Benefits Collaborative Questions & Answers: Transgender Services

This document summarizes:

- Stakeholder questions regarding the Colorado Department of Health Care Policy & Financing’s (Department) efforts to define the Transgender Benefit through the Benefits Collaborative process; and
- Suggestions made during the Benefits Collaborative process to improve draft Transgender Benefit coverage policy.

Below each item, the Department has provided an interim response.

**Important Note:** The development of the Transgender Benefit is ongoing. There are several stages of the Benefits Collaborative process that the draft has yet to complete. This document is a snapshot of the Department’s position as of 9/29/2016 and should not be read as a final policy determination.

**Item 1**

Why is the Department addressing transgender services through the Benefits Collaborative now?

- The Transgender Benefit was scheduled to go through the Benefits Collaborative process this year.

- A recently issued Department of Health and Human Services rule, titled [Nondiscrimination in Health Programs and Activities](https://www.samhsa.gov/campaigns/nondiscrimination-health-programs-activities), takes effect this year. The rule mandates coverage of gender transition-related services that are currently covered for
other medically necessary reasons. The Department is examining all coverage of gender transition-related services to ensure Medicaid clients receive medically appropriate care.

Item 2

Is this a new benefit?

- No, the Department is not creating a new benefit. We are codifying an existing benefit to ensure that transgender individuals can access existing benefits when medically necessary.

- The Department currently covers hormone therapy, counseling, and surgeries (such as mastectomy) when medically necessary.

Item 3

Will gender confirmation surgery, also known as sex reassignment surgery, be a covered service under Colorado Medicaid?

- Yes, the Department recognizes that gender confirmation surgery can be medically necessary to treat gender dysphoria.

Item 4

Where can I find the most recent draft transgender services benefit coverage policy?

- The most recent draft rule is posted on the Department Benefits Collaborative webpage.

- IMPORTANT NOTE: On 8/8/2016, the Department announced that it will no longer author Benefit Coverage Standards. Instead, the Department will document medical coverage policy in plain spoken rule. The format of the most recent draft reflects this change. Refer to the Benefits Collaborative Update for more information on this change.
Item 5

Where can I find previous drafts of the Transgender Benefit coverage policy the Department shared with the public earlier in the Benefits Collaborative Process (on 11/9/2015 and 2/16/16, respectively)?

- The first draft (11/2/15) and second draft (2/9/16) can be found on the Department website.

Item 6

Why does the draft policy discussed on 11/9/2015 refer to a diagnosis of gender identity disorder? Terminology used in the DSM-5 is gender dysphoria.

- The term gender identity disorder is used in the International Classification of Disease, Tenth Edition, Clinical Modification (ICD-10-CM) code series, which providers must use when entering a diagnosis on a physical and behavioral health or pharmacy claim form. The ICD-10 does not include a gender dysphoria code. Instead, ICD-10 uses the “F64 Gender Identity Disorders” series (see below), as well as diagnosis code Z87.890 for those individuals who may no longer have an F64 diagnosis, but have a history of treatment associated with such a diagnosis. The five diagnosis codes are listed below.
  - F64.1 – Gender identity disorder in adolescence and adulthood
  - F64.2 – Gender identity disorder of childhood
  - F64.8 – Other gender identity disorders
  - F64.9 – Gender identity disorder, unspecified
  - Z87.890 - Personal history of sex reassignment

- In the second draft of the benefit coverage policy, the Department amended the term gender identity disorder to gender dysphoria, as used in the Diagnostic Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). The diagnoses and specifiers are listed below.
  - 302.85 (F64.1) – Gender dysphoria in adolescents and adults
    - Specifiers:
      - With a disorder of sex development
      - Posttransition
  - 302.6 (F64.2) – Gender dysphoria in children
    - Specifiers:
- With a disorder of sex development
  - 302.6 (F64.8) – Other specified gender dysphoria
  - 302.6 (F64.9) – Unspecified gender dysphoria

- In the third draft of the benefit coverage policy, the Department amended the gender dysphoria definition to include both the DSM-5 and ICD-10 code series mentioned above.

**Item 7**

The requirement proposed in the first draft of the benefit coverage policy on 11/9/2015, that Medicaid clients have a diagnosis of gender identity disorder to access services, may exclude individuals with a medical need for services.

For example, people who have undergone surgery may no longer have or identify as having gender dysphoria, but may require continual cross-sex hormone therapy. Others may be or may become non-dysphoric with or without surgery. Others may identify as genderqueer or may not intend to transition from the sex they were assigned at birth, but may benefit from hormone therapy.

- The examples above fit within the ICD-10 and DSM-5 diagnosis series listed in Item 6 above.
  - For example:
    - ICD-10 codes F64.8 and F64.9 can be used as a primary diagnosis code for an individual who does not meet clinical criteria for gender dysphoria.
    - DSM-5 diagnoses of other specified gender dysphoria and unspecified gender dysphoria in the 302.6 series can be used as a primary diagnosis code for an individual who does not meet clinical criteria for gender dysphoria.
  - For example:
    - ICD-10 code Z87.89 can be used for a post-surgical individual who needs care, but no longer identifies as gender dysphoric.
    - The DSM-5 posttransition specifier can be used for an individual who has transitioned to living in the desired gender full-time and plans to undergo or has undergone at least one cross-sex medical procedure or treatment regimen.
Item 8

On the bottom of page 2 of the draft policy proposed 11/9/2015, the sub-heading titled "Anti-androgen Therapy" needs to be modified to include "anti-estrogen". This also needs to be reflected in the Brief Coverage Statement.

- The Department revised the subheading to "Gonadotropin-Releasing Hormone (GnRH) Therapy" in the second and third drafts of the policy.

Item 9

Leuprolides are only one class of anti-androgen/estrogen therapy and there may be more cost effective options.

- In the third iteration of the draft policy, the term "Leuprolides" has been replaced with the term "Gonadotropin-Releasing Hormone (GnRH)."

Item 10

The Department received varied feedback regarding the requirement proposed on 11/9/2015 that Medicaid clients obtain a referral letter from a licensed mental health professional before accessing certain non-surgery services. Specific feedback included:
The Eligible Providers section of the policy mentions a referral letter, however, it is not mentioned again in the standard. Additional clarity is needed.

Providers can charge roughly $100 to write a referral, which represents an additional cost to Medicaid that may not be appropriate, given that, in the version 7 guidelines of the World Professional Association for Transgender Health (WPATH v7), it states practitioners should be able to make these determinations within the scope of their practice.

If a referral letter is required, does the Department, or could the Department, provide a training to providers on referral letter requirements?

The informed consent model outlined in the WPATH v7 states that patients should be able to choose for themselves whether or not to begin hormone therapy, so long as their practitioner has explained to them the risks and benefits of the therapy and what to expect.

Part of the reason the aforementioned informed consent model became popular is because, traditionally, there weren’t many mental health professionals trained to diagnose and refer. The requirement of a referral letter could create an access to care issue. Could this policy, for example, drive out of state costs?

In the experience of certain stakeholders, once providers receive a certificate or some kind of special training to provide transgender-related care, they cease to accept Medicaid, which may also create an access to care issue.

There is no specific licensure that an otherwise licensed mental health practitioner can currently obtain related to the treatment and diagnosis of gender dysphoria. Professionals at the Gender Identity Center of Colorado, for example, are not licensed mental health professionals but assert that they often have more experience in providing counseling and writing referral letters than a Medicaid client’s mental health professional or general practitioner.

One stakeholder related that she believes that obtaining her hormones from overseas and beginning to treat herself was the wrong approach and highly recommends obtaining counseling and a referral letter prior to therapy, such as the kind of counseling and referral letter provided by the Gender Identity Center of Colorado, but that the language in the policy should read as a recommendation, not a requirement.

Several other stakeholders shared stories of obtaining hormones overseas and the risk that accompanies self-medication. These individuals raised concerns related to self-medication and appropriate access to care.
• A referral letter will not be required to begin hormone therapy.

• The following sentence was deleted from the second and third drafts of the policy:
  > Providers supplying a referral letter for Antiandrogen and/or cross-sex hormone therapy must be mental health professionals with experience in treating Gender Identity Disorder.

• As indicated in Item 2 above, all services listed under the Transgender Benefit are currently covered by Health First Colorado and most will require prior authorization, regardless of diagnosis. When submitting a prior authorization request to the Department, providers must submit documentation sufficient to demonstrate service-specific criteria and requirements. The format of this documentation is at the provider's discretion.

• The Transgender Benefit policy is based on providers’ scope of practice, including submission of clinical documentation and referrals. Medicaid does not reimburse providers for referral letters, but rather reimburses for provision of eligible services within the scope of their practice.

• See Item 11 below for more on the informed consent requirement.

• Behavioral health professionals licensed through the Department of Regulatory Agencies (DORA) must meet stringent initial and ongoing licensure criteria. Additionally, masters and doctoral clinical behavioral health programs include training on the Diagnostic Statistical Manual of Mental Disorders (DSM), diagnosis, and treatment of disorders, to include gender dysphoria. Behavioral health providers can also obtain additional certification, training, continuing education, and degrees with specialization in sexuality and gender, including gender dysphoria. The Department only recognizes medical and behavioral health providers meeting DORA licensure requirements, including necessary professional experience and education, as qualified to diagnose and treat gender dysphoria.

• The Department does not currently have data to suggest that out-of-state costs for non-surgery services will increase.

• The Department will continually evaluate the Transgender Benefit access to care to ensure that individuals have access to appropriate, high-quality health care.
• The Department discourages the use of drugs that have not been prescribed by a licensed medical professional for use by the individual.

Item 11
Who is, and is not, required to provide informed consent - and how - should be more clearly defined in the draft policy.

For example, existing standards and regulations state that children under the age of 18 must obtain a referral letter from a mental health provider in order to access hormone therapy. Also, state law requires that parents be notified and must give consent.

• Providers are required to inform clients of benefits and risks related to any treatment and must receive consent prior to treatment.

• If a client is under the age of 18, both the client and the client's parent or guardian must provide informed consent to treatment. This requirement is derived from the WPATH v7 guidelines. An explanation regarding why both informed consent and the stabilization of behavioral health conditions criteria are important can be found on pages 35-36 of WPATH v7.

• Language clarifying the informed consent requirement has been added to the third iteration of the draft policy under the Covered Services section, 1.d. – 1.e.

Item 12
Does the Department know if there are Medicaid providers willing to provide these services?

• During the 11/9/2015 Benefits Collaborative meeting, a participant directed the Department to the LGBTQIA Healthcare Guild website. This website contains a list of Colorado medical and behavioral health providers who attest to treating transgender patients. The Department is in the process of identifying which of these providers currently accept Medicaid.

• Colorado advocacy groups, such as the center and Gender Identity Center, offer similar provider directories:
The center: [https://www.glbtcolorado.org/transgender/transgender-programs-and-support/](https://www.glbtcolorado.org/transgender/transgender-programs-and-support/)
Gender Identity Center: [https://www.gic-colorado.org/resources-2/doctors/](https://www.gic-colorado.org/resources-2/doctors/)

- The Department has begun discussions with Regional Care Collaborative Organizations to identify providers within the existing Medicaid network.
- While outside the scope of the Benefits Collaborative, the Department would like to work with stakeholders and providers to encourage providers to enroll with Medicaid.
- For more information about how a provider can enroll with Colorado Medicaid, refer to [Colorado Medicaid’s provider enrollment and revalidation process](https://www.colorado.gov/pacific/coloradomedicalicaid/enrollment).

**Item 13**

Some hormones can be self-administered at home, should this be explicitly stated in the policy?

- Covered medications, including hormones, will be dispensed in accordance with the Department's Preferred Drug List (PDL) and pharmacy guidelines.
- The PDL will be updated in accordance with the policy decisions made through this Benefits Collaborative process, including changes to [Appendix P of the PDL](https://www.colorado.gov/pacific/coloradomedicalicaid/enrollment).
- The PDL is updated frequently. The third iteration of the draft policy has been written in a manner that is general enough to allow for frequent PDL updates.
Item 14

In both the 2009 Adult and Pediatric Endocrine Council guidelines and the WPATH v7 guidelines, there is no requirement that a child receive six months of counseling, nor a diagnosis of gender dysphoria, to begin receiving anti-androgens/anti-estrogens. In the opinion of one stakeholder, setting this counseling expectation could endanger the lives of youths.

- In the third iteration of the draft coverage policy, the Department amended this criteria to state that individuals receive ongoing counseling concurrent with initiation of GnRH therapy.

- Each covered service request and claim must be accompanied by a diagnosis code. Gender dysphoria, as defined in this draft coverage policy, includes ICD-10 F64 diagnosis codes as listed in Item 6 above.

Item 15

Varying opinions were expressed regarding at what Tanner stage anti-androgens should be administered.

One physician advocated for Tanner stage 1.

Another physician noted that anti-androgens are not benign and can, for example, lead to loss of bone mineral density, and advocated for early stage 2.

It was also noted that beginning treatment at Tanner stages 2-3 is consistent with the WPATH v7 and Pediatric Endocrine Council guidelines.

- The Department reviewed previous research and found no instance in which administration of GnRH analogues was allowed or recommended during Tanner stage 1.

- Evidence-based best practice aligns with initiation of treatment at Tanner stages 2-3.

- The criteria in the third iteration of the draft policy has been revised to read as follows, "Exhibits physical changes of puberty consistent with Tanner stage 2 or higher".
Item 16

Does administration of estrogen or testosterone require a manual review by pharmacists who work for the Department? If so, why?

- Testosterone requires a manual review by Department pharmacists because it is a controlled substance as defined by the Drug Enforcement Administration.

- There are prior authorization requirements in place for Elestrin (estradiol gel); specifically to verify that oral estrogen therapy has been unsuccessful.

Item 17

Where does the following language, found in the draft benefit coverage policy discussed on 11/9/2015, come from: "if significant medical or mental health conditions are present they must be well controlled"?

- This language appears in the WPATH v7 and most public and private payer policies.

- In the second and third drafts of the benefit coverage policy this sentence was amended to exclude the word "significant".

Item 18

Transgender women who are post-operative sometimes need to be administered testosterone because they no longer produce adequate levels naturally after removal of the testes. The current Preferred Drug List referenced in the second draft of the benefit coverage policy does not allow for this as worded; can this be addressed in either of the two documents?

- The Department agrees that testosterone can be medically necessary for post-surgical transgender women and will amend this language in the PDL.
Item 19

The Department received varying points of feedback on 2/16/2016 regarding the requirement in the second draft of the benefit coverage policy that Medicaid clients obtain two referral letters (one from a medical provider, the other from a behavioral health provider) prior to approval of surgery. Specific feedback included:

WPATH v7 guidelines suggest that two letters of referral be provided for genital surgery but only one for top surgery. Why require two letters for top surgery?

Often, a transgender individual’s medical provider is also their behavioral health provider; it might be easier to find a second provider recommendation if the type of provider is less prescriptive.

While a person’s medical condition may change, the assessment provided by a behavioral health specialist is not likely to change; why then must a new behavioral health letter be provided for each surgical procedure? Can the letter be re-used?

A surgeon will conduct a full medical evaluation prior to surgery; why then is a medical provider referral letter required? Can the surgeon provide the letter?

Several stakeholders approved of the requirement that the referral letter written by a medical provider be recent to within 60 days of PAR submission; one stakeholder felt this timeline is too short given current practice.

- As specified in Item 10 above, providers must submit documentation sufficient to demonstrate service-specific criteria and requirements. The format of this documentation (e.g. a letter, form, etc.) will be at the providers' discretion.

- WPATH v7 specifies that "one referral from a qualified mental health professional is needed for breast/chest surgery". This is consistent with previously proposed Transgender Benefit coverage policy, which requires behavioral health evaluation.

- Both the Department and the Department of Regulatory Agencies (DORA) make a distinction between licensed medical and behavioral health providers.
• While both medical and behavioral health conditions may remain stable over time, they can also change rapidly. Evaluation of medical and behavioral health conditions allows providers to tailor treatment plans to individual clients and best meet their needs.

• Recent evaluations are needed for all medical prior authorization requests. The medical documentation, which reflects the client’s current condition and needs, as well as relevant history, allows for comprehensive clinical review to determine medical necessity per Section 8.076.1.8. and alignment with service-specific criteria and requirements for each request. Providers will need to meet the requirements in the Prior Authorization section of the Transgender Benefit draft coverage policy.

• Provider letters or other medical documentation may be used for more than one procedure or prior authorization request if the requirements in the Prior Authorization section of the Transgender Benefit draft coverage policy are met.

• The licensed medical provider may be the client's medical provider, but could also be the surgeon.
Item 20

The Department also received varying points of feedback regarding required content of referral documentation for surgery. Specific feedback included:

Transgender individuals often use the same letters for different purposes, such as changing a name on a driver’s license. Requiring thorough documentation of all conditions for which the client is being treated by the recommending provider may therefore present confidentiality concerns when shared more widely.

A transgender individual may not want this information in their general medical record, where medical practitioners with ethical objections to transgender services may use it to deny routine medical care.

Providers should only be asked to document medical or behavioral health conditions that may impact eligibility for surgery.

When preparing for surgery a surgeon will usually contact a patient’s medical provider and request a health history and physical (H&P). Perhaps the surgeon can submit the H&P with the PAR instead of providing a detailed medical referral letter.

- The following sentence was deleted from the second and third drafts of the policy:
  
  Each letter of referral must outline any other medical or behavioral health conditions for which the provider is treating the client

- In the third iteration of the draft coverage policy the Department included language that “Any contraindicated medical and behavioral health conditions have been addressed and are well controlled.”

- Health First Colorado providers are required to maintain patient records in accordance with Colorado Medical Board Policy #40-7: Guidelines Pertaining to the Retention and Release of Medical Records.

- All licensed providers must adhere to the confidentiality requirements outlined in the Health Insurance Portability & Accountability Act (HIPAA) of 1996. Various avenues exist to report HIPAA and ethical violations. Additional information can be found at http://www.hhs.gov/hipaa/ and Nondiscrimination in Health Programs and Activities.

- Refer also to responses in Items 10 and 19 above.
Item 21

The requirement proposed on 2/16/2016 that an individual complete twelve months of cross-sex hormone therapy prior to surgery is not found in the WPATH v7 guidelines and should be amended.

For example, some individuals are able to receive surgery, but have medical conditions for which hormone therapy is contraindicated.

At minimum, the requirement should be followed by a statement such as "unless hormones are not clinically indicated for this individual."

One stakeholder also suggested, as an alternative, that an individual be required to have “Twelve months of lived experience in a gender role that is congruent with their gender identity.” Another stakeholder pointed to safety considerations that may make this latter suggestion impractical.

- The Endocrine Society, WPATH v7, and nearly all public and private payer policies recommend/require that an individual complete at least twelve months of consistent and compliant hormone treatment prior to both breast/chest and genital gender reassignment surgery. WPATH recommends "a minimum of twelve months feminizing hormone therapy" prior to breast augmentation and "one year of testosterone treatment" prior to mastectomy.

- In the third iteration of the draft coverage policy, the Department amended this criteria to state client "has completed twelve (12) continuous months of hormone therapy, unless medically contraindicated."

- After Department review of multiple public and private payer policies and medical best practices, the following criteria has been added: "has lived in the preferred gender role for twelve continuous months." WPATH v7 explains:
  
  > Changing gender role can have profound personal and social consequences, and the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role. The duration of twelve months allows for a range of different life experiences and events that may occur throughout the year (e.g., family events, holidays, vacations, season-specific work or school experiences).
Item 22

Top surgery is sufficiently different from genital surgery and the requirements for each should be differentiated in the draft policy.

For example, WPATH v7 guidelines do not require that someone receive cross-sex hormone therapy prior to undergoing breast augmentation.

- Refer to the first bullet response to Item 21 above.

Item 23

Several stakeholders opposed the stipulation proposed on 2/16/2016 that mammoplasty may only be performed if a Medicaid client has not developed breasts after a course of cross-sex hormone therapy, suggesting this be at the discretion of the provider and that gender dysphoria may persist in individuals with some breast growth.

One stakeholder suggested that it should be sufficient for a referring provider to attest to the surgery as medically necessary.

Another stakeholder communicated her understanding that transgender individuals tend to develop one to two cup sizes smaller than cis-gender individuals.

- The Department has researched this policy consideration extensively.
  - WPATH v7 recommends at least one year of hormone therapy prior to breast augmentation.
  - Endocrine Society guidelines recommend two years for maximal breast growth.
  - The Department consulted a gender confirmation surgeon who recommends at least twenty-four months of hormone therapy prior to surgical breast augmentation.
  - More than half of all public and private payers do not cover breast augmentation surgery.
  - Those public and private payers that do cover breast augmentation surgery typically only cover the surgery after twenty-four months of hormone therapy fails to produce "adult" breast size.
  - In the third iteration of the draft coverage policy, the Department amended this criteria to state mammoplasty is covered when client has completed twenty-four continuous months
of hormone therapy that has proven ineffective for breast development, unless medically contraindicated.

Item 24

On 2/5/2016, Dr. Kimberley Jackson provided the Department with an email with several links to sources in support of the following:

Adminstration of testosterone to post-operative male-to-female clients: The results of two studies can be found at the following links:
www.ncbi.nlm.nih.gov/pubmed/16362252; and

Coverage of facial feminization surgery: Dr. Jackson cited WPATH v7, which states "Although it may be much easier to see a phalloplasty or a vaginoplasty as an intervention to end lifelong suffering, for certain patients an intervention like a reduction rhinoplasty can have a radical and permanent effect on their quality of life, and therefore is much more medically necessary than for somebody without gender dysphoria". Dr. Jackson also suggested that prostatectomies not be covered, stating that "prostatectomies are extremely complicated, and current surgical techniques leave the prostate in place just anterior to the vagina. This allows it to be checked through the vagina, and also improves sexual and urinary function. In most (all?) trans women, the prostate atrophies significantly and the risk of neoplasm is almost zero".

- As indicated in item 18 above, the Department agrees that testosterone can be medically necessary post-surgery for transgender women and will amend this language in the PDL.

- A body of scientific evidence does not presently exist regarding the medical necessity and post-surgical outcomes of facial feminization surgery. The Department will revisit the decision to exclude coverage of facial feminization surgery as further research becomes available.

- Prostatectomies are currently covered when medically necessary and this policy will be extended to clients with a diagnosis of gender dysphoria.
Item 25

On 3/1/2016, the Colorado Consumer Health Initiative provided the Department with a letter that contained several policy recommendations. Considerations expressed and not previously addressed in this document include:

A request to adopt specific protocol relating to surgeries for individuals under age 20; and
The inclusion of nipple grafts under the list of covered services for transgender men.

- In the third iteration of the draft coverage policy the Department has amended the Surgical Procedures section to include the criteria mentioned in the Item 21 response above, and has also specified clients must be at least 18 years of age.

- The Department is currently in discussion with our federal partners to determine if the federally mandated age limit of 21 for sterilization procedures applies to this population. If so, the Department will raise the age limit to 21 for most genital surgeries.

- Nipple/areola reconstruction (CPT code 19350) is a covered procedure in conjunction with mastectomy and mammoplasty; this will be specified in the code-specific Transgender Services Billing Manual.

Item 26

On 3/11/2016, One Colorado provided the Department with a letter that contained several policy recommendations.

- Considerations expressed have previously been addressed in this document.