

## **MSAC Application 1754**

### **Surgical procedures for gender affirmation in adults with gender incongruence**

# **PICO Confirmation**

## 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	Adults with diagnosed gender incongruence that is marked and sustained who are electing to pursue gender affirming surgical procedures
Intervention	<p>One or more gender affirming surgical procedure(s), including first and subsequent stages of a multistage procedure.</p> <p>Gender affirming chest surgery:</p> <ol style="list-style-type: none"> <li>1. Feminising chest surgery by any method, including but not limited to insertion of prostheses, autologous fat graft or local flaps</li> <li>2. Masculinising chest surgery with surgical repositioning of the nipple areolar complex</li> <li>3. Bilateral simple mastectomy</li> </ol> <p>Genital reconfiguration surgery:</p> <ol style="list-style-type: none"> <li>4. Penectomy</li> <li>5. Bilateral orchidectomy</li> <li>6. Bilateral orchidectomy with scrotoectomy</li> <li>7. Construction of labia +/- neo-vagina and inset of urethra by any method using penoscrotal skin</li> <li>8. Construction of neo-vagina by skin grafting around a mould</li> <li>9. Construction of neo-vagina using intestinal segment or peritoneal pull through technique</li> <li>10. Subsequent stage of construction of neo-vagina surgery using local flaps or skin graft, where single stage surgery was not feasible</li> <li>11. Hysterectomy with or without bilateral salpingo-oophorectomy</li> <li>12. Construction of neo-phallus by any method using local skin flaps, first stage of a multi-staged procedure</li> <li>13. Construction of neo-phallus by any method using local skin flaps, subsequent stage of a multi-staged procedure</li> <li>14. Construction of neo-phallus using pedicled fascio-cutaneous regional flap (such as pedicled antero-lateral thigh flap)</li> <li>15. Construction of neo-phallus by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap)</li> <li>16. Construction of neo-urethra by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap)</li> <li>17. Construction of neo-phallus by metoidioplasty (formation of penis from clitoral tissue)</li> <li>18. Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) with vaginectomy</li> <li>19. Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) without vaginectomy</li> <li>20. Neo-phallus, insertion of prosthesis to</li> </ol>

Component	Description
	<p>Gender affirming facial procedures:</p> <ol style="list-style-type: none"> <li>21. Remodelling of the forehead and orbits using burring of frontal bone, including any associated advancement flap of scalp for alteration of hairline</li> <li>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</li> <li>23. Bone genioplasty</li> <li>24. One or more mandibular ostectomies (other than simple bone genioplasty) and mandibular reshaping if undertaken</li> <li>25. Insertion of facial implants or bone grafts</li> <li>26. Soft tissue surgery of the mid-face including skin advancement of local flaps to philtrum and lips and including fat grafting</li> <li>27. Rhinoplasty</li> </ol> <p>Gender affirming voice surgery:</p> <ol style="list-style-type: none"> <li>28. Chondrolaryngoplasty</li> </ol>
Comparator/s	<ol style="list-style-type: none"> <li>1. No gender affirming surgical procedures</li> <li>2. Gender affirming surgical procedures using current MBS items (for financial impact analysis only)</li> </ol>
Outcomes	<p>Safety</p> <ul style="list-style-type: none"> <li>• Surgery associated complications and adverse events both in the short term (perioperative period) and longer term</li> <li>• Rates of revision surgery for complications/suboptimal surgical outcomes</li> </ul> <p>Effectiveness - primary</p> <ul style="list-style-type: none"> <li>• Health-related quality of life (HRQoL)</li> <li>• Change in incidence, or the severity of gender dysphoria (from baseline)</li> </ul> <p>Effectiveness - secondary</p> <ul style="list-style-type: none"> <li>• Functional outcomes of surgery (e.g. incidence of categories of urinary incontinence, sexual performance)</li> <li>• Patient satisfaction/regret, reason(s) for regret (rate of de-transition)</li> <li>• Patient reported outcomes (PROs)</li> <li>• Long-term effect on health status (e.g. bone health or risk of cancer)</li> <li>• Frequency/severity of psychological disorders (change from baseline)</li> <li>• Frequency/severity of suicide ideation (change from baseline)</li> <li>• Frequency of suicide attempt (change from baseline)</li> </ul> <p>Health care resource use</p> <p>Cost-effectiveness</p> <p>Net financial impact</p> <ul style="list-style-type: none"> <li>• MBS budget</li> </ul>

Component	Description
	<ul style="list-style-type: none"> <li>• If relevant, other Commonwealth health budgets</li> <li>• If relevant, other health budgets (e.g. state government funding, private health insurers, patients out of pocket costs)</li> </ul> <p>Other relevant issues</p> <ul style="list-style-type: none"> <li>• Ethics analysis – implications for autonomy and identity (personal, familial, communal; see also Appendix A)</li> <li>• Legal implications (e.g. influence of gender affirmation surgery on ability to change legal sex on birth certificate)</li> <li>• Societal implications</li> <li>• Implementation issues (e.g. workforce availability, training in trans-affirming and gender affirming service provision, state and territory elective surgery and waitlist policy barriers)</li> </ul>
Assessment questions	<ol style="list-style-type: none"> <li>1. What is the safety, effectiveness and cost-effectiveness of gender affirmation surgery versus no surgery in adults diagnosed with gender incongruence?</li> <li>2. What is the financial impact of adding specific gender affirming surgical procedure items to the MBS versus the current scenario where some existing generic surgical procedures available on the MBS are used to perform gender affirming surgery, and some gender affirming surgical procedures are not publicly funded?</li> </ol>

MBS = Medical Benefits Services; PBS = Pharmaceutical Benefits Scheme

## 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. The Department considers that existing items may be used for the services proposed by the Applicant. The Department considers that changes to the consultation and chronic disease MBS items are not necessary to permit access to these items for people with gender incongruence as the current arrangements apply to all conditions where multidisciplinary care is required. The Department notes that the Chronic Disease Management items and Health Assessment items are currently under review as part of the MBS Review Taskforce program of 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 may be a potential alternative to developing new MBS items (MSAC Executive teleconference, 26<sup>th</sup> May 2023).

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.

*PASC noted Department advice that current MBS items for GP management plans and mental health treatment plans are available to all patients, including those with a diagnosis of gender incongruence. It was also noted that case conferencing items are currently already available for use by primary care clinicians and consultant physicians providing care to those seeking both diagnosis and treatment in the setting of gender incongruence. The Department advised that there is a known gap, which can be addressed outside of the Health Technology Assessment (HTA) process, for case conferencing items to be used by specialists working in this area.*

### **Clinical claims**

The clinical claim is:

- The use of the MBS funded gender affirmation surgical procedures results in **inferior safety and superior health outcomes** compared to no gender affirmation surgical procedures.

The clinical, economic and financial assessment should focus on the comparison of proposed gender affirmation surgery compared with no surgery. This may be supplemented with a financial impact scenario analysis only comparing the proposed intervention with the secondary comparator (Gender affirming surgical procedures using existing non-gender affirmation MBS items) if the applicant can provide specific data to inform this comparison.

## PICO criteria

### **Population**

The population for this application is adults with diagnosed gender incongruence that is marked and sustained who are electing to pursue gender affirming surgical procedures. *This was confirmed by PASC.*

Gender incongruence is described as an ICD-11 sexual health condition whereby an individual understands their gender to be different from that presumed for them at birth and is pursuing medical gender affirmation.

The World Health Organization (WHO) ICD-11 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<sup>1</sup>:

“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.”

*While the International Classification of Diseases – 11<sup>th</sup> edition (ICD-11) states that gender incongruence is a condition where an individual understands their gender to be different from that presumed for them at birth, it does not provide specific diagnostic criteria. PASC noted that there is no detailed diagnostic criteria to assist clinicians in making a diagnosis, or to define the duration of sustained gender incongruence, and that it can be difficult to determine when the incongruence starts. The World Professional Association for Transgender Health (WPATH) Standard of care for the health of transgender and gender diverse people version 8 guidelines<sup>2</sup> do not recommend any set period of social transition prior to surgery and there is no timeframe to define “marked and persistent” gender incongruence.*

*PASC noted that the applicant’s preference that specifying that patients must have a ‘diagnosis’ of gender incongruence rather than ‘experiencing’ gender incongruence, which the applicant considered would strengthen the criteria used to establish the eligible population.*

The Applicant proposed that no other restrictions be placed on eligibility for gender affirming surgery other than a presentation with gender incongruence, except for limiting the surgery to adults. There are no specific tests or criteria proposed to determine a person is a candidate for gender affirming surgery. The applicant has proposed that a diagnosis of gender incongruence should only require one practitioner to be confirmed. The confirmation/diagnosis would most often be made by a general practitioner. The diagnosing clinician will need to rule out other causes of apparent 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.

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<sup>1</sup> [ICD-11 for Mortality and Morbidity Statistics \(who.int\)](https://www.who.int/iaeg/publications/morbidity)

<sup>2</sup> [Standards of Care - WPATH World Professional Association for Transgender Health](https://www.wpath.org/standards-of-care)

*The Applicant stated the diagnosis of gender incongruence occurs in the primary care setting and is not a psychiatric diagnosis, and does not necessarily warrant psychiatric or psychological assessment prior to referral for surgery. PASC considered that although the diagnosis may be made by a single GP, not all GPs may be qualified to recognise and assess people with gender incongruence, in particular to exclude other causes of apparent gender incongruence. PASC considered a multidisciplinary care setting is the preferred setting for the assessment of individuals seeking gender affirmation treatment as they could be accurately diagnosed and be offered a range of services from qualified providers.*

Among transgender and gender diverse people (referred to as trans people for brevity) are those who experience gender incongruence and will seek medical and/or surgical interventions for gender affirmation. 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 may also experience gender dysphoria. 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 trans population (Cheung et al. 2019). The surgical or medical interventions sought for transition are an 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.

*PASC noted that gender incongruence is classified under conditions related to sexual health rather than a mental condition in ICD-11. WPATH Standards of Care note that while psychometric assessments, psychotherapy or counselling specifically focused on trans identity may be useful, they are not a requirement prior to the initiation of gender affirming medical or surgical treatments. PASC advised that other possible causes of apparent gender incongruence should be excluded. PASC advised the need for multidisciplinary assessment as part of confirming suitability for gender affirming surgery. The applicant agreed that patients should be able to access multidisciplinary care but considered that not all patients will require input from a mental health professional (a psychologist or psychiatrist) as a part of the pre-surgery multidisciplinary assessment. PASC noted that consultation input from consumers and consumer organisations and specialty colleges strongly supported a multidisciplinary approach. This included appropriate support for sexual and reproductive health.*

*The WPATH Standards of Care also note that while the role of social transition should be considered with the individual, social transition prior to treatment for gender incongruence should not be a requirement for eligibility as not all individuals with a diagnosis of gender incongruence require, are able to or wish to socially transition. PASC discussed that non-binary patients may not choose to dress as the alternate gender or use hormonal therapy, but may still wish to access surgery for gender incongruence, and that this patient group should not inadvertently be excluded from the proposed items. However, for patients seeking gonadectomy, the WPATH Standards of Care suggest that a minimum of six months of hormone therapy is recommended before irreversible surgical intervention; this may be reflected in eligibility criteria for the proposed gonadectomy items.*

#### *Care pathway and prognosis*

Many trans people experience higher levels of stigma, discrimination, abuse and violence, than their non-trans counterparts. As a result, they may live in poorer social and economic conditions and be marginalised. In addition, trans people may have poorer physical health and higher rates of 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 trans people may avoid seeking medical care because of a fear of discrimination (Cheung et al. (2019).

Recently, one Australian study found that trans people have higher rates of depression (58% vs 8%) and anxiety (40% vs 16%) compared to an age-matched Australian population (Cheung et al. 2018). Further recent Australian studies have found that 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 trans adults attempt suicide 10 times more often than the general Australian population (Zwickl et al. 2021). In the latter study, suicidality was found to be associated with wanting gender affirming surgery, gender-based victimisation and institutionalised cissexism.

An Australian position statement on hormonal management of 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 (GP, physician, psychiatrist, or psychologist). In the absence of a pathway to surgery with funding support, clinicians may choose to use MBS items intended for other conditions, trans individuals may fund surgery themselves, or trans individuals may seek surgery in countries where it is cheaper than in Australia.

#### *Australian demographics of gender incongruence*

Health data on the 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 trans in a study of 17 western culture countries who use similar definitions. Although the proposal is for gender affirming surgery to be available to anybody over the age of 18 years with gender incongruence and wishing to undergo surgery (that is, there is no upper age limit proposed), it is expected that the age group in whom most procedures will occur is between 18 and 50 years of age. This age range was used for the purposes of estimating the size of the population likely to seek gender affirmation surgery. Using an estimate of 1.05% (the midpoint of these data according to (Cheung et al. 2018)) of the ABS population data for those aged between 18 and 50 years, there may be approximately 64,101 trans people presumed male at birth (trans women and non-binary) and 64,044 trans people presumed female at birth (trans men and non-binary) birth in Australia in 2023. However, specific data are not available and the expected population remains highly uncertain. In addition, 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 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 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<sup>3</sup> who:

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<sup>3</sup> Excluding those participants who selected that their sex was assigned intersex at birth



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

At the time the survey was conducted (from September 2017 to January 2018), of those presumed male at birth who responded to survey questions on surgery, 82% had either undergone prior genital reconfiguration surgery (the most common surgery amongst this population group; 71/384, 18%) or wanted genital reconfiguration in the future (243/384, 64%). Of those presumed female at birth who responded to the survey questions on surgery, 89% had either undergone prior mastectomy/chest surgery (the most common surgery in this population; 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 trans women and non-binary (presumed male at birth) people aged 18 to 50 years 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 birth assigned trans men and non-binary people (presumed female at birth) aged 18 to 50 years 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 <sup>a</sup>	Australia 2023 <sup>b</sup>	Survey data	Australia 2023	Survey data	Australia 2023
<b>Trans women and non-binary presumed male at birth (total surveyed: N=403)</b>						
Breast augmentation (N=362) <sup>c</sup>	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
<b>Trans men and non-binary presumed female at birth (total surveyed: N=520)</b>						
Chest surgery/mastectomy (N=511) <sup>c</sup>	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 trans adults surveyed in (Bretherton et al. 2020)

b. Data is sourced from the rate of 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: trans women and non-binary birth-assigned males: n = 64,101; trans men and non-binary 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 trans adults, 10% had undergone feminising surgeries, and 21.1% had undergone prior masculinising surgery, a total of 31.1% of 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 trans services has been reported. A 10-fold increase in the number of 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 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 trans people (aged 14-25 years) reported that 6.3% of 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 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 trans adults attending endocrine clinics and 257 new 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 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 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 trans people compared to the general Australian population is given in Table 3.

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

Condition	Australian population prevalence <sup>a</sup> (%)	Prevalence in 540 trans GP and endocrine clinic attendees n (%)
Major depression	7.9% <sup>b</sup>	301 (55.7%)
Anxiety	16.3% <sup>b</sup>	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

**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.

### **Intervention**

The Application requested 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.

Gender affirming surgical procedures are intended as one component of helping people with gender incongruence affirm their defined gender. Surgeries are often but not always used in conjunction with other components such as hormone therapy, social 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. It is proposed that gender affirming surgeries are offered as a suite of procedures to individuals, and also assessed as a suite of procedures for their impact on gender dysphoria and HRQoL.

*PASC confirmed the intervention was a suite of gender affirming surgical procedures. This would ideally be provided in addition to other forms of gender affirmation care as relevant for the individual (including medical, psychological, social).*

Gender affirming surgical procedures should be offered in a multidisciplinary health care 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 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, if available.

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 should be appropriately qualified and have experience and training in treating trans people. They need to discuss the options and likely outcomes of surgery for the individual seeking it. Many 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. The applicant advised that 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.

*PASC considered people with gender incongruence should receive care in a supportive and inclusive environment and that it was important that all people involved in providing health care should use appropriate language.*

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.

*PASC noted that the intervention included revision surgery where the procedure is performed over multiple stages or to refine a suboptimal surgical outcome. PASC confirmed the intervention does not include reversal procedures. It was noted at the meeting that multiple revisions undertaken when a more extreme cosmetic outcome is desired, rather than for a medically indicated correction, may not fall within the rules of the MBS.*

Currently there are MBS items that can be used to perform some of these surgeries, however access criteria for some items are restricted, making them difficult to use. Specific surgical procedures within the scope of this application are described in

Table 4 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**

<b>Chest surgery</b>
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
<b>Genital reconfiguration surgery</b>
Penectomy
Bilateral orchidectomy
Bilateral orchidectomy with scrotoectomy
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
<b>Gender affirming facial surgery</b>
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 osteotomies (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
<b>Voice surgery</b>
Chondrolaryngoplasty

Gender affirming surgeries conducted in an Australian population were reported in a retrospective study of 540 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 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)

### **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.

A secondary comparator could 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, and the applicant should aim to provide specific data to inform this comparison):

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 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)<sup>4</sup> (either in Australia or overseas)<sup>5</sup>, 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 small number of healthcare providers use existing MBS items for gender affirmation surgery (given the

<sup>4</sup> MSAC executive teleconference 26<sup>th</sup> May 2023

<sup>5</sup> Considered to be out of scope as comparators (MSAC executive teleconference, 26<sup>th</sup> May 2023)

non-specific nature of the items)<sup>6</sup>. 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 no 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 established before the cost-effectiveness of the intervention could be assessed<sup>7</sup>. However, as noted above, the most appropriate comparator is no 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 Assessment Report to compare the safety, effectiveness and cost-effectiveness of the intervention (i.e., all gender affirmation surgical procedures) against the comparator of 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).

#### *Non-surgical care*

Alongside gender affirming surgery, the recommended standard of care for people with gender incongruence can include medical care (hormone therapy) and psychological or psychiatric care. 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.

The applicant has advised that hormonal therapy is not within the scope of this application. Apart from surgical intervention, hormone therapy is the main stay of interventions sought in people with gender incongruence who seek physical transition. Hormone therapy carries risks and adverse effects and requires a health assessment and ongoing monitoring. An Australian position statement on hormonal management of trans adults (Cheung et al. 2019) recommends individuals should be informed of the physical changes to expect with hormonal therapy, 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 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

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<sup>6</sup> Personal communication, pre-PASC teleconference between the Department, the Applicants, and the Assessment group, 10<sup>th</sup> October 2023)

<sup>7</sup> 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.



for cancer based on the presence of organs in trans individuals, not gender identity or hormonal therapy status (Cheung et al. 2019).

Other non-surgical management strategies can also be used. Voice training by a speech therapist can be initiated for the feminisation or masculinisation of the voice. Removal or permanent changes to facial and body hair can also be offered professionally. Chest binding is one technique used when mastectomy is not an option. Chest binding is used to reduce the appearance of breasts, but tight compression can also carry risks such as severe skin irritation, bruising and cracked ribs. The position statement recommends correctly sized commercially purchased binders and limiting their use to 8-12 hours per day. Similarly, genital tucking can minimise the appearance of genitals, and specialty garments are available to do this, although there are similar risks to those with chest binding. There are no data on the safety of this practice however (Cheung et al. 2019).

*PASC confirmed that the comparator should be “no surgery” for the assessment of safety, effectiveness, and cost-effectiveness. It was noted that “no surgery” is defined as what occurs in the absence of surgery. In this scenario services would include other interventions used by people with gender incongruence, including hormonal therapy. PASC noted that hormonal therapy is commonly used before and after surgery to help optimise surgical outcomes.*

*PASC considered it reasonable to assume that all other forms of gender affirmation care (medical, psychological, social) are equivalent between intervention and comparator groups. PASC noted that the Applicant considered that endocrine therapy or psychiatric care are not an alternative to surgery. Hormone therapies are not registered on the Australian Therapeutic Goods Register (ARTG) and/or reimbursed on the PBS for use by people diagnosed with gender incongruence.*

## **Outcomes**

The assessment of the effectiveness of surgical procedures for gender affirmation compared to no gender affirming surgery should consider health-related quality of life (HRQoL) and the incidence or severity of gender dysphoria as the primary outcome measures. Gender dysphoria is defined in the Diagnostic Statistical Manual Fifth edition text revision (DSM-5-TR) as clinically significant distress or impairment related to gender incongruence, which may include desire to change primary and/or secondary sex characteristics. 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 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.

The assessment of safety of surgical procedures for gender affirmation will need to be determined by type of procedure as outcomes such as adverse events and complications are specific to surgical procedure. The applicant considered the rate and nature of adverse events reported in literature for gender affirming surgeries should inform the assessment of safety. The applicant also considered that a comparison of safety outcomes reported for similar surgical procedures performed in gender affirming and non-gender affirming contexts would provide an additional relevant assessment of safety.

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

A consideration of other relevant issues should be included. This section would be considered separately to the clinical evidence and economic analysis but includes issues that may impact MSAC decision making for the proposed new items. The section could comprise a review or analysis of ethical considerations (including considerations relating to autonomy and identity), as well as legal and social implications. The impact of gender affirmation surgery on mental health can be influenced by societal reactions to the individuals. For example, if discrimination occurs in people who have undergone gender affirmation surgery, a small proportion of individuals may regret having undergone surgery, however this should not be interpreted to mean that the individuals would regret the surgery if the situation were different. An extended list of recommended issues for ethics consideration is given in Appendix A Additional information.

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 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.

### Effectiveness

#### Primary effectiveness outcomes

- Change in HRQoL
- Change in incidence, or the severity, of gender dysphoria (from baseline)

#### Secondary effectiveness outcomes

- Functional outcomes of surgery (e.g. incidence of categories of urinary incontinence, sexual performance)
- Change in body satisfaction/attitude/image
- Satisfaction/regret with procedure, reason(s) for regret, rate of detransition
- Other patient reported outcomes (PROs)
- Long-term effect on health status (e.g. bone health or risk of cancer)
- Change in incidence, frequency and severity of psychological disorders (separately reported for individuals with and without a history of psychological disorder)
- Change in suicide ideation (reported separately for individuals with and without a history of suicide ideation)
- Change in suicidal attempt (reported separately for individuals with and without a history of suicide attempt)

## Safety

- Surgery associated complications and adverse events both in the short term (perioperative period) and longer term
- Rates of revision surgery for complications/suboptimal surgical outcomes

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

## Other relevant considerations

- Ethics analysis – implications for autonomy and identity (personal, familial, communal) (see further items suggested for ethics analysis in Appendix A)
- Legal implications (e.g. influence of gender affirmation surgery on ability to change legal sex on birth certificate)
- Societal implications (e.g. the impact of social acceptance on well-being)
- Implementation issues (e.g. workforce capacity for an increase in demand, training in trans-affirming and gender affirming service provision, state and territory elective surgery and waitlist policy barriers)

*PASC agreed that it was appropriate to present outcomes as primary and secondary outcomes as drafted by the assessment group, according to standard HTA approaches and MSAC guidelines.*

*PASC confirmed that the primary outcomes should be HRQoL, and change in incidence or severity of gender dysphoria.*

*PASC noted that there would be challenges in measuring some outcomes as patients may have different experiences with gender incongruence. PASC noted that patients with gender incongruence who are also experiencing gender dysphoria may experience outcomes that are not experienced by patients who have gender incongruence without gender dysphoria. Therefore, the assessment could consider separately assessing clinical outcomes in the subgroup with gender dysphoria and those without. Likewise, PASC considered that it may be more informative for some outcomes to be assessed as a change in baseline for patients with and without a history of that outcome where possible (e.g. suicidal ideation and suicide attempt). That is, the assessment should assess the change in incidence of suicidal ideation or attempt among those with no prior history of suicidal ideation, with and without surgery and separately present the change in severity or recurrence of suicidal ideation or attempt among those with past or current symptoms with and without surgery.*

*Outcomes should include the assessment of satisfaction and/or regret, and the rates of detransition. PASC agreed with the applicant's comments that dissatisfaction with surgical outcomes (which is not uncommon) and regret about the decision to have surgery/transitioning (less common) could be considered separate outcomes.*

*The financial impact analysis outcomes should not have explicit mention of PBS, since the application does not encompass the use of medical therapy.*

PASC advised that ethical, legal and social considerations should be considered in the assessment report and that these are relevant for MSAC's consideration as outlined in the MSAC Guidelines.

## **Clinical management algorithms**

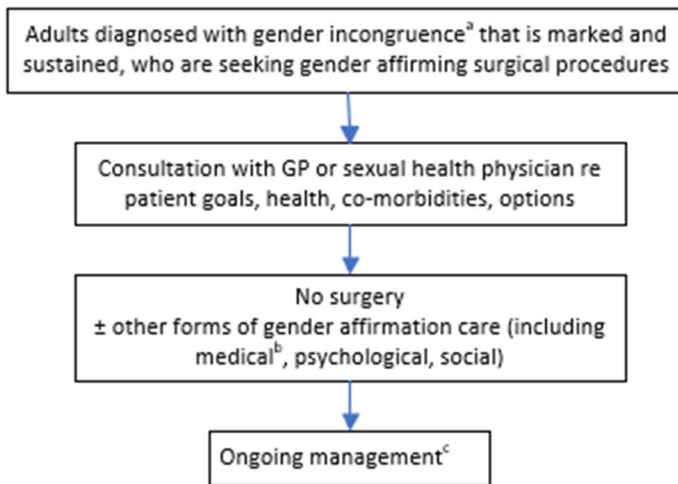
The current and proposed clinical algorithms are illustrated in Figure 1 and Figure 2 respectively.

*PASC noted the clinical algorithms developed by the assessment group and also the alternative algorithms presented in the applicant's pre-PASC response. PASC noted the positioning of MDT in the applicant's alternative algorithm appeared to be later in the management pathway. PASC considered that the clinical management algorithms should be updated to depict multidisciplinary care and assessment earlier in the clinical algorithm, prior to surgery.*

### ***Current clinical pathway for non-surgical care only in adults with gender incongruence***

Under the current clinical pathway individuals with gender incongruence would seek help firstly through their GP, who is likely to provide a physical and mental health assessment. Should the patient be seeking hormone therapy the GP may initiate this, or they may provide a referral to an endocrine specialist. Hormone therapies have risks and side effects, so will need to be monitored – 3-monthly initially, then less frequently once stabilised on therapy. Monitoring of mental health is also important – particularly the primary outcomes described in this PICO document (change in gender incongruence, and separately, gender dysphoria and HRQoL). Monitoring may be performed by the GP initiating treatment.

Although many trans people may currently self-fund gender affirmation surgery, this is not considered part of the comparator for the purposes of establishing the safety and effectiveness of the surgical procedures and is therefore not illustrated in Figure 1.



**Figure 1 Clinical practice for management and treatment of adults with gender incongruence in the absence of surgery for gender affirmation**

AE = adverse event; HRQoL = health-related quality of life

**Notes:** a. Adults assessed using The World Health Organization (WHO) International Classification of Diseases – 11<sup>th</sup> edition (ICD-11) HA60

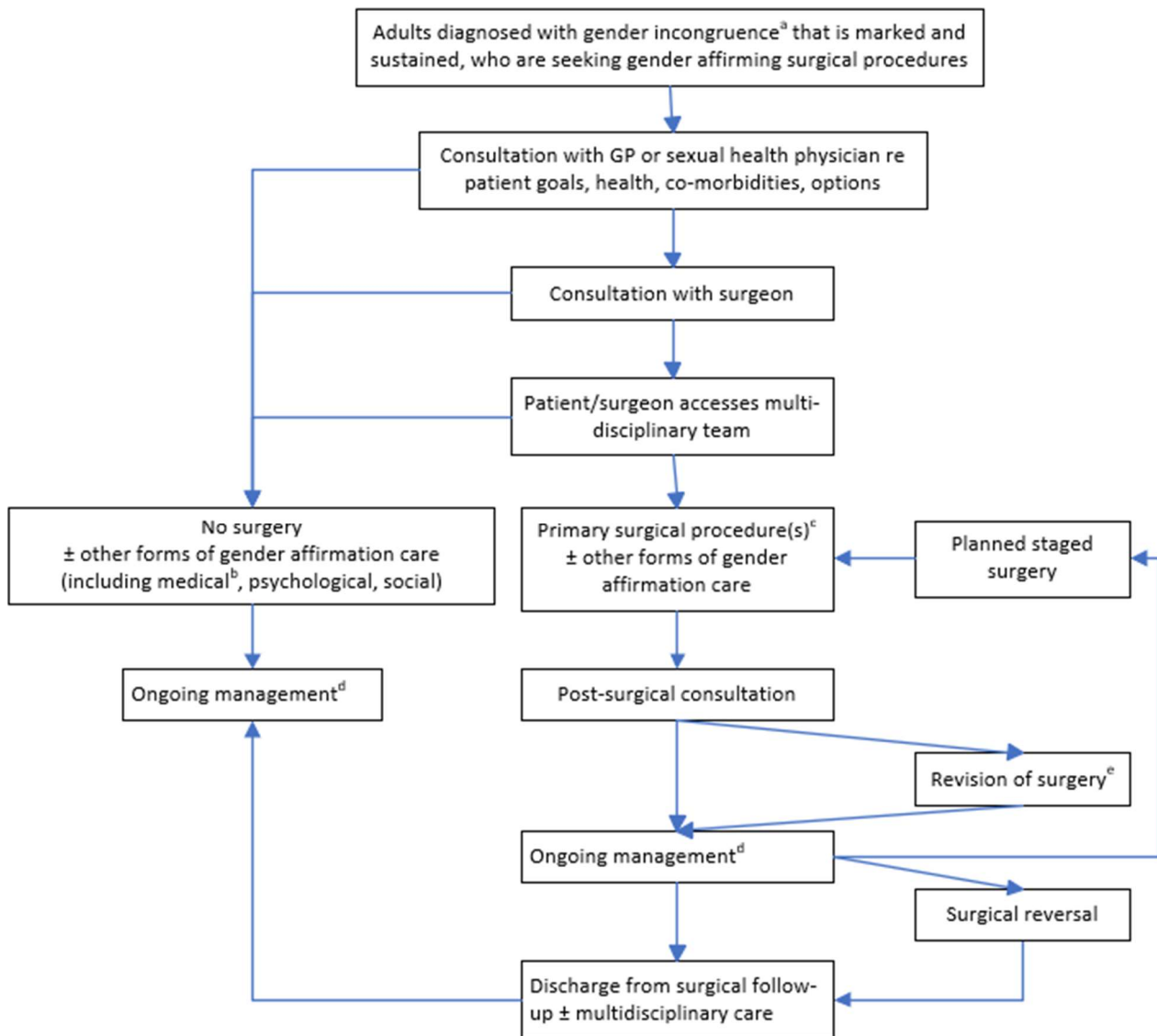
b. Medical therapies include estradiol and testosterone therapies. See also (Cheung et al. 2019) for more information on hormone regimens.

c. Including assessment of outcomes

### ***Proposed clinical pathway for gender affirming surgery in adults with gender incongruence***

For the proposed pathway, individuals with gender incongruence may approach their GP for help initially as in current practice, where health evaluation will be performed. The GP will be able to refer the person to a surgical specialist if surgery is sought. After consultation with a surgeon, and prior to undergoing surgery, assessment by a multi-disciplinary team should occur. Following a surgical procedure, management would include monitoring for surgery-related adverse events and complications. There may be follow-up stages of the surgical procedure to carry out. Additional and previously unplanned revision surgery would not be considered as part of the primary surgery. Once the surgery is completed, an individual should continue to be monitored, but this may be performed by the GP, rather than the surgeon or multi-disciplinary team.

Under both current and proposed clinical pathways, individuals may be offered or already undergoing additional services. These include psychological or psychiatric services, social services, counselling, and legal advice. Hair removal services, and speech therapy are among others that are available to all individuals in both pathways.



**Figure 2 Clinical practice for management and treatment of adults with gender incongruence including surgery for gender affirmation**

AE = adverse event; HRQoL = health-related quality of life

**Notes:** Clinical algorithms amended based on advice from the applicant and PASC

a. Adults assessed using The World Health Organization (WHO) International Classification of Diseases – 11<sup>th</sup> edition (ICD-11) HA60

b. Medical therapies include estradiol and testosterone therapies. See also (Cheung et al. 2019) for more information on hormone regimens.

c. Individuals may or may not be undergoing medical therapy. Primary surgical procedures include gender affirming surgeries for the chest, genitals, face, and voice.

d. Including assessment of outcomes

e. Additional and previously unplanned revision surgery that would not be considered as part of the primary surgery

## Proposed economic evaluation

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

Based on a clinical claim of inferior safety and superior effectiveness, the proposed economic evaluation for gender affirmation surgery compared to no surgery in adults diagnosed with gender incongruence is likely to be a cost-utility analysis (CUA). A supplementary cost-consequences analysis may be useful to demonstrate specific health outcomes of interest that are not obvious in an aggregated evaluation.

*PASC noted and agreed with advice from the MSAC Executive that this application should progress as a two-stage assessment, where the first stage would be to assess and present the comparative clinical evidence, so that ESC and MSAC may provide guidance on the appropriate economic evaluation to be performed that would align with the clinical claim and be supported by the available evidence. The second stage would present the economic evaluation and financial analysis to ESC and MSAC.*

**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 <sup>a</sup>	Noninferior <sup>b</sup>	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain <sup>a</sup>	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior <sup>b</sup>	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

<sup>a</sup> '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

<sup>b</sup> An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

If it is possible for the applicant to find specific data on the use of existing non-gender affirmation MBS items being used for the purposes of gender affirmation, then a supplementary financial impact scenario analysis is suggested. This analysis would compare the financial impact of introducing the proposed gender affirmation surgical MBS items compared to the use of existing non-gender affirmation MBS items. The analysis will include the impact of increased uptake in the proposed pathway.

## 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<sup>8</sup>. New items are therefore proposed, and are grouped into chest, genital, facial and voice surgery

<sup>8</sup> MSAC Executive teleconference 1 July 2022, final ratified minutes.

items, alongside current MBS items which may be similar to the new items (to provide a guide for establishing the proposed fees). Some of the proposed MBS items do not have an equivalent MBS item, or have multiple equivalent MBS items proposed, so it is unclear what the appropriate fee should be. Appropriate fees will need to be proposed and justified prior to the economic and financial analysis.

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).

For the purposes of MBS listing, item descriptors should differentiate the items where the Multiple Operation Rule should apply or alternatively which items are considered a "complete service" meaning no other T8 items can be claimed on the same day.

*PASC noted the proposed new MBS items and amendments to existing MBS items, and noted MSAC Executive's comments that a disadvantage of using existing MBS items is the inability for the Department to measure utilisation for the purpose of gender affirming care.*

*PASC considered that the requirement for pre-surgical multidisciplinary assessment should be included in an explanatory note for the item descriptors. This will help ensure patients receive the appropriate surgical intervention. PASC identified the involvement of an MDT pre-surgery would be consistent with other complex surgical interventions that have MBS funded case conference items.*

*It was noted by PASC, that for the purposes of MBS listing, item descriptors should clearly differentiate where there is a clinical or functional need for a service, versus where the service might be considered cosmetic. The applicant will need to address this in the assessment.*

### **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 in the following table.



**Table 7 Proposed and existing MBS items applicable to chest surgery**

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
<p>Proposed MBS item Chest 1</p> <p>Masculinising chest surgery, with surgical repositioning or free grafting of the nipple-areolar complex in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee: \$1,993.85 Benefit: 75% = \$1,495.40</p>	<p>MBS item 31523</p> <p>Skin sparing mastectomy (bilateral)</p> <p>Fee: \$1,993.85 Benefit: 75% = \$1,495.40</p> <hr/> <p>MBS item 31529</p> <p>Nipple sparing mastectomy (bilateral)</p> <p>Fee: \$1,993.85 Benefit: 75% = \$1,495.40</p>
<p>Proposed MBS item Chest 2</p> <p>Bilateral simple mastectomy in the context of gender affirming surgery in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee: \$1,410.75 Benefit: 75% = \$1,058.10</p>	<p>MBS item 31520</p> <p>Total mastectomy (bilateral)</p> <p>Fee: \$1,410.75 Benefit: 75% = \$1,058.10</p>
<p>Proposed MBS item Chest 3</p> <p>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</p> <p>Suggested fee: \$1,218.25 Benefit: 75% = \$913.70</p>	<p>MBS item 45528</p> <p>Mammoplasty, augmentation, bilateral (other than a service to which item 45527 applies), if:</p> <p>(a) reconstructive surgery is indicated because of:</p> <p>(i) developmental malformation of breast tissue (excluding hypomastia); or</p> <p>(ii) disease of or trauma to the breast (other than trauma resulting from previous elective cosmetic surgery); or</p> <p>(iii) amastia secondary to a congenital endocrine disorder; and</p> <p>(b) photographic or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes</p> <p>Fee: \$1,218.25 Benefit: 75% = \$913.70</p> <hr/> <p>MBS item 45535</p> <p>Autologous fat grafting, bilateral service (harvesting, preparation and injection of adipocytes) if:</p> <p>(a) the autologous fat grafting is for one or more of the following purposes:</p> <p>(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;</p> <p>(ii) the preparation of post mastectomy thin or irradiated skin flaps in patients intending to have breast reconstruction;</p> <p>(iii) breast reconstruction in breast cancer patients;</p> <p>(iv) the correction of developmental disorders of the breast; and</p> <p>(b) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes</p> <p>Up to a total of 4 services, other than a service associated with a service to which item 45006 or 45012 applies</p> <p>Fee: \$1,210.90 Benefit: 75% = \$908.20</p>

**Genital reconfiguration items**

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

PASC noted that the WPATH Standards of Care suggest that a minimum of six months of hormone therapy is recommended before irreversible surgical intervention; this may be reflected in eligibility criteria for the proposed gonadectomy items.

**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. It would be subject to the multiple operation rule and does not involve insertion of a prosthesis)	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: \$2000.00 Benefit: 75% = \$1500.00 (suggested by the applicants due to additional complexity associated with scrotectomy)	
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	MBS item 35565 VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus Fee: \$749.05 Benefit: 75% = \$561.80
Proposed MBS item Genital 5 Construction of neo-vagina by skin grafting around a mould in an individual with a diagnosis of gender incongruence Suggested fee: \$1400.00 Benefit: 75% = \$1050.00 (Midpoint of suggested fee range provided by the applicant, \$1300 to \$1500).	MBS item 35565 VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus Fee: \$749.05 Benefit: 75% = \$561.80
	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: \$2,269.95 Benefit: 75% = \$1,702.50	MBS item 30750 Oesophagectomy with colon or jejunal interposition graft, by any approach, including: (a) any gastrointestinal anastomoses (except vascular anastomoses); and (b) anastomoses in the chest or neck (if appropriate) One surgeon Fee: \$2,269.95 Benefit: 75% = \$1,702.50

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
<p>Proposed MBS item Genital 7</p> <p>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</p> <p>Suggested fee:</p>	<p>MBS item 35565</p> <p>VAGINAL RECONSTRUCTION for congenital absence, gynatresia or urogenital sinus</p> <p>Fee: \$749.05 Benefit: 75% = \$561.80</p>
<p>Proposed MBS item Genital 8</p> <p>Hysterectomy with or without bilateral salpingo-oophorectomy in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee: \$859.30 Benefit: 75% = \$644.50</p>	<p>MBS item 35750</p> <p>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)</p> <p>Fee: \$859.30 Benefit: 75% = \$644.50</p>
	<p>MBS item 35751</p> <p>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)</p> <p>Fee: \$859.30 Benefit: 75% = \$644.50</p>
	<p>MBS item 35753</p> <p>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)</p> <p>Fee: \$950.20 Benefit: 75% = \$712.65</p>
	<p>MBS item 35754</p> <p>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)</p> <p>Fee: \$1,836.05 Benefit: 75% = \$1,377.05</p>
<p>Proposed MBS item Genital 9</p> <p>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</p> <p>Suggested fee:</p>	<p>MBS item 45006</p> <p>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)</p> <p>Fee: \$1,136.50 Benefit: 75% = \$852.40</p>

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
<p>Proposed MBS item Genital 10</p> <p>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</p> <p>Suggested fee:</p>	<p>MBS item 45537</p> <p>Perforator flap, such as a thoracodorsal artery perforator (TDAP) flap or a lateral intercostal artery perforator (LICAP) flap, or similar, raising on a named source vessel, for reconstruction of a partial mastectomy defect, other than a service associated with a service to which item 45006 or 45012 applies (H)</p> <p>Fee: \$865.80 Benefit: 75% = \$649.35</p>
	<p>MBS item 45538</p> <p>Perforator flap, such as a deep inferior epigastric perforator (DIEP) flap or similar, raising in preparation for microsurgical transfer of a free flap for post mastectomy breast reconstruction, other than a service associated with a service to which item 45006 or 45012 applies (H)</p> <p>Fee: \$990.65 Benefit: 75% = \$743.00</p>
<p>Proposed MBS item Genital 11</p> <p>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</p> <p>Suggested fee:</p>	
<p>Proposed MBS item Genital 12</p> <p>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</p> <p>Suggested fee:</p>	<p>MBS item 45562</p> <p>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</p> <p>Fee: \$1,204.10 Benefit: 75% = \$903.10 85% = \$1,110.90</p>
	<p>MBS item 45564</p> <p>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):</p> <ul style="list-style-type: none"> <li>(a) anastomoses of all required vessels; and</li> <li>(b) raising of tissue on a vascular pedicle; and</li> <li>(c) preparation of recipient vessels; and</li> <li>(d) transfer of tissue; and</li> <li>(e) inseting of tissue at recipient site; and</li> <li>(f) direct repair of secondary cutaneous defect, if performed;</li> </ul> <p>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, principal specialist surgeon (H)</p> <p>Fee: \$2,788.80 Benefit: 75% = \$2,091.60</p>

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
	<p>MBS item 45565</p> <p>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):</p> <ul style="list-style-type: none"> <li>(a) anastomoses of all required vessels; and</li> <li>(b) raising of tissue on a vascular pedicle; and</li> <li>(c) preparation of recipient vessels; and</li> <li>(d) transfer of tissue; and</li> <li>(e) inseting of tissue at recipient site; and</li> <li>(f) direct repair of secondary cutaneous defect, if performed;</li> </ul> <p>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)</p> <p>Fee: \$2,091.70 Benefit: 75% = \$1,568.80</p>
<p>Proposed MBS item Genital 13</p> <p>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</p> <p>Suggested fee: \$1,204.10 Benefit: 75% = \$903.10</p>	<p>MBS item 45562</p> <p>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</p> <p>Fee: \$1,204.10 Benefit: 75% = \$903.10 85% = \$1,110.90</p>
<p>Proposed MBS item Genital 14</p> <p>Construction of neo-phallus by metoidioplasty (formation of penis from clitoral tissue) in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee:</p>	<p>MBS item 37423</p> <p>Penis, lengthening by translocation of corpora, in conjunction with partial penectomy or penile epispadias secondary repair, either as primary or secondary procedures</p> <p>Fee: \$1,012.80 Benefit: 75% = \$759.60</p> <p>MBS item 45563</p> <p>Neurovascular island flap for restoration of essential sensation in the digits or sole of the foot, or for genital reconstruction, including:</p> <ul style="list-style-type: none"> <li>(a) direct repair of secondary cutaneous defect (if performed); and</li> <li>(b) formal dissection of the neurovascular pedicle;</li> </ul> <p>other than a service performed on simple V-Y flaps or other standard flaps, such as rotation or keystone</p> <p>Fee: \$1,210.10 Benefit 75% = \$1,111.40</p>
<p>Proposed MBS item Genital 15</p> <p>Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) with vaginectomy in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee:</p>	<p>MBS item 35561</p> <p>VAGINECTOMY, radical, for proven invasive malignancy - 1 surgeon (H)</p> <p>Fee: \$1,681.20 Benefit: 75% = \$1,260.90</p> <p>MBS item 35562</p> <p>VAGINECTOMY, radical, for proven invasive malignancy, conjoint surgery - abdominal surgeon (including aftercare) (H)</p> <p>Fee: \$1,416.30 Benefit: 75% = \$1,062.25</p> <p>MBS item 35564</p> <p>VAGINECTOMY, radical, for proven invasive malignancy, conjoint surgery - perineal surgeon (H)</p> <p>Fee: \$708.15 Benefit: 75% = \$531.15</p>

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
Proposed MBS item Genital 16 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: \$1,179.10 Benefit: 75% = \$884.35	MBS item 45527 Breast reconstruction (unilateral), following mastectomy, using a permanent prosthesis, other than a service associated with a service to which item 45006 or 45012 applies (H) Fee: \$1,179.10 Benefit: 75% = \$884.35

### 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 Pedicle 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 Pedicle 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
	<p>(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</p> <p>Fee: \$819.95 Benefit: 75% = \$615.00</p>
<p>Proposed MBS item Facial 4</p> <p>Feminising/masculinising facial surgery, one or more mandibular osteotomies (other than simple bony genioplasty) and mandibular reshaping if undertaken in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee:</p>	<p>MBS item 46155</p> <p>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)</p> <p>Fee: \$1,662.20 Benefit: 75% = \$1,246.65</p>
<p>Proposed MBS item Facial 5</p> <p>Feminising/masculinising facial surgery, insertion of facial implants or bone grafts in an individual with a diagnosis of gender incongruence</p> <p>Suggested fee: \$518.90 Benefit: 75% = \$389.20</p>	<p>MBS item 45051</p> <p>Contour reconstruction by open repair of contour defects, due to deformity, if:</p> <p>(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</p> <p>(b) insertion of a non-biological implant is required, other than one or more of the following:</p> <p>(i) insertion of a non-biological implant that is a component of another service specified in Group T8;</p> <p>(ii) injection of liquid or semisolid material;</p> <p>(iii) an oral and maxillofacial implant service to which item 52321 applies;</p> <p>(iv) a service to insert mesh; and</p> <p>(c) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes</p> <p>Fee: \$518.90 Benefit: 75% = \$389.20</p>
<p>Proposed MBS item Facial 6</p> <p>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</p> <p>Suggested fee:</p>	<p>MBS item 45000</p> <p>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</p> <p>Fee: \$592.85 Benefit: 75% = \$444.65 85% = \$503.95</p> <p>MBS item 45209</p> <p>Pedicled flap repair (forehead, cross arm, cross leg, abdominal or similar), first stage of a multistage procedure</p> <p>Fee: \$518.90 Benefit: 75% = \$389.20 85% = \$441.10</p> <p>MBS item 45212</p> <p>Pedicled flap repair (forehead, cross arm, cross leg, abdominal or similar), subsequent stage of a multistage procedure</p> <p>Fee: \$257.45 Benefit: 75% = \$193.10 85% = \$218.85</p> <p>MBS item 45589</p> <p>Autologous fat grafting (harvesting, preparation and injection of adipocytes) if:</p> <p>(a) the autologous fat grafting is for either or both of the following purposes:</p>

Proposed items for gender affirmation surgery	Existing items potentially similar to proposed procedure
	<p>(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;</p> <p>(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</p> <p>(b) both:</p> <p>(i) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes; and</p> <p>(ii) for craniofacial disorders, evidence of diagnosis of the qualifying craniofacial disorder is documented in the patient notes</p> <p>Fee: \$691.90 Benefit: 75% = \$518.95</p>

**Table 10 Proposed and existing rhinoplasty MBS items**

Proposed items for gender affirmation surgery	Existing items similar to proposed procedure
<p>Proposed MBS item Facial 7</p> <p>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</p> <p>Fee: \$1,167.50 Benefit: 75% = \$875.65</p>	<p>MBS item 45641</p> <p>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:</p> <p>(a) the indication for surgery is:</p> <p>(i) airway obstruction and the patient has a self-reported NOSE Scale score of greater than 45; or</p> <p>(ii) significant acquired, congenital or developmental deformity; and</p> <p>(b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes</p> <p>Fee: \$1,167.50 Benefit: 75% = \$875.65</p>
<p>Proposed MBS item Facial 8</p> <p>Rhinoplasty, partial, involving correction of bony vault only, in an individual with a diagnosis of gender incongruence</p> <p>Fee: \$643.55 Benefit: 75% = \$482.70 85% = \$550.35</p>	<p>MBS item 45632</p> <p>Rhinoplasty, partial, involving correction of bony vault only, if:</p> <p>(a) the indication for surgery is:</p> <p>(i) airway obstruction and the patient has a self-reported NOSE Scale score of greater than 45; or</p> <p>(ii) significant acquired, congenital or developmental deformity; and</p> <p>(b) photographic and/or NOSE Scale evidence demonstrating the clinical need for this service is documented in the patient notes</p> <p>Fee: \$643.55 Benefit: 75% = \$482.70 85% = \$550.35</p>
<p>Proposed MBS item Facial 9</p> <p>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</p> <p>Fee: \$560.70 Benefit: 75% = \$420.55 85% = \$476.60</p>	<p>MBS item 45632</p> <p>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:</p> <p>(a) the indication for surgery is:</p>



Proposed items for gender affirmation surgery	Existing items similar to proposed procedure
	(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

## **Summary of public consultation input**

*PASC noted and welcomed consultation input from 18 organisations and 9 individuals. Of the individuals, 5 were consumers that included caregivers and 4 were health professionals or other interested individuals.*

*The 18 organisations that submitted input were:*

- Parents of Adolescents with Gender Distress - Victoria
- Royal Australian and New Zealand College of Psychiatrists (RANZCP)
- Gender Pathways Service – WA Department of Health
- Thorne Harbour Health (THH)
- Genspect
- Royal Australian and New Zealand College of Obstetricians & Gynaecologists (RANZCOG)
- Trans Health Research
- Urological Society of Australia and New Zealand (USANZ)
- Family Planning Alliance Australia (FPAA) and Sexual Health Quarters (SHQ) – WA
- Transfolk of WA
- ACON
- Public Health Association of Australia – Diversity, Equity and Inclusion Special Interest Group
- Monash Health Gender Clinic (MHGC)
- Australian Medical Association (AMA)

- Transgender Victoria (TGV)
- LGBTIQ+ Health Australia (LHA)
- Australian and New Zealand Association of Oral and Maxillofacial Surgeons Inc. (ANZAOMS)
- Royal Australasian College of Surgeons (RACS)

Consultation feedback was mixed. Of the consultation feedback received, 20 responses were supportive (4 individuals and 16 organisations) and 7 responses were unsupportive (5 individuals and 2 organisations) of public funding for patient consultations and surgical procedures for gender affirmation in adults with gender incongruence.

*PASC noted that extensive consultation input was received. PASC noted the consultation input was either strongly supportive or strongly unsupportive.*

### **Clinical need and public health significance**

The main benefits of public funding received in the consultation feedback included:

- Reduced stigma associated with gender diversity and gender affirming care.
- Equity in access to medically necessary interventions for trans and gender diverse people.
- Encouraging public health systems to provide gender affirming surgery as a therapeutic service and increased training for medical specialists providing this service.
- Reduced need for trans people to self-fund gender affirming surgery, acknowledging that trans people are a financially disadvantaged group.
- Reduced gender affirming surgeries sought overseas and reduced difficulty accessing follow-up care for these in Australia.
- Improved health-related quality of life including improved social and emotional wellbeing.
- Ability for people to affirm their gender (including where surgery is required for legal recognition) and engage fully with work, education, sport, social life and community.
- Reduced gender dysphoria, which is associated with increased suicidality and more severe mental health symptomatology.

The main disadvantages of public funding received in the consultation feedback included:

- Complications and poor outcomes from gender affirming surgery including loss of sexual function, fertility, or both.
- Possibility for grief or regret post-surgery and the absence of publicly funded reversal surgery.
- Concern that there is insufficient good quality research to indicate that surgical treatments improve mental health outcomes or lessen suicidality.
- Concern that some patients view hormonal and surgical interventions as the solution to their distress. Some patients can suffer tunnel vision and focus on gender surgery as a strategy to avoid thinking about the complexity of their feelings regarding their body, their relationships, their adverse life experiences, and their current life challenges.
- Concern that adolescents and young adults will be eligible for surgery and are vulnerable populations not yet able to adequately consider the long-term consequences and risks of gender affirming surgery.

Other services identified in the consultation feedback as being needed to be delivered before or after the intervention included comprehensive care that may include mental health support, hormonal care and

monitoring, voice therapy, occupational therapy, hair removal services, post-surgery rehabilitative care, fertility specialists and social support. Most of the consultation feedback considered that a multidisciplinary model of care is necessary to facilitate gender affirmation surgery and that the services required and model of care may differ between individual patients in order to allow individuals to make choices about their bodies that align with their sense of self.

### **Indication(s) for the proposed medical service and clinical claim**

The consultation feedback ranged from strongly agreeing to strongly disagreeing with the proposed population, comparator and clinical claim.

Consultation feedback noted that the proposed population correctly identifies that not all trans people elect to access gender affirming surgery and recognises that gender non-binary persons are also in need of gender affirming healthcare. The Australian Medical Association (AMA) strongly supported the proposed changes to funding arrangements for surgical procedures and considered that current arrangements did not appropriately fund a multi-disciplinary best model of care framework for patients pursuing medical interventions for gender affirmation. The Royal Australasian College of Surgeons (RACS) strongly support gender affirming surgery noting that clarity is required regarding the consent process and proof that a multidisciplinary team was established prior to making decisions regarding surgery. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) were supportive of public funding however cautioned against developing specific Medicare Benefits Schedule (MBS) items for people experiencing gender incongruence. The RANZCOG considered the MBS fees associated with current MBS items are insufficient to account for patients with complex presentations and instead supported the extension of current MBS items to compensate for the 'complexities' and counselling involved in gynaecological consultations and surgery for all complex presentations not just those involving gender incongruence, including intersex and cis-women living with complex gynaecological presentations. Some consultation feedback that did not support the proposed population did not consider gender incongruence to be a genuine condition and considered gender incongruence may be socially influenced. Some consultation feedback raised concerns that there is a lack of minimum standards for diagnosis and no psychological assessment or treatment required prior to being eligible for surgery. Consultation feedback also raised that there are high levels of neurodiversity, mental illness and history of trauma in people experiencing gender incongruence.

Of the consultation feedback that agreed with the comparator, several organisations acknowledged the MBS codes and services currently utilised for consulting and providing gender affirming surgeries are not fit for purpose. Two of the individuals and two organisations that were unsupportive of public funding for gender affirming surgery strongly disagreed with the comparator stating that psychological therapy for gender incongruence to help the person become comfortable in their own body should be the comparator.

The consultation feedback on the clinical claim was mixed. Consultation input that agreed with the clinical claim stated that public funding for gender affirming medical interventions is needed and that the evidence base is well established linking the unmet need and lack of access to safe gender affirming surgery, and poor mental, physical, and social health outcomes. Trans Health Research stated that peer-reviewed research publications have consistently and unequivocally observed this link internationally and it has been validated through observations in the Australian context. The consultation feedback that disagreed with the clinical claim had concerns that the research was of very low quality, had inadequate length of follow-up and subject to a high risk of bias. One individual stated that the research conducted so far on hormonal and surgical treatments for gender incongruence has been conducted on a cohort of people who experienced gender dysphoria from early childhood which persisted into adulthood and that there is no long-term research outcomes for the much larger cohort of people who presented over the last

seven to eight years with gender dysphoria in adolescence and no objective cross-sex identification in childhood.

*PASC noted that the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) believes that all people deserve equal access to publicly funded care. RANZCOG cautioned against the creation of a specialised code to be made available only to those experiencing gender incongruence. RANZCOG considered that equivalent funding needs to be made available for intersex and ciswomen living with complex gynaecological presentations.*

### **Cost information for the proposed medical service**

The consultation feedback ranged from strongly agreeing to strongly disagreeing with the proposed service descriptor, with those disagreeing with the proposed service descriptor objecting to public funding for gender affirmation surgery and listing on the MBS.

The consultation feedback noted that the fees are still to be determined with USANZ requesting that the small number of reconstructive urologists fellowship trained in genital gender affirmation surgery be consulted on any future service fees. Concerns were raised that even with public funding for gender affirmation surgery there would be substantial out of pocket costs.

### **Consumer Feedback**

Consumer feedback was received from individuals, caregivers and organisations with a consumer focus, most of the consumer feedback was supportive of public funding for gender affirming surgery. Feedback was received that people wanting to access these services are frequently unable to due to the high cost and long waiting times, and that this is placing financial and emotional stress on people and their families. Consumers stated that these long delays or being unable to afford gender affirming surgery is preventing trans people from affirming their gender and is limiting their ability to engage in society. Being unable to present to the world as the gender they identify with is holding trans and gender diverse people back from work, study and socialising, and delaying their ability to thrive and give back to society in abundance. The consumer feedback unsupportive of gender affirming surgery all raised the concerns that gender affirming care is often provided without a robust diagnostic process or long-term psychological therapy to address co-morbidities and potential reasons for experiencing gender incongruence such as internalised homophobia, body dysmorphia, neurodiversity and other trauma.

*PASC requested the Department seek consultation input from RACGP and other primary care organisations as the application progressed through to ESC and MSAC for consideration.*

## **Next steps**

The applicant indicated they wish to prepare an applicant developed assessment report (ADAR). *PASC advised that the assessment report should progress as a two-stage assessment report, consistent with MSAC Executive advice. The first stage will assess the clinical component for ESC and MSAC consideration. This will enable MSAC to advise on the appropriate approach to economic evaluation.*

## **Applicant Comments on Ratified PICO**

The Applicant had no comments.



## Appendix A Additional information

### *Recommended considerations for an ethics review or analysis*

- Issues around self-concept and personal identity, perhaps affected by the surgeries in multiple, nuanced ways (some good, some bad, some ambivalent, some mixed, etc.)
- Related legal issues, e.g., institutional identity (birth certificate, passport, etc.). May be relevant for any legal parenting arrangements, e.g., birth mother.
- Community affiliations and belonging and dynamics, and how this is affected for an individual
- As above for family members
- What is the level of understanding the population (and public) has about gender affirming surgery, and how does this impact things, esp. the pre-surgical counselling to ensure informed consent
- The appropriate counselling requirements pre-surgery - is it discriminatory to require formal psychological review, or necessary? Are there any post-surgical counselling requirements or recommendations? What is appropriate follow-up?
- Why people do and don't opt for the surgeries, where they stop along the surgical pathways and why
- Impacts on reproductive function and reproductive planning
- Impacts on empowerment and autonomy (good, bad, ambivalent, mixed)
- What are the attitudes of general and affected publics towards the surgeries, and what implications might these have?
- Emotional experiences: e.g., worry, anxiety, grief, guilt, regret
- Issues relating to stigma and discrimination (including on the part of the medical profession) - could these increase or change the value of the interventions, e.g., helping a stigmatised and disadvantaged population
- Equity of access, barriers and facilitators with respect to access to the surgeries (with and without funding)
- Do any sub-populations face specific and unique issues?