Insurance Coverage of Gender Affirming Healthcare: WPATH SOC8 Updates

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Changes from SOC7 to SOC8

Theme	SOC7 (2011)	SOC8 (2022)
Methodology	Relied heavily on professional consensus	Evidence-based & avoids non-evidence-based recommendations
Standards for professionals	Experience based because of lack of formal training opportunities	Greater emphasis on training, certification, cont education
Barriers to care	Improved on prior SOC versions but still restrictive	More pt centered & individualized. No minimum age for GAHT, less pre-op GAHT requirements, no RLE requirements
Mental health assessment and diagnosis “letters”	1 for most 2 for genital surgeries (1 doctoral level)	At most 1 assessment needed by competent professional (MH or medical), if required

Changes from SOC7 to SOC8

Theme	SOC7 (2011)	SOC8 (2022)
Patient focus: age	Adults >> Children/Adolescents 11/122 pages addressed under 18s	Children/Adolescents given appropriate attention - separate chapters
Patient focus: spectrum of identities and conditions	Nonbinary and Genderqueer - together mentioned 6 times	Full chapter
	Intersex - 4 page chapter, little guidance, uses the term DSD	Extensive guidance, patient centered, recommends delaying non-urgent surgeries until later childhood
	Eunuchs - 1 mention	Full chapter, recognizes identity, concrete recommendations for tx

Changes from SOC7 to SOC8

Theme	SOC7 (2011)	SOC8 (2022)
Treatments and medical necessity	Mental health, GAHT, Surgery - genital, mastectomy. “While most professionals agree that genital surgery and mastectomy cannot be considered purely cosmetic, opinions diverge as to what degree other surgical procedures (e.g., breast augmentation, facial feminization surgery) can be considered purely reconstructive.”	Recognition of the medical necessity for comprehensive individualized treatments with the therapeutic goal of reducing gender dysphoria. Affirmed the medical necessity of treatments & procedures including: gender affirming facial surgery, hair removal, speech therapy and voice surgery, body contouring procedures, reproductive healthcare services, and others (see appendix E in SOC8)

Things that didn’t change from SOC7 to SOC8

Theme	SOC7 (2011) and SOC8 (2022)
How is SOC to be used	**Flexible guidelines** - “[T]he criteria put forth in this document for gender-affirming interventions are clinical guidelines; [Providers] may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient’s unique anatomic, social, or psychological situation; an experienced health care professional’s evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies.”

Further Evidence of Medical Necessity and Evidence Based Medicine

- GAHT improves patient quality of life, decreases depression, and decreases anxiety
  - Baker, Kellan E., et al. "Hormone therapy, mental health, and quality of life among transgender people: a systematic review." Journal of the Endocrine Society 5.4 (2021): bvab011.

- Vaginoplasty improves patient quality of life, high satisfaction (93% overall), complications relatively low (2% fistula, 4% necrosis, 4% prolapse, 14% stenosis), low regret rate (1%)
  - Manrique, Oscar J., et al. "Complications and patient-reported outcomes in male-to-female vaginoplasty—where we are today: a systematic review and meta-analysis." Annals of Plastic Surgery 80.6 (2018): 684-691.

Further Evidence of Medical Necessity and Evidence Based Medicine

- Gender Affirming Surgery - including most procedures (genital and non-genital) - improved quality of life
    - Passos, Taciana Silveira, Marina Sá Teixeira, and Marcos Antonio Almeida-Santos. "Quality of life after gender affirmation surgery: a systematic review and network meta-analysis." Sexuality Research and Social Policy 17.2 (2020): 252-262.
- Limitations: small study size, variability in measures, no double blinded RCTs

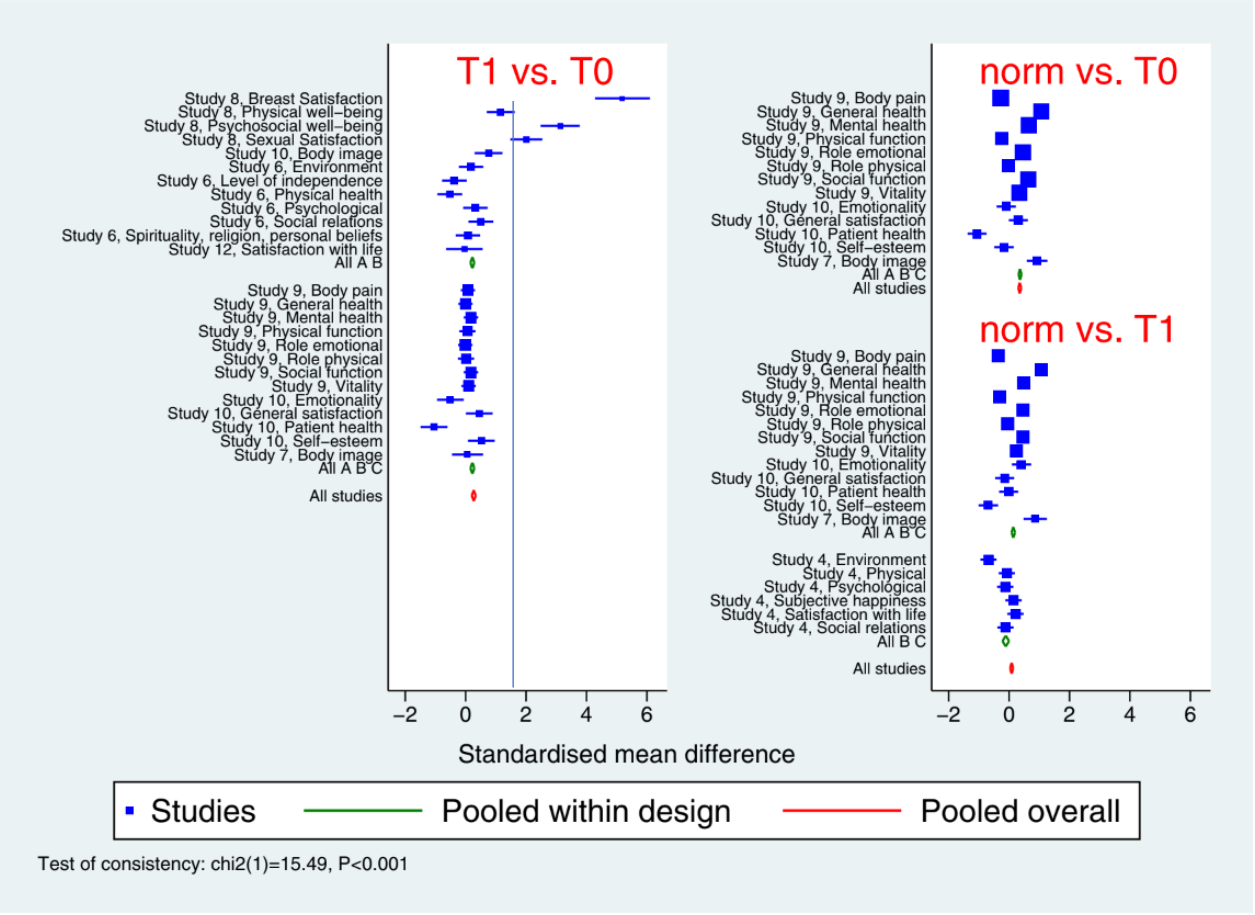
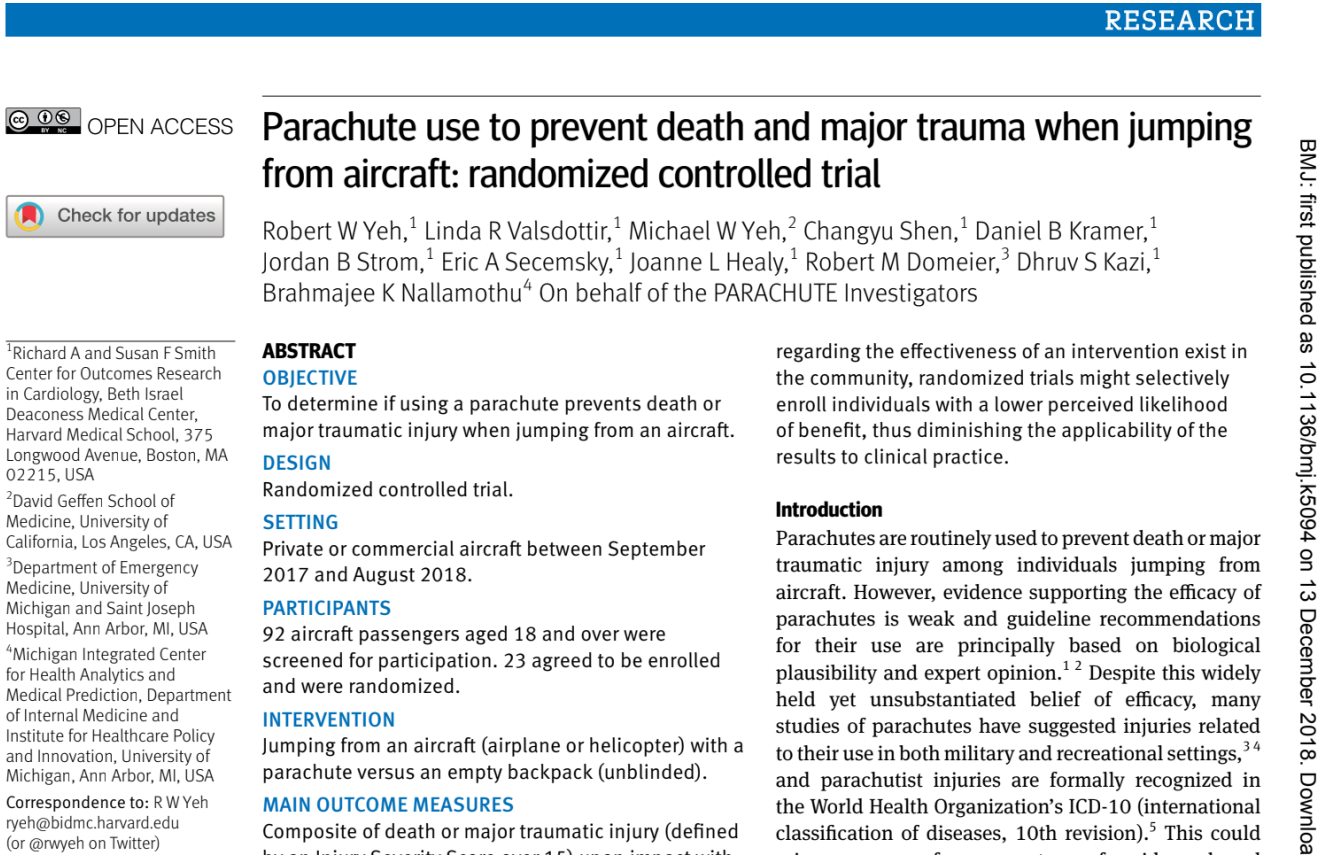


Fig. 2 Forest plot of data for quality of life before GAS (A), after GAS (B), and normative data (C) included in the meta-analysis

Why not the “gold standard”?



RESEARCH

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Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial

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ABSTRACT

OBJECTIVE
To determine if using a parachute prevents death or major traumatic injury when jumping from an aircraft.

DESIGN
Randomized controlled trial.

SETTING
Private or commercial aircraft between September 2017 and August 2018.

PARTICIPANTS
92 aircraft passengers aged 18 and over were screened for participation. 23 agreed to be enrolled and were randomized.

INTERVENTION
Jumping from an aircraft (airplane or helicopter) with a parachute versus an empty backpack (unblinded).

MAIN OUTCOME MEASURES
Composite of death or major traumatic injury (defined

regarding the effectiveness of an intervention exist in the community, randomized trials might selectively enroll individuals with a lower perceived likelihood of benefit, thus diminishing the applicability of the results to clinical practice.

Introduction

Parachutes are routinely used to prevent death or major traumatic injury among individuals jumping from aircraft. However, evidence supporting the efficacy of parachutes is weak and guideline recommendations for their use are principally based on biological plausibility and expert opinion.[1 2] Despite this widely held yet unsubstantiated belief of efficacy, many studies of parachutes have suggested injuries related to their use in both military and recreational settings,[3 4] and parachutist injuries are formally recognized in the World Health Organization’s ICD-10 (international classification of diseases, 10th revision).[5] This could

Yeh, Robert W., et al. "Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial." *BMJ* 363 (2018).

Why not the “gold standard”?

Sackett, David L., et al. "Evidence based medicine: what it is and what it isn't." BMJ 312.7023 (1996): 71-72

> “Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”
>
> “Evidence based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions.”

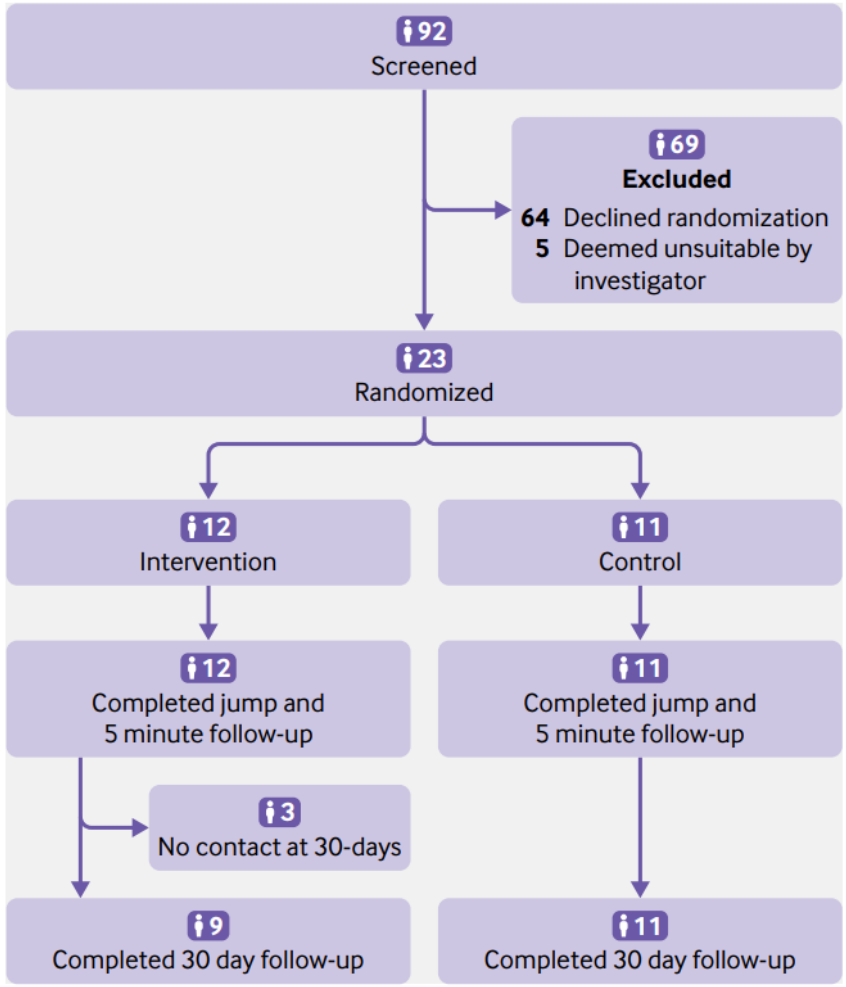

Fig 1 | Study flow diagram

Yeh, Robert W., et al. "Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial." *BMJ* 363 (2018).v

Further Evidence of Medical Necessity and Evidence Based Medicine

- Multi-center prospective cohort: FFS significantly improves QOL, has high satisfaction rates, and significantly improves gendered appearance
    - Morrison, Shane D., et al. "Prospective quality-of-life outcomes after facial feminization surgery: an international multicenter study." Plastic and Reconstructive Surgery 145.6 (2020): 1499-1509.
- Puberty blockers as adolescents associated with a lower lifetime prevalence of suicidal ideation in adulthood (adjusted odds ratio = 0.3; 95% confidence interval = 0.2–0.6)
    - Turban, Jack L., et al. "Pubertal suppression for transgender youth and risk of suicidal ideation." *Pediatrics* 145.2 (2020).

Further Evidence of Medical Necessity and Evidence Based Medicine

- Whole population study (Sweden) - likelihood of needing care for mood or anxiety disorder was reduced by 8% each year since last gender-affirming surgery
  - Bränström, Richard, and John E. Pachankis. "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study." American journal of psychiatry 177.8 (2020): 727-734.
- Significant reduction in suicidal ideation and depression in US veterans who received GAHT as well as chest and genital GAST c/w vets who received only some of these treatments
  - Tucker, Raymond P., et al. "Hormone therapy, gender affirmation surgery, and their association with recent suicidal ideation and depression symptoms in transgender veterans." Psychological medicine 48.14 (2018): 2329-2336.

Regret?

- Bustos, Valeria P., et al. "Regret after gender-affirmation surgery: a systematic review and meta-analysis of prevalence." Plastic and reconstructive surgery Global open 9.3 (2021).
  - 27 studies 7928 patients - 77 had regret - **1%**

- Regret after multiple other surgical procedures:
  - **14%** Wilson, Ana, Sean M. Ronnekleiv-Kelly, and Timothy M. Pawlik. "Regret in surgical decision making: a systematic review of patient and physician perspectives." World Journal of Surgery 41 (2017): 1454-1465.
  - **10%** Surgical sterilization in women: Danvers, Antoinette A., and Thomas Andrew Evans. "Risk of Sterilization Regret and Age: An Analysis of the National Survey of Family Growth, 2015–2019." Obstetrics & Gynecology 139.3 (2022): 433-439.
  - **20%** Hypospadias repair: Vavilov, Sergey, et al. "Parental decision regret in childhood hypospadias surgery: A systematic review." Journal of paediatrics and child health 56.10 (2020): 1514-1520.
  - **17%** knee replacement, **5%** hip replacement: Cassidy, Roslyn S., et al. "Decision regret after primary hip and knee replacement surgery." Journal of Orthopaedic Science (2021).

Insurers Must Use SOC8 as the Basis for their Gender Affirming Care Eligibility Policies

- WPATH's SOC8 is the most up to date world standard of care for Trans Healthcare. All insurers must review their current policies to ensure they are in compliance with SOC8 recommendations.
- Using outdated versions of the WPATH SOC can result in unlawful coverage denials and increase in liability and costs for insurance plans (CA DOI Economic Impact Assessment).
- The DMHC and DOI will be using SOC8 to determine whether insurers are compliant with CA's Gender Insurance Non-Discrimination Act (IGNA) and can enact major fines if insurers are found to be out of compliance.

Name/Gender Marker Considerations

- Trans people may or may not change the gender markers on their identity documents as a part of their transition. Some may change it to X, rather than M or F: 22 states now have X as a gender marker option, including CA.
- Many Trans people experience unlawful denials of care due to mismatching gender markers or because the gender marker listed does not align with the gender marker someone is assumed to have based on testing particular “gendered” body parts.
- Insurance plans must cover preventative healthcare services even when the gender marker does not match (ob/gyn care for Trans Masculine pts with M or X gender marker; ob/gyn care for Trans Feminine pts with M or X gender marker) (IGNA)
- Insurers must allow names and gender markers to be updated to reflect the pts self-identified gender, including X, even if they have not updated their legal name and gender marker. Insurers can implement this by creating a separate field from the legal name and gender marker by adding a field for self-identified name and gender marker. Or, insurers may also remove gender markers completely from the clients file (or do so for everyone).

Insurers Must Update Adult Hormone Therapy Criteria to be in Alignment with SOC8

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
d. Other possible causes of apparent gender incongruence have been identified and excluded;
e. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
f. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

Insurers Must Update Adult Surgery Eligibility Criteria to be in Alignment with SOC8

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
d. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
e. Other possible causes of apparent gender incongruence have been identified and excluded;
f. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
g. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).*

*Graded as suggested criteria, not required

Insurers Must Update Adolescent Puberty Blockers Eligibility Criteria to be in Alignment with SOC8

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Insurers Must Update Adolescent GAHT Eligibility Criteria to be in Alignment with SOC8

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Insurers Must Update Adolescent Surgery Eligibility Criteria to be in Alignment with SOC8

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. At least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

Insurers Must Update Policies to Reflect SOC8-Recommended Gender Affirming Interventions and Surgeries as Explicitly Included in Plan Coverage

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

Packers, Stand to Pee Devices (STPs), Binders, Gaffs, Breast Forms

- SOC8 states these affordable DME interventions are significantly beneficial to treat dysphoria by changing the shape and function of the body with or without need or desire for hormones and/or surgery.
- Insurers can consider contracting with suppliers and covering such gender affirming interventions as a cost saving measure due to the complications of using DIY substitutes.
- Using DIY methods like duct tape (or worse) can cause recurring UTIs, genital skin problems, and significant chronic pain. Binding in particular can also cause breathing problems and even rib fractures.
    - Peitzmeier, Sarah M., et al. "Time to First Onset of Chest Binding–Related Symptoms in Transgender Youth." *Pediatrics* 147.3 (2021).

Reminder: Insurers Must Cover Needles & Syringes for Medically Necessary Injectable Medication

- If an insurer covers injectable medication, it should also cover the needles and syringes required to use the injectable medication.
- 1 or 3cc syringe
- 18 g, 1 in needle to draw up
- 23 g, 1 or 1.5 in needle for IM injection
- 25 g, 5/8 in needle for SubQ injection
- Alcohol Swabs, Gauze
- Sharps Container
- Without clean and safe needles to inject, the risk of septic complications from needle reuse like abscesses, cellulitis, and if forced to share needles, even blood-borne pathogen transmission is a risk.

Insurers Must Remove Exclusions of Gender Affirming Interventions & Surgeries

- “WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage for any medically necessary procedures or treatments for the health and well-being of TGD individuals. In other words, governments should ensure health care services for TGD people are established, extended or enhanced (as appropriate) as elements in any Universal Health Care, public health, government subsidized systems, or government-regulated private systems that may exist. Health care systems should ensure ongoing health care, both routine and specialized, is readily accessible and affordable to all citizens on an equitable basis.”

Documentation of Assessment

- A visit note and/or referral order is sufficient to document all the information needed to demonstrate SOC8 criteria has been met for the surgeon and/or insurance company.

- If a letter is required by the surgeon or insurance company, only a single written opinion/signature from an HCP competent to independently assess and diagnose should be required.

- The HCP can be any HCP, including the PCP, Mental Health Provider, or Surgeon themselves.

- Further written opinions/signatures may be requested only where there is a specific clinical need.

Staged Surgeries and Revisions Should be Covered without Re-Assessment

- Re-assessment should not be required for surgeries that are staged, such as phalloplasty, or those with sub-optimal results, requiring revision.
- If the original surgery is approved for coverage, then the following stages, or revisions required to correct the original surgery to alleviate dysphoria or restore function should also be covered.

Reminder: Timely Access and Network Adequacy Requirements apply to Gender Affirming Care too!

- Primary Care Appointment with Gender Affirming PCP within 10 business days
- Mental Health Appointment with Gender Affirming MHP within 10 business days, if necessary
- Specialty Care Appointment with Gender Affirming Surgeon (or other specialist) within 15 business days

Implementation: Insurers Should Expand Networks to Ensure Timely Access & Network Adequacy Requirements are Met

- In order to implement coverage for all of the above listed surgeries, not only must insurers revise policy to explicitly include all of these services and update eligibility criteria, but insurers must also proactively contract with gender affirming PCPs, Mental Health Providers, and Surgeons to allow for timely access.
- In addition, insurers should maintain up to date databases of contracted surgeons and what surgeries they provide.
- All customer service representatives and appeals staff should be trained on SOC8, IGNA, the updated contracted surgeon database, and the updated insurance policy, so they may accurately provide answers when pts call asking for support in finding contracted surgeons.

Aftercare Requirements & Coverage Considerations

- “Gender affirming surgeries often have specific aftercare requirements.” These would also be seen as medically necessary and a part of the package of covered care.
- Given there are relatively few gender affirming surgeons, pts may travel great distances to access necessary surgeries. Travel is often prohibitively expensive and may require lodging close to surgery center for a sufficient period after surgery.
- If network has no specialist local to patient, insurers must cover travel, post-op lodging or SNF admission for those traveling long distances (or unhoused patients generally)
- As with all surgeries, must cover pre-op testing, relevant aftercare supplies (including DME, pads, dilators, wound care supplies, urinary supplies, etc), home health nursing, PT, OT, or other necessary rehab services, and additional care for complications.

Case Management

- Case Management is a crucial part of providing support to Trans people and should be a covered benefit and/or provided by the health plan itself.
- Case Managers can support Trans people in navigating the name and gender marker change process, assisting with surgery navigation (knowing which surgeons are contracted with the insurance plan and who does what surgery) and providing peri-operative support planning (connecting pts with pre and post op resources for travel, lodging, aftercare supplies, food delivery, home healthcare, etc).
- Case management in transgender women associated with a significant (31%) decrease in homelessness, significant improvements on multiple Brief Symptoms Inventory subscales including depression and anxiety, and decreased by half reliance on exchange sex as a primary source of income.

  - Reback, Cathy J., Steven Shoptaw, and Martin J. Downing. "Prevention case management improves socioeconomic standing and reduces symptoms of psychological and emotional distress among transgender women." *AIDS care* 24.9 (2012): 1136-1144.

ICD & CPT Codes

- Between the 1980s (when insurance exclusions for gender affirming care were introduced in the US) and 2010 there was almost no US insurance coverage for gender affirming care
- So, prior to 2010, there was little need to code for reimbursement
- Linkage of ICD to CPT can be problematic
  - Pathologizing ICD codes may be (appropriately) avoided
    - F64.1 - Dual role transvestism
    - F64.2 - Gender identity disorder of childhood
    - F64.8 - Other gender identity disorders
    - F64.9 - Gender identity disorder, unspecified

ICD & CPT Codes

- Condition Code 45 as an option to flag for individual review
- Z-codes
  - Z87.890 - Personal history of sex reassignment
  - Z51.81 - Encounter for non-surgical aftercare following gender reassignment surgery
  - Z79.899 - Other long-term (current) drug therapy
- Non-specific diagnoses
  - E30.8 - Other specified disorders of puberty
  - E89.5 - Postprocedural endocrine and metabolic complications and disorders
- ICD-11: Z77.0 – Z77.9 Gender Incongruence

CPT Codes

- There are no true transgender specific CPT codes (yet)
- Vast majority of GAS are procedures not exclusive to transgender people
- CMS A53793 - Billing and Coding: Gender Reassignment Services for Gender Dysphoria
  - https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53793&ver=22&bc=CAAAAAAAAAAA