Hormonal Therapy for Gender Dysphoria Zero Copay Exception

Summary

This coverage policy complies with Illinois Insurance Code Section 356z.60 regarding coverage for hormonal therapy medication used to treat gender dysphoria. Hormone therapy is used to induce physical changes in alignment with a person's gender identity as part of medically necessary gender-affirming care. Coverage will be provided for hormonal therapy medications approved by the FDA for gender dysphoria, including off-label use as required by Illinois Insurance Code Section 356z.60.

Table 1: Common Hormonal Medications Used for Gender Affirming Therapy

Medication	Brand Name Examples	Formulations
Testosterone		
Testosterone cypionate	Depo-Testosterone	Injectable

Testosterone enanthate	Delatestryl	Injectable
Testosterone undecanoate	Aveed	Injectable
Testosterone gel	Androgel, Fortesta, Testim	Transdermal
Testosterone patch	Androderm	Transdermal
Estrogens		
Estradiol	Estrace, Estraderm, Elestrin	Oral, patch, gel
Ethinyl estradiol	Estinyl	Oral
Conjugated estrogens	Premarin	Oral
Anti-androgens		
Spironolactone	Aldactone	Oral
Cyproterone acetate↓	Androcur↓	Oral
gonadotropin releasing hormone (GnRH) agonists	Lupron, Zoladex	Injectable, implant
5-alpha reductase inhibitors (e.g., finasteride, dutasteride)	Propecia, Proscar	Oral

↯not all-inclusive

↓not available in the US

Definitions

"**FDA**" refers to the U.S. Food & Drug Administration, a federal agency responsible for the safety and efficacy of drugs, medical devices, and more.

"**Formulary**" means a list of medications available to members with or without Prior Authorization.

"**Hormonal therapy medication**" means medications administered to alter physical characteristics as part of gender-affirming medical treatment. This includes medications to feminize or masculinize features and suppress endogenous sex hormone secretion.

"**Off-label use**" refers to the use of a drug or medical device for a purpose or in a manner that is not included in the approved product labeling. This includes:

- Using an approved drug or device for a different indication, age group, dosage, or route of administration than what is specified in the FDA-approved labeling
- Prescribing a medication at a different dose than the dose specified in the approved labeling
- Prescribing a medication for longer than the approved duration

"**Therapeutic Equivalent Version**" refers to different products that are expected to have the same clinical effect and safety profile when given in equivalent doses. Refer to The Illinois Insurance Code (215 ILCS 5/356z.60) for the actual and full text as used in Section 356z.60.

Coverage Criteria

The requested hormonal therapy medication will be covered at $0 member cost share when the following criteria are met:

1. The medication is U.S. FDA-approved or prescribed off-label for gender dysphoria; ***AND***
2. The requested medication is **EITHER**:
    a. on the Plan's Formulary; ***or***
    b. the attending provider deems it medically necessary; ***AND***
3. The attending provider provides documentation supporting the medical necessity of the requested medication.

If the above criteria are met, the requested product will be authorized at $0 cost share for up to 12 months or the duration deemed medically necessary by the attending provider, whichever is greater.

References

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2. "Illinois General Assembly - Illinois Compiled Statutes." www.ilga.gov, www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=021500050K356z.60. Accessed 14 Nov. 2023.
3. 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,

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4. Deutsch MB. Guidelines for the primary and gender-affirming care of transgender and gender nonbinary people. University of California, San Francisco. June 17, 2016. https://transcare.ucsf.edu/guidelines.
5. Klein DA, Paradise SL, Goodwin ET. Caring for transgender and gender-diverse persons: what clinicians should know. Am Fam Physician 2018;98:645-53.
6. Rainbow Health. Guidelines for gender-affirming primary care with trans and non-binary patients. 2019. https://www.rainbowhealthontario.ca/wp-content/uploads/woocommerce_uploads/2019/12/Guidelines-FINAL-Dec-2019-iw2oti.pdf.

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