Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1754 – Surgical procedures for gender affirmation in adults with gender incongruence

Applicant: **Australian Society of Plastic Surgeons**

Date of MSAC consideration: **3-4 April 2025**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of a suite of items for gender affirming surgery for adults with gender incongruence was received from the Australian Society of Plastic Surgeons (ASPS) by the Department of Health and Aged Care (the department).

Although the request for new MBS items was for specific surgical items, the intention was for a person-centred approach to the assessment of these medical services.

The applicant developed assessment report (ADAR) followed the advice of the MSAC Executive and the PICO[1] advisory subcommittee (PASC), using a two stage Assessment Report pathway, so that MSAC may advise on the appropriate approach to economic evaluation. This is the first stage, considering only the comparative clinical evidence, and the second stage is planned to include the economic evaluation and financial analysis.

2. MSAC's advice to the Minister

MSAC considered the clinical evidence presented for the creation of new Medicare Benefits Schedule (MBS) items for surgical procedures for gender affirmation in adults with gender incongruence. MSAC noted that this application is following a two-stage assessment report pathway where the current MSAC consideration (first stage) is to assess the comparative clinical evidence of safety and effectiveness, and if suitable to progress, the second stage would complete the economic evaluation and financial analysis.

MSAC acknowledged that there is an unmet clinical need for gender affirming surgeries for people with gender incongruence.

MSAC considered that gender affirming surgery should be provided as a part of a care pathway where gender incongruence and the decision to undergo surgery is established through a comprehensive, patient-centred, multidisciplinary assessment by health care professionals experienced in transgender health. MSAC considered that establishing these care pathways is critical to ensure patients who have surgery are those most likely to benefit, to attain the best

[1] Population, intervention, comparator and outcomes

outcome for the patient. MSAC considered further work is required to develop these clinical pathways to meet the needs of people with gender incongruence.

MSAC noted that the Government had tasked the National Health and Medical Research Council to undertake a comprehensive review of the Australian Standards and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents (first published in 2018) and develop new national guidelines. MSAC considered that there is a need for Australian evidence-based guidelines to inform treatment (including surgical intervention) for adults with gender incongruence and gender dysphoria.

MSAC noted the large amount of consultation feedback received for this application, the majority of which was from individuals who had lived experience of gender incongruence. MSAC appreciated the effort that respondents had put into providing input and the generosity of respondents in sharing their experiences with the committee. MSAC noted the considerable impact of gender incongruence (and any associated distress) on individuals, and noted that surgical and non-surgical care pathways for this population in Australia are evolving, in the setting of rapidly increasing reported prevalence of gender incongruence.

MSAC considered that the systematic review included in the Applicant Developed Assessment Report did not undertake a sufficiently robust literature review, and was limited in its assessment of all relevant clinical evidence according to the MSAC Guidelines. MSAC considered that the identified evidence appeared to support superior clinical outcomes in the short term, but was of the view further assessment of the comparative safety and clinical effectiveness of gender affirming surgeries is required before the application can progress to economic and financial analysis. MSAC requested this further assessment should also include evidence of the natural history of gender incongruence and dysphoria, qualitative data on the nature of distress experienced by individuals before and after surgery, further information on regret/detransition rates, longer-term outcomes, and the care pathways in practice in Australia and in other similar jurisdictions. MSAC considered that the assessment should take into consideration the applicability of the evidence to the proposed Australian population, noting the significant changes in the demographics in the transgender population (including the increasing number of individuals identifying as non-binary) and relevant guidelines over time. MSAC considered that while extensive consultation input had already been received, additional consultation input is required from consumer groups and all medical and allied health disciplines involved in the provision of gender affirming care to address the outstanding clinical concerns and provide more certainty to inform the economic and financial analysis.

Consumer summary
This is an application from the Australian Society of Plastic Surgeons Inc requesting Medicare Benefits Schedule (MBS) listing of 30 surgical procedures for gender affirmation in adults with gender incongruence. Gender incongruence is where an individual's experienced gender does not align with the sex assigned at birth. A person with gender incongruence may seek healthcare services including gender affirming surgery to align their body with their experienced gender. The surgeries proposed in this application included 3 items for gender affirming chest surgery, 17 items for genital reconstruction surgery, 9 items for gender affirming facial surgery and 1 item for gender affirming voice surgery. This application is following a 2-stage process – the first stage (the current stage of this application) is an assessment of the clinical evidence. Once the first stage is complete, the second stage involves an economic and financial assessment informed by MSAC's (and the Evaluation subcommittee's) advice on the clinical evidence. This application is not considering medicines used for gender affirmation, such as hormone treatment or hormone blockers (also called 'puberty blockers'). If the surgery items proposed in this application are listed on the MBS, an MBS rebate will be paid for these services when provided to a private patient. The Australian Government will set

Consumer summary

the MBS fee for each service, which determines the rebate that will be provided. For services provided in hospital the MBS rebate will be 75% of the MBS fee. If private health insurance is used for hospital services, the insurance will pay the remaining 25% of the MBS fee if the service is covered under the private health insurance policy. Private health insurance also assists with covering the costs of hospital accommodation, operating theatre fees, the cost of medical devices and human tissue products, dressings and other in hospital therapies for eligible policy holders. The amount private health insurance will contribute to these will vary depending on the policy. Individual doctors may also choose to charge a fee higher than the MBS fee, which may result in out-of-pocket costs. Some insurers may pay more than what is required which may assist with out of pocket costs. It is anticipated that if the surgery items proposed in this application are listed, even with an MBS rebate and private health insurance, the current fees charged by doctors for these procedures in a private setting mean there will likely be out-of-pocket costs for private patients accessing these surgeries.

MBS rebates are only available for patients who have their surgery in private hospitals or patients who elect to be a private patient in a public hospital. Public patients treated in public hospitals are not eligible for MBS rebates. Public hospitals are funded via other means to provide no cost treatments for public patients. State and territory governments are responsible for public hospitals and the services they provide. This application only considers the funding of MBS items, meaning the outcome of this application will not impact funding available for public patients or the provision of surgeries for public patients in public hospitals.

Numerous organisations and thousands of people with lived and practice-based experience and clinical expertise shared their views on this application through the MSAC consultation process. Most inputs were from people who have lived experience of gender incongruence. Most of the input was supportive of public funding and highlighted several benefits of the proposed surgeries, such as in improving a person's quality of life and improving mental health and wellbeing. MSAC appreciated the effort that respondents had put into providing input and the generosity of respondents in sharing their experiences with the committee. MSAC noted that some inputs raised issues related to hormone therapy and puberty blockers, however noted that public funding of these medicines are not being considered in the current MSAC application.

MSAC considered that there is a clinical need for gender affirming surgeries for people with gender incongruence. MSAC considered that the group of patients who are most likely to benefit from surgery was not well defined in the MSAC application. MSAC strongly believed that a team of health professionals (a multidisciplinary team) should be involved and support the person's healthcare journey, including in the diagnostic process and the decision to have surgery. MSAC considered it very important that people who may have gender incongruence receive this support to make sure that the people who have gender affirming surgery are those most likely to benefit and avoid (or reduce as much as possible) any harms associated with the surgery (for example complications from surgery). MSAC considered that more work needs to be done to establish care pathways to meet the needs of people with gender incongruence.

MSAC considered the report of clinical studies compiled by the Australian Society of Plastic Surgeons for this application. MSAC noted that the report contained some evidence gaps. This led to uncertainty in interpreting the safety and effectiveness of the surgeries. In addition, the evidence presented in the application was based on mainly short term follow up data. MSAC noted the critical need for longer term data on the outcomes of surgery, including the benefits to health and wellbeing, potential harms, rates of regret and detransition post-surgery.

In terms of safety, MSAC noted that gender affirming surgery (as with all other surgery) is associated with a risk of complications, and that the rate of complications greatly differs according to the type of surgical procedure. With regards to effectiveness, based on the evidence presented in the application, MSAC considered that many gender affirming surgeries

Consumer summary

appeared to be effective in the short term, however, further data is required to ensure that they are also effective in the long term.

Overall, MSAC considered a more comprehensive assessment of the clinical evidence is needed. This is so that MSAC can consider the relevant clinical studies, the quality of the studies and how applicable they are to Australians with gender incongruence who may want surgical treatment. This will allow MSAC to provide better informed advice about the effectiveness and safety of gender affirming surgery. This is also needed to inform the economic and financial analysis in the second stage of this application. MSAC noted the increasing number of people in Australia who may wish to undergo these surgeries. MSAC expressed a desire to find a way forward in identifying the people who may benefit the most and least likely to experience harm from these surgeries. MSAC advised that further consultation is required with a broad range of groups to ensure that all relevant issues are identified and fully considered, so that future decisions are accurate, clear and trauma informed.

MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC requested a more comprehensive assessment of the clinical evidence for gender affirming surgery for adults with gender incongruence prior to progressing to the second stage (economic and financial analysis) of this application. MSAC considered that more work needs to be done to establish care pathways to meet the needs of people with gender incongruence. MSAC considered that the proposed surgeries are likely to be effective in the short term for some people, however considered this to be highly uncertain due to limitations in the evidence review presented in the application and therefore requested a more comprehensive assessment of the relevant clinical evidence. Additionally, MSAC requested further specific advice from a range of stakeholders to ensure that patients attain the best outcomes from these surgeries.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that the purpose of this application from the Australian Society of Plastic Surgeons Inc was to request Medicare Benefits Schedule (MBS) listing of a suite of 30 surgical procedures for gender affirmation in adults with gender incongruence. MSAC noted that the proposed MBS items for the surgical procedures were: 3 items for gender affirming chest surgery, 17 items for genital reconstruction surgery, 9 items for gender affirming facial surgery and 1 item for gender affirming voice surgery. MSAC noted that this is the first time it has considered these interventions for the proposed indication. MSAC noted that the MSAC Executive and the PICO[1] advisory subcommittee (PASC) had advised that the application should progress as a 2-stage assessment, where the first stage would be to assess the comparative clinical evidence (presented in the applicant-developed assessment report [ADAR] submitted for consideration at this meeting), so that the Evaluation subcommittee (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.

The MBS is a list of health professional services that the Australian Government subsidises. While the Government is responsible for setting the MBS fees and the rebates to assist individuals to access medical services, medical practitioners are not required to adhere to the scheduled fee and can charge a higher fee, potentially resulting in out-of-pocket costs for patients. It is a personal decision for individuals to obtain private health insurance to assist with

out-of-pocket costs for the medical services. When an in hospital procedure is covered under a private health insurance policy, legislation requires private health insurers to provide a 25% rebate (with the remaining 75% of the schedule fee covered by the MBS rebate). However, not all policies cover every procedure and when covered the overall total contribution to these costs by private health insurance is dependent on a patient's individual policy. Given the current fees charged in the private setting in Australia for gender affirming surgery, it is anticipated that even with an MBS rebate and private health insurance a person may experience out of pocket costs for these procedures.

MSAC noted the very high number of consultation inputs received for this application. A total of 2,706 inputs had been received during the pre-MSAC consultation period, with 92.5% of these indicating support for public funding. MSAC noted that the majority of inputs were from individual consumers who indicated that they have the health condition for which this health service is proposed. MSAC appreciated the effort that respondents had put into providing input and the generosity of respondents in sharing their lived experiences with the committee. MSAC noted that the consultation input identified numerous benefits of the proposed interventions including improvement in the quality of life, improvement of mental health and wellbeing and a reduction in the personal financial burden for individuals seeking gender affirming surgeries. MSAC also noted that some consultation inputs were critical of a lack of access to multidisciplinary care and surgical expertise for gender incongruence. MSAC also noted the input concerning the issue of the age at which informed consent for such surgeries can reasonably be given, as well as risks associated with the various proposed surgeries, including their complications, long recovery times, and risk of regret. MSAC noted that some inputs raised issues related to hormone replacement therapy and hormone blockers (also called puberty blockers), however noted that public funding of these medicines are out of scope for the current MSAC application.

MSAC noted the proposed population is adults diagnosed with gender incongruence who are electing to pursue gender affirming surgical procedures. MSAC considered that this population was not sufficiently well defined in the ADAR. MSAC noted that gender incongruence is defined in the International Classification of Diseases 11th Revision (ICD-11)[2] as a condition related to sexual health 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. MSAC noted that the ADAR proposed that any sole practitioner who has expertise in the field, with current Australian Health Practitioner Regulation Agency (AHPRA) registration and an established relationship with the patient (usually a general practitioner [GP]), can assign the diagnosis of gender incongruence. However, MSAC noted that there are no formalised and specific diagnostic criteria in the description of gender incongruence in ICD-11, nor diagnostic criteria to define the severity or duration of gender incongruence to classify it as 'marked and persistent', and that there is currently a lack of education and credentialled training available for diagnosing practitioners. MSAC considered that this may lead to inconsistency in diagnoses, especially between clinicians across different disciplines. MSAC agreed with PASC and ESC that a multidisciplinary team (MDT) is integral to accurate diagnosis, and considered that this should be included earlier in the clinical management algorithm as part of the diagnostic process, and not only after a decision has been made to have surgery. Furthermore, at the stage of diagnosis, the MDT would also be able to advise regarding the most appropriate management options which may include surgery and/or other forms of non-surgical gender affirming care. If surgery is considered as an appropriate intervention, a further MDT assessment would be required that includes, but is not restricted to the relevant surgical discipline. There is a need for patient-

[2] https://icd.who.int

centred expert multidisciplinary decision making to determine what surgeries are most likely to benefit an individual with gender incongruence.

MSAC considered that the roles and functions of the MDT at diagnosis are separate to that of the surgical MDT. MSAC considered that the MDT as described in the ADAR involving a minimum of 2 participants does not provide sufficient safeguards for the patient and should be aligned with existing MBS items for MDT case conferences for surgical procedures, which stipulate at least 3 professional participants. MSAC considered that the following participants may be included in the MDT: GP, surgeon, sexual health specialist, psychologist, psychiatrist (in a liaison role to support the MDT rather than as a 'gatekeeper'), endocrinologist and other relevant allied health providers. MSAC acknowledged that there is an unmet clinical need for gender affirming surgeries for individuals with gender incongruence and considered that patient-centred comprehensive care pathways are critical to ensure patients who have surgery are those most likely to benefit, to attain the best outcomes for the patient.

MSAC considered that a comprehensive care pathway and MDT involvement have an important role in establishing gender incongruence and in assessing the appropriateness for surgery, which includes informed consent from the individual seeking gender affirming care. MSAC queried the eligible age at which individuals would be able to access the proposed services separate to, and in the context of, considerations for informed consent for other medical procedures. MSAC noted that in their pre-MSAC response the applicant had indicated a willingness to include an explicit age restriction of 18 years and over in the proposed MBS items, while consultation input from several healthcare professionals indicated that 25 years and over may be more appropriate as this is the age at which frontal lobe development is considered complete and individuals are considered to have reached full cognitive maturity to assess the risks and-benefits of surgery and which may mitigate against post-surgery regret. MSAC considered the eligible patient age to be a critical issue for patients' self-determination in relation to their own health care. MSAC considered that the conflicting opinion and advice regarding the definition of 'adult' and the appropriate eligible age needs to be addressed and resolved.

MSAC noted that the approach to gender incongruence management is evolving both nationally and internationally and noted that the National Health and Medical Research Council (NHMRC) is developing new national clinical practice guidelines for the care of trans and gender diverse children and adolescents in Australia. This will include a review of existing guidelines and evidence, including the existing guidelines used in Australia (Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents in Australia, published in 2018). MSAC considered that there is a need for Australian evidence-based guidelines to inform management and treatment (including surgical intervention) for adults with gender incongruence and gender dysphoria (a condition of distress resulting from gender incongruence, defined in the Diagnostic and Statistical Manual of Mental Disorders [DSM-5-TR]).

MSAC agreed with ESC that the limitations in the evidence review presented in the ADAR led to uncertainty in interpreting the safety and effectiveness outcomes. The literature search in the ADAR was not adequately described and may have excluded relevant studies. The ADAR did not assess the risk of bias or confounding or overall quality of evidence for each outcome, nor applicability to the Australian population as required by the MSAC Guidelines. MSAC noted that the World Professional Association for Transgender Health (WPATH) Standards of Care for gender affirmation surgery have broadened over time, by removing requirements for psychotherapy, reducing the time period in which the individual is required to live in the social role of the preferred gender identity and reducing the time period the individual is required to have gender affirming hormone therapy prior to surgery. The gradual broadening of criteria over time may mean that studies that included people who had surgery when different WPATH Standards of

Care were in use (and therefore had to meet stricter criteria) are not as applicable as more recent studies (when it is possible that a broader range of people have undergone surgery). MSAC also noted that there has been a significant change in the demographics of people seeking gender affirming care. For instance, MSAC noted that prior to 2000, individuals presenting for medical interventions for gender affirming care were mainly people assigned male at birth, in their mid-adulthood[3], whereas the prevalence of gender incongruence or gender dysphoria has significantly increased in recent years, particularly in those assigned female at birth and individuals identifying as non-binary has also increased, particularly in adolescents and young adults [3,4,5]. MSAC considered that the changing demographics of the transgender population and the changes to the WPATH guidelines over time make it difficult to assess the comparative outcomes from surgery reported in the ADAR's evidence base and whether they are applicable to the current proposed Australian population.

MSAC agreed with ESC that the ADAR did not present adequate data on clinical outcomes for nonbinary people. MSAC considered the ADAR did not adequately represent the needs and preferences of nonbinary people (who represent one third of the Australian transgender population), and that additional data and consultation input are required to inform the medical services that may be sought by this cohort.

MSAC also requested an assessment of qualitative data on the nature of distress of the people presenting for surgery and benefits of surgery, data to inform the natural history of gender incongruence over the life-course and how it relates to development of gender dysphoria and its sequelae, and further information about what constitutes best available care in the absence of surgery. MSAC also noted that very limited long term surgical outcomes data were presented in the ADAR, which increases uncertainty about the risks of the proposed interventions and the ongoing needs of this population. MSAC considered that there is a critical need for long-term data, including qualitative data to inform the full range of patient-relevant outcomes and data on decision regret and rates of detransition. MSAC noted that while the commonly cited rate of regret is 1% based on the systematic review by Bustos et al. (2021)[6], MSAC agreed with ESC that this may be an underestimate as a number of studies included in the review were based on people who had gender affirming surgery under more restrictive circumstances as clinical guidelines for gender affirming surgical procedures have changed over time. Therefore, MSAC considered the populations included in these studies may not reflect the current Australian population seeking gender affirming surgery. MSAC noted the majority of studies had a follow up of less than 5 years, which is shorter than the median time to seeking a legal reversal to the original gender as reported by a long term case series in Sweden[7]. MSAC noted data from the Gender-Q international field test provided by the applicant that the majority of respondents

[3] Jorgensen SCJ. Transition Regret and Detransition: Meanings and Uncertainties. Arch Sex Behav. 2023 Jul;52(5):2173-2184. doi: 10.1007/s10508-023-02626-2. Epub 2023 Jun 2. PMID: 37266795; PMCID: PMC10322945.

[4] Jarvis SW, Fraser LK, Langton T, et al Epidemiology of gender dysphoria and gender incongruence in children and young people attending primary care practices in England: retrospective cohort study Archives of Disease in Childhood Published Online First: 24 January 2025. doi: 10.1136/archdischild-2024-327992

[5] Klinger D, Oehlke SM, Riedl S, et al. Mental health of non-binary youth: a systematic review and meta-analysis. *Child Adolesc Psychiatry Ment Health*. 2024;18(1):126. Published 2024 Oct 9. doi:10.1186/s13034-024-00822-z

[6] Bustos, Valeria P et al. "Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence." *Plastic and reconstructive surgery. Global open* vol. 9,3 e3477. 19 Mar. 2021, doi:10.1097/GOX.0000000000003477

[7] Dhejne, C, Oberg, K, Arver, S & Landen, M 2014, 'An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets', Arch Sex Behav, vol. 43, no. 8, Nov, pp. 1535-1545 10.1007/s10508-014-0300-8.

strongly agreed with the statement 'If I had to [undergo gender affirming surgery] again, I would', and approximately 1-6% disagreed with the statement. MSAC noted that long-term data would also be important for any future economic modelling. MSAC advised that it would be preferable for a registry to be established to provide evidence for long-term outcomes after these surgeries, including quality of life, recovery, complications, regret and incidence of detransition.

MSAC considered that the ADAR's clinical claim of inferior safety compared to no surgery was appropriate. MSAC agreed with ESC's concerns regarding comparative safety, particularly that most of the safety data presented in the ADAR were based on short-term outcomes (<30 days), and that the rate of complications, including infections, are likely to be higher in the longer term. MSAC noted that complication rate depended on the type of surgical procedure, and in general removing healthy organs was associated with a lower risk (e.g. orchidectomy had an overall complication rate of 2.9-3.7%) than creating new structures, particularly new structures involving vascular or erectile tissue (e.g. phalloplasty had an overall complication rate of 31.5-43.8%).

Regarding comparative clinical effectiveness, MSAC noted that the evidence base was predominantly before and after case series, which were likely to be at high risk of bias due to attrition, or cross-sectional studies that were at risk of confounding. MSAC agreed with ESC that, while the presented data suggested effectiveness in the short term (for both primary and secondary outcomes), the level and quality of the evidence appeared to be low and the average magnitude of effect for each outcome unclear. MSAC noted the applicant's pre-MSAC response, which provided a recent systematic review on patient reported outcomes of participants who had received hormone therapy and/or gender affirming surgery[8]. MSAC noted from this review that the hormone and/or surgery interventions significantly improved mental health, gender dysphoria, self-esteem and body image based on patient reported outcomes, however also noted that the majority of the studies were small and had limited follow up. MSAC noted results from another recent study of individuals with gender dysphoria across 64 US healthcare organisations with matched cohorts showing that those who had gender affirming surgery were at significantly higher risk of depression, anxiety, suicidal ideation and substance use disorders than those without surgery[9]. Overall, MSAC considered that the ADAR's clinical claim of superior effectiveness compared with no surgery was highly uncertain and not well supported due to the previously outlined limitations in the ADAR.

MSAC agreed with ESC's advice on considerations for a future economic evaluation and financial analysis. MSAC considered that a patient centred exemplar approach is likely appropriate for the economic evaluation, and considered that more than one exemplar may be needed to capture the breadth of possible surgeries or groups of surgeries. Given that different surgeries have different risk/benefit profiles, MSAC agreed with ESC that more granular data by surgical group or subtype will be needed to identify the surgery or groups of surgeries that has/have better outcomes and therefore may be more cost effective.

[8] Ireland, K., Hughes, M. and Dean, N.R. (2025), Do hormones and surgery improve the health of adults with gender incongruence? A systematic review of patient reported outcomes. ANZ Journal of Surgery. https://doi.org/10.1111/ans.70028

[9] Lewis, J., Patterson, A., Effirim, M., et al. Examining gender-specific mental health risks after gender-affirming surgery: a national database study, *The Journal of Sexual Medicine*, 2025;, qdaf026, https://doi.org/10.1093/jsxmed/qdaf026

In regard to financial considerations, MSAC noted that the number of individuals in the proposed population seeking gender affirming care is increasing rapidly in Australia[10,11] and that this should be considered in the financial estimates. With an estimated 227,112 surgeries required to meet the current demand (using Bretherton et al 2020[12] and recent Australian Bureau of Statistics data[13]) that is likely to significantly increase in subsequent years, MSAC noted the significant implications for workforce availability and training.

MSAC noted that currently some MBS items may be able to be utilised for the purposes of gender affirming surgery, however these items did not cover the entire suite of proposed surgeries. MSAC recognised the generic nature of current MBS items does not provide sufficient information to identify gender affirmation from the broader cohort of surgical patients and that any current usage of these items for the clinical purpose of gender affirmation could not be accurately quantified (based on MBS usage data) for the purposes of the financial analysis. MSAC reviewed the proposed MBS items and considered having new surgical items for the proposed indications appropriate (rather than incorporating into existing item numbers) as it allows for clearer and specific item descriptors for the target population, provides clarity for consumers and clinicians by explicitly recognising the range of procedures that are deemed clinically relevant and assists with monitoring and participation in any registry that may be established to generate data on long-term outcomes. MSAC considered that once the issues regarding eligible age, and MDT involvement (including the minimum number and clinical role of participants) are addressed, this information should be included in the MBS item descriptors. MSAC noted that while currently there are no specific credentialled training programs for diagnosing and managing gender incongruence, it will be expected that providers of these services have the appropriate qualifications and that the educational and training requirements for patient diagnosis and surgery be included in the explanatory note of the MBS items. MSAC also advised that the MBS descriptors should use gender-nonspecific language, be outcome based and method agnostic where possible. MSAC noted that the current WPATH standards of care (version 8) recommends that people undergoing gonadectomy consider a minimum of 6 months of hormone therapy before undergoing irreversible surgical intervention. MSAC considered that this requirement be specified in the explanatory note of the relevant MBS items, noting that there may be instances where hormone therapy may not be clinically appropriate. MSAC agreed with ESC that the proposed item descriptors for procedures that may be repeated for revision surgery should include a requirement that photographic or diagnostic evidence demonstrating the clinical need for this service be documented in the patient notes, in line with other similar items (e.g. MBS item 45528 – Mammaplasty, augmentation; MBS item 45051 – Contour reconstruction by open repair of contour defects). MSAC requested the applicant to provide information on how frequently the subsequent stage items are performed to inform whether a frequency restriction is required. MSAC considered that appropriate fees for the proposed items will need to be identified and justified as part of the subsequent stage of assessment.

Overall, MSAC acknowledged that there is an unmet clinical need for gender affirming surgery in individuals with gender incongruence and considered that patient-centred comprehensive care pathways are critical to ensure patients who have surgery are those most likely to benefit, in

---

[10] Amos AJ. Rapidly expanding gender-affirming care based on consensus instead of evidence justifies rigorous governance and transparency. *Australas Psychiatry*. 2024;32(4):346-353. doi:10.1177/10398562241249579

[11] South Australia Health (2023), State-wide gender diversity model of care, SA Health Website

[12] Bretherton I, Thrower E, Zwickl S, et al. The Health and Well-Being of Transgender Australians: A National Community Survey. *LGBT Health*. 2021;8(1):42-49. doi:10.1089/lgbt.2020.0178

[13] Australian Bureau of Statistics (2022), Estimates and characteristics of LGBTI+ populations in Australia, ABS Website.

order to attain the best outcomes for patients. MSAC considered that further advice and assessment of the comparative clinical evidence (summarised below) is required to better inform the economic and financial assessment in a subsequent stage.

MSAC advised that further consultation was required with the full range of clinical disciplines involved in providing care to the proposed population including sexual health physicians, psychologists, psychiatrists, paediatricians, endocrinologists, surgeons from relevant disciplines [e.g. plastic surgery, gynaecology, urology, breast surgery, ear nose and throat and maxillofacial surgery] and GPs to provide advice specifically related to the eligible patient age, diagnostic criteria, members who should be in the MDT, role of the MDT in assessment, diagnosis and management, the appropriate clinical management algorithm, education, training and credentialling requirements, and broader care of the patient including post-surgical and long-term care and support (including mental health). MSAC advised that the Department engage with relevant clinical professional organisations to seek the appropriate expertise and advice on the appropriate care pathways. MSAC advised that consultation should also include consumer and carer groups and ensure that discussions are accurate, clear and trauma informed. MSAC requested that the Department engage with the HTA Consumer Consultative Committee to seek its advice on the appropriate approach to engage purposefully and constructively with all these different stakeholders. Given the different legislative frameworks relating to transgender healthcare across jurisdictions, MSAC advised that input from state and territory representatives would also be informative.

Informed by and in parallel to the consultation stated above, MSAC advised that a further assessment of the comparative safety and effectiveness of gender affirming surgery is required based on recent evidence (<5 years) that is applicable to the proposed population. MSAC advised the Department to progress this further assessment. MSAC considered that this assessment should be a robust critical appraisal of the evidence, including an assessment of long term outcomes, rates of and reasons for regret and de-transition, qualitative data on the nature of distress pre- and post-surgery and prevalence and likely impact of changing demographics. The assessment should also include information related to the natural history of gender incongruence over the life-course and how it relates to risk for gender dysphoria, the preferences and outcomes for non-binary individuals and information about what constitutes best available care in the absence of surgery. Given that different surgeries have different risk/benefit profiles, MSAC suggested that the assessment could examine the types of surgeries separated into appropriate groups based on their risk/benefit profiles and potential downstream economic/financial considerations. MSAC advised that the data included in the evidence base be critically assessed for their applicability to the proposed Australian population. MSAC considered that this further assessment of the comparative clinical evidence would require consideration by ESC and MSAC.

4. Background

MSAC has not previously considered gender affirming surgery for adults with gender incongruence. In May 2023, the MSAC Executive considered that the appropriate HTA pathway for MSAC application 1754 was via the full MSAC pathway (consideration by PASC, ESC and MSAC), and that the assessment should be progressed as a two stage assessment report pathway where the first stage would assess the comparative clinical evidence and the second stage would consider the economic evaluation and financial analysis. Parallel to the HTA assessment of the application, the MSAC Executive advised that the Department consider options to support multidisciplinary care for the proposed patient group.

This application was considered by PASC in the December 2023 meeting.

5. Prerequisites to implementation of any funding advice

The MSAC Executive and PASC highlighted that a multidisciplinary model of care framework extending before and after gender affirming surgery was needed. The ASPS fully supports the provision of gender affirming surgery within a multidisciplinary framework.

6. Proposal for public funding

The ASPS proposed a suite of new MBS items, for gender affirming therapies in the following categories:

Gender affirming chest surgery (

- Table 2)
- Genital reconstruction surgery (Table 3)
- Gender affirming facial surgery (

- Table 4)
- Gender affirming voice surgery (Table 5).

Where it was clear from the ratified PICO that the proposed fees were based on similarity to existing MBS items, the proposed fees in the ADAR were updated in line with fee increases to the existing items. Some of the proposed MBS items do not have an equivalent MBS item, or have multiple possible equivalent MBS items so it was unclear what the appropriate fee should be. Appropriate fees will need to be proposed and justified prior to the economic and financial analysis.

All items are proposed to include an explanatory note requiring pre-surgical multidisciplinary assessment, in alignment with PASC advice. The proposed note is shown in Table 1. The "first participant" should be a specialist surgeon, such as a plastic surgeon or a reconstructive urologist. These should be registered and have met the training and qualification requirements set out by their professional boards. It is the responsibility of the multidisciplinary team (MDT) to determine whether gender affirmation surgery is clinically appropriate.

The proposed items all require that the individual has a diagnosis of gender incongruence.

Several of the MBS items proposed in the ADAR use the terms 'feminising' and 'masculinising'. MSAC agreed with ESC that the language in the proposed MBS item descriptors should be amended to be gender non-specific and be described using strictly anatomical terminology where possible (as presented for the proposed MBS items for genital reconfiguration).

Table 1 Proposed explanatory note wording regarding pre-surgery multidisciplinary assessment

Proposed TN.X.XX explanatory note for all gender affirmation surgeries
Gender affirmation surgery should be preceded by a multidisciplinary assessment involving a team of 2 or more participants where: a) The first participant is a surgeon; and b) The second and subsequent participants include 1 or more of a specialist surgeon from a different speciality, non-surgical specialist, physician, general practitioner, sexual health physician or psychiatrist

Source: ADAR Table 7

Table 2 Proposed items for gender affirming chest surgery

Proposed MBS item gender affirming chest surgery 1
Masculinising chest surgery, with surgical repositioning or free grafting of the nipple-areolar complex in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $2,073.95 Benefit: 75% = $1,555.50
Proposed MBS item gender affirming chest surgery 2
Bilateral simple mastectomy in the context of gender affirming surgery in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,467.40 Benefit: 75% = $1,100.55
Proposed MBS item gender affirming chest surgery 3
Feminising chest surgery, by any method, including but not limited to, insertion of prostheses, autologous fat graft or local flaps in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,267.20 Benefit: 75% = $950.40

Source: ADAR Table 8 (with prices updated in line with MBS items reference-priced)

The current World Professional Association for Transgender Health (WPATH) Standards of Care (SoC, version 8) recommend that people undergoing irreversible genital reconfiguration surgery should receive a minimum of 6 months of hormone therapy prior to surgery. PASC suggested that this could be incorporated into the eligibility criteria for the proposed items in Table 3, although this would be inappropriate where hormone use is contraindicated or not required, so provisos would be needed that this eligibility criterion only applies when clinically appropriate.

Table 3 Proposed items for genital reconfiguration surgery

Proposed MBS item genital reconfiguration surgery 1
Penectomy in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,053.45 Benefit: 75% $790.10
Proposed MBS item genital reconfiguration surgery 2
Bilateral orchidectomy in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,727.40 Benefit: 75% = $1,295.55
Proposed MBS item genital reconfiguration surgery 3
Bilateral orchidectomy with scrotectomy in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $2,000.00 Benefit: 75% = $1500.00

Proposed MBS item genital reconfiguration surgery 4
Construction of labia with or without neo-vagina and inset of urethra by any method using penoscrotal skin segment in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,204.10 Benefit: 75% = $903.10
Proposed MBS item genital reconfiguration surgery 5
Construction of neo-vagina by skin grafting around a mould in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,400.00 Benefit: 75% = $1050.00
Proposed MBS item genital reconfiguration surgery 6
Construction of neo-vagina using intestinal segment or peritoneal pull through technique in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $2,349.40 Benefit: 75% = $1,762.05
Proposed MBS item genital reconfiguration surgery 7
Subsequent stage of construction of neo-vagina surgery using local flaps or skin graft, where single stage surgery was not feasible in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 8
Hysterectomy with or without bilateral salpingo-oophorectomy in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $893.85 Benefit: 75% = $670.40
Proposed MBS item genital reconfiguration surgery 9
Construction of neo-phallus by any method using local skin flaps, first stage of a multi-staged procedure in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 10
Construction of neo-phallus by any method using local skin flaps, subsequent stage of a multi-staged procedure in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC

Proposed MBS item genital reconfiguration surgery 11
Construction of neo-phallus using pedicled fascio-cutaneous regional flap, (such as pedicled antero-lateral thigh flap) in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 12
Construction of neo-phallus by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap) in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 13
Construction of neo-urethra by microvascular transfer of free autologous tissue (such as radial forearm flap or antero-lateral thigh flap) in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,252.45 Benefit: 75% = $939.35
Proposed MBS item genital reconfiguration surgery 14
Construction of neo-phallus by metoidioplasty (formation of penis from clitoral tissue) in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 15
Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) with vaginectomy in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 16
Construction of neo-urethra in metoidioplasty (formation of penis from clitoral tissue) without vaginectomy in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item genital reconfiguration surgery 17
Neo-phallus, insertion of prosthesis in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $1,220.35 Benefit: 75% = $915.30

TBC = To be confirmed in the second stage of the assessment report
Source: ADAR Table 9 (with prices updated in line with MBS items reference-priced)

Feedback from the Urological Society of Australia and New Zealand (USANZ) suggested that the proposed new suite of MBS items for genital reconfiguration surgery was incomplete, as it does not capture the full range of different variations of surgical techniques possible (or allow for revisions due to adverse events). They suggested that the following procedures should also be described:

- Construction of neo-clitoris on its mobilised neurovascular pedicle
- Construction of labia minora/hood of clitoris
- Construction of labia majora
- Urethral reconstruction
- Colposuspension
- Construction of a "dimple" rather than a full depth vagina
- Construction of neo-vagina after previous failed genital affirmation surgery
- Construction of neo-vagina after previous (ultra-)low anterior resection, radical prostatectomy, complete resection of the rectum/anus
- Revision vaginal introitus neo-vagina (for prolapse/stenosis/other)
- Urethroplasty neo-urethra, with or without debulking corpus spongiosum
- Labial revision after previous gender affirmation surgery
- Hysterectomy with unilateral salpingo-oophorectomy
- Bilateral salpingo-oophorectomy, without hysterectomy
- Separate items to distinguish between construction of neo-phallus (by microvascular transfer of free autologous tissue or pedicled regional autologous tissue) *without formation of urethra* or *with formation of urethra.*
- Glans sculpting
- Scrotoplasty / perineoplasty
- Release and trans-positioning clitoris
- Urethral hook-up / urethroplasty, *with* anterior vaginal mucosal advancement flap
- Urethral hook-up / urethroplasty, *without* anterior vaginal mucosal advancement flap
- Vaginectomy / colpocleisis
- Separate items for construction of neo-phallus by metoidioplasty, *with* and *without* urethral lengthening (using buccal mucosa graft)
- Clarification that items for the construction of the neo-urethra should be with or without vaginectomy *or colpocleisis*
- Separate items for mons reduction, *with* or *without* corporal lengthening via release of suspensory ligaments
- Separate items for penile prosthesis in neo-phallus (cylinders) *with corporal reconstruction using graft material* or *reservoir/ pump*
- Testicular implant in neo-scrotum, unilateral
- Testicular implant in neo-scrotum, bilateral
- Construction neo-phallus after previous genital gender affirming surgery
- Urethroplasty in neo-urethra (*single stage, first stage and second stage)*
- Genitourinary fistula repair after previous genital gender affirmation surgery
- Fat grafting of neo-phallus for volume
- Recontouring/debulking of neo-phallus

Table 4 Proposed items for gender affirming facial surgery

Proposed MBS item gender affirming facial surgery 1
Feminising or 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 (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item gender affirming facial surgery 2
Feminising or 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 (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item gender affirming facial surgery 3
Feminising or masculinising facial surgery, bony genioplasty in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item gender affirming facial surgery 4
Feminising or masculinising facial surgery, one or more mandibular ostectomies (other than simple bony genioplasty) and mandibular reshaping if undertaken in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item gender affirming facial surgery 5
Feminising or masculinising facial surgery, insertion of facial implants or bone grafts in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: $539.75 Benefit: 75% = $404.85
Proposed MBS item gender affirming facial surgery 6
Feminising or 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 (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC
Proposed MBS item gender affirming facial surgery 7
Rhinoplasty, total, including correction of all bony and cartilaginous elements of the external nose, with or without autogenous cartilage or bone graft from a local site (nasal), in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Fee: $1,214.40 Benefit: 75% = $910.80

Proposed MBS item gender affirming facial surgery 8
Rhinoplasty, partial, involving correction of bony vault only, in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Fee: $669.40 Benefit: 75% = $502.05 85% = $569.00
Proposed MBS item gender affirming facial surgery 9
Rhinoplasty, partial, involving correction of one or both lateral cartilages, one or both alar cartilages or one or both lateral cartilages and alar cartilages in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Fee: $583.20 Benefit: 75% = $437.40 85% = $495.75

TBC = To be confirmed in the second stage of the assessment report
Source: ADAR Table 10 (with prices updated in line with MBS items reference-priced)

Table 5 Proposed item for gender affirming voice surgery

Proposed MBS item gender affirming voice surgery
Chondrolaryngoplasty in an individual with a diagnosis of gender incongruence (See TN.X.XX of explanatory notes to this category) Suggested fee: TBC

TBC = To be confirmed in the second stage of the assessment report
Source: ADAR Table 11

ESC noted that access to specialists at centres performing gender affirmation surgeries would likely be restricted to capital cities, and hence the availability of MBS items for these procedures would reduce but not eliminate current inequities in access to gender afforming surgery. Currently, the only people who may access gender affirmation surgeries are those who can afford to pay for the procedures privately in Australia, sometimes using MBS items which were not originally intended for this purpose, and that do not adequately cover the cost of the procedure. Some patients may have the procedures performed overseas.

Currently, jurisdiction-based barriers exist that limit gender affirmation surgeries being performed in public hospitals. According to the ADAR, the following restrictions apply:

- Australian Capital Territory: no breast augmentation or prosthesis or any reproductive organ surgery (except in the context of oncology treatment or congenital correction) is accessible as a public patient
- New South Wales: 'gender reassignment surgery' is "discretionary", meaning different Local Health District Director of Surgeries determine whether it may be performed in a specific public hospital
- Northern Territory: gender affirming surgery is not allowed in the public health system
- Queensland: gender affirming surgery is not allowed in public hospitals
- Tasmania: urological and gynaecological surgery is only allowed in public hospitals if it is for congenital abnormalities in children, or if there is evidence of trauma or other conditions that are chronic or congenital

- Victoria: some gender affirming procedures are listed as aesthetic procedures and are only available in public hospitals if they are due to significant clinical symptoms or significant deformity
- Western Australia: gender affirmation procedures are excluded from delivery in public hospitals unless there are exceptional circumstances
- South Australia: The Restricted and Discretionary Elective Surgery Policy is currently under review.

If supported, the public funding of a suite of MBS items specific for gender affirming care would increase access to private services for eligible patients, which may include private patients in public hospitals. Under the National Health Reform Agreement (NHRA), States and Territories manage their respective hospital systems within their jurisdictions. Under the NHRA, access to public hospital services is based on clinical need, a service must be available within a clinically appropriate period, and must be offered free of charge. ESC noted it is therefore unclear whether the introduction of MBS items would address barriers that currently exist in public hospitals as stated in the ADAR.

The Health Insurance Act 1973 requires that MBS services must be 'clinically relevant'. A clinically relevant service is defined as one that is generally accepted in the medical profession as being necessary for the appropriate treatment of the patient to whom it is rendered. MBS items are not available for non-therapeutic cosmetic surgery. The MBS Review Taskforce defined cosmetic surgery as "*any invasive procedure where the primary intention is to achieve what the patient perceives to be a more desirable appearance and where the procedure involves changes to bodily features that have a normal appearance on presentation to the doctor"*[14]. Although appearance may be considered anatomically consistent with the assigned sex at birth, people with gender incongruence perceive their bodily features as significantly abnormal and distressing. For people with gender incongruence seeking gender affirmation surgery, the assessment of what is accepted would be related to the individuals' experienced gender rather than the sex assigned at birth.

7. Population

The population is adults with diagnosed gender incongruence, who are electing to undergo gender affirming surgical procedures. Gender incongruence is defined as a marked and persistent incongruence between the individual's experienced gender and the assigned sex (International Classification of Diseases 11th Revision maintained by the World Health Organization[15]).

The population in the ADAR was consistent with the PICO confirmation. However, the term "persistent incongruence" (as per the ICD-11 definition of gender incongruence) is not well specified and may lead to different interpretations between individual patients and clinicians. PASC noted that there are 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.

Gender affirming procedures would be used in addition to current standard of care (including psychological support, social support, voice and communication training, occupational therapy,

[14] https://www.health.gov.au/sites/default/files/documents/2021/05/taskforce-final-report-plastic-and-reconstructive-surgery-items-taskforce-report-for-plastic-and-reconstructive-surgery-items.pdf

[15] https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f90875286

hair removal services, post-surgery rehabilitative care, fertility specialists, legal advice, with/without hormone therapy).

ESC and MSAC noted that the proposal from ASPS is that there be no requirement for an individual to experience gender dysphoria (discomfort or distress caused by the gender incongruence[16]) in order to access the proposed gender affirmation surgery. The intention is that gender affirmation surgery would help prevent the onset of gender dysphoria and its sequelae. However, ESC noted that proponents of gender affirmation consider that comorbid mental health problems should not prevent people from accessing surgery (i.e. mental health problems should neither be required nor preclude people from accessing gender affirmation surgery).[17]

The WPATH SoC version 8 has recommended that in order to access gender affirming treatments, physical health, mental health and substance abuse disorders that interfere with a patients' ability to provide informed consent are treated first. They also recommend that the patient is abstinent from tobacco/nicotine. In order to be eligible for genital reconfiguration surgery, they must have discussed reproductive options and have been on at least 6 months of gender affirming hormones or gonadal suppression.[18] Although the ASPS proposal is that a MDT would discuss the suitability of gender affirmation surgery for individuals, ESC noted that it is not clear whether the MDT would require that the WPATH SoC be met.

MSAC noted that previous versions of the WPATH SoC have been more restrictive (e.g. WPATH SoC versions 5-6 recommended at least 12 months of continuous hormone therapy, and two providers need to give letters of support, with one letter including a comprehensive psychosocial assessment). Up until version 5 of the WPATH SoC, genital sex rearrangement was recommended to be preceded by the person having lived at least 12 months full-time in the social role of their preferred gender. MSAC considered that the gradual easing of restrictions over time may mean that studies which included people who were approved for surgery when different WPATH SoC were in use (and therefore had to meet stricter criteria) are not as applicable as more recent studies (when it is possible a broader range of people have undergone surgery).

MSAC noted that the number of people identifying as gender incongruent has been increasing. In Australia, data were not available for adults, but the Royal Children's Hospital Gender Service in Melbourne (the largest paediatric gender service clinic in Australia) reported a rapid increase in the number of referrals, from 13 prior to 2011, to 200 received between 2015-2016. This has corresponded with a shift favouring those assigned female at birth[19]. Data obtained under Freedom of Information (FOI) have indicated that the growth in gender services has continued to increase since 2016 in Australia, with increases in the number of patients, staff and interventions[20].

[16] Note that the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR) lists the specific criteria for gender dysphoria.

[17] Jorgensen SCJ. Transition Regret and Detransition: Meanings and Uncertainties. Arch Sex Behav. 2023 Jul;52(5):2173-2184. doi: 10.1007/s10508-023-02626-2. Epub 2023 Jun 2. PMID: 37266795; PMCID: PMC10322945.

[18] Amengual, T, Kunstman, K, Lloyd, RB, Janssen, A & Wescott, AB 2022, 'Readiness assessments for gender-affirming surgical treatments: A systematic scoping review of historical practices and changing ethical considerations', Front Psychiatry, vol. 13, p. 1006024 10.3389/fpsyt.2022.1006024.

[19] Cheung, AS, Ooi, O, Leemaqz, S, Cundill, P, Silberstein, N, Bretherton, I, et al. 2018, 'Sociodemographic and Clinical Characteristics of Transgender Adults in Australia', Transgend Health, vol. 3, no. 1, pp. 229-238.

[20] Amos, AJ 2024, 'Rapidly expanding gender-affirming care based on consensus instead of evidence justifies rigorous governance and transparency', Australas Psychiatry, vol. 32, no. 4, Aug, pp. 346-353 10.1177/10398562241249579.

8. Comparator

The ADAR comparator (for the assessment of safety and effectiveness) was no gender affirming surgery. This comparator was consistent with the PASC-ratified PICO confirmation.

All forms of gender affirmation care, other than surgery (e.g. medical, psychological, social) are assumed to be equivalent between the intervention and comparator groups. Gender affirmation surgery would therefore be used in addition to, rather than as a replacement, for other forms of care.

A small number of surgical procedures may currently be performed using existing MBS items not specifically listed for the indication of gender affirmation, but an assessment of comparative safety, effectiveness or cost-effectiveness is not required with this as a comparator. The ratified PICO confirmation noted that a supplementary financial impact analysis may be performed to determine the budget impact of utilisation shifting from the existing MBS items to the proposed gender affirmation surgical MBS items.

9. Summary of public consultation input

Consultation input was received from 2,706 respondents, including individuals, health professionals/academics, consumer organisations, and medical, health, or other (non-consumer) organisations during the pre-MSAC consultation period.

Level of support for public funding

Most respondents (92.5%) indicated support for the public funding of these services. Respondents who identified they 'have the health condition that this service or technology is for' or 'have the health condition…and have experience with the proposed health service or technology' were most likely to support public funding (97.6 %). Around half of the responses submitted on behalf of a consumer group (51.8 %) or medical/health/non-consumer group (50%) indicated support for public funding.

Perceived Advantages

Respondents identified numerous advantages to the proposed service, including:

- An opportunity for individuals to live authentically and improve their quality of life.
- A decrease in mental health issues such as depression and anxiety, self-harm, suicidal ideation, and suicide attempts.
- A reduced personal financial burden on those seeking gender-affirming surgeries.
- A reduction in long-term healthcare costs.
- Increased opportunities for research and innovation, leading to greater understanding of gender incongruence.
- Increased supply of healthcare professionals and quality of care in the gender-affirming space, reducing the need for patients to travel overseas for surgery.
- A reduction in harm and injury associated with current management, including damage to ribs, spine and lungs from chest binding or blood flow issues and testicular torsion from tucking.

Perceived Disadvantages

Many respondents who disagreed with public funding of the service noted the following:

- Conflicts with personal, religious, or cultural beliefs.
- A belief that gender incongruence is a symptom of mental health concerns that require psychological management rather than gender-affirming care (including surgery).
- Concerns that the 'gender affirmation model of care' is an ideological construct and is inequitable to women and girls.
- The ethics of performing surgery on what is perceived as physiologically healthy tissue or organs.
- Higher priorities for government spending.

Many respondents noted the risks involved with any form of surgery, such as infection, complications, and risks associated with anaesthesia. In addition, respondents noted potential disadvantages specific to the proposed services, including:

- The irreversible nature of gender affirmation surgeries and the risk of regretting changes to gender, fertility or sexual functioning.
- The long recovery time following some surgeries and the continued inaccessibility for those unable to self-fund breaks from work/study or receive general post-operative care and help.
- The need for ongoing management and monitoring to avoid complications.
- Concerns about confidentiality and privacy regarding medical records.
- Dissatisfaction with the results of surgeries, requiring revisions.
- Long-term negative psychological harm post-surgery. Those who supported public funding and also identified potential disadvantages frequently emphasised the positives outweighed the negatives, noting many disadvantages could be managed through thorough informed-consent procedures and additional support mechanisms.

Implementation

In their input, respondents noted a range of issues relevant to implementation, including:

- The proposed eligible population, with some respondents stating the eligible population should start at 25 years of age.
- Some of those in support of public funding interpreted the application as limiting surgery to those aged 18-50 years (although no upper age limit was proposed in the application). These respondents argued that a cut off age of 50 was arbitrary and would be a significant disservice to gender-diverse consumers over 50. They wanted no upper limit, but rather for this to be a decision between the surgeon and the patient, based on the type of surgery and the patient's health status.
- Some respondents raised concerns regarding the possibility of limiting the number of surgeries that an individual could access.
- Many respondents stated a gender incongruence diagnosis should be required by a mental health professional prior to accessing surgery.
- Access issues continued to be of concern, with respondents noting the need for training and support for health professionals, mechanisms to support those in rural and remote areas, and the need to minimise additional out-of-pocket costs that pose a barrier to access.
- Additional services were identified by respondents as important, including pre-requisites to surgery such as hair removal, physical and occupational therapy post-surgery, psychological and psychiatric support, and social work services.

- Several respondents raised concerns regarding terminology used in MBS descriptors, including clear definitions of the procedures covered (e.g., vaginoplasty, phalloplasty, chest masculinisation, facial feminisation surgery), the use of inclusive language that reflects affirming and respectful terminology, and language that captures the full spectrum of gender-affirming surgeries, not just genital reconstruction, including:
    - Genital surgeries (vaginoplasty, phalloplasty, metoidioplasty)
    - Chest surgeries (mastectomy, breast augmentation)
    - Facial surgeries (facial feminisation and masculinisation)
    - Voice surgeries
    - Hysterectomy and oophorectomy
    - Some respondents raised issues related to the availability under the PBS or privately of hormone replacement therapy, puberty blockers and other medications, or other types of gender-affirming care not covered by this application. This input was noted as relevant to the experience of consumers, but access to medicines and other types of gender-affirming care is out of scope for this application.

10. Characteristics of the evidence base

The assessment process for a therapeutic technology is well established in the MSAC Guidelines.[21] The ADAR followed only some of the MSAC Guidelines when conducting their systematic review. A summary of the steps from the Guidelines on performing a systematic review, and reporting study results is provided in Table 7, highlighting what was missing from the ADAR.

A large volume of evidence on the safety and effectiveness of gender affirmation surgery in people with gender dysphoria or gender incongruence has been published. Initial searches by the ADAR retrieved 3,156 potentially relevant citations. However, it was considered in the ADAR that it would be impractical to screen this many titles and abstracts, so a decision was made to restrict consideration to more recent literature (2010 onwards). 1,189 citations were screened. Based on the inclusion and exclusion criteria applied, the ADAR then presented a total of 51 studies as its evidence base. Although the ADAR specified that they included systematic reviews, no systematic reviews were mentioned in the ADAR. However, MSAC noted that multiple systematic reviews were identified during the evaluation of the ADAR. It was therefore unclear how inclusion/exclusion decisions were made. Systematic reviews (which were identified by the commentary) looking at quality of life in those who undergo gender affirmation surgery did not identify any relevant before-and-after case series that were missing in the ADAR evidence base, although cross-sectional designs were either not identified or were often excluded from the ADAR. ESC noted that the systematic review by Oles et al. (2022)[22] included relevant outcomes, and was more comprehensive than the evidence base presented in the ADAR (Oles et al 2022

[21] https://www.msac.gov.au/resources/guidelines-preparing-assessments-msac

[22] Oles, N, Darrach, H, Landford, W, Garza, M, Twose, C, Park, CS, Tran, P, Schechter, LS, Lau, B & Coon, D 2022, 'Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 1: Breast/Chest, Face, and Voice)', Ann Surg, vol. 275, no. 1, Jan 1, pp. e52-e66 10.1097/SLA.0000000000004728.

Oles, N, Darrach, H, Landford, W, Garza, M, Twose, C, Park, CS, Tran, P, Schechter, LS, Lau, B & Coon, D 2022, 'Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 2: Genital Reconstruction)', Ann Surg, vol. 275, no. 1, Jan 1, pp. e67-e74 10.1097/SLA.0000000000004717.

included 406 publications containing gender-affirming surgical cohorts, having screened 15,186 references).

The ADAR described the study designs and stratified the included studies by sample size, but did not provide any explicit assessment of the risk of bias of included studies. This was insufficient to identify the key issues that may have affected the treatment effect observed in the studies, as described in the MSAC Guidelines. The ADAR stated they used the "Let Evidence Guide Every New Decision" (LEGEND) approach[23] to assess the level of evidence, but this is not a formal assessment of the risk of bias. Likewise, the ADAR did not provide an overall assessment of the quality of the evidence by outcome, as requested by the MSAC Guidelines.

MSAC noted that most included studies in the ADAR provided relatively short-term outcomes data (6-12 months), and considered this could bias the results. For example, a Swedish study that looked at the rate of regret after gender affirmation surgery between 1960 and 2010[24] reported that the median time lag until applying for a reversal was 8 years[25].

ESC noted that some included studies had high loss to follow-up, and may therefore be at high risk of attrition bias. ESC noted that this is an important potential source of bias as there is a risk that people who are less satisfied and regret undergoing surgery would be more likely to not respond to further contact with gender services.

MSAC noted that the ADAR was not always explicit regarding the criteria used in the primary studies to determine the inclusion of participants (such as whether they were required to have gender dysphoria, or to have met the WPATH standards of care criteria that were in use at the time of their surgery). It is unclear whether populations who often had to undergo extensive psychiatric assessment prior to gender affirmation surgery, would be representative of those proposed to be eligible for gender affirmation surgery under the proposed MBS items (as it is proposed that no psychiatric assessment is required, and no requirements for people to live in the social role of their preferred gender for a particular time period prior to surgery etc). There is also a shift in the demographics of those undergoing gender affirmation surgery, with people seeking treatment now being younger, and with a larger proportion of trans men seeking treatment compared to historical trends. The ADAR extracted only limited study/sample characteristics, and did not report on study or population details such as the mean/median age of patients or the country in which the study was performed.

A summary of the body of evidence included in the ADAR and additional evidence identified during the evaluation of the ADAR (i.e. primary studies from the systematic reviews identified during the evaluation) is shown in Table 6. MSAC noted that it was unclear why the systematic reviews had not been identified, or had been excluded in the ADAR. The additional studies included in the commentary provided non-comparative information that had either not been identified, or had been excluded by the ADAR due to the volume of evidence. The study designs were redefined during evaluation, to be explicit that no cohort studies were included. The ADAR stated that cohort studies were included. However, ESC agreed with the commentary that the ADAR had inappropriately described the design of included/excluded studies: a cohort study would have required both the intervention and comparator arms to be followed longitudinally

[23] Clark, E, Burkett, K, et al. (2009). "Let Evidence Guide Every New Decision (LEGEND): an evidence evaluation system for point-of-care clinicians and guideline development teams." Journal of Evaluation in Clinical Practice **15**(6): 1054-1060.

[24] More recent years were considered uninformative as they had been performed too recently to meet the median time to regret from previous decades.

[25] Dhejne, C, Oberg, K, Arver, S & Landen, M 2014, 'An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets', Arch Sex Behav, vol. 43, no. 8, Nov, pp. 1535-1545 10.1007/s10508-014-0300-8.

(either retrospectively or prospectively), whereas the included studies either followed the intervention arm longitudinally (case series), or compared an intervention with a comparator arm at one point in time (cross-sectional studies). MSAC considered the literature search in the ADAR was not adequately described and may have excluded relevant studies. MSAC noted that the ADAR did not assess the risk of bias or confounding or overall quality of evidence for each outcome, nor applicability to the Australian population as required by the MSAC Guidelines.

Table 6 Key features of the evidence included in the ADAR and additional evidence identified by the commentary

Outcome(s)	No. of studies	N	Design/duration	Risk of bias	Patient population
Quality of life	K=13	832	Before and after case series	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (pre- and post-)
Gender dysphoria	K=16	NA	Before and after case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (pre- and post-) for gender dysphoria
Functioning	K=113	5,079	Case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (non-comparative)
Regret	K=27	7,298	Case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (non-comparative)
Satisfaction	K=203	6,805	Case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (non-comparative)
Suicidal ideation/ attempts	K=10	7,216	Before and after case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (pre- and post-) or non-comparative
Depressive symptoms	K=8	3,962	Before and after case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (pre- and post-) or non-comparative
Anxiety	K=5	3,544	Before and after case series or cross-sectional	Not assessed (likely high due to attrition bias)	People who underwent gender affirmation surgery (pre- and post-) or non-comparative

Source: Compiled during the evaluation. The total volume of evidence includes studies from the ADAR and commentary.

Table 7 Required steps of the MASC Guidelines approach for the assessment of therapeutic technologies (see MSAC Guidelines Section 2A[2121])

Guidance step	Guidance location	Conducted in ADAR
Presentation of the characteristics of the evidence		
A systematic literature search for relevant evidence	Appendix 2	A limited literature search was performed Eligibility criteria were unclear
An assessment of the risk of bias of the included evidence (using appropriate appraisal tools)	Appendix 3	Not performed
Presentation of the characteristics of the included studies	Appendix 5	Yes, tabulated
An overall assessment of the certainty of the evidence for each outcome	Appendix 4	Not performed
Presentation of the results		
Results from individual studies preferably presented by outcome in tables or graphs rather than narratively	Technical Guidance 6.1	No Results were not collated by outcome, rather studies were reported individually. Results were not tabulated or compared across studies.
Meta-analysis of results (if appropriate)	Technical Guidance 6.2	Not performed Without a full literature search it is unclear whether meta-analysis would be appropriate for some outcomes
Indirect comparisons (if appropriate)	Technical Guidance 6.3	Not performed Without a full literature search it is unclear whether an indirect comparison would be appropriate for some outcomes
Discussion of quality and certainty of the included evidence	Appendix 4	Not performed
Discussion of the overall evidence base in the context of risk of bias, quality, confounding, and applicability to the proposed target population	Appendices 3, 4 & 5	Not performed

Source: Compiled during the evaluation.

11. Comparative safety

ESC noted that none of the identified studies explicitly compared the safety of gender affirmation surgery to the comparator of no gender affirmation surgery. Surgery inevitably is associated with risks, so the use of gender affirmation surgery cannot be assumed to have non- inferior safety.

MSAC noted that while individuals' risk tolerance for adverse events varies, a patient would still need to be assessed by a MDT as to their individual ability to tolerate the procedure.

MSAC noted that although the ADAR argued that the effectiveness of individual procedures cannot be determined (as the psychological impact relates to the suite of procedures that individuals choose to have), data on adverse events and complications are available for various procedures in the broad categories - chest surgery, genital reconfiguration surgery, and facial surgery. No results on safety were identified for vocal cord surgery or metoidioplasty. No deaths associated with the physical impact of surgery were reported. Some studies categorised adverse events according to degree of severity, but they were not consistent in the way they categorised severity.

Chest surgery

ESC noted that the majority of data on the safety of gender affirmation chest surgery came from the National Surgical Quality Improvement Program (NSQIP) (3 out of the 4 publications) and reported low rates of all-cause complications (1.8% to 4.7%). Complications included haematoma, infection, bleeding, surgical injury, necrosis, and implant complications (rupture, contracture, or inflammatory response). Cuccolo et al. (2019a&b) reported that the rates of complications were as safe, or safer, than similar procedures in cisgender patients (who underwent mastectomy or breast augmentation for non-gender affirmation purposes).

A single institution (Karolinska University Hospital) reported higher rates of complications than the NSQIP data. The data from this institution published in Kamali et al. (2021) reported 103 complications (in 99 patients), of which 62/103 (60.2%) required either no intervention or medical intervention (Clavien-Dindo grade I or II), 40/103 (38.8%) required surgical intervention, and 1/103 (9.7%) was life threatening (a case of deep vein thrombosis)[26]. ESC noted that it is unclear why the rates from Kamali et al. (2021) differed from the other studies, but several surgical techniques were used, and some cases underwent surgical techniques that had particularly high complication rates.

Table 8 All-cause complications from chest surgery

Study	Gender-affirming procedure	Complications	Cisgender procedure	Complications	p-value[a]
Cuccolo et al. (2019a), NSQIP 2005 – 2017	Mastectomy	<30 days: 28/591 (4.7%)	Prophylactic mastectomy	92/887 (10.4%)	p<0.001
Kamali et al. (2021), Karolinska University Hospital 2009-2018	Mastectomy	<30 days: 99/464 (21.3%) >30 days: 99/464 (21.3%)	NA	NA	NA
Jolly et al. (2023), NSQIP 2005 – 2019	Mastectomy	<30 days: 79/1,857 (4.3%)	NA	NA	NA
	Breast augmentation	<30 days: 16/648 (2.5%)	NA	NA	NA
Cuccolo et al. (2019b) NSQIP 2006 – 2017	Breast augmentation	<30 days: 5/280 (1.8%)	Breast augmentation	18/1080 (1.6%)	p=0.89

Source: compiled from ADAR 1754
NA = not applicable; NSQIP = National Surgical Quality Improvement Program
[a]p-value for comparison between safety of gender affirming surgery vs similar procedure for cisgender patients

Rates of unplanned revision chest surgery (for either suboptimal results or complications) varied between 0% (Beaufils et al, 2023) and 20.4% Kaur et al, 2023) (Table 9). The most common complication requiring reoperation was haematoma. Kaur et al. (2023) was an outlier in regard to complication rates that required revision surgery (20.4%), with a high rate of "dog ears"

[26] Kamali, A, Sigurjonsson, H, Gran, I, Farnebo, F, Conneryd Lundgren, K, Granath, F & Sommar, P 2021, 'Improved Surgical Outcome with Double Incision and Free Nipple Graft in Gender Confirmation Mastectomy', Plast Reconstr Surg Glob Open, vol. 9, no. 7, Jul, p. e3628 10.1097/GOX.0000000000003628.

(excess skin and fat that bulges at the ends of surgical incisions)[27]. This outcome is neither dangerous nor causes discomfort or pain, and can be corrected through a subsequent procedure. Excluding the dog ear revisions, the reoperation rate was 5.6% for the study.

ESC noted that there were six included studies that reported on mastectomies (or breast reductions) finding reoperation rates between 0% and 7.1%, and three reported on breast augmentation, finding reoperation rates of between 1.4% and 2.1% (Table 9).

A systematic review of complications requiring reoperation after gender affirming breast augmentation, found that the most common reasons for reoperation were haematoma (0.4%) and infection (0.4%). A larger proportion of patients required reoperation due to implant complications at >30 days post-surgery, such as rupture (5.7%), capsular contracture (4.9%)[28].

Table 9 Rates of unplanned revision chest surgery

Study	Gender-affirming procedure	Rate of revision surgery for complications / suboptimal surgical outcomes	Cisgender procedure	Rate of revision surgery for complications / suboptimal surgical outcomes	p-value[a]
Jolly, Boskey & Ganor 2023 NSQIP 2005 - 2019	Chest masculinisation (mastectomy or breast reduction)	52/1,857 (2.8%) 29/52 (55.8%) haematomas 4/52 (7.7%) injury	NA	NA	NA
(Beaufils et al. 2023)	Chest masculinisation	0/15 (0%)	NA	NA	NA
Cuccolo et al. 2019b, NSQIP 2005 - 2017	Mastectomy	19/591 (3.2%) 8/19 (57.1%) haematoma 5/19 (35.7%) abscess or wound debridement	Prophylactic mastectomy	43/887 (4.8%)	Not stated
			Mastectomy for gynecomastia	57/2,692 (2.1%)	Not stated
Kamali et al. 2021 Karolinska University Hospital 2009-2018	Chest masculinisation (mastectomy)	33/464 (7.1%)	NA	NA	NA
Kaur et al. 2023	Chest masculinisation	22/108 (20.4%) 15/22 (68.1%) dog ears, 5/22 (22.7%) haematoma	NA	NA	NA
Bertrand et al. 2024	Mastectomy	3/111 (2.7%) 3/3 (100%) haematomas	NA	NA	NA

[27] Kaur, MN, Gallo, L, Wang, Y, Rae, C, McEvenue, G, Semple, J, Johnson, N, Savard, K, Pusic, AL, Coon, D & Klassen, AF 2023, 'Health state utility values in patients undergoing chest masculinization surgery', J Plast Reconstr Aesthet Surg, vol. 81, Jun, pp. 26-33 10.1016/j.bjps.2023.02.004.

[28] Sijben, I, Timmermans, FW, Lapid, O, Bouman, MB & van der Sluis, WB 2021b, 'Long-term Follow-up and Trends in Breast Augmentation in 527 Transgender Women and Nonbinary Individuals: A 30-year experience in Amsterdam', *Journal of Plastic, Reconstructive and Aesthetic Surgery*, vol. 74, no. 11, Nov, pp. 3158-3167 doi:10.1016/j.bjps.2021.03.107.

Jolly, Boskey & Ganor 2023 NSQIP 2005 - 2019	Chest feminisation (breast augmentation)	10/648 (1.5%) 5/10 (50%) haematomas	NA	NA	NA
Cuccolo et al. 2019a NSQIP 2006 – 2017	Chest feminisation (breast augmentation)	4/280 (1.4%) 3/4 (75%) haematomas	Breast augmentation	10/1,080 (0.90%) 8/10 (80%) haematomas	
Gabrick et al. 2021, NSQIP 2007 - 2016	Chest feminisation (breast augmentation)	3/137 (2.1%)	Breast augmentation	49/4,234 (1.2%)	p=0.324

Source: compiled from ADAR 1754
NA = not applicable; NSQIP = National Surgical Quality Improvement Program
[a]p-value for comparison between safety of gender affirming surgery vs similar procedure for cisgender patients

Genital surgery

ESC noted that the evidence suggested that genital reconfiguration surgery had similar safety, whether it was performed for the purposes of gender affirmation, or for other reasons in cisgender patients. However, some types of genital reconfiguration surgery were associated with a high rate of complications (

Table 10). The rate of complications associated with hysterectomy was 3.4 – 4.8%, and most common complications were transfusion, dehiscence, pulmonary embolus, and deep vein thrombosis. The rate of complications associated with phalloplasty was 31.5% - 43.8% and the most commonly occurring complications were infection, urethral stricture or fistula, partial loss, dehiscence, and mechanical failure. The rate of complications associated with vaginoplasty was 11.1% - 32.1% and the most commonly occurring major complications were infection (deep surgical and organ site), sepsis, pneumonia, and rectal or urethral injuries.

In some studies, the high rate of all-cause complications associated with genital reconfiguration surgery also resulted in a high rate of revision surgery. Phalloplasty (with implantation of penile prosthesis) reoperation rates were reported in one study (Falcone et al, 2018). The procedure was associated with a high surgical revision rate (43.3%), due to patient dissatisfaction (44.8% of revision surgeries), mechanical failure (35.5% of revision surgeries) or infection (19.6% of revision surgeries). No studies included in the ADAR reported on the rate of complications associated with metoidioplasty.

MSAC noted that the evidence was predominantly short-term (less than 30 days).

Table 10 All-cause complications from genital reconfiguration surgery

Study	Gender affirming procedure	Complications	Cisgender procedure	Complications	p-value [a]
Bretschneider et al. (2018), NSQIP 2013 – 2016	Hysterectomy	<30 days: 16/468 (3.4%)	Hysterectomy	31/936 (3.3%)	p=0.92
Gardella et al. (2021)	Hysterectomy and bilateral salpingo-oophorectomy	Intraoperative: 0/60 (0%) Early postoperative: 3/60 (4.8%)	Hysterectomy and bilateral salpingo-oophorectomy	Intraoperative: 1/52 (1.9%) Early postoperative: 4/52 (7.7%)	p>0.05
Ascha et al. (2018), single centre 2013 – 2016	Phalloplasty: pedicled anterolateral thigh	6+ months follow-up: 28/64 (43.8%)	NA	NA	NA
	Radial forearm free	6+ months follow-up: 47/149 (31.5%)	NA	NA	NA
Saxena et al. (2023), NSQIP 2013 – 2019	Scrotoplasty	<30 days: 4/28 (14%)	Scrotoplasty	19/66 (29%)	0.19
Falcone et al. (2018), single centre, 2001 – 2015	Penile prosthesis, 63.5% radial forearm free phalloplasty 36.4% antero-lateral thigh pedicled flap phalloplasty	Mean 20 months: 107/247 (43.3%)	NA	NA	NA
Saltman et al. (2023), NSQIP 2010 – 2020	Orchidectomy	<30 days: 9/246 (3.7%)	Orchidectomy for testicular torsion	27/607 (4.4%)	p=0.6
			Orchidectomy for testicular pain	23/390 (5.9%)	p=0.2
Russell et al. (2023), NSQIP 2015 – 2020	Concurrent orchidectomy + vaginoplasty	<30 days: 40/260 (15.4%)	NA	NA	NA
	Orchidectomy alone	<30 days: 7/241 (2.9%)			
	Vaginoplasty alone	<30 days: 30/270 (11.1%)			
Levy et al. (2019), Hahnemann University Hospital 2016 – 2018	Penile inversion vaginoplasty	30-day: 57/240 (23.8%) 90-day: 77/240 (32.1%)	NA	NA	NA
Mishra et al. (2023), NSQIP 2011 – 2019	Penile inversion vaginoplasty	30-day: 54/488 (11.1%)	NA	NA	NA
Manero Vazquez et al. (2022), 2015 – 2016	Vaginoplasty (60% penile inversion vaginoplasty, 15% penile inversion vaginoplasty with penoscrotal skin graft, 35% with colovaginoplasty)	30-day: 16/84 (19%) 3-months: 10/84 (12%) 6-months: 11/84 (13%) 12-months: 1/84 (1%)	NA	NA	NA

Source: compiled from ADAR 1754
NA = not applicable
[a]p-value for comparison between safety of gender affirming surgery vs similar procedure for cisgender patients

Facial surgery

ESC noted that only two case series were identified that reported on the safety of gender affirmation facial procedures. The rate of complications was low (1.3 – 3.9%). Only one study specified the complications, the most common complication was surgical site infection (3.4%) (Murphy et al, 2022).

Murphy et al. (2022) reported that no patients required revision surgery for complications/ suboptimal surgical outcomes, whereas of the 23 patients who underwent fat grafting (as reported by Chaya et al. 2023), 3 patients (13%) had revision surgery, due to dissatisfaction with the aesthetic outcomes. The rate of satisfaction with malar implants was high (97.7%) compared to fat grafting.

Table 11 All-cause complications from facial procedures

Study	Gender affirming procedure	Complications
Murphy et al. (2022), NSQIP 2005 – 2019	Facial surgery	<30 days: 8/203 (3.9%)
Chaya et al. (2023), 2017 – 2022	Feminising facial surgery (85% porous polyethylene malar implant placement; 15% fat grafting in cheeks)	Intra-operative: 0% Postoperative: 2/152 (1.3%)

Source: compiled from ADAR 1754
NSQIP = National Surgical Quality Improvement Program

Safety conclusions

MSAC considered that based on the evidence included in the ADAR, gender affirmation surgery is associated with additional physical harms (as is the case for all surgery), when compared to no surgery. The safety of gender affirmation surgery differed depending on the procedures chosen, with additional procedures associated with cumulative risks of harms.

The most common procedures undertaken in trans females, as reported by a clinic in Melbourne, were vaginoplasty and orchidectomy (18.4% for the two combined) and breast augmentation (3.1%)[19]. From the included studies, 11.1% - 32.1% of vaginoplasties were associated with complications within the first 90 days. More than half of these were major complications[29] (deep surgical and organ site infections), sepsis, pneumonia, and rectal or urethral injuries. Minor complications were superficial surgical site infection, urinary tract infection and bleeding requiring transfusion. The proportion of patients experiencing complications from orchidectomies was small (2.9% and 3.7%) and consistent with the rate of complications for orchidectomies performed for reasons other than gender-affirmation. Breast augmentations had a reasonable short-term safety profile, with only 1.8 – 2.5% of patients experiencing complications. These were most frequently haematomas, that required surgical intervention. A small proportion (3.8%) of patients also underwent re-operation for aesthetic reasons (such as dislocation or asymmetry). Longer-term complications were more frequent, such as implant rupture (5.7% after a mean of 12.9 years) and capsular contraction (4.9% after a mean of 6.8 years).

The most common procedures undertaken in trans men, were reported to be a mastectomy (40%) and hysterectomy (5.9%)[19]**Error! Bookmark not defined.**. Most studies reported low rates

[29] Russell, CB, Hong, CX, Fairchild, P & Bretschneider, CE 2023, 'Complications after Orchiectomy and Vaginoplasty for Gender Affirmation: An Analysis of Concurrent Versus Separate Procedures Using a National Database', Urogynecology, vol. 29, no. 2, pp. 202-208

of complications associated with mastectomies, with adverse events within the first 30 days of 4.3% to 4.7%, which was consistent with the complication rate in cis-people who undergo mastectomies for reasons other than gender-affirmation. Most of the complications were haematomas or abscesses. One institution reported a much higher rate of complications (21.3%), potentially due to differences in their definition of complications (including more minor complications that required no intervention). A total of 3.4 – 4.8% of people who underwent a hysterectomy for gender affirmation purposes had complications, with 2.4% requiring a transfusion, 0.4% having dehiscence (failure of the wound to heal properly), 0.4% having a pulmonary embolus and 0.4% having deep vein thrombosis. Phalloplasty was associated with a very high rate of complications (31.5% - 43.8%) but was only conducted in 0.4% of trans men[19]27.

The data on the safety of gender affirmation surgery came predominantly from the National Surgical Quality Improvement Program, meaning that the bulk of the evidence came from multiple institutions and had large sample sizes. Most adverse events were reported in the short-term (<30 days), but there was also sufficient long-term evidence that conclusions based on the safety of these procedures could be made with reasonable certainty.

ESC considered that the safety implications of not receiving effective therapy (i.e. possible onset of dysphoria or suicidal ideation/intent) were unable to be assessed, as no studies provided longitudinal data on people who sought gender affirmation surgery, and did not receive it.

12. Comparative effectiveness

The primary effectiveness outcomes were determined *a priori* to be health-related quality of life, and the rate of gender dysphoria. Secondary outcomes were functional outcomes of surgery, satisfaction, regret/de-transition, long-term effect on health status, and incidence/frequency of psychological disorders and suicide-related outcomes. Effectiveness data were available for the most common procedures (although limited data were available on vocal cord surgery).

Quality of life

ESC noted that some factors that influence quality of life may include a person's body image, how they physically feel (whether there are any complications or pain), how society responds to them, and how their body functions (such as sexual functioning for genital reassignment surgery). A broad range of quality of life questionnaires were used in the primary literature summarised in the ADAR, which precluded a meta-analysis without standardisation of outcome measures. ESC further noted that although these outcome tools have been validated in general populations, they have not necessarily been validated in trans or gender diverse populations[22].

Results that were tabulated for before-and-after data or change data in the ADAR are presented below. Outcome measures without a summary score (i.e. where results for every individual question were provided or results were presented graphically) have not been tabulated[30]. Four studies discussed health-related quality of life in people who had a mix of gender affirmation surgical procedures, and the remainder focused on particular procedures. Thirteen before-and-after case series and three cross-sectional studies (one included in the ADAR and two additional ones identified during the evaluation) reported on the impact that gender affirmation surgery had on quality of life. In total, 13 of the 16 studies reported statistically significant improvements in

[30] Van de Grift et al. 2018 was therefore omitted, as they only provided post-surgery data, comparing satisfaction and happiness in those satisfied versus dissatisfied. Sir and Tuluy 2022 was omitted as the TRANS-Q instrument provided no overall summary score.

either overall quality of life, or psychological quality of life, with mean differences large enough that they would likely be considered clinically important. Although psychological quality of life was reported to be improved in the majority of studies, one study reported poorer physical health (Cardoso da Silva et al. 2016) and another reported non-significant differences in physical quality of life (Caprini et al. 2023). Two additional studies were included in a systematic review by Swan et al. (2022) identified during the evaluation, that reported that 81 – 84% of people who underwent gender affirming surgery considered that the surgery improved their quality of life. Although most of the studies were small, and all the studies reporting on the impact of gender affirmation surgery on quality of life likely had a high risk of bias (such as attrition bias and bias due to subjective outcome measures), the relatively high level of consistency of findings between studies provides some certainty in the results, at least in the short-term (6 – 12 months). However, the ADAR did not provide a summary measure of the size of effect, and this would be difficult to determine given the different outcome measurement tools used in the studies mean that meta-analyses without standardising would be inappropriate. Longer-term quality of life outcomes were uncertain as very few studies provided data beyond the first 6-12 months. Lindqvist et al. 2017 reported that there was a trend towards outcomes being more favourable at 1 year follow-up than at 3 and 5 year follow-up. The authors hypothesised that participants could be disappointed in the long-term effects of surgical treatment, or alternatively, suggested that only those dissatisfied with treatment or suffering from complications completed follow-up questions (attrition bias). Other data on the long-term impact of gender affirmation surgery on quality of life were lacking.

No quality of life data were reported in the ADAR specific to people who had undergone breast augmentation. The systematic review by Oles et al. (2022a) included one study (Weigert et al. 2013) that reported quality of life before and after breast augmentation. Weigert et al. reported significant improvements from prior to surgery to 4 months after surgery, in psychosocial well-being and sexual well-being, although not physical well-being (which was high to start with).

Table 12 Health-related quality of life from gender affirming surgery (mix of procedures)

Trial/Study	N	Intervention	Key outcome(s)	Preoperative	Postoperative	p-value for difference between pre- and post values
Lindqvist et al. 2017	146	Male-to-female gender affirming surgery in people with gender dysphoria *(It was not stated what procedures this involved, or how many procedures participants had undergone)*	SF-36 Mental health	66.6 ± 24.2	1 year: 70.1 ± 24.0	>0.05
			SF-36 Physical functioning	91.2 ± 13.7	1 year: 92.4 ± 13.9	>0.05
			SF-36 General health	52.0 ± 10.4	1 year: 51.9 ± 12.2	>0.05
			EQ-5D[31]	0.84	0.86	
Papadopulos et al. 2017	39	Male-to-female gender affirming surgery. Primarily genital surgery but also chest surgery	FLZM	61.74 ± 40.33	≥6 months: 80.46 ± 37.62	<0.01
Gumussoy et al. 2022	63	Hysterectomy, oophorectomy and mastectomy (male genital reconstruction not performed)	WHOQOL-BREF	76.9 ± 8.3	6 months: 107.8 ± 10.1	<0.05
Naeimi et al. 2019	42	Female-to- male gender affirming surgery in people with gender dysphoria *(It was not stated what procedures this involved, or how many procedures participants had undergone)*	SF36 total physical health	20.63±2.90	6 months: 39.19±11.30	0.001
			SF36 total psychological health	21.73±2.17	6 months: 40.25±10.17	0.001
			EQ-5D**Error! Bookmark not defined.**	0.25	0.43	

Source: compiled from ADAR 1754
EQ-5D = standardised quality of life measure by EuroQol; FLZM = Questions on Life Satisfaction (FLZM) instrument (German version); SF36 = Short form -36 item; WHOQOL-BREF = World Health Organization Quality of Life Scale Short Form. Higher scores indicated better quality of life for these scales.

[31] SF-36 outcomes mapped to EQ-5D by Kirey-Sitnikova and Ahmed (2022)

Table 13 Health-related quality of life from chest surgery

Trial/Study	N	Intervention	Key outcome(s)	Preoperative	Postoperative	p-value
Kaur et al. 2023	80	Chest masculinisation surgery	EQ-5D HSUV	0.81 ± 0.15	6 months: 0.87 ± 0.13	0.29
	65		EQ-5D VAS	74.7 ± 16.8	6 months: 80.4 ± 14.4	0.51
Bertrand et al. 2024	20	Mastectomy	BIQLI (+3 to -3)	-0.8 ± 1.3	≥8 weeks: 1.1 ± 0.9	<0.001
			BREAST-Q psychosocial wellbeing	33.9 ± 13.5	≥8 weeks: 72.2 ± 12.6	<0.001
			BREAST-Q sexual wellbeing	37.1 ± 14.1	≥8 weeks: 59 ± 19.3	<0.001
van de Grift et al. 2016	26	Mastectomy	BIQLI	0.32 ± 1.33	≥6 months: 0.38 ± 0.78	NS
Agarwal et al. 2018	42	Chest wall masculinisation	BREAST-Q psychosocial wellbeing	31.3 ± 14.2	6 months: 78.9 ± 15.9	<0.001
			BREAST-Q sexual wellbeing	30.7 ± 20.9	6 months: 71.4 ± 19.2	<0.001
			BREAST-Q physical wellbeing	65.3 ± 13.7	6 months: 80.3 ± 11.8	<0.001
Weigert et al. 2013	35	Breast augmentation	BREAST-Q psychosocial wellbeing	35 ± 16	4 months: 80 ± 21	<0.001
			BREAST-Q sexual wellbeing	33 ± 25	4 months: 75 ± 24	<0.001
			BREAST-Q physical wellbeing	84 ± 18	4 months: 79 ± 14	0.11

Source: compiled from ADAR 1754
BIQLI=Body Image Quality of Life Inventory; HSUV=health state utility values; VAS=visual analogue scale. Higher scores indicated better quality of life for these scales.

Table 14 Health-related quality of life from genital reconfiguration surgery

Trial/Study	N	Intervention	Key outcome(s)	Preoperative	Postoperative	p-value
Chaovanalikit, Wirairat & Sriswadpong 2022	41 37 with both preoperative and 6 month postoperative responses	Vaginoplasty	WHOQOL-BREF-THAI Physical domain	26.9 ± 4.5	6 months: 28.0 ± 4.5	0.001
			Psychological domain	23.1 ± 4.1	6 months: 24.8 ± 3.5	<0.001
			QoL rating	3.6 ± 0.7	6 months: 3.7 ± 0.6	0.157
			Transformed score	74 ± 7.06	6 months: 78.9 ± 7.1	<0.001
Cardoso da Silva et al. 2016	47	Vaginoplasty (not clear whether chest surgery was also offered)	WHOQOL-100 Domain I- physical health	-	Change at least 1 year after: 1.23 ± 2.61 (worsened)	0.002
			Domain II- psychological domain	-	Change at least 1 year after: -0.75 ± 2.44 (improved)	0.041

Source: compiled from ADAR 1754
WHOQOL-BREF-THAI = World Health Organization Quality of Life Scale Short Form Thai version; WHOQOL-100 = World Health Organization-100 questionnaire. Higher scores indicated better quality of life.

Published systematic reviews identified three additional studies on quality of life after facial feminisation surgery, that reported similar results to those included in the ADAR, i.e. that quality of life was better in those who had undergone facial feminisation surgery than prior to surgery. Although quality of life after facial feminisation surgery was found to be better than prior to surgery, the results were still worse than the general population[32].

[32] Javier, C, Crimston, CR & Barlow, FK 2022, 'Surgical satisfaction and quality of life outcomes reported by transgender men and women at least one year post gender-affirming surgery: A systematic literature review', Int J Transgend Health, vol. 23, no. 3, pp. 255-273 10.1080/26895269.2022.2038334.

Table 15 Health-related quality of life from facial feminisation surgery

Trial/Study	N	Intervention	Key outcome(s)	Preoperative	Postoperative	p-value
Caprini et al. 2023	169	Facial feminisation surgery	Depression (higher scores worse)	57.0 ± 8.9	≥10 weeks: 52.2 ± 9.2	0.001
			Positive affect	42.9 ± 8.7	≥10 weeks: 46.6 ± 8.9	0.01
			Global physical health	50.0 ± 7.5	≥10 weeks: 51.7 ± 6.1	0.15
			Global mental health	43.1 ± 9.2	≥10 weeks: 46.7 ± 7.6	0.01
Morrison et al. 2020	66	Facial feminisation (average of 4.2 procedures each)	Facial Feminization Surgery Outcome Score	Median 47.2 IQR 38.9, 55.6	≥6 months: Median 80.6 IQR 66.7, 86.1	<0.0001
Alper et al. 2023	20 in matched preoperatively and postoperatively group	Facial feminisation	FACE-Q psychological function domain	38.0 ± 19.7	≥6 months: 64.9 ± 25.8	<0.001
			WHOQOL-BREF physical	46.4 ±13.7	≥6 months: 60.7 ± 17.9	0.001
			WHOQOL-BREF psychological	45.8 ± 23.4	≥6 months: 59.8 ± 21.6	<0.001
Schmidt et al. 2023	15 in matched preoperatively and postoperatively group	Facial feminisation surgery (frontal osteotomy)	FACE-Q psychological distress domain	58.1± 21.1	≥1 year: 22.9 ± 30.7	0.001

Source: compiled from ADAR 1754
IQR = interquartile range; WHOQOL-BREF = World Health Organization Quality of Life Scale Short Form. Outcomes reported by Caprini et al. 2023 were all calibrated to a United States population mean of 50 and standard deviation of 10. Higher scores were better, for all outcomes except 'depression' in the table above.

Dysphoria

A summary of gender dysphoria and congruence/incongruence scale results reported in the ADAR is given in Table 16[33]. ESC noted that the scales were not consistent in direction of scores (i.e. whether an increase in score was beneficial or detrimental). Although the outcome per the ratified PICO relates to gender dysphoria, any scale used to measure the degree of dysphoria or incongruence was considered relevant to the evaluation of the outcome. The studies conducted before and after comparisons within patients, or comparisons between patients who had undergone surgery and those waiting for surgery. MSAC agreed with ESC and the commentary that the quality of these studies appeared to be poor, but noted that all results indicated a reduction in the rate of gender dysphoria or incongruence following gender affirming surgery when a comparison was made between scores of those who had and those who had not undergone surgery.

[33] Note, this omitted results included in the ADAR by van de Grift et al. 2018, as this study compared results of those who were satisfied with surgery, vs those dissatisfied with surgery, and this comparison was not informative.

Table 16 Summary of gender dysphoria/congruence scores

Study	Population n	Instrument	Subgroup	Preoperative /study entry	Postoperative /follow-up	P
Van Der Grift 2017	Masculinising chest surgery 133 hormone + surgery 35 hormone therapy 28 no intervention	UGDS	Both hormone therapy and surgery	54.3 ± 5.3	Mean 2.6 years: 15.5 ± 4.3	<0.001
			Hormone therapy only	52.0 ± 5.4	Mean 4.7 years: 20.1 ± 8.8	<0.001
			No intervention	48.4 ± 9.1	20.2 ± 12.8	<0.001
Bertrand 2024	Mastectomy 111 surgical 35 awaiting surgery	TCS	Cross-sectional survey	2.8 ± 0.9	4.1 ± 0.7	<0.001
			Prospective cohort	3 ± 0.9	4.2 ± 0.5	<0.001
Agarwal 2018	Masculinising chest surgery 42	BUT-A	Global severity	2.68 ± 0.73	6 months: 1.2 ± 0.68	<0.0001
Hung 2023	Various GAS 207 total 92 preoperative 107 post-operative	VMP-G	Gender dysphoria (overall)	16.2 ± 4.2	Median 1.1 months: 20.5 ± 4.2	<0.001
			How often do feeling of gender dysphoria disrupt daily life?	2.3 ± 0.8	Median 1.1 months: 3.4 ± 0.9	<0.001
English 2023	Phalloplasty or metoidioplasty 326	GCLS	Overall score	3.47 ± 0.62	Metoidioplasty 3.86 ± 0.51 Phalloplasty 3.97 ± 0.51	<0.001

Source: compiled from ADAR 1754
BUT-A, body uneasiness test (higher scores indicate higher uneasiness); GAS, gender affirming surgery; GCLS, Gender congruence life satisfaction scale (higher scores indicated higher congruence); TCS, Transgender congruence Scale (higher scores indicate higher levels of congruency); VMP-G, the Vanderbilt Mini Patient Reported Outcome Measure- Gender (higher scores indicate superior outcomes); UGDS, Utrecht Gender Dysphoria Scale (higher scores indicate stronger gender dysphoria)

Two systematic reviews were identified during the evaluation and are included here as they appear to have conducted a high quality literature review and synthesis of results.

Javier, Crimston & Barlow (2022)[32] included 79 studies, and reported results of gender affirming surgery at least one year post surgery in transgender men and women. Two studies included in this systematic review reported results relevant to gender dysphoria or incongruence. One retrospective study ((Massie et al. 2018); low strength of evidence[34]) in 66 transgender women reported that the majority (71%) of those who underwent genital surgery found that their gender dysphoria was resolved. A second retrospective study of 220 transgender women ((Telang 2020); medium strength evidence[34][34][34]34) found that most who underwent facial surgery report feeling less incongruent with their gender identity, as well as fewer instances of misgendering (no numerical data reported).

[34] In the Systematic review by Javier, Crimston & Barlow (2022) risk of bias was assessed using the Risk Of Bias In Non-randomised Studies – of Interventions tool (ROBIN-S), and overall strength of evidence was assessed for quality of life outcomes using adapted GRADE methodology.

A second systematic review (Murad et al. 2010)[35], assessed the impact of hormonal therapy as part of a gender affirmation process (including surgery) in people with gender identity disorder (GID), that is individuals with gender incongruence or dysphoria. This systematic review included twenty-eight studies (n = 1833 participants), and the mean follow-up was six years. The authors reported outcomes of gender dysphoria resolution post treatment, and conducted analyses by pooling results across the studies included in the systematic review. The results are summarised separately in Table 17. The majority of participants had undergone both hormonal and surgical interventions, but results were not separated.

The results were consistent across 10 studies from the two systematic reviews in reporting a reduction in gender dysphoria and gender incongruence following gender affirming surgery.

Murad et al. also reported results from Utrecht Gender Dysphoria Scale surveys (no statistical data reported), to determine improvement in gender incongruence or dysphoria following gender reassignment. Their finding was that transgender men and women had minimal gender dysphoria remaining after transition.

The results from both systematic reviews aligned with those presented in the ADAR.

Table 17 Outcomes of the systematic review by Murad et al. 2010: Resolution of gender dysphoria for GID after transition

Population	Proportion of participants with GID with significant improvement	Heterogeneity
All participants	80% (95%CI 68%, 89%)	8 studies; I^2 = 82%
Transgender women	71% (range 71% - 93%)	
Transgender men	86% (range 65% - 98%)	

Source: compiled during the evaluation.
GID, gender identity disorder

Effectiveness - Secondary outcomes

Functional outcomes of surgery

Functional outcomes of surgery were listed as a secondary outcome in the ratified PICO. The ADAR included nine studies stated to include functional outcomes, of which two were excluded during the commentary due to only including cosmetic or satisfaction outcomes. The systematic review by Oles et al (2022a&b)[22] reported results from objective and patient reported outcomes that assessed function following genital reassignment and voice surgery. The systematic review included three of the studies on functioning included in the ADAR. An additional four studies were included in the ADAR, that had been published too recently to be included in the systematic review. Results from Oles et al. (2022a&b) are summarised in Table 18. The additional four studies had results consistent with the large number of published studies included by Oles et al.

There were 171 studies identified that reported on outcomes for vaginoplasty. The types of objective measures related to functionality included vaginal width and vaginal depth (quantitatively measured). Patient reported outcomes for function included ability to orgasm,

[35] Murad, MH, Elamin, MB, Garcia, MZ, Mullan, RJ, Murad, A, Erwin, PJ & Montori, VM 2010, 'Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes', Clin Endocrinol (Oxf), vol. 72, no. 2, Feb, pp. 214-231.

genital sensitivity, and vaginal depth (the latter also reported as an objective measure). The majority of patients were able to achieve these functions post-surgery (Table 18).

Table 18 Functional outcomes of voice surgery, and genital surgeries (Oles et al. 2022a&b)

Surgery	No. of studies	Outcomes	Results
Vaginoplasty	57	Vaginal depth/width	Mean depth 12.2cm (range 6.5 – 16.5cm) from 823 patients Mean width 3.2cm (range 2.8 – 3.9cm) from 823 patients
	41	Ability to achieve orgasm	76.4% (range 28.6% - 100%), 1560/2042 patients
	21	Genital sensitivity	93.0% (range 74.0% - 100.00%), 1133/1218 patients reported sensate or satisfactorily sensate genitals
Phalloplasty	22	Successful voiding while standing	88.7% (range 15.0% - 100%), 1235 /1392 patients
	10	Penile length	15.7cm (range 8.8 – 19.0cm) from 574 patients
	9	Penile girth	13.3cm (range 12.2 – 14.0) from 538 patients
Metoidioplasty	4	Ability to obtain an erection	89.3% (range 24% - 100%) 184/206 patients
Voice surgery (feminising voice surgery)	26	Fundamental frequency (F_0)	195.0 Hz (range 140.9 - 315.0 Hz), average post-surgical F_0 for 955 patients According to authors, this is lower than the average female F_0, but high enough to permit identification as a female
	7	Maximum phonation	17.0 seconds (range 13.3 – 20.8 seconds), average post-surgical result for 423 patients Average adult female phonation is 15 – 25 seconds[a]
	6 cohorts	Perceptual analysis of patients' voices by expert or non-expert raters	77% (range 55.6% - 95.0%) of patients' voices were perceived as female, 97/126 patients

Source: compiled during the evaluation
a. https://medicine.uiowa.edu/iowaprotocols/voice-clinic;

Satisfaction

Satisfaction was assessed without any validated tools, and satisfaction with surgery could only be assessed after surgery (so there was no relevant comparator group). The ADAR only included one study on the satisfaction with phalloplasty surgery in general, with an additional three studies that assessed satisfaction with particular body parts after mastectomy. Given the limited evidence included in the ADAR, the commentary sought more comprehensive systematic reviews. A systematic review published in two parts by Oles et al. (2022a&b) included two out of four studies included in the ADAR for satisfaction, and an additional 118 studies, so was considered more informative than the ADAR by the assessment group. The results of this systematic review are shown in Table 19. The small number of studies included in the ADAR were consistent with the volume of evidence included in the systematic review, that the majority of people were

satisfied with the surgical procedures they had undergone, including from a functioning and/or aesthetic perspective.

Table 19 Satisfaction with surgery (Oles et al. 2022a&b)

Surgery	No. of studies	Outcomes	Results
Mastectomy	8	Satisfaction with aesthetic appearance	91.8% (range 73.1% - 100.0%), 685/746 patients
Breast augmentation	1	Satisfaction with aesthetic appearance	75%, 80/107 patients 16.8% of people in one study reported they felt their breasts were still too small
Vaginoplasty	49	Overall satisfaction	92.3% (range 23.1% - 100.0%), 2410/2601 patients
	31	Satisfaction with sexual function	84.1% (range 30.8% - 100.0%) 911/1084 patients
	17	Satisfied with vaginal depth	80.2% (range 42.9% - 100.0%), 372/464 patients
	32	Satisfaction with genital appearance	80.6% (range 66.6% - 100.0%), 1320/1638 patients
Phalloplasty	27	Overall satisfaction (from aesthetic and functional perspective)	89.6% (range 45.0% - 100.0%), 1306/1458 patients
Metoidioplasty	7	Overall satisfaction	91.3% (range 60.0% - 100.0%), 408/447 patients
	8	Satisfied with ability to urinate while standing	89.4% (range 20.0% - 100.0%), 617/690 patients
Facial feminisation surgery	14	Overall satisfaction	97.1% (range 80.0% - 100.0%) 534/550 patients
	7	Satisfied with femininity of face or change in their face	79.7% (range 70.0% - 100.0%), 235/295 patients
Vocal surgery / thyrochondroplasty	13	Overall satisfaction/satisfaction with femininity of voice after vocal surgery	75.5% (range 31.1% - 100.0%) 493/653

Source: compiled during the evaluation

Regret

The ADAR only included a small proportion of the volume of evidence published on this topic (3 studies). A systematic review by Bustos et al. (2021) synthesised 27 studies on the rate of regret after any type of gender affirmation surgery and reported that the pooled prevalence of regret (across 7,298 people) was 1% (95%CI <1% - 2%)[36]. However, there was a high degree of heterogeneity (I^2=75.1%), and a high risk of publication bias (as determined by an asymmetrical funnel plot). There was also a lack of a validated questionnaire to evaluate regret. Although regret was rare, nearly half of those who experienced it, either underwent or sought to undergo detransition surgery, and/or had experienced an increase in gender dysphoria from the new

[36] Bustos, VP, Bustos, SS, Mascaro, A, Del Corral, G, Forte, AJ, Ciudad, P, Kim, EA, Langstein, HN & Manrique, OJ 2021, 'Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence', Plast Reconstr Surg Glob Open, vol. 9, no. 3, Mar, p. e3477 10.1097/GOX.0000000000003477.

gender. The most common reason for regret was difficulties with social and family environments (such as lack of social acceptance). Another factor was poor surgical outcomes, such as loss of sensation, chronic pain, or poor aesthetic outcomes. Only 3 of the 27 studies reported that the mean follow-up was over 5 years, which was shorter than the median time to seeking a legal reversal to the original gender, as reported by a long-term case series in Sweden (median time to reversal application was 7.5 years for trans men and 8.5 years for trans women)[25]. There was therefore the risk that the rates of regret published may underestimate the total number of people who experience regret.

Long-term effect on health status

One study was included in the ADAR on the long-term effect of gender affirmation surgery on health status. Sijben et al. 2021a reported that 1/527 (0.2%) of patients who had undergone gender affirming breast augmentation were diagnosed with anaplastic large-cell lymphoma (over an unclear follow-up period)[28]. An additional study was by Motta et al. 2020 was identified that was initially excluded due to being a cross-sectional study of <200 participants[37], but subsequently included in the ADAR as supplementary evidence as it was the only identified study reporting on bone health. Motta et al. reported that people who were receiving hormone therapy after gender affirmation surgery had a 40% prevalence of low bone mass. However, it is unclear to what degree gender affirming surgery contributed to the low bone density. Low bone mass has been reported in transwomen prior to initiation of surgery or hormones, due to reduced levels of physical activity and vitamin D[38].

Psychological disorders and suicide-related outcomes

The ADAR included six studies reporting psychological and suicidal outcomes. An additional primary study and two systematic reviews identified in the commentary also provided evidence.

Three out of four studies assessing rates of suicidal ideation or the rate of suicide attempts, reported significantly lower rates in people post-surgery (compared to their pre-surgical levels) or in people who had undergone gender affirmation surgery (compared to those who had not). The remaining study also reported significantly lower rates of suicidal ideation in those who undergone both chest and genital surgery compared to those who were receiving hormone therapy or no interventions for gender incongruence. However, this study also reported that those who underwent chest surgery or genital surgery (but not both) fared no better than those who were receiving only hormone therapy or no interventions[39].

Five studies reported that gender affirmation surgery was associated with lower rates of depressive symptoms (which was statistically significant in four out of five studies). One of these was a cross-sectional study that reported that the rate of psychological distress was lower in people who had undergone all their desired procedures, than in those who had only undergone

---

[37] Motta, G, Marinelli, L, Barale, M, Brustio, PR, Manieri, C, Ghigo, E, Procopio, M & Lanfranco, F 2020, 'Fracture risk assessment in an Italian group of transgender women after gender-confirming surgery', *Journal of Bone and Mineral Metabolism*, vol. 38, pp. 885-893

[38] Van Caenegem, E, Taes, Y, Wierckx, K, Vandewalle, S, Toye, K, Kaufman, JM, Schreiner, T, Haraldsen, I & T'Sjoen, G 2013, 'Low bone mass is prevalent in male-to-female transsexual persons before the start of cross-sex hormonal therapy and gonadectomy', Bone, vol. 54, no. 1, May, pp. 92-97 10.1016/j.bone.2013.01.039.

[39] Tucker, RP, Testa, RJ, Simpson, TL, Shipherd, JC, Blosnich, JR & Lehavot, K 2018, 'Hormone therapy, gender affirmation surgery, and their association with recent suicidal ideation and depression symptoms in transgender veterans', Psychol Med, vol. 48, no. 14, Oct, pp. 2329-2336 10.1017/S0033291717003853.

some of their desired procedures[40]. Three studies assessed levels of anxiety, and reported significantly lower levels of anxiety than either pre-surgery, or in those who had not undergone surgery.

A systematic review by Javier et al. (2022)[32]**Error! Bookmark not defined.** reported on psychological and psychosocial functioning, depression and anxiety in transgender men and women one year post surgery. In this systematic review, one retrospective study on transgender men who underwent chest surgery (n = 36), and one prospective study in transgender women who underwent chest surgery (n = 21) found the psychological and social functioning improved post-surgery, but the evidence was low strength.[3434]

Medium strength evidence[3434] from three studies was identified for levels of depression and anxiety post-surgery. Depression and anxiety improved when assessed in transgender men who underwent genital surgery. Their levels were comparable with those in the German general population post-surgery in one of the studies. Trans women who had undergone genital surgery reported low levels of depression.

A systematic review by Murad et al (2010)[3535] assessed the impact of transition therapy and surgery in people with gender incongruence or dysphoria (Table 20). Data were not separated between those who underwent hormone therapy and surgery. The mean follow-up was 6 years. The majority of people (78%) reported significant improvements in their psychiatric comorbidities. Murad et al. also found that individuals with more pre-existing or more severe psychopathology were more likely to retain more psychological symptoms after transition (k=2).

Murad et al. (2010) reported on the change in suicide rates following gender affirmation interventions (including surgery). The results were consistent across five studies in showing reduction in psychological symptom severity, depression and anxiety following transgender surgery. Likewise, the results were consistent across 11 studies reporting that suicide rate showed a decrease following gender affirming surgery, however rates were still higher than the general population, and some individuals experienced worse symptoms after surgery.

[40] Almazan, AN & Keuroghlian, AS 2021, 'Association Between Gender-Affirming Surgeries and Mental Health Outcomes', JAMA Surg, vol. 156, no. 7, Jul 1, pp. 611-618 10.1001/jamasurg.2021.0952.

Table 20 Outcomes of systematic review by Murad et al. 2010: severity of psychiatric comorbidities following intervention for GID

Population	Proportion of participants with GID with significant improvement	Heterogeneity
Improvement in psychiatric comorbidity symptoms		
All participants	78% (95% CI 56%, 94%)	7 studies; I^2 = 86%
Transgender men	84% (range 73% - 92%)	
Transgender women	70% (range 33% - 96%)	
Suicide attempt		
Rate of suicide attempt	Self-reported rate improved from 29.3% to 5.1% after transition by the SCL-90 in one study. Overall there was a decrease after gender affirmation surgery, but the rate remained higher than the general population rate of 0.15%	4 studies; heterogeneity NR

Source: compiled during the evaluation
CI = confidence interval; GID = gender identity disorder; NR = not reported; SCL-90 = symptom checklist inventory

Effectiveness conclusions

MSAC agreed with ESC and the commentary that the studies identified in the ADAR and those identified during the evaluation collectively support the clinical claim that gender affirmation surgery is effective at improving short term (up to 12 months) quality of life and reducing levels of gender dysphoria, in people who have gender incongruence. The majority of people who underwent gender affirmation surgery were satisfied with the results of the surgery, and only 1% of people expressed regret on non-validated questionnaires regarding having had the surgery.

ESC and MSAC noted that the ADAR did not seek to identify the effectiveness of individual procedures, arguing that each individual person would choose a different combination of procedures to undergo, and their effectiveness would depend on the importance the individual person places on the procedures. However, ESC and MSAC considered that it would have been informative if the ADAR had attempted to pool results to establish the average benefit of the proposed procedures (as a whole suite, and/or by class of procedure).

ESC noted that the most commonly performed procedures in trans women were reported to be vaginoplasty, orchidectomy and breast augmentation[19]**Error! Bookmark not defined.**. For those who underwent male-to-female gender affirming surgery (either a combination of procedures, vaginoplasty or breast augmentation), four out of five studies reported significantly improvements in quality of life/psychosocial wellbeing/sexual wellbeing after surgery (8 weeks to 1 year after surgery), from pre-surgical levels. Given the small sample sizes, those studies with statistically significant results also had effect sizes that would be considered clinically important. The reasons for the heterogeneity between these studies and the single study that reported non-significant improvements was unknown. Lindqvist et al. 2017 reported on-significant improvements in mental health on the Short Form-36 (SF-36) questionnaire, although participants had moderately high levels of mental health at baseline (approximately half a standard deviation below the general population score, despite having gender dysphoria). Two studies found that gender affirmation surgery in trans women resulted in a reduction in gender dysphoria, and incongruence with their gender identity.

Many different measurement tools were used to assess quality of life, which prohibited a meta-analysis without standardisation of outcome measures.

The most commonly performed procedures in trans men were reported to be mastectomies and hysterectomies[19]**Error! Bookmark not defined.**. For those who underwent female-to-male gender affirming surgery (either a combination of procedures or a mastectomy), four out of six studies reported statistically significant improvements at 8 weeks to 6 months post-surgery from baseline levels. The remaining two studies reported favourable trends that were not statistically significant. The results were therefore considered relatively consistent.

No studies reported on quality of life after a hysterectomy alone. As per the results for trans women, the different outcome measurement tools precluded a meta-analysis using the original scales. No overall effect size could therefore be determined. Levels of gender dysphoria were significantly reduced, and levels of gender congruence were significantly increased after masculinising chest surgery.

Overall, the evidence for the effectiveness of gender affirmation surgery was based on a relatively large number of small studies that had moderate consistency in their results (although the heterogeneity was regarding whether the effect sizes were statistically significant or not, no studies had results in the opposite direction). The evidence base was predominantly before-and-after case series which were likely to be at high risk of bias due to attrition, or cross-sectional studies, that were likely to be at risk of confounding. No studies were available that compared outcomes in those who wanted gender affirmation surgery and received it, versus those who did not receive it (although this evidence would also have been confounded). There were a large number of different surgical procedures assessed, but there was insufficient information to establish whether there was any optimal combination of procedures that may be used, or any diminishing returns beyond which additional procedures would not provide the same benefits. However, a small volume of evidence was identified that suggested that people who had all of the procedures they sought for had significantly lower levels of psychological distress than those who had only undergone some of the procedures they sought. Similarly, those who had both genital and chest surgery reported significantly lower rate of depression than those who only had one type of surgery (genital or chest but not both).

Very little long-term data were available on the effectiveness of gender affirmation surgery. Of the limited evidence available, one study which assessed the quality of life at 3 and 5 years post-surgery reported that the benefits diminished over time. However, the authors suggested that these results could have been due to attrition bias due to incomplete follow-up. Modelling of long-term outcomes will therefore be highly uncertain.

Clinical claim

The ADAR made the following clinical claims:

- Gender affirming surgery has inferior safety compared with no surgery, however the safety profile is acceptable.
- Gender affirming surgery has non-inferior safety compared with similar surgical procedures performed for non-gender affirming purposes in a cisgender population.
- Gender affirming surgery has superior effectiveness compared with no surgery.

The evidence included in the ADAR and additional evidence identified in the evaluation supports these clinical claims. Although most studies were small and likely at high risk of bias (due to confounding or attrition bias), the relative consistency of the studies does increase the level of confidence in the evidence base.

Although the evidence of effectiveness was consistent in the direction of effect for the psychological impact of gender affirming surgery, and the majority of studies reported statistically significant benefits, the overall size of effect was not calculated. ESC noted that this will be required for the economic evaluation. Given the claim of superiority of gender affirmation surgery compared to no surgery, the appropriate form of economic evaluation for the second stage of the ADAR would be a cost-effectiveness or cost-utility analysis.

13. Other relevant information

Ethics

Transgender people have a higher rate of unemployment or underemployment than cisgender people. The costs associated with gender affirming surgery can therefore cause financial hardship or may also prevent people from undergoing surgical procedures. It was claimed in the ADAR that a lack of access to gender affirming care can contribute to poorer mental health.

Legal

In Western Australia, Victoria, Queensland and South Australia, people are not required to undergo surgery to legally change the gender on formal documents. However, in New South Wales, trans people who wish to change the sex on their birth certificate are required to first have gender affirming surgery. The proposed MBS items therefore have legal implications, making it easier for people to update their birth certificate, and avoiding people inadvertently being "outed" by outdated documents.

Implementation issues

The prevalence of identifying as trans or gender diverse is increasing, and the demand for gender affirming care is increasing. For example, Cheung et al. 2018 reported a 10-fold increase in demand for endocrine specialist clinics between 2011 and 2016, and SA Health reported a doubling of demand for their SA Health Model of Care from 2020 to 2021 (1754 PICO confirmation). There will need to be corresponding increases in the workforce with appropriate training, available to provide this care.

Societal implications

The ADAR claimed that access to gender affirming surgeries will have a profound flow-on effect in relation to the health and wellbeing of trans people, and that this will contribute to closing the gap between trans and cisgender individuals regarding discrimination, unemployment and stigma.

Anti-conversion laws aim to eliminate discredited and harmful practices aimed at suppressing a person's gender identity. Most Australian states and territories now have anti-conversion legislation (Victoria, Australian Capital Territory, New South Wales and South Australia), while Queensland has a ban on conversion practices in health settings, and Tasmania and Western Australia have recently committed to reforms. The ADAR suggests that the ongoing shift away from conversion practices in Australia reflects the importance of evidence-based research and clinical practice in driving health policy for trans health in Australia.

No information was provided in the ADAR on the impact of gender affirmation surgery on community affiliations, or feelings of belonging, or the impact of gender affirmation surgery on

family dynamics. No information was provided on the impact of gender affirmation surgery on feelings of empowerment and autonomy, or issues relating to stigma or discrimination.

14. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- Limited data were provided in the ADAR to inform the natural history of gender incongruence and how it relates to risk for gender dysphoria, and surrounding what constitutes best available care in the absence of surgery. It is likely that the demographics of the transgender population in Australia have changed significantly in the last few years, similar to changes observed in the UK. This makes it difficult to assess the comparative outcomes from surgery reported in the presented literature and whether they are applicable to the current Australian population.
- The ADAR was unclear on the definitions and relationships between gender incongruence and gender dysphoria. ESC noted that the term 'gender incongruence' has a formalised definition in ICD 11, with a separate definition for gender incongruence of adolescence and adulthood, but without clear, detailed or specific diagnostic criteria (so as not to medicalise the term as a psychiatric diagnosis) whereas there is a DSM- 5-TR definition of gender dysphoria.
- The binary nature of and the description of outcomes presented in the ADAR (i.e. use of the terms 'masculinisation' and 'feminisation') does not appear to capture the preferences and needs of the entire transgender population. In Australia, those currently identifying as non-binary represent one-third of the transgender population.
- The literature search performed by the applicant was not adequately described and excluded relevant studies, and the application did not assess the risk of bias or confounding, or overall quality of evidence for each outcome, or applicability to the Australian population.
- The comparative safety data included in the ADAR was predominately based on reported short-term outcomes, with no assessment of the outcome for regret following initial surgery and/or de-transition procedures. In general, there were greater reported risks for phalloplasty and vaginoplasty compared to some procedures that removed otherwise healthy tissue or organs. ESC noted the uncertainty of interpreting these safety outcomes given the low quality of the evidence review in the ADAR.
- The claim of superior effectiveness did not appear to be fully supported based on the evidence provided, although the short-term studies presented reported meaningful improvements in quality of life (with variation according to country where reported) and a reduction in gender dysphoria. Post-surgery rates of suicide, depression and anxiety were reported to be lower. ESC noted the uncertainty of interpreting these effectiveness outcomes given the low quality of the evidence review.
- The lack of long-term outcome data presented in the ADAR increases uncertainty about the risks of the proposed interventions and the ongoing needs of this population. Long-term data is likely to be important for any future economic modelling. There is a need for long-term data, including qualitative data to inform the full range of patient-relevant outcomes, including decision regret and use of detransition services.

Economic issues:

- Issues with the quality of clinical evidence and relatively short length of follow-up presented in the ADAR (as outlined above) flow through to any future economic analysis.

- The data provided in the ADAR do not assist in understanding which surgery or groups of surgeries have superior outcomes (including impact on pre-surgery gender dysphoria, or its prevention, and impact on health related quality of life) to inform the assessment of cost-effectiveness. More granular data by surgical item group or sub-type may provide greater insight into risks and benefits and the value of the proposed interventions.
- If MSAC accepts the ADAR's clinical claim, a cost-utility or cost-effectiveness analysis would be appropriate. A range of complexities would be associated with the development of the economic model, including the large number of proposed interventions, the number and mix of procedures, the specification of the multidisciplinary care professionals to include in the analysis, and the variable number of surgical procedures per patient.

Financial issues:

- The utilisation of current MBS items for surgical procedures relating to individuals with gender incongruence is not ascertainable.
- The prevalence of people identifying as transgender and the demand for gender affirming care is increasing. Financial considerations should account for the mix of procedures (using scenario analyses), the prevalence of gender diversity in adolescents (for future potential uptake), and a range of potential barriers to uptake.

Policy issues:

- ESC advised the diagnostic process for gender incongruence and pre-surgery assessment provided by the applicant is considered inadequate for the purpose of determining eligibility to the proposed MBS items, given the lack of formalised and specific diagnostic criteria in the description of gender incongruence in ICD 11.
- ESC noted conflicting feedback regarding ability to provide informed consent and the age at which adults might be eligible for surgery, and the possibility of higher rates of detransition following surgery in young adults. The definition of 'adult' and ability to provide informed consent to determine eligibility to the proposed services needs consideration.
- In relation to service providers, the need for multidisciplinary assessment, restriction to specific providers, and accreditation and training need to be resolved.
- For the specific MBS items proposed, the need to restrict frequency of use (or re-use) and whether documentary evidence pre- and post-surgery is required need to be resolved.

Other relevant information:

- Given the range of complex ethical issues involved, ESC was of the view that input from a medical ethicist would assist with further consideration of this application.
- If supported, a substantial number of surgeries (in the range of ~227,112) may be required based on current demand. This raises issues of workforce availability and training in gender affirming services.

ESC discussion

ESC noted that the purpose of this application was to request Medicare Benefits Schedule (MBS) listing of a suite of 30 surgical procedures for gender affirmation in adults with gender incongruence. ESC noted that the proposed MBS items for the surgical procedures were: 3 items for gender affirming chest surgery, 17 items for genital reconstruction surgery, 9 items for gender affirming facial surgery and 1 item for gender affirming voice surgery. ESC noted that the MSAC Executive had advised that the application should progress as a two stage assessment, where the first stage would be to assess the comparative clinical evidence (presented in the applicant-developed assessment report [ADAR] submitted for consideration at this meeting), 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.

ESC noted the very high number of consultation inputs received for this application. A total of 1,960 inputs had been received during the pre-MSAC consultation period as of 5 February 2025 (additional inputs were received by the time consultation closed on 14 February 2025 and analysis of the full set of inputs would be provided to MSAC). Of the 1,960 inputs received as of 5 February 2025, 1,867 were from consumers, the majority of whom had lived experience of the health condition and/or the proposed health service; 9 were from organisations; 36 were from health professionals; and 48 were from health professionals who had lived or carer experience of the health condition. ESC noted that a total of 93% of all respondents supported public funding of the proposed health service, 5% did not support public funding, and 2% did not specify whether they supported or did not support the current proposal for public funding. ESC noted a similar trend (i.e. the majority of the feedback being supportive of public funding) across the different categories of inputs (e.g. organisations, health professionals, consumers). Examples of inputs in support of public funding noted improvement in quality of life (QoL) and mental health, particularly for those with suicidal ideation as a result of gender incongruence or gender dysphoria, for whom these interventions could be lifesaving. Other inputs included concerns about safety and potentially poor outcomes from the proposed procedures which may require lifelong care, potentially high cost to the health system, an inadequate evidence base, the need for psychological support services, and inequities in access for people in rural and remote areas. ESC welcomed these responses and acknowledged the effort that respondents had put into providing input.

ESC considered that while the proposed interventions are restricted to surgical services, there are multiple clinical disciplines involved in the broader care of the proposed population. Therefore, in order to obtain a more holistic view, ESC advised the department to seek further input from the range of clinical disciplines involved in providing care to the proposed population, including psychologists, psychiatrists, paediatricians, endocrinologists and general practitioners.

ESC noted from the latest Australian Bureau of Statistics (ABS) data obtained from four ABS household surveys conducted between 2020-2023, that an estimated 178,900 Australians aged 16 years and older (i.e. 0.9% of Australians 16 years and older) reported a gender that is different to their sex recorded at birth[41]. Of the estimated 178,900 people, ESC noted that 37.5% are trans men, 29.3% are trans women and 32.7% are non-binary people. Although a significant proportion of the transgender population identify as non-binary people, ESC considered that relevant data pertaining to this sub-population have not been adequately presented in the ADAR, and considered that additional data and consultation input is required to inform the medical services that may be sought by this cohort. ESC noted from the ABS data that the largest proportion of people who reported that their gender did not match their sex recorded at birth were in the 16-24 year age group (with three in ten [28.4%] transgender people in this age category) and noted that this proportion decreased with increasing age. ESC noted from a study conducted in the United Kingdom (UK) that in children and young people (age 0-18 years), the highest prevalence of gender incongruence or gender dysphoria was recorded in the 17-18 year age group. ESC further noted from this study that the reported prevalence of gender incongruence or gender dysphoria increased substantially in children and young people between 2011 (0.16 per 10,000 persons) and 2021 (8.3 per 10,000 persons), particularly in those

[41] Australian Bureau of Statistics (2022), Estimates and characteristics of LGBTI+ populations in Australia, ABS Website, accessed 24 February 2025.

recorded as female at the time of presentation to primary care[42]. ESC considered that the trends observed in the UK are likely to be comparable to those occurring in Australia.

ESC noted that the proposed population was adults with diagnosed gender incongruence (defined in the International Classification of Diseases 11th Revision[43] as a condition related to sexual health with marked and persistent incongruence between the individual's experienced gender and the assigned sex), who are electing to undergo gender affirming surgical procedures. ESC noted that some people with gender incongruence may experience gender dysphoria (a condition of distress resulting from gender incongruence, defined in the Diagnostic and Statistical Manual of Mental Disorders [DSM-5-TR]). ESC considered that the natural history of gender incongruence, the proportion of people who will experience/proceed to gender dysphoria, and the proportion of those who seek care, are unclear. ESC noted that the terms gender incongruence and gender dysphoria are sometimes used interchangeably in the literature, which can lead to confusion. ESC noted from a systematic review that distress in people with gender dysphoria can relate to individual (how a person feels about themselves and their body), interpersonal (a person's relationships with others) and/or societal (how a person feels about their place and acceptance in society) factors[44]. ESC considered that while surgery may alleviate individual body-focused distress, it was unclear whether surgery may also improve distress caused by interpersonal or societal factors, and if so, to what degree. ESC considered that qualitative data relating to the nature of distress experienced by people presenting for gender affirmation surgery would be informative, and more data on outcomes following gender affirming care (including surgery) for each of these groups.

ESC noted that the comparator was no surgery, including standard care, which it considered to be appropriate. However, ESC noted the lack of a consensus on best practice care for people with either gender incongruence or gender dysphoria. ESC also noted the proposed outcomes. Conceptually, ESC considered that surgery for people with gender incongruence has been proposed by the applicant as a preventive intervention for gender dysphoria (although no data has been presented to support this), and surgery for people with gender dysphoria proposed as a treatment. ESC noted the proposed clinical management algorithm. ESC considered that the diagnostic process for gender incongruence presented in the ADAR was inadequate and considered that a multidisciplinary team (MDT) is integral to this process and therefore should be better reflected in this clinical management algorithm. ESC noted advice from the department that existing MBS items, together with the proposed introduction of specialist case conference items, would support multidisciplinary care for the patient group.

ESC noted the proposed MBS item descriptors, and agreed with the commentary that the language should be amended to be gender non-specific (rather than 'masculinising' or 'feminising') and be described using strictly anatomical terminology where possible (as presented for the proposed MBS items for genital reconfiguration). ESC considered the applicant should consult with other groups that may perform the relevant surgical procedures to update the wording of the proposed MBS item descriptors. ESC agreed with the applicant's pre-ESC response that the proposed items do not require amendment to encompass the additional

[42] Jarvis SW, Fraser LK, Langton T, et al Epidemiology of gender dysphoria and gender incongruence in children and young people attending primary care practices in England: retrospective cohort study Archives of Disease in Childhood Published Online First: 24 January 2025. doi: 10.1136/archdischild-2024-327992

[43] https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f90875286

[44] Cooper K, Russell A, Mandy W, Butler C. The phenomenology of gender dysphoria in adults: A systematic review and meta-synthesis. *Clin Psychol Rev*. 2020;80:101875. doi:10.1016/j.cpr.2020.101875

services proposed by other stakeholder groups, and considered that the item descriptors should be outcome based and method agnostic wherever possible.

ESC considered the patient-eligible age, and whether this should be legislated in the item descriptors. ESC noted that a UK Parliamentary report had reported that detransition rates can range from less than 1% to 30% (depending on the population, context and study design, noting that this range also includes discontinuation rates of gender affirming hormone use), and initial research suggests that a higher proportion of people who detransition had initially transitioned before the age of 25 years[45]. ESC noted that in current Australian practice, some patients aged under 18 years of age are able to make complex decisions regarding their own medical treatment if they are considered to have capacity to provide informed consent. ESC noted that examples of this include whether to continue/discontinue chemotherapy. ESC considered that this may not be directly applicable to the current proposed interventions as in the chemotherapy example patients have already experienced being on the treatment, and therefore are likely able to more clearly identify their own preferences based on experience, and therefore make a more informed decision. ESC considered that further consultation with relevant bodies including The Royal Australian and New Zealand College of Psychiatrists is required in order to determine the appropriate patient eligible age. ESC considered that the appropriate patient eligible age should be included in the explanatory note of the MBS items.

ESC considered that the explanatory note should also clarify the elements of the pre-surgery assessment to align with other items that involve a MDT, and include the eligible diagnosing providers. ESC advised that the requirement for providers to have appropriate education and training in treating transgender people should be in the item descriptor. It was noted that the Australian Professional Association for Trans Health is intending to establish a professional development course focused on the assessment and diagnosis of gender incongruence in adults, however, this would be for professional development (not for formal accreditation). ESC noted that the World Professional Association for Transgender Health (WPATH) Standards of Care recommend that people undergoing irreversible genital reconfiguration surgery should receive a minimum of 6 months of hormone therapy before surgery. ESC considered that 6 months of prior hormone therapy should be specified in the explanatory note of the relevant MBS items, noting that there may be instances where hormone therapy is not clinically appropriate (e.g. when hormone use is contraindicated). ESC considered that there is not sufficient information to inform if a frequency restriction is required for the proposed subsequent stage items for the construction of a neo-phallus or neo-vagina, and as such requested the applicant provide information on if the subsequent stage items are performed once only for a patient (i.e. a two stage procedure only). ESC noted that the fees proposed for some of the items aligned with those for existing similar MBS items, which ESC considered to be reasonable. ESC noted that appropriate fees for all the proposed items would need to be identified and justified before future economic and financial analyses could be undertaken.

ESC considered that the proposed item descriptors for procedures that may be repeated for revision surgery should include a requirement that photographic or diagnostic evidence demonstrating the clinical need for this service be documented in the patient notes, in line with other similar items (e.g. MBS item 45528 – Mammaplasty, augmentation; MBS item 45051 – Contour reconstruction by open repair of contour defects). ESC noted that The *Health Insurance Act 1973* requires that MBS services must be 'clinically relevant'. A clinically relevant service is defined as one that is generally accepted in the medical profession as being necessary for the appropriate treatment of the patient to whom it is rendered. ESC noted that the department and

[45] Parliamentary Office of Science and Technology (POST). 2023. POSTbrief 53: Factors shaping gender incongruence and gender dysphoria, and impact on health services. UK Parliament. DOI: https://doi.org/10.58248/PB53

MSAC Executive had accepted that gender affirmation surgery for patients with gender incongruence is a clinically relevant service and would not be dissimilar to some of the other MBS items for plastic surgery in specific patient cohorts that have been considered previously by MSAC.

ESC agreed with the commentary that the ADAR's systematic review of the evidence was not systematic, inclusion and exclusion criteria were not transparent, and numerous potentially relevant studies were not captured. There was limited information on demographics of study participants (age/country). In particular, ESC noted that participants in some studies had undergone extensive psychiatric assessment prior to surgery which is not part of the current application. ESC noted that the ADAR did not present any assessment of the quality of evidence for each outcome and the overall evidence base (including risk of bias, confounding and applicability). Importantly, most outcomes measured were short term (≤12 months). ESC noted that the evidence base did not include publications prior to 2010 in order to identify studies most applicable to contemporary surgical methods and gender affirming care.

Regarding comparative safety, ESC considered that the clinical claim of inferior safety compared with no surgery may be appropriate. ESC noted that many of the included studies involved either no comparator group, or the comparator was cis gender people who have undergone similar procedures. ESC noted that complication rate depended on the type of surgical procedure and noted that, in general, removing healthy organs was associated with a lower risk (e.g. orchidectomy had an overall complication rate of 2.9 - 3.7%) than creating new structures, particularly new structures involving vascular or erectile tissue (e.g. phalloplasty had an overall complication rate of 31.5 – 43.8%). ESC noted that majority of the safety data were short term outcomes (<30 days) and considered that the rate of complications (including infections) are likely to be higher in the longer term. ESC considered that the incidence of regret and/or detransition should be included as a safety outcome, as this is an unintended adverse outcome. ESC considered that clinicians and patients may be reluctant to report adverse outcomes, particularly those which potentially reflect decision making and which can involve guilt and shame.

ESC noted the data on comparative effectiveness. ESC noted that the evidence base was predominantly before and after case series which were likely to be at high risk of bias due to attrition, or cross-sectional studies that were at risk of confounding (but noting that no formal risk of bias assessments were undertaken by the applicant). For the primary outcome of QoL, ESC noted that the majority of studies reported statistically significant improvements in either overall QoL or psychological QoL. However, ESC noted that majority of the evidence was limited to the short term (≤ 12 months), and that there was no average measure of the improvement in QoL as all studies used various outcome tools (none of which have been validated in the transgender population) and the ADAR did not attempt to standardise the outcome measures. ESC noted that there were significant differences in baseline QoL across studies, and considered that this may be partly due to the societal differences (e.g. different societal levels of acceptance) in the countries where these studies were conducted. For the primary outcome of dysphoria, while ESC noted that there was a consistent reduction in gender dysphoria across the included studies, ESC considered that the transferability of the evidence to the proposed Australian population is unclear especially due to the lack of regularity in the pre-surgery assessment and supportive mental health care across the studies. For the secondary outcomes, ESC noted that post-surgery suicide, depression and anxiety were observed to be lower, however considered that the reporting of these outcomes was likely to be at significant risk of selection/response bias and confounding. ESC noted that compared to the number of included studies identified on functional outcomes of surgery and satisfaction, there was less data available to inform the outcomes of change in psychological status, suicidality or regret. ESC noted from a systematic review by

Bustos et al. (2021)[46] that the rate of regret was 1%. However, ESC noted that this maybe underestimated as a number of studies included in the Bustos systematic review were old (some dating back to 1988) and the majority of studies had a follow-up of less than 5 years, which was shorter than the median time to seeking a legal reversal to the original gender, as reported by a long-term case series in Sweden (median time to reversal was between 7.5-8.5 years)[47]. ESC further considered that the rates of published regret/detransition may be underestimated due to reporting bias. Overall, ESC considered that while the presented data suggested effectiveness in the short term, the level and quality of the evidence appeared to be low and the average magnitude of effect for each outcome unclear. Therefore, ESC considered that the clinical claim of superior effectiveness compared with no surgery was highly uncertain and not well supported by the data provided in the ADAR. ESC considered that more data were required on preferences and outcomes for non-binary people, qualitative data on the nature of distress of the people presenting for surgery and benefits of surgery, longer-term outcomes, and data on regret and/or detransition.

ESC noted a range of issues to be considered in future economic and financial analyses of this application. Given the applicant's claim of superior effectiveness, a cost-utility analysis or cost-effectiveness analysis would be appropriate; however, ESC considered that the issues identified in the ADAR evidence (as noted above) would impact the economic evaluation. ESC considered that a review of relevant economic literature (limited to the past 10 years) should be conducted to inform the economic analysis for the proposed interventions. ESC noted two existing cost-effectiveness evaluations on this topic: a study by Kirey-Sitnikova and Ahmed (2022, preprint)[48] was conducted in Sweden, although ESC considered that this model was limited in its structure and inputs; and a study by Padula et al. (2015)[49] from the United States which was more comprehensive and could potentially be used to inform an economic model for this application.

ESC considered that the following should be taken into consideration when developing the future economic model:

- model structure – whether separate models would be required for trans men, trans women and non-binary people, or whether a weighted approach may be appropriate.
- interventions – the number and mix of procedures that are sought by each person will vary, and there is some evidence that people who undergo all of the procedures they sought have better outcomes. While ESC agreed with the applicant's pre-ESC response that there is no 'average' patient journey, an economic analysis with all the different possible permutations of the number and type of surgeries may not be realistic to generate, nor informative for MSAC. An exemplar approach where key surgeries that have the greatest influence on health outcomes and costs could be considered. The number of procedures per patient could then be explored in sensitivity analyses.

[46] Bustos, Valeria P et al. "Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence." *Plastic and reconstructive surgery. Global open* vol. 9,3 e3477. 19 Mar. 2021, doi:10.1097/GOX.0000000000003477

[47] Dhejne, C, Oberg, K, Arver, S & Landen, M 2014, 'An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets', Arch Sex Behav, vol. 43, no. 8, Nov, pp. 1535-1545 10.1007/s10508-014-0300-8.

[48] Kirey-Sitnikova Y & Ahmed S (preprint). Cost-effectiveness analysis of gender transition medical interventions in Sweden. https://www.researchsquare.com/article/rs-1476354/v1

[49] Padula WV, Heru S & Campbell JD (2015). Societal implications of health insurance coverage for medically necessary services in the U.S. transgender population: a cost-effectiveness analysis. *Journal of General Internal Medicine* 31:394–401. https://link.springer.com/article/10.1007/s11606-015-3529-6

- resources – the number and mix of clinicians in the MDT, and the inclusion of 6 months prior hormone replacement therapy in line with WPATH guidelines (noting that a proportion of patients may already be on hormone replacement therapy).
- choice of outcome – quality-adjusted life years (QALYs) are an appropriate measure, using health utilities estimated by appropriate tools (e.g. SF-36, EQ5D), as well as other outcome measures such as depression scores and number of people with clinically important improvement in health-related QoL.
- data inputs – consideration of the Australian social context before applying data estimates from countries with vastly different social or cultural settings.
- time horizon – a medium term time horizon of 15 years may be appropriate to capture complications and reversal surgeries.
- handling of gender incongruent and gender dysphoria – conceptualise the proposed surgeries as a preventive intervention for gender incongruence, and as treatment for the prevention of worsening symptoms for gender dysphoria.

ESC noted the estimated uptake of the proposed items from the PICO confirmation (based on data for ages 18-50 years). The total number of estimated surgeries was 211,472, and ESC noted that this includes multiple surgeries per person. An updated estimate using the latest ABS data suggested a slightly higher number of surgeries of 227,112 required to meet the current demand. ESC noted that the prevalence of people identifying as transgender and the demand for gender affirming care is increasing. For the financial estimates, ESC considered that this should be based on a mix of procedures (rather than being patient based), and that the future eligible adult patient population numbers should be based on current adolescent data. ESC considered that when determining the uptake rate for proposed services in the financial estimates, barriers to uptake such as time off work for recovery, availability of support at home, and financial hardship should be considered. ESC noted from departmental advice that the utilisation of existing MBS surgical items in the proposed population is not available in Medicare data as the reason why a procedure is performed is not recorded for generic MBS items. However, ESC considered that a sensitivity analysis should be conducted (for example using assumptions based on clinical expert opinion) to determine the impact of the proposed gender affirmation surgical MBS items replacing use of the existing MBS items. ESC considered that the economic model and financial analysis for this application will be complex.

ESC noted that there is a range of ethical, legal, social and implementation issues related to this application. ESC noted the ethical implications for autonomy, identity, right to self-determination, consent, access to treatment, competency of health professionals, quality of care and patient-centred care. ESC considered it to be important that the evidence presented for assessment in this application is interpreted in a culturally sensitive and values-based way. ESC noted a publication by Saarni et al. (2022)[50] that presented the process and findings of integrating ethical analysis into the HTA of medical treatments for gender dysphoria. The publication notes that ethicists were important for formulating a nuanced view of autonomy, clarifying conflicting views, ensuring that justice and equality were given sufficient attention, and facilitating coherence of views (though not necessarily consensus). ESC considered that it would be beneficial to engage medical ethical expertise to assist with consideration of Section 5 (additional relevant information) matters relevant to this application.

ESC noted the legal implications for patients undergoing the proposed surgeries, including changing names on birth certificates and other identification documents (which is usually reasonably accessible) and changing sex on birth certificates (for which eligibility requirements vary by jurisdiction). ESC also noted the social implications for patients undergoing these

[50] Saarni SI, Uusitalo S & Autti-Ramo I (2022). The role of ethical analysis in conducting a health technology assessment of medical treatments for gender dysphoria. *International Journal of Technology Assessment in Health Care* 38:e82, 1-6 https://doi.org/10.1017/S0266462322003257

surgeries, including social acceptance of new identified gender and harmful beliefs that are present in society. ESC noted the potential implementation issues, particularly availability of workforce with the appropriate training in gender affirming services.

15. Applicant comments on MSAC's Public Summary Document

The Australian Society of Plastic Surgeons (ASPS) thanks MSAC for its thoughtful consideration of the safety and efficacy of gender affirming surgery. The Applicant Developed Assessment Report (ADAR) presented evidence from 51 studies reporting outcomes from 156,312 individuals. This is a very substantial body of evidence, and the ASPS appreciates the detailed consideration MSAC has given to the evidence. The ASPS is pleased that MSAC acknowledges the unmet clinical need for gender affirming surgeries for people with gender incongruence and that MSAC considered the studies presented in the ADAR appeared to support that gender affirming surgery is effective in the short term at improving quality of life and reducing levels of gender dysphoria in people who have gender incongruence, but there were limitations with the evidence presented.

The ASPS firmly disagrees with areas of the PSD suggesting the application did not capture the needs of people identifying as non-binary. The ASPS wants to reassure the transgender community that assessment of safety and efficacy presented in the ADAR intended to adopt a non-binary approach and considered the needs of the entire transgender community, including people identifying as non-binary. The ASPS will work with MSAC to understand its concerns in this area and will continue to advocate for the gender affirming care needs for people identifying as non-binary.

The ASPS acknowledge that MSAC have requested the Department engage with clinical professional organisations to seek advice on appropriate care pathways for gender affirming care. MSAC have also requested further assessment of clinical evidence on specific outcomes, many of which were not specified in the PICO. The ASPS is fully supportive of these steps and looks forward to working with all stakeholders involved in the next phase of MSAC's consideration of this important application.

16. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website