



STATE OF WASHINGTON
HEALTH CARE AUTHORITY

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August 7, 2015

TO: Interested Persons

FROM: Amy Emerson
Rules and Publications
Division of Legal Services

SUBJECT: CONCISE EXPLANATORY STATEMENT (RCW 34.05.325)
For Rules Not Considered Significant
For Rules Proposed as WSR 15-08-100

WAC(s):

WAC 182-531-1675 Gender Dysphoria Treatment Program

WAC 182-531-0200 Physician-related and health care professional services requiring prior authorization

WAC 182-501-0070 Health Care Coverage – Noncovered Services

REASON FOR ADOPTION:

Based on current medical evidence, HCA has established gender dysphoria coverage policy in WAC and removed gender reassignment surgery from the noncovered health care services list.

CHANGES MADE SINCE THE RULE WAS PROPOSED: (check one)

- The text being adopted does not differ from the text of the proposed rule.
- The text being adopted contains only editorial changes from the proposed rule.
- The text of the adopted rule varies from the text of the proposed rule. The changes (other than editing changes) follow:

Citation	Change to Text
182-531-1675 (1)(a)	The medicaid agency covers the following medically-necessary services, consistent with the services-program rules identified-described as covered in Title 182 WAC, to treat gender dysphoria:
182-531-1675 (1)(a)(iii)(E) through (G)	(iii) (E) <u>Hospitalization</u> ; and (F) <u>Physician services</u> ; and (G) <u>Hospitalizations and physician services required to treat postoperative complications of procedures performed under component four.</u>
182-531-1675 (1)(b)	The agency's gender dysphoria treatment program has four stages <u>components</u> . Prior authorization is required for <u>services provided in stage-component four</u> only. Any medicaid provider can refer a client to stage-component <u>one</u> . <u>These components are not intended to be sequential and may run concurrently to meet the client's medical needs.</u> The stages <u>components</u> are as follows: <ul style="list-style-type: none"> (i) <u>Stage-Component one</u> - ... ; (ii) <u>Stage-Component two</u> - ... ; (iii) <u>Stage-Component three</u> - Presurgical requirements <u>for prior authorization for component four</u>; and (iv) <u>Stage-Component four</u> - Gender reassignment surgery.
182-531-1675 (1)(d) through (f)	(d) The agency evaluates requests for noncovered-services as an exception to rule under the provisions of WAC 182-501-0160. <u>(de) The agency evaluates requests for clients under age twenty-one according to If gender dysphoria-treatment is requested or prescribed for clients age-twenty one and younger under the early and periodic screening, diagnosis, and treatment (EPSDT) program described in chapter 182-534 WAC., the agency-evaluates it as a covered service under the EPSDT-program's requirement Under the EPSDT program, that the a service is may be covered if it is medically necessary, safe, effective, and not experimental.</u>

	<p>(ef) The agency covers ...</p> <p>(f) Any out of state care, including a <u>presurgical consultation, must be approved as an out of state service under WAC 182-501-0182.</u></p>
182-531-1675 (2)(b)(i)	Possess knowledge about current community, advocacy, and public policy issues relevant to transgender people and their families (<u>knowledge about sexuality, sexual health concerns, and the assessment and treatment of sexual disorders is preferred</u>);
182-531-1675 (2)(b)(iii)	Agree to provide services consistent with this section. <u>The agency's forms are available online at http://www.hca.wa.gov/medicaid/forms/Pages/index.aspx.</u>
182-531-1675 (2)(c) and (d)	<p>(c) Diagnosis in stage<u>component one</u> must be made <u>or confirmed</u> by ...</p> <p>(d) Mental health professionals who provide stage<u>component two</u> mental health treatment described in subsection (4)(de) of... :</p>
182-531-1675 (2)(d)(ii)	Sign an <u>the agency's</u> form (<u>HCA 18-493</u>) attesting that they:
182-531-1675 (2)(e)(i)	Be a board-certified <u>or board qualified</u> : ...
182-531-1675 (2)(e)(iii)	<u>Sign the agency's form (HCA 18-492) a</u> Attesting to...
182-531-1675 (2)(f)(i)(A)	A licensed, board certified, <u>or board qualified</u> :
182-531-1675 (2)(f)(ii)	(ii) Sign an <u>the agency's form (HCA 18-494)</u> attesting to...
182-531-1675 (3)	(StageComponent <u>one - Initial assessment and diagnosis of gender dysphoria</u>. The purpose of stage<u>component one</u> is to assess and diagnose the client, and refer the client to <u>other qualified providers as needed for additional medically necessary services</u>.
182-531-1675 (3)(d) and (e)	(d) Refer the client to qualified providers for the stage <u>component two</u> services described in subsection (4) of this section; and

	<p>(e) Assist and support the client in navigating stage component two and stage component three requirements, and provide services consistent with WPATH guidelines and WAC 182-531-1675.</p>
<p>182-531-1675 (4)</p>	<p>(4) <u>Stage Component two - Mental health and medical treatment.</u></p> <p>(a) <u>Clients enrolled with an agency managed care organization (MCO) plan are subject to the respective plan's policies and procedures for coverage of these services.</u></p> <p>(b) <u>Mental health and medical treatment are covered only after a health professional who meets the qualifications in subsection (2)(c) of this section has diagnosed, or confirmed the diagnosis of, gender dysphoria as defined by the DSM-5 criteria.</u></p> <p>(c) <u>Medical treatment in stage component two is limited to covers androgen suppression...</u></p> <p>(d) <u>The agency covers mental health treatment for the client and his or her the client's ... :</u></p>
<p>182-531-1675 (5)</p>	<p><u>Stage Component three - Presurgical requirements.</u></p>
<p>182-531-1675 (5)(a), (a)(i), and (a)(ii)</p>	<p>(a) To proceed to stage component four gender reassignment surgery, the client must:</p> <p>(i) <u>Be age eighteen or older, unless allowed under EPSDT as described in subsection (1)(d) of this section;</u></p> <p>(ii) <u>Be competent to give consent for treatment and have this competency documented in clinical records;</u> <u>and</u></p>
<p>182-531-1675 (5)(c)</p>	<p>The client must have received continuous hormonal <u>hormone</u> therapy as required by the treatment plan to meet treatment objectives. For exceptions, see subsection (5)(f)(vi) <u>(6)(b)</u> of this section.</p>
<p>182-531-1675 (5)(d)</p>	<p>The client must have lived in a gender role congruent with the client's gender identity immediately preceding surgery as required by the treatment plan to</p>

	meet treatment objectives. For exceptions, see subsection (5)(f)(vi) <u>(6)(b)</u> of this section.
182-531-1675 (5)(f)	A member of the treatment team must write a comprehensive referral letter and submit it to the agency along with the prior authorization request for surgery. The contents of the comprehensive referral letter <u>or its attachments</u> must include:
182-531-1675 (5)(f)(vi)	(vi) An explanation that the criteria for surgery described in subsection (5)(a) through (d) of this section have been met. If the criteria are not met, the letter must describe the clinical decision-making process so that medical necessity can be established;
182-531-1675 (5)(f)(vii)	(vii) A statement about the client's adherence to the medical and mental health treatment plan, including keeping scheduled appointments;
182-531-1675 (5)(f)(viii)	(viii) A description of the outcome of the client's hormonal <u>hormone</u> therapy;
182-531-1675 (5)(f)(ix)	(ix) A copy of the client's signed informed consent according to the requirements under WAC 182-531-1550, or written acknowledgement of acknowledging the permanent impact on their male and female reproductive capacity if WAC 182-531-1550 is not applicable;
182-531-1675 (5)(f)(x)	(x) A statement that ... ;
182-531-1675 (5)(f)(x)(i)	(xi) A description of ... ;
182-531-1675 (5)(f)(x)(A)	List all <u>planned</u> surgical procedures, including any <u>listed below in subsection (6)(e) of this section, with clinical justification</u> planned ; and
182-531-1675 (5)(f)(x)(i)(i)	(xi) Signatures from the following treatment team members:
182-531-1675 (5)(f)(x)(i)(A)	The two mental health professionals for genital surgery and one mental health professional for chest surgery who completed the responsibilities described in subsections (4)(<u>de</u>) and (5)(a)(iii) of this

	section;
182-531-1675 (6), (6)(a), and (6)(b)	<p>(6) Stage<u>Component four - Gender reassignment surgery.</u></p> <p>(a) The agency requires prior authorization for stage<u>component four</u>. Subsection (5) of this section lists the documentation that is required to be submitted with the authorization requests. <u>Surgeries are not required to be completed at the same time. Surgeries may be performed in progressive stages.</u></p> <p>(b) If the client fails to complete all of the requirements in subsection (5) of this section, the agency will not authorize gender reassignment surgery unless the clinical decision-making process is provided in the comprehensive referral letter <u>and attachments</u> described in subsection (5)(f) of this section.</p>
182-531-1675 (6)(b)(ii)	The medical provider who managed the medical care in stage <u>component two</u> and stage <u>component three</u> ; and
182-531-1675 (6)(d)	<p>(d) The agency covers the following surgical procedures in stage<u>component four</u> <u>with prior authorization</u>:</p> <ul style="list-style-type: none"> (i) <u>Abdominoplasty</u>; (ii) <u>Blepharoplasty</u>; (iii) <u>Breast reconstruction (male to female)</u>; (iv) <u>Bilateral mastectomy with or without chest reconstruction</u>; (iv) <u>Cliteroplasty</u>; (iv) <u>Colovaginoplasty</u>; (v) <u>Colpectomy</u>; (v) <u>Genital surgery</u>; (v) <u>Genital electrolysis as required as part of the genital surgery</u>; (v) <u>Hysterectomy</u>; (viii) <u>Labiaplasty</u>; (x) <u>Laryngoplasty</u>; (xiii) <u>Metoidioplasty</u>; (xiv) <u>Orchiectomy</u>;

	<p>(xiv) Penectomy;</p> <p>(xvi) Phalloplasty;</p> <p>(xvii) Placement of testicular prosthesis;</p> <p>(xviii) Rhinoplasty;</p> <p>(xix) Salpingo-oophorectomy;</p> <p>(xxx) Scrotoplasty;</p> <p>(xvixxi) Urethroplasty;</p> <p>(xxii) Vaginectomy; and</p> <p>(xviii) Vaginoplasty.</p>
<p>182-531-1675 (6)(e)</p>	<p>(e) <u>For the purposes of this section, the agency will review on a case-by-case basis and may pay for the following noncovered services under exception to rule:</u></p> <p>does not cover the following surgical procedures in stage four:</p> <ul style="list-style-type: none"> (i) Abdominoplasty; (ii) Blepharoplasty; (iii) Breast augmentation; <u>(i) Cosmetic procedures and services:</u> <ul style="list-style-type: none"> (ivA) Brow lift; (vB) Calf implants; (viC) Cheek/malar implants; (viiD) Chin/nose implants; (viiiE) Collagen injections; (ixF) Drugs for hair loss or growth; (xG) Facial or trunk electrolysis, except for the limited electrolysis described in subsection (6)(d)(viii) of this section; (xiH) Facial feminization; (xiiI) Face lift; (xiiiJ) Forehead lift; (xivK) Hair transplantation; (xvL) Jaw shortening; (xvi) Laryngoplasty; (xviiM) Lip reduction; (xviiiN) Liposuction; (xixO) Mastopexy; (xxP) Neck tightening; (xxiQ) Pectoral implants;

	<p>(xxiii<u>R</u>) Reduction thyroid chondroplasty; (xxiii<u>S</u>) Removal of redundant skin; (xxiv) Rhinoplasty; (xxv<u>T</u>) Suction-assisted lipoplasty of the waist; <u>and</u> (xxvi<u>U</u>) Trachea shave; (xxvii) Voice modification surgery; and (xxviii) Voice therapy.</p>
182-531-1675 (6)(f)	<p><u>The agency evaluates a request for any noncovered service listed in subsection (6)(e) of this section as an exception to rule under the provisions of WAC 182-501-0160. The justification included in the surgical plan for any of the procedures listed in subsection (6)(e) of this section may be recognized by the agency as meeting the documentation requirements of WAC 182-501-0160.</u></p>

The changes were made because:

<p align="center">SUMMARY OF COMMENTS RECEIVED</p>	<p align="center">THE AGENCY CONSIDERED ALL THE COMMENTS. THE ACTIONS TAKEN IN RESPONSE TO THE COMMENTS, OR THE REASONS NO ACTIONS WERE TAKEN, FOLLOW.</p>
<p>Comment 1: Stakeholders expressed concern about the four stages of treatment for gender dysphoria. The stakeholders are concerned that these stages do not fully reflect the <i>Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7</i>, as developed by the World Professional Association for Transgender Health (WPATH), the world leader in standards for transgender care. The stakeholders state that the agency’s proposed program already outlines rigorous standards to ensure that only highly qualified and specialized providers deliver transgender health services, and those providers are fully equipped with the skills and expertise to determine a patient’s course of treatment using the WPATH guidelines.</p>	<p>Response to Comment 1: The agency has replaced the word “stage” with “component.” The agency also added a statement that “these components are not intended to be sequential and may run concurrently to meet the client’s medical needs.” The statement can be found in WAC 182-531-1675 (b).</p>
<p>Comment 2: Stakeholders disagreed with the age limitation listed in section 5(a)(i). Stakeholders stated that there are situations where transgender people under age 18 should be allowed surgical services.</p>	<p>Response to Comment 2: Services for clients under age 18 are available under the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program. The EPSDT Program (a separate program described in Chapter 182-534 WAC) allows medically necessary services for clients age 21 and younger, and thus includes clients under age 18. The agency plans to use age 18 as a guideline for authorizing gender reassignment surgery. However, clients under age 18 may be authorized for surgery through the EPSDT Program. The EPSDT Program has always been referenced in drafts of proposed WAC 182-531-1675 – specifically in subsection (1)(d). The agency added another reference to the EPSDT program in WAC 182-531-1675 (5)(a)(i) to make it very clear to the reader that services are available for clients under the age of 18.</p>
<p>Comment 3: Stakeholders expressed concern with the pre-surgical requirement for a provider to submit a statement about the client’s adherence to the medical and mental health treatment plan, including keeping scheduled appointments. Stakeholders felt this requirement was intrusive. Client advocates are also concerned that the ability to keep scheduled appointments can be difficult for clients with limited transportation options.</p>	<p>Response to Comment 3: The agency disagrees. Verification of a client’s adherence to the treatment plan is needed to determine the client’s commitment to gender reassignment. This verification is a requirement in other programs. The agency agrees to strike the phrase “including keeping scheduled appointments.”</p>
<p>Comment 4: Stakeholders suggest that WACs listing covered and noncovered services be amended to include coverage for gender dysphoria treatment.</p>	<p>Response to Comment 4: The agency agrees that clarifications may be required in other WACs. The agency may make amendments to related WACs in the immediate future.</p>

<p>Comment 5: Stakeholders expressed concern about the loss of privacy that may occur as the client works with the agency while participating in the Gender Dysphoria Treatment Program. Specifically, the required pre-surgical description of the outcome of the client’s hormone therapy as described in WAC 182-531-1675 (5)(c)(viii). Stakeholders do not believe this requirement fits within the HIPAA requirement to gather the minimum medical information necessary to make an assessment for treatment. Stakeholders state that the agency has an obligation to avoid overly intrusive details about a client’s genitals, secondary sex characteristics, or other highly sensitive medical information.</p>	<p>Response to Comment 5: The agency disagrees. The agency needs to know the outcome of hormonal therapy in order to determine medical necessity for surgical procedures. And regarding privacy, agency employees are subject to the Health Insurance Portability and Accountability Act (HIPAA). HIPAA’s key provisions are the Privacy Rule, the Security Rule, and the Breach Notification Rule. These rules require the agency to protect the privacy of people’s information. The agency reviews the private health care data of thousands of people each month. The agency is subject to significant fines if privacy laws are violated. Individual employees are subject to criminal prosecution if HIPAA rules are violated. There will be no change made as a result of the comment.</p>
<p>Comment 6: Stakeholders expressed concerns about whether or not the exception to rule (ETR) process in WAC 182-501-0160 is adequate or appropriate for making coverage decisions for services excluded from coverage under stage four subsection 182-531-1675 (6) (e) of the proposed rule. Stakeholders felt ETR is overly burdensome and were also concerned about the lack of any ability to challenge negative HCA decisions in either the Fair Hearing process or ultimately in court.</p>	<p>Response to Comment 6: Language was added to the new WAC to make it easier to comply with the requirements of WAC 182-501-0160.</p>
<p>Comment 7: A stakeholder encourages the agency to make certain that the final rules establish consistency among the insurance carriers. The stakeholder maintains that transgender people who are suffering cannot afford to wait long and play the “switching carriers” game to receive care.</p>	<p>Response to Comment 7: The agency asks that clients bring any problems to the agency’s attention and the agency will address them. There will be no change made as a result of the comment.</p>
<p>Comment 8: A stakeholder would like to see the implementation of a Transgender Support Program. The stakeholder maintains that the Gender Dysphoria Treatment Program is a very complicated process, and a central program coordinator is needed.</p>	<p>Response to Comment 8: No additional staffing is planned. There will be no change made as a result of the comment.</p>
<p>Comment 9: Stakeholders assert that gender dysphoria manifests uniquely to each person, and the treatment is highly individual. Stakeholders say the list of covered procedures in 182-531-1675 (6)(d) is quite limited – and will often not address the underlying cause of gender dysphoria. Nor will the list of covered procedures address the safety issues transgender people face from society when</p>	<p>Response to Comment 9: The agency has always acknowledged that gender dysphoria manifests differently from person to person, and must be treated on a case-by-case basis. WAC 182-531-1675, as presented at the public hearing, was written to allow the agency the ability to authorize noncovered services for clients on a case-by-case basis. Noncovered services may be covered through the exception to rule (ETR) process. The ETR process has always been listed in WAC 182-531-1675. ETR is the provision for an individual who needs a service the agency considers noncovered for the entire population. The agency cannot arbitrarily provide services for gender dysphoria that are not covered for other conditions. The ETR</p>

<p>they do not present as their preferred gender. Additionally, stakeholders expressed concern that denying some procedures could put clients at risk of suicide. Chest reconstruction, facial electrolysis, and voice therapy are among the noncovered procedures that most concerned stakeholders.</p>	<p>process is the only procedure the agency has to authorize noncovered services. To make the intentions of the WAC clear, the agency relocated the ETR information in the WAC so that it directly follows the list of noncovered services. The agency also inserted more details about the ETR process. Regarding safety issues and suicide risks, these issues will be considered when determining medical necessity in the ETR process.</p>
<p>Comment 10: Stakeholders felt that the proposed rules arbitrarily exclude coverage for certain medically necessary surgeries that are covered for other health conditions.</p>	<p>Response to Comment 10: Regarding noncovered procedures that are covered for other health conditions, the agency agrees that changes can be made to the WAC to address this concern. The following changes have been made:</p> <ul style="list-style-type: none"> • Abdominoplasty, blepharoplasty laryngoplasty, rhinoplasty were previously on the noncovered list. Though these services can be purely cosmetic, they can sometimes be used for noncosmetic treatment of conditions, and are therefore covered services for those medical conditions. Because these services could be used in the noncosmetic treatment of gender dysphoria, the agency has moved them to the covered list in WAC 182-531-1675. The agency will determine the medical necessity for these services through the established prior authorization process. • There are services that, although possibly covered for noncosmetic treatment of other health conditions, will remain on the final list of noncovered services for gender dysphoria because they are primarily used for cosmetic treatment of gender dysphoria. For example, collagen injections are covered for some other health conditions because they can be used as a noncosmetic treatment for those conditions— collagen injections, for instance, can treat arthritis of the hand. Collagen injections as a treatment for gender dysphoria, however, are primarily cosmetic and therefore, noncovered. There is no established criteria under WAC 182-531-1675 to determine medical necessity for the listed noncovered services. It is important to note that any item on the noncovered list may be covered if medical necessity is established under exception to rule in WAC 182-501-0160, and the agency will consider it on a case by case basis for what is medically necessary to treat gender dysphoria for each client.
<p>Comment 11: Stakeholders felt the agency was guilty of creating a double standard by refusing to cover chest reconstruction for transgender women while covering chest reconstruction for transgender men.</p>	<p>Response to Comment 11: The agency does not believe the WAC created a double standard. However, further research has helped the agency understand why stakeholders felt a double standard existed. Under the WAC as presented at the public hearing, transgender men can have a surgical procedure (a mastectomy) to create a masculine chest, whereas transgender women cannot. The agency’s logic was that transgender women can develop a feminine chest with hormones. The agency felt that breast augmentation was not appropriate for transgender women because it is a service not provided to other women. The only exception would be for women undergoing breast reconstruction after cancer treatment or physical trauma. The rule, as it was originally written, was designed to be fair to all women. However, the agency now understands that hormone therapy may not always lead to the type of breast development that will treat the incongruence between psychological gender and physical gender. The agency now also understands that what the agency views as “breast augmentation” is referred to as “breast reconstruction” by the transgender population and their health care providers. The agency has removed breast augmentation from the noncovered list, and added “breast reconstruction (male to female)” to the covered list. The agency has also added “with or without chest reconstruction” to bilateral mastectomy, already a covered procedure.</p>

<p>Comment 12: A stakeholder asserts that medications prescribed during stage two should not be subject to prior authorization. The proposed rule states that “prior authorization is required for stage four only.” However, under stage two, proposed WAC 182-531-1675(4)(b) states: “Some of these prescriptions may be subject to prior authorization as required by pharmacy policy in chapter 182-530 WAC.” Since stage two treatment for gender dysphoria will be provided by managed care organizations (MCOs), rather than as a fee-for-service carve out, this language expresses acquiescence with MCOs’ application of prior authorization requirements to hormone treatment. MCO formularies should include a wide assortment of hormones used in androgen suppression, puberty suppression, and continuous hormone therapy. WPATH describes treatment plans for gender dysphoria as individualized. No one receiving stage two treatment should be required to try alternate medications (“fail first”) or wait through a lengthy authorization process. Center of excellence (COE) providers are the proper decision-makers as to which hormone therapy is appropriate for individuals with gender dysphoria.</p>	<p>Response to Comment 12: The agency disagrees. It is not possible to automatically bypass authorization based on a client’s transitional status. Both Managed Care and FFS coverage have existing restrictions on some drugs which may be used for the transgender population. While transgender status may be a reason for expedited approval of an authorization for hormone therapy, the drugs themselves cannot be taken off of prior authorization status simply because they might be used for a transgender client. The WAC in question merely makes transparent the fact that some drugs used in the population may require authorization.</p> <p>HCA will work closely with its contracted MCOs to ensure that additional barriers are not put in place in regard to necessary medications, and that appropriate allowances are made for transgender clients.</p> <p>There will be no change made as a result of the comment.</p>
<p>Comment 13: A stakeholder believes that the proposed gender dysphoria rules should not be more restrictive than the World Professional Association for Transgender Health (WPATH) standards. WPATH promotes the highest standards of health care for transgender people and the <i>Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People</i> (SOC 7) are based on the best available science and international expert consensus.</p>	<p>Response to Comment 13: The agency disagrees. The agency believes that the rules are not restrictive, but create the best program to care for transgender clients. There will be no change made as a result of the comment.</p>

cc: HCA Rules Coordinator