

Title of Rule: Revision to the Medical Assistance Act Rule Concerning Gender-Affirming Care, Section 8.735, Section 8.735
Rule Number: MSB 22-12-13-A
Division / Contact / Phone: Health Policy Office / Chris Lane / 6259

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

The proposed changes to the rule are necessary to align policy with the most recent standards of care. The changes will allow members to more easily access gender-affirming care by removing outdated requirements. The changes remove the requirement for members to engage in behavioral health counseling prior to or concurrent with gender-affirming care, reduce hormone requirements prior to surgery, and simplify the documentation required for prior authorization. The changes also remove the lists of covered procedures to allow for flexibility as best practices change. More inclusive language has been added throughout the rule.

2. An emergency rule-making is imperatively necessary

to comply with state or federal law or federal regulation and/or
 for the preservation of public health, safety and welfare.

Explain:

3. Federal authority for the Rule, if any:
42 C.F.R. §§ 440.50, 440.120, 440.210 (2023)

4. State Authority for the Rule:

Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2023)
Section 25.5-5-102(1)(d), C.R.S. (2023)

Initial Review **06/09/23**
Proposed Effective Date **08/30/23**

Final Adoption **07/14/23**
Emergency Adoption

DOCUMENT #04

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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Members with diagnoses of gender dysphoria will benefit from the proposed rule through improved access to care. Providers of gender-affirming care will benefit through reduced administrative burden.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Removing unnecessary barriers to gender-affirming care will reduce wait times and increase access to lifesaving care. Members will no longer be required to receive multiple evaluations prior to surgery or to ensure those evaluations are within 60 days of scheduled surgery. Members will also no longer be required to engage in behavioral health counseling, which is time consuming and can be stigmatizing when required based solely on a diagnosis of gender-dysphoria.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The Department does not anticipate additional costs related to this rule change. No new services are being covered.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Not updating this rule would require providers and members to continue to rely on outdated criteria for accessing gender-affirming care. Transgender and gender diverse people are at far greater risk of suicide and being victims of violence than the general public, and delays in access to care can exacerbate these risks.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no other methods to implement this policy change.

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6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

There is no alternative method for achieving the purpose for the proposed rule.

1 **8.735 GENDER-AFFIRMING CARETRANS GENDER SERVICES**

2 **8.735.1 Definitions**

3 Gender-Affirming~~Cross-Sex~~ Hormone Therapy means a course of hormone replacement therapy
4 intended to induce or change secondary sex characteristics.

5 Gender-Affirming~~Confirmation~~ Surgery means a surgery to change primary or secondary sex
6 characteristics to affirm a person's gender identity. Also known as gender confirmation~~affirmation~~ surgery
7 or sex reassignment surgery.

8 Gender Dysphoria means either: gender dysphoria, as defined in the Diagnostic Statistical Manual of
9 Mental Disorders, 5th Edition (DSM-5), codes 302.85 or 302.6; or gender identity disorder, as defined in
10 the International Classification of Disease, 10th Edition (ICD-10), codes F64. 1-9, or Z87.890.

11 Gonadotropin-Releasing Hormone Therapy means a course of reversible pubertal or gonadal
12 suppression therapy used to block the development of secondary sex characteristics in adolescents.

13 **8.735.2 Client Eligibility**

14 8.735.2.A. Clients with a clinical diagnosis of Ggender Dysphoria are eligible for the gender-
15 affirming care~~transgender services~~ benefit, subject to the service-specific criteria and restrictions
16 detailed in Section 8.735.4.

17 **8.735.3 Provider Eligibility**

18 8.735.3.A. Enrolled providers are eligible to provide gender-affirming care~~transgender services~~ if:

- 19 1. Licensed by the Colorado Department of Regulatory Agencies or the licensing agency of
20 the state in which the provider practices;
- 21 2. Services are within the scope of the provider's practice; and
- 22 3. Knowledgeable about gender diverse~~nonconforming~~ identities and expressions, and the
23 assessment and treatment of Ggender Dysphoria.

24 **8.735.4 Covered Services**

25 8.735.4.A. The following requirements apply to all covered gender-affirming care~~transgender~~
26 services:

- 27 1. Client has a clinical diagnosis of Ggender Dysphoria;
- 28 2. Requested service is medically necessary, as defined in Section 8.076.1.8.;
- 29 3. Any co-existing physical and behavioral health conditions do not interfere with diagnostic
30 clarity or capacity to consent, and associated risks and benefits have been discussed
31 contraindicated medical and behavioral health conditions have been addressed and are
32 well-controlled;
- 33 4. Client has given informed consent for the service; and

1 5. Subject to the exceptions in §13-22-103, C.R.S., if client is under 18 years of age, client's
2 parent(s) or legal guardian has given informed consent for the service.

3 8.735.4.B. Requests for services for clients under 21 years of age are evaluated in accordance with
4 the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program criteria detailed in
5 Section 8.280.

6 8.735.4.C. Behavioral health services are covered in accordance with Section 8.212.

7 8.735.4.D. Hormone Therapy

8 1. Covered hormone therapy services are limited to the following:

9 a. Gonadotropin-Releasing Hormone (GnRH) Therapy

10 i) GnRH therapy is a covered service for a client who:

11 1) Meets the criteria at Section 8.735.4.A.;

12 2) Meets the applicable pharmacy criteria at Section 8.800; and

13 ~~3) Has been referred to a licensed behavioral health provider and~~
14 ~~has a plan in place to receive behavioral health counseling~~
15 ~~concurrent with GnRH therapy.~~

16 ~~3) Has reached Tanner Stage 2.~~

17 b. ~~Gender-Affirming~~~~Cross-Sex~~ Hormone Therapy

18 i) ~~Gender-Affirming~~~~Cross-sex~~ ~~H~~ormone ~~T~~herapy is a covered service for
19 a client who:

20 1) Meets the criteria at Section 8.735.4.A.; ~~and~~

21 2) Meets the applicable pharmacy criteria at Section 8.800; ~~and~~

22 ~~3) Has been informed of the possible reproductive effects of~~
23 ~~hormone therapy, including the potential loss of fertility, and the~~
24 ~~available options to preserve fertility;~~

25 ~~4) Has reached Tanner Stage 2; and~~

26 ~~5) If under 18 years of age, demonstrates the emotional and~~
27 ~~cognitive maturity required to understand the potential impacts of~~
28 ~~the treatment.~~

29 ii) Other ~~Gender-Affirming~~~~Cross-sex~~ ~~H~~ormone ~~T~~herapy requirements

30 1) Prior to beginning ~~Gender-Affirming~~~~Cross-sex~~ ~~H~~ormone
31 ~~T~~herapy, a licensed ~~behavioral health provider~~~~health care~~
32 ~~professional who has competencies in the assessment of~~
33 ~~transgender and gender diverse people, with whom the client~~
34 ~~has an established and ongoing relationship, must determine~~
35 that any behavioral health conditions that could negatively

~~impact the outcome of treatment have been assessed and the with-risks and benefits have been discussed with the client or concerns have been addressed and are well-controlled; and-~~

2) For the first twelve (12) months of ~~Gender-Affirming~~ ~~cross-sex~~ ~~H~~hormone ~~T~~therapy:

~~a) Client must receive ongoing behavioral health counseling at a frequency determined to be clinically appropriate by the behavioral health provider; and~~

~~b) Client must receive medical assessments at a frequency determined to be clinically appropriate by the prescribing provider.~~

8.735.4.E. Permanent Hair Removal

1. Permanent hair removal is a covered service when:

- a. Client meets the criteria at Section 8.735.4.A.; and
- b. Used to treat a surgical site.

8.735.4.F. Surgical Procedures

1. ~~Gender-Affirming Surgery~~ ~~A surgical procedure listed in Section 8.735.4.F.3-5.~~ is a covered service for a client who:

- a. Meets the criteria at Section 8.735.4.A.1-4;
- b. Is 18 years of age or older;

~~i) Requests for surgery for clients under 18 years of age will be reviewed by the Department and considered based on medical circumstances and clinical appropriateness of the request;~~

~~c. Has lived in the preferred gender role for twelve (12) continuous months;~~

~~cd. Has completed six (6) twelve (12) continuous months of hormone therapy, unless hormone therapy is not clinically indicated or is inconsistent with the client's desires, goals, or expressions of individual gender identity medically contraindicated;~~

~~i) This requirement does not apply to mastectomy surgeries at Section 8.735.4.F.4.a;~~

~~ii) Twelve (12) continuous months of hormone therapy are required for mammoplasty, unless hormone therapy is not clinically indicated or is inconsistent with the client's desires, goals, or expressions of gender identity;~~

~~d. Understands the potential effect of the Gender-Affirming Surgery on fertility.~~

1 ~~e. Has been evaluated by a licensed medical provider within the past sixty (60)~~
2 ~~days; and~~

3 ~~f. Has been evaluated by a licensed behavioral health provider within the past sixty~~
4 ~~(60) days.~~

5 2. Requests for surgery for clients under 18 years of age will be reviewed by the
6 Department and considered based on medical circumstances and clinical
7 appropriateness of the request;

8 23. Rendering surgical providers must retain the following documentation for each client:

9 a. A signed statement from a licensed health care professional who has
10 competencies in the assessment of transgender and gender diverse
11 people behavioral health provider, with whom the client has an established and
12 ongoing relationship, demonstrating that:

13 i) Criteria in Section 8.735.4.F.1.a.–d. ~~and f.~~ have been met; and

14 ii) A post-operative care plan is in place.

15 ~~b. A signed statement from a licensed medical provider, with whom the client has~~
16 ~~an established and ongoing relationship, demonstrating that:~~

17 ~~i) Criteria in Section 8.735.4.F.1.a. e. have been met; and~~

18 ~~ii) A post-operative care plan is in place.~~

19 34. Covered genital Gender-Affirming Surgeries ~~include~~ are limited to the following:

20 a. Genital surgery;

21 b. Breast/chest surgery; and

22 c. Facial and neck surgery.

23 45. Requests for other medically necessary Gender-Affirming Surgeries will be reviewed by
24 the Department and considered based on medical circumstances and clinical
25 appropriateness of the request.

26 ~~a. Ovariectomy/oophorectomy~~

27 ~~b. Salpingo-oophorectomy~~

28 ~~c. Hysterectomy~~

29 ~~d. Vaginectomy~~

30 ~~e. Vulvectomy~~

31 ~~f. Metoidioplasty~~

32 ~~g. Phalloplasty~~

- h. ~~Erectile prosthesis~~
- i. ~~Scrotoplasty~~
- j. ~~Testicular prostheses~~
- k. ~~Urethroplasty~~
- l. ~~Orchiectomy~~
- m. ~~Penectomy~~
- n. ~~Prostatectomy~~
- o. ~~Clitoroplasty~~
- p. ~~Vaginoplasty~~
- q. ~~Vulvoplasty~~
- r. ~~Labiaplasty~~

~~4. Covered breast/chest surgeries are limited to the following:~~

- a. ~~Mastectomy~~
- b. ~~Mammoplasty is covered when:~~
 - i) ~~Client has completed twenty four (24) continuous months of hormone therapy that has proven ineffective for breast development, unless medically contraindicated.~~

~~56.~~ Pre- and post-operative services are covered when:

- a. Related to a ~~covered~~ surgical procedure covered under listed in Section 8.735.4.F.; and
- b. Medically necessary, as defined in Section 8.076.1.8.

8.735.5 Prior Authorization

8.735.5.A. Prior authorization is required for hormone therapy services listed in Section 8.735.4.D. in accordance with pharmacy benefit prior authorization criteria at Section 8.800.7.

8.735.5.B. ~~Prior authorization is required for covered surgeries listed in Sections 8.735.4.F.3-4~~Surgical services may require prior authorization.

8.735.5.C. All prior authorization requests must provide documentation demonstrating that the applicable requirements in Section 8.735.4 have been met.

8.735.6 Non-Covered Services

8.735.6.A. The following services are not covered under the gender-affirming care~~transgender services~~ benefit:

- 1 1. Any items or services excluded from coverage under Section 8.011.1.
- 2 2. Reversal of surgical procedures ~~covered under listed in~~ Section 8.735.4.F.

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