KAISER PERMANENTE®

UR 65 Gender-Affirming Procedures Medical Necessity Criteria

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Gene deHaan, MD, Gender Pathways Clinic; Pattie Sandholm, MD, Plastic Surgery	Number: UR 65 Effective: 12/2023 Last Reviewed/Approved: 11/22, 1/24, 4/24, 5/24, 6/24, 11/24, 2/18/25

BACKGROUND

Goals of surgery: to bring appearance into the cisgendered range for the patient's expressed gender identity, with the goal of alleviating gender dysphoria/gender incongruence.

Internal & Outside Referral Guidelines:

Kaiser Foundation Health Plan (KFHP) provides Gender-Affirming Procedures for the treatment of gender dysphoria/ gender incongruence when the below medical criteria are met.
Members whose employer groups do not cover Gender-Affirming Procedures but who wish to access these services out of pocket, will be evaluated according to the same medical criteria.

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	NCD 140.9 "Gender Dysphoria and Gender Reassignment Surgery"
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	The available NCD indicates that CMS determined that no NCD is appropriate at this time for "gender reassignment surgery for Medicare beneficiaries with gender dysphoria" and that "in the absence of an NCD, coverage determinations for gender reassignment surgery…will continue to be made by the local Medicare Administrative Contractors (MACs) on a case-by-case basis." For Medicare lines of business, use the KP criteria below.

Members are eligible for coverage of gender-affirming procedures if they meet all of the following criteria and any related procedure-specific criteria (if they exist – see below):

1. Referral must be generated by a Gender Pathways Clinic (GPC) physician; AND
2. Age 18 years or older OR age less than 18 years with parent/guardian consent or are legally emancipated, AND
3. Persistent, well-documented gender incongruence; AND
4. Capacity to make a fully informed decision and to consent for treatment; AND

5. Documented mental health assessment(s) and/or 1 WPATH letter from an experienced gender therapist in accordance with WPATH guidelines dated within the past 12 months (this criterion applies only to the initial surgical consultation but does not apply to subsequent stages of surgery and to revision surgeries; this criterion does not apply to patients who have established care for gender-affirming services outside of KPNW prior to becoming a KP member); AND
6. If significant medical or mental health concerns are present, they are reasonably well-controlled. Prior to placing a surgery referral the GPC physician should assess that there has been no significant change to mental health since the date of the WPATH letter. Prior to surgery, the surgeon should assess that there has been no significant change to mental health from the time of the referral to surgery. If there has been a significant change in mental health (e.g., ED or hospital admission related to mental health instability), patient should be referred back to the writer of the WPATH letter or to Mental Health for reassessment and care; AND
7. Must be nicotine-free in order for surgery; AND
8. Patient is paneled with a Primary Care provider; AND

A. Chest Surgery and Related Procedures (e.g., medical tattoos)

a. Feminizing chest surgery (Breast Augmentation)
   i. 12 months of estradiol treatment unless contraindicated. Hormone therapy for at least 12 months is recommended to maximize breast development. .
   ii. Surgery is intended to change physical appearance that is NOT within cisgender anatomic variation consistent with the member's gender identity.

B. Genital Surgery and Related Procedures (e.g., medical tattoos) (including but not limited to vaginoplasty, vulvoplasty, labiaplasty, penectomy, orchiectomy, scrotectomy, hysterectomy, oophorectomy, metoidioplasty, phalloplasty, scrotoplasty, testicular implants, penile implants, monsplasty, vaginectomy, etc.)

C. Hair Removal

a. Genital Hair Removal in preparation for genital gender-affirming surgery
   i. Surgical site hair removal can begin at the time of referral for vaginoplasty.
   ii. Surgical site hair removal for phalloplasty can begin after consultation with a surgeon to determine graft site for surgery.
b. Body Hair Removal (face, neck, back, buttocks, chest, abdomen for members assigned male at birth)
   i. Testosterone levels <100 ng/dL; OR
   ii. On anti-androgen and/or hormone therapy for at least 2 years, unless contraindicated or hormones are not consistent with patient's goals.

D. Hair Transplants

a. Patient with androgenic alopecia for members assigned male at birth; AND
b. Androgenic alopecia is not due to a side effect of medication (e.g., gender-affirming testosterone therapy); AND
c. 12 months of hormone therapy, unless contraindicated; AND
d. Documented failure or contraindication to standard conservative management (e.g., Finasteride, spironolactone, oral dutasteride, minoxidil)

E. Gender-affirming Facial Procedures

(To qualify for a referral to Plastic Surgery for consultation, member must meet criterion "a" and "c"; to qualify for gender-affirming facial procedures, member must meet criteria "a", "b" and "c".)

a. On hormone therapy for at least 12 months unless medically contraindicated; AND
b. Documentation by Plastic Surgery about which facial feature(s) cause member's gender incongruence and which facial features can be reasonably surgically altered; AND
c. Surgery is not for the purpose of reversing the appearance of aging.

F. Body Contouring

a. Member has completed at least 12 months of hormone therapy to allow stable body fat redistribution to occur, unless contraindicated.
b. Surgery is intended to change physical appearance that is NOT within cisgender anatomic variation consistent with the member's gender identity.
c. Body contouring will not be covered when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight.

G. Voice Modification Surgery

a. Gender-affirming voice modification surgery is considered medically necessary when:
    i. Masculinizing surgery (pitch lowering surgery, e.g., Type III thyroplasty)
        1. Member has completed 18+ months of consistent masculinization hormone therapy; AND
        2. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 below 150 Hz as determined by a Speech Therapist.
    ii. Feminizing surgery (pitch elevation surgery, e.g., anterior glottal web formation, cricothyroid approximation (CTA)).
        1. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 above 150 Hz as determined by a Speech Therapist

H. Surgical Detransition Procedures

a. Surgery to reverse partially or fully completed gender-affirming procedures when medically necessary as indicated by:
    i. 2 WPATH letters within past 12 months; AND
    ii. Documentation from GPC physician, surgeon, and mental health provider that surgical detransition procedures are necessary

I. Surgical Revisions

a. Surgical revisions following gender-affirming surgery may be considered medically necessary if at least one of the following is true, as determined by a physician board-certified in the relevant specialty (see below):

    Plastic Surgery: chest contouring, breast augmentation, body contouring, surgical detransition;
    Head and Neck Surgery: ~~facial feminization~~, tracheal shave, gender-affirming facial feminization and masculinization procedures, voice modification;
    Gender Pathways Clinic: genital surgery, hair removal, hair transplant; AND

    i. Revision would result in improved function; OR
    ii. Revision is likely to result in relief of pain associated with the gender-affirming surgery; OR
    iii. Revision is intended to change physical appearance that is NOT within cisgender anatomic variation consistent with the member's gender identity. Revisions of prior gender-affirming procedures will not be covered when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight.

Special Group Considerations

These criteria apply to OR/WA Commercial members.

These criteria apply to Federal Employees Health Benefits (FEHB) members

These criteria apply to Medicare.

These criteria do NOT apply to WA Medicaid/Molina. Surgical procedures related to gender affirmation/reassignment are covered on a fee-for-service basis (HCA Physician-Related Services/Healthcare Professional Services Medicaid Provider Guide, Transgender Health Services; and WAC 182-531-1675)

OHP (Oregon Medicaid) see OHP Prioritized List, Guideline Note 127 for treatment of Gender Dysphoria.

Self-Funded (SF) groups must be verified to see if they have a benefit for gender-affirming procedures (GRS in CM). If so, the above criteria apply.

Visiting Members: refer to National Visiting Member policy.

RATIONALE

EVIDENCE BASIS

The World Professional Association for Transgender Health (WPATH) *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,* published in 2022, includes a summary of the evidence for gender-affirming procedures. Their findings include the following:

Gender-Affirming Procedures

"In appropriately selected TGD individuals, the current literature supports the benefits of gender-affirming surgery (GAS). While complications following GAS occur, many are either minor or can be treated with local care on an outpatient basis. In addition, complication rates are consistent with those of similar procedures performed for different diagnoses (i.e., non-gender-affirming procedures).

In individuals AFAB, gender-affirming chest surgery or "top surgery" (i.e. "subcutaneous mastectomy") has been studied in prospective, retrospective, and cross-sectional cohort. The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention.

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation") and include 2 prospective, 1 retrospective cohort, and 3 cross-sectional cohort studies. All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated a positive trend toward improvement in both depression and anxiety scores with increasing levels of gender-affirming interventions. However, there was no statistical comparison between individuals who underwent top surgery and any other group.

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective, 15 retrospective cohort, and 3 cross-sectional cohort studies have recently been reported.

Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort, 6 retrospective cohort, and 4 cross-sectional studies, which reviewed the risks and benefits of these procedures. In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

Gender-Affirming Facial Procedures

"In recent years, facial GAS (FGAS) has received increased attention, and current literature supports its benefits. Eight recent publications include 1 prospective cohort, 5 retrospective cohort, and 2 cross-sectional studies. All 8 studies clearly demonstrated individuals were very satisfied with their surgical results (between 72% and 100% of individuals). Additionally, individuals were significantly more satisfied with the appearance of their face compared with individuals who had not undergone surgery. One prospective, international, multicenter, cohort study found facial GAS significantly improves both mid- and long-term quality of life. The results were direct and consistent, but somewhat imprecise because of certain study limitations. While gender-affirming facial surgery for AFAB individuals is an emerging field, current limited data points toward equal benefits in select patients. Future studies are recommended."

Voice Modification Procedures

"Reported acoustic benefits of pitch-raising surgery include increased voice pitch (average frequency (f_o)) and increased Min f_o (the lowest frequency in physiological voice range). TGD people's self-rating ratings show general satisfaction with voice postsurgery, although individuals who are interested in more comprehensive changes to vocal self-presentation may need to engage in behavioral interventions with a voice and communication specialist in addition to laryngeal surgery. Potential harms of pitch-raising surgery can be assessed and addressed in voice training by a voice and communication specialist. Reported harms of pitch-raising surgery include voice problems such as dysphonia, weak voice, restricted speaking voice range especially upper range (lowered Max f_o, in the physiological voice range), hoarseness, vocal instability, and lowering of frequency values over time, although the rate of these outcomes is inconsistent.

Research on pitch-lowering surgeries is limited. However, studies including eight TGD people who elected to undergo thyroplasty type III after continued dissatisfaction with hormonal treatment and one person who received injection augmentation after testosterone therapy and voice training, reported statistically significant lowering of fundamental frequency, perceived as pitch."

REFERENCES

Coleman, E., Radix, A. E., Bouman, W.P., Brown, G.R., de Vries, A. L. C., Deutsch, M. B., Ettner, R., Fraser, L., Goodman, M., Green, J., Hancock, A. B., Johnson, T. W., Karasic, D. H., Knudson, G. A., Leibowitz, S. F., Meyer-Bahlburg, H. F.L., Monstrey, S. J., Motmans, J., Nahata, L., ... Arcelus, J. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *International Journal of Transgender Health*, *23*(S1), S1-S260. https://doi.org/10.1080/26895269.2022.2100644