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Gender Dysphoria Hormone Therapy

PRODUCTS AFFECTED

Androgens: methyltestosterone, testosterone buccal, testosterone cypionate, testosterone enanthate, testosterone nasal gel, testosterone pellet for implant, testosterone topical gel, testosterone transdermal patch, testosterone undecanoate

Estrogens: estradiol cypionate, estradiol gel, estradiol implant pellet, estradiol oral tablet, estradiol TD gel, estradiol transdermal patch, estradiol transdermal spray, estradiol valerate

5-Alpha Reductase Inhibitor: finasteride, Propecia (finasteride), Proscar (finasteride)

Aldosterone Receptor Antagonist: Aldactone (spironolactone), spironolactone

Progestin: Depo-Provera (medroxyprogesterone acetate), medroxyprogesterone acetate, progesterone, Prometrium (progesterone)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Please note that there may be State mandates and Health Plan regulations regarding coverage of gender dysphoria treatment. Refer to the State's current information prior to applying this policy; State mandates and/or regulations supersede this policy. Please refer to the Appendices for additional information on State-specific restrictions.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes.
Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Gender Dysphoria

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. GENDER DYSPHORIA:

Note: All other covered, FDA labeled indications for Estrogens, 5-Alpha Reductase Inhibitors, Aldosterone Receptor Antagonists, and Progestins are covered without prior authorization requirement

1. Member is 18 years of age or older, subject to state-specific coverage requirements (Appendix 1) and restrictions (Appendix 2) detailed in the Appendices.
   AND
2. Prescriber attests that the member has the capacity to make a fully informed decision and to consent for treatment
   AND
3. A definitive diagnosis of persistent gender dysphoria has been made and documented by a qualified health care professional and all of the following are present:
   a. The desire to live and be accepted as a member of the opposite gender, usually accompanied by the wish to make his or her body as congruent as possible with the preferred gender through gender-affirming medical and/or surgical treatments
      AND
   b. The gender incongruence has been present persistently for at least two years
      AND
   c. The disorder is not a symptom of another mental disorder
      AND
   d. The disorder causes clinically significant distress or impairment in social, occupational, or other important areas of functioning

   AND
4. Hormone replacement treatment has been recommended as a result of the diagnosis of persistent gender dysphoria by an expert multidisciplinary team comprised of medical professionals and *****mental health professional (MHP) specializing in the management of hormone therapy for gender dysphoria (preferred) **OR** by a qualified mental health professional or qualified health care professional as *****defined by The Endocrine Society (2017) or World Professional Association for Transgender Health (WPATH).
   * - Refer to Prescriber Requirements section
   AND
5. Initial hormone therapy must be prescribed by a qualified health professional (See Prescriber Requirements) preceded by documentation that the individual has lived as their new gender full-time for 3 months or more prior to the administration of hormones
   AND
6. Documentation that the individual has demonstrable knowledge of the risks and benefits of hormone replacement

CONTINUATION OF THERAPY:

A. GENDER DYSPHORIA:

1. Documentation that member has been assessed by prescriber at least every 3 to 6 months for response to treatment, compliance, side effects (through regular monitoring of parameters such as height, weight, sitting height, Tanner stage, FH, FSH, estradiol/testosterone levels, renal/liver

function, lipids, glucose, insulin, glycosylated hemoglobin, bone density, bone age, etc.), and discussion of treatment plan (e.g., hormone therapy)

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation, with 1) an Endocrinologist, OR 2) an expert multidisciplinary team comprised of medical professionals and *mental health professional (MHP) specializing in the management of hormone therapy for gender dysphoria (preferred) OR 3) qualified MHP or health care professional as *defined by The Endocrine Society (2017) or World Professional Association for Transgender Health (WPATH) trained specialist (refer to definition below)

The Endocrine Society Clinical Practice Guideline (Hembree et al. 2017)

- Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment.
- Advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in ***adults:*** (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender- affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings.

WPATH Guidelines (2022)
Statements of Recommendations
Adults:
5.1- We recommend health care professionals assessing transgender and gender diverse **adults** for physical treatments:
5.1.a- Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field
relevant to this role and granted by a nationally accredited statutory institution.
5.1.b- For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest
edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not
implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as
practicable.
5.1.c- Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria,
incongruence, and diversity.
5.1.d- Are able to assess capacity to consent for treatment.
5.1.e- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity.
5.1.f- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.
5.2- We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment
liaise with professionals from different disciplines within the field of transgender health for consultation and

referral, if required.

AGE RESTRICTIONS:
18 years of age and older
MOLINA REVIEWER NOTE: For state-specific coverage mandates, please see Appendix 1. For state-specific coverage restrictions, please see Appendix 2. For members age 19 through 20, Medicaid coverage is not available for "any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing." 42 C.F.R. §§ 441.251, 441.253.

QUANTITY:
Per WPATH and Endocrine Society guidelines. See Appendix 2 for specific regimen dosing.

PLACE OF ADMINISTRATION:
The recommendation is that oral and topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous and intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

The recommendation is that injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products be administered in a place of service that is a non-hospital facility-based location.

DRUGINFORMATION

ROUTE OF ADMINISTRATION:
Injectable (intramuscular, subcutaneous, subcutaneous implant), topical, oral

DRUG CLASS:
Androgens, Estrogens, Antineoplastic Agent, 5-Alpha Reductase Inhibitor, Progestins

FDA-APPROVED USES:
Androgens: Primary or Hypogonadotropic Hypogonadism (congenital or acquired), Delayed Puberty, Metastatic Breast Cancer
Estrogens: Menopause, Metastatic Breast Cancer, Hypogonadism, Post-menopausal osteoporosis, Advanced Androgen-Dependent Prostate Cancer (for palliation)
5-Alpha Reductase Inhibitor: Benign prostatic hyperplasia, alopecia
Aldosterone Receptor Antagonist: Edema, Heart failure, Hyperaldosteronism, Hypertension
Progestin: Contraception, Endometriosis, Endometrial carcinoma/hyperplasia, Renal cell carcinoma, Secondary Physiologic amenorrhea

COMPENDIAL APPROVED OFF-LABELED USES:
Transgender health

APPENDIX

APPENDIX 1: State Marketplace and Medicaid Gender Dysphoria Treatment Coverage Mandates
State Marketplace
California (Source: California Code of Regulations)
10 Cal. Code Regs. § 2561.2
(a) An admitted insurer shall not, in connection with health insurance as defined in subdivision (b) of Insurance Code section I 06, discriminate on the basis of an insured's or prospective insured's actual or

perceived gender identity, or on the basis that the insured or prospective insured is a transgender person. The discrimination prohibited by this Section 2561.2 includes any of the following:

…

(4) Denying or limiting coverage, or denying a claim, for services including but not limited to the following, due to an insured's actual or perceived gender identity or for the reason that the insured is a trans gender person:

(A) Health care services related to gender transition if coverage is available for those services under the policy when the services are not related to gender transition, including but not limited to hormone therapy, hysterectomy, mastectomy, and vocal training; or

(B) Any health care services that are ordinarily or exclusively available to individuals of one sex when the denial or limitation is due only to the fact that the insured is enrolled as belonging to the other sex or has undergone, or is in the process of undergoing, gender transition.

(b) This Section 2561.2 shall have no bearing on the question of whether or not a particular health care service is medically necessary in any individual case.

Nevada (Source: Nevada Revised Statutes)

Nev. Rev. Stat. Ann. § 689A.0432

1. Except as otherwise provided in this section, an insurer that issues a policy of health insurance shall include in the policy coverage for the medically necessary treatment of conditions relating to gender dysphoria and gender incongruence. Such coverage must include coverage of medically necessary psychosocial and surgical intervention and any other medically necessary treatment for such disorders

…

4. An insurer that issues a policy of health insurance may prescribe requirements that must be satisfied before the insurer covers surgical treatment of conditions relating to gender dysphoria or gender incongruence for an insured who is less than 18 years of age. Such requirements may include, without limitation, requirements that:

(a) The treatment must be recommended by a psychologist, psychiatrist or other mental health professional;

(b) The treatment must be recommended by a physician;

(c) The insured must provide a written expression of the desire of the insured to undergo the treatment;

(d) A written plan for treatment that covers at least 1 year must be developed and approved by at least two providers of health care; and

(e) Parental consent is provided for the insured unless the insured is expressly authorized by law to consent on his or her own behalf.

5. When determining whether treatment is medically necessary for the purposes of this section, an insurer must consider the most recent Standards of Care published by the World Professional Association for Transgender Health, or its successor organization.

New Mexico (Source: New Mexico Statutes)

N.M. Stat. Ann. § 24-34-2

As used in the Reproductive and Gender-Affirming Health Care Freedom Act:

A. "gender-affirming health care" means psychological, behavioral, surgical, pharmaceutical and medical care, services and supplies provided to support a person's gender identity;

B. “public body” means a state or local government, an advisory board, a commission, an agency or an entity created by the constitution of New Mexico or any branch of government that receives public funding, including political subdivisions, special tax districts, school districts and institutions of higher education

N.M. Stat. Ann. § 24-34-3

A. A public body or an entity or individual acting on behalf of or within the scope of the authority of a public body shall not discriminate against a person based on that person's use of or refusal to use reproductive health care or gender-affirming health care services.

B. A public body or an entity or individual acting on behalf of or within the scope of the authority of a public body shall not deny, restrict or interfere with a person's ability to access or provide reproductive health care or gender-affirming health care within the medical standard of care.

New York (Source: New York Compilation of Codes, Rules, and Regulations)
11 N.Y. Comp. Codes R. & Regs. § 52.75

(a) In addition to the prohibitions against discrimination set forth in section 52.72 of this Part, an insurer shall not discriminate based on an insured's or prospective insured's actual or perceived sexual orientation, gender identity or expression, or transgender status. Discrimination prohibited by this section includes any of the following:

(1) including a policy clause that purports to deny, limit, or exclude coverage based on an insured's sexual orientation, gender identity or expression, or transgender status;
(2) denying, limiting, or otherwise excluding medically necessary services or treatment otherwise covered by a policy on the basis that the treatment is for gender dysphoria; provided further that an insurer shall provide an insured with the utilization review appeal rights required by Insurance Law and Public Health Law articles 49 for gender dysphoria treatment that is denied based on medical necessity;
(3) designating an insured's sexual orientation, gender identity or expression, or transgender status as a pre-existing condition for the purpose of denying, limiting, or excluding coverage; or
(4) denying a claim from an insured of one gender or sex for a service that is typically or exclusively provided to an individual of another gender or sex unless the insurer has taken reasonable steps, including requesting additional information, to determine whether the insured is eligible for the services prior to denial of such claim.

Washington (Source: Revised Code of Washington)
Rev. Code Wash. § 48.43.0128

(3) For health plans issued or renewed on or after January 1, 2022:

(a) A health carrier may not deny or limit coverage for gender affirming treatment when that treatment is prescribed to an individual because of, related to, or consistent with a person's gender expression or identity, as defined in RCW 49.60.040, is medically necessary, and is prescribed in accordance with accepted standards of care.

. . .

(c) A health carrier may not issue an adverse benefit determination denying or limiting access to gender-affirming services, unless a health care provider with experience prescribing or delivering gender-affirming treatment has reviewed and confirmed the appropriateness of the adverse benefit determination.

(4) For the purposes of this section, "gender-affirming treatment" means a service or product that a health care provider, as defined in RCW 70.02.010, prescribes to an individual to treat any condition related to the individual's gender identity and is prescribed in accordance with generally accepted standards of care. Gender-affirming treatment must be covered in a manner compliant with the federal mental health parity and addiction equity act of 2008 and the federal affordable care act. Gender-affirming treatment can be prescribed to two spirit, transgender, nonbinary, intersex, and other gender diverse individuals.

State Medicaid

California (Source: Department of Health Care Services)
All-Plan Letter 20-018

MCPs [managed care health plans] are contractually obligated to provide medically necessary covered services to all members, including transgender members. State law defines "medically necessary" as follows:

(a) For individuals 21 years of age or older, a service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
(b) For individuals under 21 years of age, a service is "medically necessary" or a "medical necessity" if the service corrects or ameliorates defects and physical and mental illnesses and conditions

….

Nationally recognized medical experts in the field of transgender health care have identified the

following core services in treating gender dysphoria: mental health services; psychotherapy; hormone therapy; and a variety of surgical procedures and treatments that bring primary and secondary gender characteristics into conformity with the individual's identified gender.

New Mexico (Source: New Mexico Statutes; State of New Mexico Medical Assistance Program Manual Supplement Number 24-15)

N.M. Stat. Ann. § 24-34-2

As used in the Reproductive and Gender-Affirming Health Care Freedom Act:

A. "gender-affirming health care" means psychological, behavioral, surgical, pharmaceutical and medical care, services and supplies provided to support a person's gender identity;

B. "public body" means a state or local government, an advisory board, a commission, an agency or an entity created by the constitution of New Mexico or any branch of government that receives public funding, including political subdivisions, special tax districts, school districts and institutions of higher education

N.M. Stat. Ann. § 24-34-3

A. A public body or an entity or individual acting on behalf of or within the scope of the authority of a public body shall not discriminate against a person based on that person's use of or refusal to use reproductive health care or gender-affirming health care services.

B. A public body or an entity or individual acting on behalf of or within the scope of the authority of a public body shall not deny, restrict or interfere with a person's ability to access or provide reproductive health care or gender-affirming health care within the medical standard of care.

State of New Mexico Medical Assistance Program Manual Supplement Number 24-15

In the 2023 legislative session, the New Mexico legislature passed House Bill 7 codifying access to both abortion and gender affirming healthcare. This supplement is to provide guidance and clarification as to what constitutes medically necessary gender affirming healthcare.

1. Recipient Eligibility Requirements: MAD will allow and reimburse services for recipients with the following requirements. Requirements and indications must be documented in the member's medical record.

a. Age:

i. Recipients twelve years to seventeen years of age are eligible for hormone therapy only,

ii. Recipients eighteen years of age and older are eligible for hormone therapy, procedural and surgical interventions

New York (Source: New York Compilation of Codes, Rules and Regulations)

18 N.Y. Comp. Codes R. & Regs. § Section 505.2

(l) Gender dysphoria treatment.

(1) As provided in this subdivision, payment is available for medically necessary hormone therapy and/or gender reassignment surgery for the treatment of gender dysphoria.

(2)

(i) Hormone therapy, whether or not in preparation for gender reassignment surgery, shall be covered as follows:

(a) treatment with gonadotropin-releasing hormone agents (pubertal suppressants), based upon a determination by a qualified medical professional that an individual is eligible and ready for such treatment, i.e., that the individual:

(1) meets the criteria for a diagnosis of gender dysphoria;

(2) has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;

(3) does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

(4) has adequate psychological and social support during treatment; and

(5) demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment;

(b) treatment with cross-sex hormones for patients who are sixteen years of age and older, based upon a determination of medical necessity made by a qualified medical professional; patients who are under eighteen years of age must meet the applicable criteria set forth in clause (a).

(ii) Notwithstanding the requirement in clause (b) of subparagraph (i) of this paragraph that an individual be sixteen years of age or older, payment for cross-sex hormones for patients under sixteen years of age who otherwise meet the requirements of clause (b) of subparagraph (i) of this paragraph shall be made in specific cases if medical necessity is demonstrated and prior approval is received.

Appendix 2: State Medicaid Gender Dysphoria Treatment Coverage Restrictions
Idaho

Idaho Code Ann. § 18-8901

(1) For the purposes of this section, "exempted surgical operations or medical interventions" means a surgical operation or medical intervention that is:

(a) Necessary to the health of the person on whom it is performed and is performed by a person licensed in the place of its performance as a medical practitioner, except that a surgical operation or medical intervention is never necessary to the health of the minor or adult on whom it is performed if it is for the purpose of altering the appearance of an individual in order to affirm the individual's perception of the individual's sex in a way that is inconsistent with the individual's biological sex;

(b) For the treatment of any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of gender transition procedures, whether or not the procedures were performed in accordance with state and federal law; or

(c) Performed in accordance with the good faith medical decision of a parent or guardian of a child or an adult born with a medically verifiable genetic disorder of sex development, including:

(i) A person with external biological sex characteristics that are ambiguous and irresolvable, such as a person born having 46, XX chromosomes with virilization, 46, XY chromosomes with undervirilization, or with both ovarian and testicular tissue; or

(ii) When a physician has otherwise diagnosed a disorder of sexual development in which the physician has determined through genetic testing that the minor or adult does not have the normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female.

(2) Public funds shall not be used, granted, paid, or distributed to any entity, organization, or individual for the provision or subsidy of any surgical operation or medical intervention described in section 18-1506C(3), Idaho Code, for purposes of altering the appearance of an individual in order to affirm the individual's perception of the individual's sex in a way that is inconsistent with the individual's biological sex regardless of whether the surgical operation or medical intervention is administered to a minor or an adult, except for exempted surgical operations or medical interventions.

(3) Any amount paid by an entity, organization, or individual during a taxable year for the provision of surgical operations or medical interventions described in section 18-1506C(3), Idaho Code, for purposes of altering the appearance of an individual in order to affirm the individual's perception of the individual's sex in a way that is inconsistent with the individual's biological sex regardless of whether the surgical operation or medical intervention is administered to a minor or an adult shall not be tax-deductible, except exempted surgical operations or medical interventions.

(4) The Idaho Medicaid program shall not reimburse or provide coverage for the use of the surgical

operations or medical interventions described in section 18-1506C(3), Idaho Code, for purposes of altering the appearance of an individual in order to affirm the individual's perception of the individual's sex in a way that is inconsistent with the individual's biological sex regardless of whether the surgical operation or medical intervention is administered to a minor or an adult, except exempted surgical operations or medical interventions.

(5) No physician or other health care professional in the course and scope of employment by the state or a county or local government may provide the surgical operations or medical interventions described in section 18-1506C(3), Idaho Code, for purposes of altering the appearance of an individual in order to affirm the individual's perception of the individual's sex in a way that is inconsistent with the individual's biological sex regardless of whether the surgical operation or medical intervention is administered to a minor or an adult, except exempted surgical operations or medical interventions.

(6) No state property, facility, or building may be used to provide the surgical operations or medical interventions described in section 18-1506C(3), Idaho Code, for purposes of altering the appearance of an individual in order to affirm the individual's perception of the individual's sex in a way that is inconsistent with the individual's biological sex regardless of whether the surgical operation or medical intervention is administered to a minor or an adult, except exempted surgical operations or medical interventions.

(7) Any intentional violation of the provisions of this chapter by a public officer or public employee shall be considered a misuse of public moneys punishable pursuant to section 18-5702, Idaho Code.

Idaho Code Ann. § 18-1506C(3) (surgical operations or medical interventions not covered by Idaho Medicaid)

. . .

(c) Administering or supplying the following medications that induce profound morphologic changes in the genitals of a child or induce transient or permanent infertility:

(i) Puberty-blocking medication to stop or delay normal puberty;

(ii) Supraphysiological doses of testosterone to a female; or

(iii) Supraphysiological doses of estrogen to a male

Iowa

Iowa Code Ann. § 249A.14

1. Moneys appropriated from the general fund of the state to the department for the medical assistance program shall not be used for reimbursement for sex reassignment surgery or associated procedures, including hormone therapy or other medical interventions intended to alter primary or secondary sex characteristics related to an individual's gender dysphoria diagnosis.

2. This section shall not be construed to prohibit Medicaid program reimbursement for services not described under subsection 1 that are otherwise covered under the Medicaid program.

Kentucky

Ky. Rev. Stat. Ann. § 205.5365

Notwithstanding any provision of law to the contrary and unless required under federal law, the Department for Medicaid Services and any managed care organization with whom the department contracts for the delivery of Medicaid services are hereby prohibited from expending any Medicaid funds on any of the following:

(1) Cross-sex hormones when prescribed or administered primarily or solely for the treatment of gender dysphoria

South Carolina

S.C. Code Ann. § 44-42-340

Public funds may not be used directly or indirectly for gender transition procedures.

S.C. Code Ann. § 44-42-310

(6) "Gender transition procedures" means puberty-blocking drugs, cross-sex hormones, or genital or nongenital gender reassignment surgery, provided or performed for the purpose of assisting an individual with a physical gender transition.

South Carolina Medicaid Provider Manual Pg. 191

Services and procedures related to gender transition are not covered.

Texas

Texas Provider Manual § 1.11

The following services, supplies, procedures, and expenses are not benefits of Texas Medicaid. This list is *not* all inclusive.

…

Prescription medications and surgical procedures used for the purposes of transitioning biological sex, including sex change operations, except when provided to individuals with a medically verifiable genetic disorder of sex development

Utah (Source: Utah Code; Utah Department of Health & Human Services)Utah Code Ann. § 58-1-603

(1) As used in this section:

…

(d) "Health care provider" means:

(i) a physician;

(ii) a physician assistant licensed under Chapter 70a, Utah Physician Assistant Act; or

(iii) an advanced practice registered nurse licensed under Subsection 58-31b-301(2)(e).

(e)(i) "Hormonal transgender treatment" means administering, prescribing, or supplying for effectuating or facilitating an individual's attempted sex change:

(A) to an individual whose biological sex at birth is female, a dose of testosterone or other androgens at levels above those normally found in an individual whose biological sex at birth is female;

(B) to an individual whose biological sex at birth is male, a dose of estrogen or a synthetic compound with estrogenic activity or effect at levels above those normally found in an individual whose biological sex at birth is male; or

(C) a puberty inhibition drug.

(ii) "Hormonal transgender treatment" does not include administering, prescribing, or supplying a substance described in Subsection (1)(e)(i) to an individual if the treatment is medically necessary as a treatment for:

(A) precocious puberty;

(B) endometriosis;

(C) a menstrual, ovarian, or uterine disorder;

(D) a sex-hormone stimulated cancer; or

(E) a disorder of sexual development.

…

(g) "Minor" means an individual who is less than 18 years old.

Utah Code Ann. § 58-1-603.1

(1) As used in this section:

(a) "Health care provider" means the same as that term is defined in Section 58-1-603.

(b) "Hormonal transgender treatment" means the same as that term is defined in Section 58-1-603.

(2) A health care provider may not provide a hormonal transgender treatment to a patient who:

(a) is a minor as defined in Section 58-1-603; and

(b) is not diagnosed with gender dysphoria before January 28, 2023.

Utah Department of Health & Human Services Medicaid Information Bulletin (February 2023)

Drug and Biologic Coverage Criteria

- Effective January 28, 2023
  - The following services are non-covered for patients who are less than 18 years of age:
    - Hormonal transgender treatment including:
      - Puberty Blocker Therapy (Gonadotropin Releasing Hormone (GnRH)) and
      - Gender Dysphoria Hormone Therapy (cross-sex hormonal transgender treatment)
    - Sex characteristic surgical procedures for the purpose of effectuating a sex change.
- Exception to this policy:
  - Minors who have been diagnosed with gender dysphoria before January 28, 2023. Minors with the diagnosis prior to January 28th, 2023, may receive treatment with supporting medical documentation from a provider who has been treating the minor for gender dysphoria for at least six months.
  - Coverage of these services requires that providers submit:
  - The Gonadotropin Releasing Hormone (GnRH) Prior Authorization form to request coverage of GnRH releasing hormone medications.
  - The Hormone Therapy for Gender Dysphoria Prior Authorization form to request transgender hormonal treatments for patients less than 18 years of age.
- Effective January 1, 2024, providers treating patients less than 18 years of age for gender dysphoria are required to complete and show proof of the Transgender Treatment Certification, which is under development by the Department of Professional Licensing (DOPL).

MOLINA REVIEWER NOTE: For requests for members <19 years of age, refer to Gonadotropin-Releasing Hormone (GnRH) MHUT C24948-A or Hormone Therapy for Gender Dysphoria MHUT C24947-A.

Appendix 3: Hormone Regimens in Transgender Persons (Endocrine Society, 2017)

Testosterone for transgender males					
Parenteral			Transdermal		Implant
Testosterone enanthate	Testosterone cypionate	Testosterone undecanoate	Testosterone gel 1.6%	Testosterone transdermal patch	Testopel®
100 – 200 mg/10 - 14 days or 50 – 100 mg/week		1000 mg every 12 weeks	50 – 100 mg/day	2.5 – 7.5 mg/day	75 mg/pellet

Estrogen for transgender females			
Oral	Transdermal	Parenteral	
Estradiol	Estradiol patch	Estradiol valerate	Estradiol cypionate
2-6 mg/d	0.025 – 0.2 mg/d *new patch placed Q3-5 d	5 – 30mg IM Q2 weeks	2 – 10mg IM Q week

Anti-androgens for transgender females					
Progesterone	Medroxyprogesterone acetate	GnRH agonist (leuprolide)	Histrelin implant	Spironolactone	Finasteride
20 – 60 mg PO daily	150mg IM Q3 months	3.75 – 7.5mg SQ monthly 11.25mg SQ every 3 months	50 mg implanted Q 12 months	100 – 300 mg PO daily	1 mg PO daily

Table 3. Gender-Affirming Hormone Regimens In Transgender And Gender Diverse Youth (Adapted from the Endocrine Society Guidelines; Hembree et al., 2017) (WPATH, 2022)

Induction of female puberty (estrogen-based regimen) with oral 17ß-estradiol

Initiate at 5µg/kg/d and increase every 6 months by 5 µg/kg/d up to 20 µg/kg/d according to estradiol levels

Adult dose = 2-6mg/day

In postpubertal TGD adolescents, the dose of 17ß-estradiol can be increased more rapidly: 1mg/d for 6 months followed by 2mg/d and up according to estradiol levels

Induction of female puberty (estrogen-based regimen) with transdermal 17ß-estradiol

Initial dose 6.25-12.5 µg/24 h (cutting 24 g patch to ¼ then ½) Titrate up by every 6 months by 12.5 µg/24 h according to estradiol levels
Adult dose = 50-200 µg/24 hours

For alternatives once at adult dose (Table 4)

Induction of male puberty (testosterone-based regimen) with testosterone esters
25mg/m2 /2 weeks (or alternatively half this dose weekly)

Increase by 25mg/m2 /2 weeks every 6 months until adult dose and target testosterone levels are achieved. See alternatives for testosterones (Table 4)

Table 4. Hormone regimens in transgender and gender diverse adults (WPATH, 2022)

Estrogen-based regimen (Transfeminine)

Estrogen
- Oral or sublingual
- Estradiol 2.0-6.0mg/day
- Transdermal
  - Estradiol transdermal patch 0.025-0.2mg/day
- Estradiol gel various ‡ daily to skin
- Parenteral
  - Estradiol valerate or cypionate 5-30mg IM every 2 weeks 2-10 IM every week
- Anti-Androgens
  - Spironolactone 100–300mg/day
  - Cyproterone acetate 10mg/day**
  - GnRH agonist 3.75–7.50mg SQ/IM monthly
  - GnRH agonist depot formulation 11.25/22.5mg SQ/IM 3/6 monthly

‡ Amount applied varies to formulation and strength

Testosterone-Based Regimen (Transmasculine) Transgender males

Testosterone Parenteral
- Testosterone enanthate/ cypionate 50–100 IM/SQ weekly or 100–200 IM every 2 weeks
- Testosterone undecanoate 1000mg IM every 12 weeks or 750mg IM every 10 weeks

Transdermal testosterone
- Testosterone gel 50-100mg/day
- Testosterone transdermal patch 2.5–7.5mg/day

* Doses are titrated up or down until sex steroid hormone levels are in the therapeutic range. Hormone regimens do not reflect all formulations that are available in all pharmacies throughout the world. Hormone regimens may have to be adapted to what is available in local pharmacies.
**Kuijpers et al (2021)

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Gender dysphoria is the condition in which a person with apparently normal somatic sexual differentiation of one gender is convinced that he or she is actually a member of the opposite gender. It is associated with an irresistible urge to be in the opposite gender hormonally, anatomically, and psychosocially. According to the American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders (DSM-V) gender dysphoria is described as a condition in which an individual is intensely

uncomfortable with their biological gender and strongly identifies with, and wants to be, the opposite gender. For a person to be diagnosed with gender dysphoria there must be a marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. In children, the desire to be of the other gender must be present and verbalized. This condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. Gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of the other gender. It is recommended that patients meet the DSM-5 and/or ICD-10 criteria to be diagnosed with gender dysphoria.[7]

The current ICD-10 criteria for transsexualism include: [10]

- The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
- The transsexual identity has been present persistently for at least two years.
- The disorder is not a symptom of another mental disorder or a genetic, intersex, or chromosomal abnormality.

The current DSM-5 criteria for gender dysphoria in adolescents and adults include[4,7]

A. Marked incongruence between one's experienced/expressed gender and natal gender of at least 6 months in duration, as manifested by at least two of the following:
    a. A marked incongruence between one's experienced/expressed gender and primary and or/ secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
    b. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics
    c. A strong desire for the primary and/or secondary sex characteristics of the other gender
    d. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
    e. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
    f. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
    Specify if:
    1. The condition exists with a disorder of sex development
    2. The condition is post transitional, in that the individual has transitioned to full- time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex- related medical procedure or treatment regimen – namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

The treatment of gender dysphoria requires a multidisciplinary team and stepwise approach to promote optimal health for individuals of this diverse population. The initial assessment of a patient with transsexualism is based on psycho-diagnostic instruments and ideally should be performed by a mental health professional who is trained in using the DSM-5 or ICD criteria. "Gender affirmation" or "transitioning" is defined as the process of reflection, acceptance, and intervention. Counseling is essential before initiating hormonal or surgical treatment for gender affirmation. It is recommended that when or before hormone treatment starts, the individual should begin living in the role of the opposite gender. The World Professional Association for Transgender Health Standards of Care provides the

following criteria for starting hormone therapy and for undergoing surgical procedures: diagnosis of persistent, well-documented gender dysphoria, the capacity to make a well-informed decision, the person must be of legal age; and any medical or mental issues are well controlled.

Hormone replacement can begin at or after the age of 16 years. The goal of treatment in female-to- male transsexual individuals is to stop menses and induce virilization, including a male pattern of sexual hair, male physical contours, and clitoral enlargement. The principal hormonal treatment is a testosterone preparation. For male-to-female transsexual individuals the goal is elimination of sexual hair growth, induction of breast formation, and a more female fat distribution are essential. To accomplish this, a near-complete reduction of the biological effects of androgens is required.

Hormone treatment recommendations: [7,21]

A. There are different regimens to change secondary sex characteristics for transgender males. Parenteral, or transdermal preparations of testosterone can be used to achieve testosterone values in the normal male range, which is typically 320 to 1000 ng/dL. After the age of 40, transdermal formulations are recommended as they bypass first pass metabolism and seem to be associated with better metabolic profiles.

Testosterone for transgender males				
Parenteral		Transdermal		Implant
Testosterone enanthate	Testosterone cypionate	Testosterone gel 1.6%	Testosterone transdermal patch	Testopel®
100 – 200 mg/10 – 14 days or 50 – 100 mg/ week		50 – 100 mg/d	2.5 – 7.5 mg/d	75mg/pellet

A. The hormone regimen for transgender females is more complex. While estrogens are the choice of therapy for transgender females, monotherapy is typically not enough to reach testosterone levels in the female range (100 – 200 pg/mL and <50 ng/dL). Adjunctive anti- androgenic therapy may be necessary to achieve desirable androgen suppression. Transdermal preparations and injectable estradiol cypionate or valerate are advantageous in older transgender females who may be at higher risk for thromboembolic disease.

Estrogen for transgender females			
Oral	Transdermal	Parenteral	
Estradiol	Estradiol patch	Estradiol valerate	Estradiol cypionate
2-6 mg/d	0.025 – 0.2 mg/d *new patch placed Q3-5 d	5 – 30mg IM Q2 weeks	2 – 10mg IM Q week

Anti-androgens for transgender females					
Progesterone	Medroxyprogesterone acetate	GnRH agonist (leuprolide)	Histrelin implant	Spironolactone	Finasteride
20 – 60 mg PO daily	150mg IM Q3 months	3.75 – 7.5mg IM monthly	50 mg implanted Q 12 months	100 – 300 mg PO daily	1mg PO daily

Surveillance recommendations:

For transgender men on Testosterone [7]

a. Monitor for virilizing and adverse effects every 3 months for the first year, then every 6- 12 months.
b. Obtain baseline hematocrit and lipid profile and monitor every 3 months for the first year, then every 6 – 12 months.
    a. Monitor weight, blood pressure, and lipids regularly during visits
c. Obtain baseline bone mineral density if at risk for osteoporosis; routine screening after age 60, or earlier if sex hormone levels consistently low.

d. Monitor serum estradiol during the first 6 months and thereafter until uterine bleeding has ceased.
e. Monitor serum testosterone every 3 months until at, target levels, 320 – 1000 ng/dL
    a. Peak levels for parenteral testosterone measured 24-48 hours after injection.
f. Trough levels for parenteral measured before injection. If mastectomy was performed, conduct sub- and peri areolar annual breast examinations.
    a. If no mastectomy was performed, consider mammograms as recommended by the recommended by the American Cancer Society.

American Cancer Society For transgender women on Estrogen [7]

a. Monitor for feminizing and adverse effects every 3 months for the first year, then every 6- 12 months.
b. Obtain baseline hematocrit and lipid profile and monitor at follow up visits.
c. Obtain baseline bone mineral density if at risk for osteoporosis; routine screening after age 60, or earlier if sex hormone levels consistently low.
d. Obtain prolactin at baseline, at 12 months after initiation of treatment, biennially thereafter.
e. Monitor serum testosterone every 3 months, target <50 ng/dL
f. Monitor serum estradiol every 3 months, target 100-200 pg/mL .
g. Obtain baseline serum potassium level and renal function, then every 3 months in the first year, and annually thereafter, when using Spironolactone.

Other considerations:[22-25]

A. Breast cancer:
    i) FTM [female to male]: Intact breasts, routine screening as for natal females. Post- mastectomy: Yearly chest wall and axillary exams.
    ii) MTF [male to female]: Screening in members >50 years with additional risk factors for breast cancer (estrogen therapy >5 years, family history, BMI >35).

B. Cervical cancer:
    i) FTM: Cervix intact, routine screening as for natal females.

C. Prostate cancer:
    i) MTF: Routine screening as for natal males.

D. Cardiovascular disease:
    i) Screen for risk factors.

E. Diabetes mellitus:
    i) MTF: Increased risk on estrogen.
    ii) FTM: Routine screening.

Summary of Medical Evidence

There are no randomized controlled trials evaluating the effectiveness of hormone treatment for gender dysphoria. Available evidence consists of cross-sectional studies where a group of transgender individuals, some of whom had undergone cross-sex hormone therapy and some of whom had not, responded to questionnaires. Sample sizes in these studies of adults ranged from 50 to 376. The studies most commonly evaluated quality of life (QOL) or functional status with instruments such as the SF-36 Health Survey (Quality Metric Inc.), mood-related conditions such as depression or anxiety, and/or psychosocial conditions such as perceived social support or partnership status. A variety of other behavioral and social outcomes were each assessed, and results were generally positive.18-24 A systematic review based on 28 studies (1833 participants; 1091 MtF and 801 FtM) published from 1996 to February 2008 included a meta-analysis of the QOL and psychosocial outcomes of hormone therapy. 80% of the study participants reported significant improvement in quality of life and reported significant improvement in psychiatric symptoms. Medically necessary criteria were developed according to the World Professional Association for Transgender Health Standards of Care, 7th version and the 2017 Endocrine Society clinical Practice Guidelines. [22, 23]

U.S. Department of Health and Human Services (HHS) Report [26]

On May 1, 2025, the U.S. Department of Health and Human Services (HHS) released a policy report titled

Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices, issued under Executive Order 14187. This report revises federal positions on the treatment of gender dysphoria in minors.
The report re-evaluates existing evidence supporting medical and surgical interventions for pediatric gender dysphoria, concluding that the overall evidence quality for benefits of puberty blockers and gender-affirming hormone therapy in minors is low to very low. Citing methodological limitations, lack of long-term outcome data, and potential risks (such as impacts on bone density, fertility, and cardiovascular health), HHS no longer endorses these interventions as medically necessary for individuals under 18 years of age.
The report explicitly supports psychotherapeutic interventions, described as "exploratory therapy," as the recommended first-line and only covered intervention for pediatric gender dysphoria.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Members with an FDA labeled contraindication to an individual agent are excluded from coverage unless the prescriber provides an attestation of medical necessity.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1000	Injection, depo-estradiol cypionate, up to 5 mg
J1050	Injection, medroxyprogesterone acetate, 1 mg
J1071	Injection, testosterone cypionate, 1 mg
J1380	Injection, estradiol valerate, up to 10 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg

AVAILABLE DOSAGE FORMS:
Aldactone TABS 25MG, 50MG, 100MG
Alora PTTW 0.025MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Androderm PT24 2MG/24HR, 4MG/24HR
AndroGel GEL 20.25 MG/1.25GM(1.62%), 40.5 MG/2.5GM(1.62%)
AndroGel GEL 25 MG/2.5GM(1%), 50 MG/5GM(1%)
AndroGel Pump GEL 20.25 MG/ACT(1.62%)
Aveed SOLN 750MG/3ML
CaroSpir SUSP 25MG/5ML
Climara PTWK 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.06MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Delestrogen OIL 10MG/ML, 20MG/ML, 40MG/ML
Depo-Estradiol OIL 5MG/ML
Depo-Provera SUSP 150MG/ML
Depo-Provera SUSY 150MG/ML

Depo-SubQ Provera 104 SUSY 104MG/0.65ML
Depo-Testosterone SOLN 100MG/ML, 200MG/ML
Divigel GEL 0.25MG/0.25GM, 0.5MG/0.5GM, 0.75MG/0.75GM, 1MG/GM, 1.25MG/1.25GM
Dotti PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Elestrin GEL 0.52 MG/0.87 GM(0.06%)
Eligard KIT 7.5MG, 22.5MG, 30MG, 45MG
Estrace TABS 0.5MG, 1MG, 2MG
Estradiol GEL 0.25MG/0.25GM, 0.5MG/0.5GM, 0.75MG/0.75GM, 0.75MG/1.25GM(0.06%), 1MG/GM, 1.25MG/1.25GM
Estradiol PLLT 6MG
Estradiol PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Estradiol PTWK 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.06MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Estradiol TABS 0.5MG, 1MG, 2MG
Estradiol Valerate OIL 10MG/ML, 20MG/ML, 40MG/ML
Estrogel GEL 0.75 MG/1.25 GM(0.06%)
Evamist SOLN 1.53MG/SPRAY
Fensolvi (6 Month) KIT 45MG
Finasteride TABS 1MG, 5MG
Fortesta GEL 10 MG/ACT(2%)
Jatenzo CAPS 158MG, 198MG, 237MG
Kyzatrex CAPS 100MG, 150MG, 200MG
Lyllana PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
medroxyPROGESTERone Acetate SUSP 150MG/ML
medroxyPROGESTERone Acetate SUSY 150MG/ML
Menostar PTWK 14MCG/24HR
Methitest TABS 10MG
methylTESTOSTERone CAPS 10MG

Minivelle PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Natesto GEL 5.5MG/ACT
Progesterone CAPS 100MG, 200MG
Prometrium CAPS 100MG, 200MG
Propecia TABS 1MG
Proscar TABS 5MG
Spironolactone SUSP 25MG/5ML
Spironolactone TABS 25MG, 50MG, 100MG
Testim GEL 50 MG/5GM(1%)
TestoneCIK KIT 200MG/ML
Testopel PLLT 75MG
Testosterone Cypionate SOLN 100MG/ML, 200MG/ML
Testosterone Enanthate SOLN 200MG/ML
Testosterone GEL 1.62%
Testosterone GEL 10 MG/ACT(2%)
Testosterone GEL 12.5 MG/ACT(1%)
Testosterone GEL 20.25 MG/1.25GM(1.62%), 40.5 MG/2.5GM(1.62%)
Testosterone GEL 20.25 MG/ACT(1.62%)
Testosterone GEL 25 MG/2.5GM(1%), 50 MG/5GM(1%)
Testosterone PLLT 25MG, 50MG, 100MG, 200MG
Tlando CAPS 112.5MG
Vivelle-Dot PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Vogelxo GEL 50 MG/5GM(1%)
Vogelxo Pump GEL 12.5 MG/ACT(1%)
Xyosted SOAJ 50MG/0.5ML, 75MG/0.5ML, 100MG/0.5ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coverage Policy Required Medical Information Appendix	Q4 2025
REVISION- Notable revisions: Products Affected Diagnosis Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions Drug Class FDA-Approved Uses Appendix Coding/Billing Information Available Dosage Forms References	Q3 2025
REVISION- Notable revisions: Age Restrictions Compendial Approved Off-Labeled Uses References	Q3 2024
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Duration of Approval Prescriber Requirements Quantity Appendix Coding/Billing Information Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Products Affected Required Medical Information Quantity Place of Administration Route of Administration Coding/Billing Information Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file