of surgical procedures for gender affirmation compared to no gender affirming ~~surger~~surgical procedures~~y~~ ~~(non-surgical care only) will be focused on~~ should consider patient

s47C reported outcomes (PROs); HRQoL s47C and incidence or severity of gender dysphoria s47C The choice of surgery and desired physical result varies between individuals, but universal outcomes such as HRQoL can be measured across broad patient groups such as those undergoing chest surgery, using universal measures that apply to all surgery types. Patient outcomes should be s47C -reported as a frequency, or by the change from baseline level following surgery (or no surgery). Not all patient outcomes are relevant to all individuals, for example, suicidal ideation and suicide attempt occur only in some individuals. A change from baseline in occurrence of these outcomes should be reported in those with, and without a history of suicide ideation or attempt.

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The economic section should include a cost effectiveness analysis comparing surgical procedures with no gender affirming surgical procedures s47C and an assessment of financial impact which incorporates consideration of the number of procedures currently being performed using existing MBS items.

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Implementation issues (such as workforce capacity) should also be considered. For example, the SA Health Model of Care for Gender Diversity (2023) made an estimation of services demand for the future, finding that current services were inadequate for the current demand. Any increase in demand for multidisciplinary care services is going to require an increase in service providers, and possibly facilities. In addition, clinicians who work in the s4 -trans area will need training in competence in using the DSM and/or ICD for diagnosis, and ability to diagnose gender dysphoria and distinguish it from other conditions with similar features, among other requirements (SA Health 2023). They are therefore proposing a phased approach to implementation (focusing on timely access to 'top' surgery within 1-2 years post implementation, and timely access to 'bottom' surgery in 3-5 years post implementation) (SA Health 2023).

The outcomes relevant to the assessment are listed below.

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[redacted]

suicidal attempt (reported separately for individuals with and without a history of suicide attempt)

Safety

Procedure-related adverse events, rate of surgical complications

Revision rates and reasons for revision (i.e. e.g. revisions that are not planned as stages of a primary surgical procedure)

Cost-effectiveness

Incremental cost of proposed surgery over no surgery, estimate of ICER

Financial impact analysis

Cost of the suite of MBS items (existing verses new) accessed for gender affirmation

- MBS budget
- If relevant, other Commonwealth health budgets (e.g. PBS)
- If relevant, other health budgets (e.g. state government funding, private health insurers, patients out of pocket costs)

Other relevant considerations

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Implementation issues (e.g. workforce capacity for an increase in demand, training in s4 -trans service provision)

Applicant comments to PASC:

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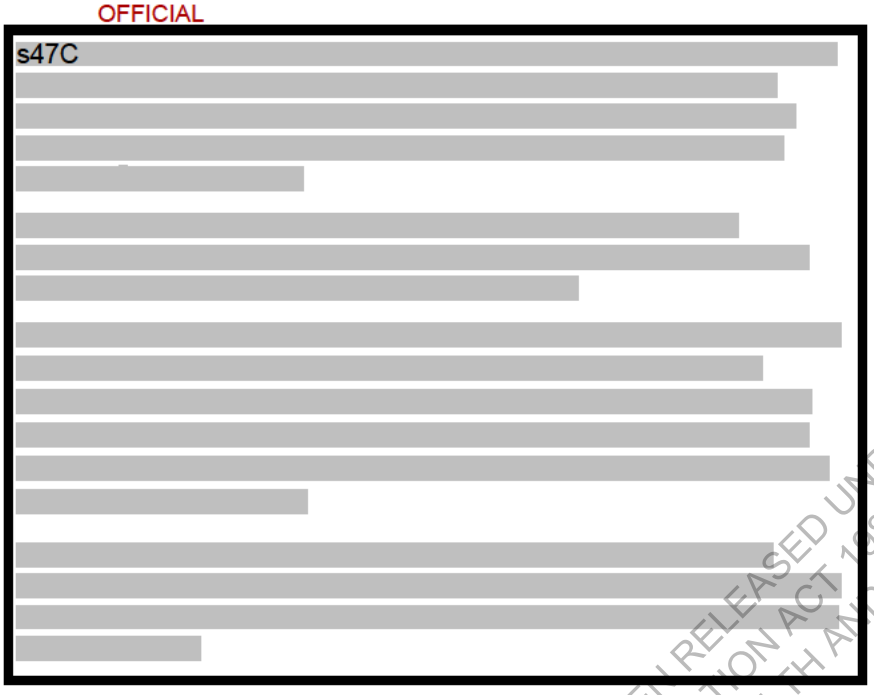

Clinical management algorithms

The current and proposed clinical algorithms are illustrated in Attachment 1 (current) and Attachment 2 (proposed).s47C

[9] http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-terms-of-reference

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Proposed economic evaluation

Table 6 provides a guide for determining which type of economic evaluation is appropriate.

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Table 6 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	**? Likely CUA**
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations

[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

The financial impact analysis for gender affirming surgery using the proposed gender MBS items will need to take into account changes in use of existing non-gender affirmation MBS items. The analysis will include the impact of increased uptake in the proposed pathway.

Applicant comments to PASC: s47C

Proposal for public funding

The Applicant proposed a suite of new items and amendments to some existing MBS items, for the purposes of gender affirmation surgery. The MSAC Executive noted that a disadvantage of using existing

MBS items is the inability for the Department to measure utilisation for the purposes of gender-affirming care[10]. New items are therefore proposed, and are grouped into chest, genital, facial and voice surgery items, alongside current MBS items which may be similar to the new items (to provide a guide for establishing the proposed fees).

The Applicant's proposal is that access to claiming the proposed MBS items would be restricted to medical practitioners that are registered specialists (who have met the training and qualification requirements set out by their professional board).

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Chest surgery items

Three items are proposed by the Applicant for gender affirming chest surgery (Table 7). Existing items on the MBS which are similar to the proposed procedures are also shown. Additional items (45523 and 45520) were also identified for similar procedures, but were specific to complete local excision of malignant tumour of the breast and unilateral rather than bilateral, so have not been shown below.

[10] MSAC Executive teleconference 1 July 2022, final ratified minutes.

Table 7 Proposed and existing MBS items applicable to chest surgery

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
Proposed MBS item Chest 1 Masculinising chest surgery, with surgical repositioning or free grafting of the nipple-areolar complex in an individual with a diagnosis of gender incongruence Suggested fee: $1,993.85 Benefit: 75% = $1,495.40	MBS item 31523 Skin sparing mastectomy (bilateral) Fee: $1,993.85 Benefit: 75% = $1,495.40
	MBS item 31529 Nipple sparing mastectomy (bilateral) Fee: $1,993.85 Benefit: 75% = $1,495.40
Proposed MBS item Chest 2 Bilateral simple mastectomy in the context of gender affirming surgery in an individual with a diagnosis of gender incongruence Suggested fee: $1,410.75 Benefit: 75% = $1,058.10	MBS item 31520 Total mastectomy (bilateral) Fee: $1,410.75 Benefit: 75% = $1,058.10
Proposed MBS item Chest 3 Feminising chest surgery, by any method, including but not limited to, insertion of prostheses, autologous fat graft or local flaps in an individual with a diagnosis of gender incongruence Suggested fee: $1,218.25 Benefit: 75% = $913.70	MBS item 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 or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes Fee: $1,218.25 Benefit: 75% = $913.70
	MBS item 45535 Autologous fat grafting, bilateral service (harvesting, preparation and injection of adipocytes) if: (a) the autologous fat grafting is for one or more of the following purposes: (i) the correction of defects arising from treatment and prevention of breast cancer in patients with contour defects, greater than or equal to 20% volume asymmetry, post-treatment pain or poor prosthetic coverage; (ii) the preparation of post mastectomy thin or irradiated skin flaps in patients intending to have breast reconstruction; (iii) breast reconstruction in breast cancer patients; (iv) the correction of developmental disorders of the breast; and (b) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes Up to a total of 4 services, other than a service associated with a service to which item 45006 or 45012 applies Fee: $1,210.90 Benefit: 75% = $908.20

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Genital reconfiguration items

Seventeen items are proposed for genital reconfiguration surgery (previously known as 'sex reassignment surgery') (Table 8).

Table 8 Proposed and existing MBS items applicable to genital surgery

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
Proposed MBS item Genital 1 Penectomy in an individual with a diagnosis of gender incongruence Suggested fee: $1,012.80 Benefit: 75% $759.60	MBS item 37405 PENIS, complete or radical amputation of Fee: $1,012.80 Benefit: 75% $759.60
Proposed MBS item Genital 2 Bilateral orchidectomy in an individual with a diagnosis of gender incongruence Suggested fee: $1660.70 Benefit: 75% = $1245.60 (based on twice the fee of MBS 30642 for unilateral orchidectomy) s47C	MBS item 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 Fee: $830.35 Benefit: 75% = $622.80
Proposed MBS item Genital 3 Bilateral orchidectomy with scrotectomy in an individual with a diagnosis of gender incongruence Suggested fee: $1660.70 Benefit: 75% = $1245.60 (based on twice the fee of MBS 30642 for unilateral orchidectomy)	
Proposed MBS item Genital 4 Construction of labia +/- neo-vagina and inset of urethra by any method using penoscrotal skin segment in an individual with a diagnosis of gender incongruence Suggested fee: $1,204.10 Benefit: 75% = $903.10 85% = $1,110.90	MBS item 35565 VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus Fee: $749.05 Benefit: 75% = $561.80
	MBS item 45563 Neurovascular island flap for restoration of essential sensation in the digits or sole of the foot, or for genital reconstruction, including: (a) direct repair of secondary cutaneous defect (if performed); and (b) formal dissection of the neurovascular pedicle; other than a service performed on simple V-Y flaps or other standard flaps, such as rotation or keystone Fee: $1,204.10 Benefit: 75% = $903.10 85% = $1,110.90
Proposed MBS item Genital 5 Construction of neo-vagina by skin grafting around a mould in an individual with a diagnosis of gender incongruence	MBS item 35565 VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus Fee: $749.05 Benefit: 75% = $561.80

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Commented [A37]: This is complex difficult surgery with no existing MBS items relevant for benchmarking.

The applicants suggests a fee in the range of $1300 to $1500

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
Suggested fee:	MBS item 45451 Full thickness skin graft to one defect, with an average diameter of 5 mm or more Fee: $518.90 Benefit: 75% = $389.20 85% = $441.10
Proposed MBS item Genital 6 Construction of neo-vagina using intestinal segment or peritoneal pull through technique in an individual with a diagnosis of gender incongruence Suggested fee: $749.05 Benefit: 75% = $561.80	MBS item 35565 VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus Fee: $749.05 Benefit: 75% = $561.80
Proposed MBS item Genital 7 Subsequent stage of construction of neo-vagina surgery using local flaps or skin graft, where single stage surgery was not feasible in an individual with a diagnosis of gender incongruence Suggested fee:	
Proposed MBS item Genital 8 Hysterectomy with or without bilateral salpingo-oophorectomy in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 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) Fee: $859.30 Benefit: 75% = $644.50
	MBS item 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) Fee: $859.30 Benefit: 75% = $644.50
	MBS item 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) Fee: $950.20 Benefit: 75% = $712.65
	MBS item 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;

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Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
	(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) Fee: $1,836.05 Benefit: 75% = $1,377.05
Proposed MBS item Genital 9 Construction of neo-phallus by any method using local skin flaps, first stage of a multi-staged procedure in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 45006 Single stage large myocutaneous flap repair to one defect (pectoralis major, latissimus dorsi, or similar large muscle), other than a service associated with a service to which any of items 45524 to 45542 apply (H) Fee: $1,136.50 Benefit: 75% = $852.40
Proposed MBS item Genital 10 Construction of neo-phallus by any method using local skin flaps, subsequent stage of a multi-staged procedure in an individual with a diagnosis of gender incongruence Suggested fee:	
Proposed MBS item Genital 11 Construction of neo-phallus using pedicled fascio-cutaneous regional flap, (such as pedicled antero-lateral thigh flap) in an individual with a diagnosis of gender incongruence Suggested fee:	
Proposed MBS item Genital 12 Construction of neo-phallus by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap) in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 45562 Free transfer of tissue (microvascular free flap) for non-breast defect involving raising of tissue on vascular pedicle, including direct repair of secondary cutaneous defect (if performed), other than a service associated with a service to which item 45564, 45565, 45567, 46060, 46062, 46064, 46066, 46068, 46070 or 46072 applies Fee: $1,204.10 Benefit: 75% = $903.10 85% = $1,110.90
	MBS item 45564 Free transfer of tissue (reconstructive surgery) for the repair of major tissue defect of the head and neck or other non-breast defect, using microvascular techniques, all necessary elements of the operation including (but not limited to): (a) anastomoses of all required vessels; and (b) raising of tissue on a vascular pedicle; and (c) preparation of recipient vessels; and (d) transfer of tissue; and (e) insetting of tissue at recipient site; and (f) direct repair of secondary cutaneous defect, if performed; other than a service associated with a service to which item 30166, 30169, 30175, 30176, 30177, 30179, 45501, 45502, 45504, 45505,

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Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
	45507, 45562 or 45567 applies—conjoint surgery, principal specialist surgeon (H) Fee: $2,788.80 Benefit: 75% = $2,091.60
	MBS item 45565 Free transfer of tissue (reconstructive surgery) for the repair of major tissue defect of the head and neck or other non-breast defect, using microvascular techniques, all necessary elements of the operation including (but not limited to): (a) anastomoses of all required vessels; and (b) raising of tissue on a vascular pedicle; and (c) preparation of recipient vessels; and (d) transfer of tissue; and (e) insetting of tissue at recipient site; and (f) direct repair of secondary cutaneous defect, if performed; other than a service associated with a service to which item 30166, 30169, 30175, 30176, 30177, 30179, 45501, 45502, 45504, 45505, 45507, 45562 or 45567 applies—conjoint surgery, conjoint specialist surgeon (H) Fee: $2,091.70 Benefit: 75% = $1,568.80
Proposed MBS item Genital 13 Construction of neo-urethra by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap) in an individual with a diagnosis of gender incongruence Suggested fee:	
Proposed MBS item Genital 14 Construction of neo-phallus by metoidioplasty (formation of penis from clitoral tissue) in an individual with a diagnosis of gender incongruence Suggested fee: $1,012.80 Benefit: 75% = $759.60	MBS item 37423 Penis, lengthening by translocation of corpora, in conjunction with partial penectomy or penile epispadias secondary repair, either as primary or secondary procedures Fee: $1,012.80 Benefit: 75% = $759.60
Proposed MBS item Genital 15 Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) with vaginectomy in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 35561 VAGINECTOMY, radical, for proven invasive malignancy - 1 surgeon (H) Fee: $1,681.20 Benefit: 75% = $1,260.90
	MBS item 35562 VAGINECTOMY, radical, for proven invasive malignancy, conjoint surgery - abdominal surgeon (including aftercare) (H) Fee: $1,416.30 Benefit: 75% = $1,062.25
	MBS item 35564 VAGINECTOMY, radical, for proven invasive malignancy, conjoint surgery - perineal surgeon (H) Fee: $708.15 Benefit: 75% = $531.15
Proposed MBS item Genital 16	

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Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) without vaginectomy in an individual with a diagnosis of gender incongruence Suggested fee:	
Proposed MBS item Genital 17 Neo-phallus, insertion of prosthesis in an individual with a diagnosis of gender incongruence Suggested fee:	

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Facial surgery items

Six items have proposed for facial surgery items, and the suggestion that three rhinoplasty may also be used (Table 9). If specific items are preferred, to monitor usage specific for the population of those with gender incongruence, then a total of nine items may be relevant (Table 10).

Table 9 Proposed and existing MBS items applicable to facial surgery

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
Proposed MBS item Facial 1 Feminising/masculinising facial surgery, remodelling of forehead and orbits using burring of frontal bone, including any associated advancement flap of scalp for alteration of hairline in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 40600 Cranioplasty, reconstructive, other than a service associated with a service to which item 39113, 39638, 39639, 39641, 39651, 39654, 39656, 39700, 39710, 39712, 39715, 39801, 39803, 40703 or 41887 applies (H) Fee: $1,045.95 Benefit: 75% = $784.50
Proposed MBS item Facial 2 Feminising /masculinising facial surgery, remodelling of forehead and orbits using bone flap and remodelling of the frontal sinus, including any associated advancement flap of scalp for alteration of hairline in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 45209 Pedicled flap repair (forehead, cross arm, cross leg, abdominal or similar), first stage of a multistage procedure Fee: $518.90 Benefit: 75% = $389.20 85% = $441.10
	MBS item 45212 Pedicled flap repair (forehead, cross arm, cross leg, abdominal or similar), subsequent stage of a multistage procedure Fee: $257.45 Benefit: 75% = $193.10 85% = $218.85
Proposed MBS item Facial 3 Feminising / masculinising facial surgery, bony genioplasty in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 45761 Genioplasty, including transposition of nerves and vessels and bone grafts taken from the same site, if: (a) the deformity: (i) is secondary to congenital absence of tissue; or (ii) has arisen from trauma (other than from previous cosmetic surgery) or a diagnosed pathological process; and

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
	(b) the service is required for maintaining lip competency; and (c) sufficient photographic evidence demonstrating the clinical need for the service is included in patient notes Fee: $819.95 Benefit: 75% = $615.00
Proposed MBS item Facial 4 Feminising/masculinising facial surgery, one or more mandibular ostectomies (other than simple bony genioplasty) and mandibular reshaping if undertaken in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 46155 Mandible, procedure for reshaping arch of, by complex segmental osteotomies, including genioplasty (if performed) and fixation by any means (including application of distractors if used), one service per patient on the same occasion (H) Fee: $1,662.20 Benefit: 75% = $1,246.65
Proposed MBS item Facial 5 Feminising/masculinising facial surgery, insertion of facial implants or bone grafts in an individual with a diagnosis of gender incongruence Suggested fee: $518.90 Benefit: 75% = $389.20	MBS item 45051 Contour reconstruction by open repair of contour defects, due to deformity, if: (a) contour reconstructive surgery is indicated because the deformity is secondary to congenital absence of tissue or has arisen from trauma (other than trauma from previous cosmetic surgery); and (b) insertion of a non-biological implant is required, other than one or more of the following: (i) insertion of a non-biological implant that is a component of another service specified in Group T8; (ii) injection of liquid or semisolid material; (iii) an oral and maxillofacial implant service to which item 52321 applies; (iv) a service to insert mesh; and (c) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes. Fee: $518.90 Benefit: 75% = $389.20
Proposed MBS item Facial 6 Feminising/masculinising facial surgery, soft tissue surgery of the mid-face including skin advancement or local flaps to philtrum and lips and including fat grafting in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 45000 Single stage local muscle flap repair, on eyelid, nose, lip, neck, hand, thumb, finger or genitals not in association with any of items 31356 to 31383 Fee: $592.85 Benefit: 75% = $444.65 85% = $503.95
	MBS item 45209 Pedicled flap repair (forehead, cross arm, cross leg, abdominal or similar), first stage of a multistage procedure Fee: $518.90 Benefit: 75% = $389.20 85% = $441.10
	MBS item 45212 Pedicled flap repair (forehead, cross arm, cross leg, abdominal or similar), subsequent stage of a multistage procedure Fee: $257.45 Benefit: 75% = $193.10 85% = $218.85

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
	MBS item 45589 Autologous fat grafting (harvesting, preparation and injection of adipocytes) if: (a) the autologous fat grafting is for either or both of the following purposes: (i) the correction of asymmetry arising from volume and contour defects in craniofacial disorders—up to a total of 4 services if each service is provided at least 3 months after the previous service; (ii) the treatment of burn scar or associated skin graft in the context of scar contracture, contour deformity or neuropathic pain, for patients who have undergone a minimum of 3 months of topical therapies, including silicone and pressure therapy, with an unsatisfactory or minimal level of improvement—up to a total of 4 services per region of the body (upper or lower limbs, trunk, neck or face) if each service provided per region of the body is provided at least 3 months after the previous such service; and (b) both: (i) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes; and (ii) for craniofacial disorders, evidence of diagnosis of the qualifying craniofacial disorder is documented in the patient notes Fee: $691.90 Benefit: 75% = $518.95

Table 10 Proposed and existing rhinoplasty MBS items

Proposed items for gender affirmation surgery	Existing items similar to proposed procedure
Proposed MBS item Facial 7 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), in an individual with a diagnosis of gender incongruence Fee: $1,167.50 Benefit: 75% = $875.65	MBS item 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 Fee: $1,167.50 Benefit: 75% = $875.65
Proposed MBS item Facial 8 Rhinoplasty, partial, involving correction of bony vault only, in an individual with a diagnosis of gender incongruence Fee: $643.55 Benefit: 75% = $482.70 85% = $550.35	MBS item 45632 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 Fee: $643.55 Benefit: 75% = $482.70 85% = $550.35
Proposed MBS item Facial 9 Rhinoplasty, partial, involving correction of one or both lateral cartilages, one or both alar cartilages or one or both lateral cartilages and alar cartilages in an individual with a diagnosis of gender incongruence Fee: $560.70 Benefit: 75% = $420.55 85% = $476.60	MBS item 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: (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 Fee: $560.70 Benefit: 75% = $420.55 85% = $476.60

Voice surgery

One item for a tracheal shave (reducing the size of the 'Adam's apple') is proposed (Table 11).

Table 11 Proposed and existing MBS items applicable to voice surgery

Proposed items for gender affirmation surgery	Existing items similar to proposed procedure
Proposed MBS item Voice 1 Chondrolaryngoplasty in an individual with a diagnosis of gender incongruence Suggested fee:	MBS item 41876 LARYNX, external operation on, OR LARYNGOFISSURE with or without cordectomy Fee: $643.55 Benefit: 75% = $482.70 85% = $550.35
	MBS item 41879 Tracheoplasty, laryngoplasty or thyroplasty, not by injection techniques, including tracheostomy, other than a service associated with a service to which item 41870 applies (H) Fee: $1,042.80 Benefit: 75% = $782.10

Applicant comments to PASC: s47C

Summary of public consultation input

[Instructional text] After the PASC meeting, a summary of de-identified consultation feedback received before the PASC meeting is inserted by the department. [End instructional text]

Applicant comments to PASC: s47C

Next steps

[Instructional text]

After the PASC meeting, insert the next steps.

For example:

PASC advised that, upon ratification of the post-PASC PICO, the application can proceed to the Evaluation Sub-Committee (ESC) stage of the MSAC process.

PASC noted the applicant has elected to progress its application as an ADAR (Applicant Developed Assessment Report).

[End instructional text]

Applicant comments to PASC:

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Attachment 1: Current care pathway

Attachment%201_Current%20Care%20P

Attachment 2: Proposed care pathway

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References

Bretherton, I, Thrower, E, Zwickl, S, Wong, A, Chetcuti, D, Grossmann, M, et al. 2020, 'The Health and Well-Being of Transgender Australians: A National Community Survey', LGBT Health, vol. 8, no. 1, 2021/01/01, pp. 42-49.

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