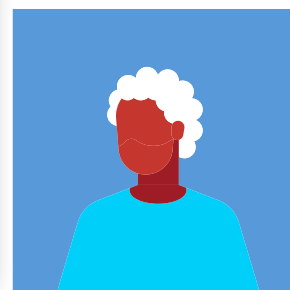
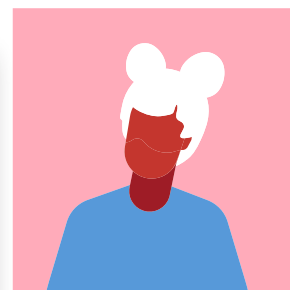
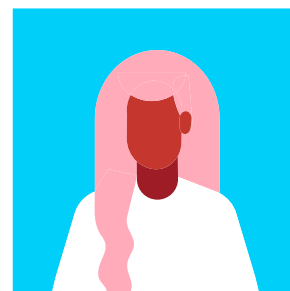




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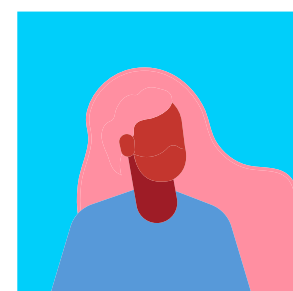
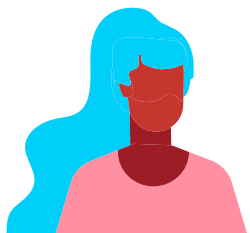
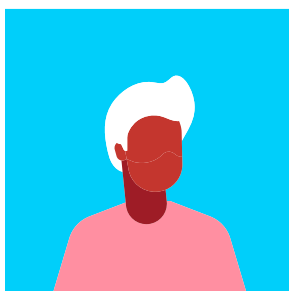
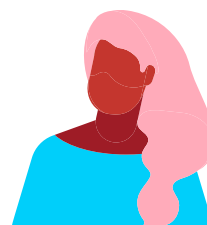
A Pharmacist’s Guide to Gender-Affirming Care in Adolescents

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Abstract

The number of transgender and gender diverse (TGD) youth in the United States, and subsequently the number of those seeking medical care, is increasing. This paper seeks to review the many facets of gender-affirming care with a primary focus on pharmacotherapy to better familiarize the healthcare professional and improve the delivery of quality care to this population that faces many unique health disparities. Through review of various professional guidelines, medical literature, and pharmacology databases, we outline the medications commonly used in gender-affirming care, including puberty blocking agents, hormonal therapy with estrogen and testosterone, and adjunctive agents such as progestins and androgen blockers. With respect to these medications, we aim to delineate indications, contraindications, potential medication interactions, common adverse effects, and necessary monitoring. We also briefly review nonpharmacologic methods utilized in gender-affirming care, as familiarity with all options is essential to collaboration with a multidisciplinary healthcare team.



In recent years, gender-affirming care (GAC) has been recognized as a critical component of healthcare. This paper discusses gender-affirming care with a specific focus on pharmacotherapy and its transformative potential. Before diving into the specifics of pharmacotherapy interventions, it is important to establish a foundational understanding of the key terminology used in this paper. These terms are defined in Table 1.¹ Gender dysphoria has replaced the term “gender identity disorder” because it is the stress of discordance, rather than the identity itself, that is a mental health issue. According to the American Psychiatric Association (APA), “being transgender or gender variant implies no impairment in judgment, stability, reliability, or gender social or vocational capabilities; however, these individuals often experience discrimination due to a lack of civil rights protections for their gender identify or expression.”²

Approximately 1.4% of the United States population aged 13-17 identify as transgender in large study estimates.³ However, a 2018 study found a difference in gender and sex identified at birth in 9.2% of high-school participants in an urban school district.⁴ The prevalence varied by identified racial category, with 7.1% of white youth describing gender diversity compared with 13.4% of American Indian youth, 9.9% of Black youth, and 14.4% of Hispanic youth. Across the United States, the geographic distribution of gender diverse youth is fairly even, with a slightly higher distribution along the coasts.³

Transgender and gender diverse (TGD) youth experience a number of socioeconomic and health disparities. TGD youth may hide their gender identity and expression to avoid bullying, harassment, or victimization.⁵⁻⁷ They experience higher rates of homelessness, physical violence (at home and in the community), substance abuse, high-risk sexual behaviors, and suicide.⁵⁻⁷ Additionally, TGD youth tend to have poorer health and lower rates of preventative health checkups.⁸ A Minnesota-based study found that 62.1% of TDG youth reported their general health as poor, fair, or good rather than very good or excellent, compared with 33.1% of cisgender youth ($X^2=763.7, P < 0.001$).⁹ These risk factors are thought to be the

TABLE 1. Definitions

Biological Sex	Refers to physical aspects of maleness and femaleness. As they may not be in line with each other (e.g., a person with XY chromosomes having female-appearing genitalia), the terms biological male or female are imprecise and should be avoided.
Cisgender	Not transgender; someone whose gender identity aligns with social expectations for their sex assigned at birth. An alternative way to describe individuals who are not transgender is “non-transgender people”.
Gender-Affirming Care	Refers to treatment modalities for those who want to adapt their bodies to their experienced gender by means of medications, procedures, or other methods.
Gender Dysphoria	The distress and unease experienced if gender identity and designated gender are not congruent. In 2013, APA released the fifth edition of the DSM-V, which replaced “gender identify disorder” with “gender dysphoria” and changed criteria for diagnosis.
Gender Expression	External manifestations of gender, expressed through one’s name, pronouns, clothing, haircut, behavior, voice, or body characteristics.
Gender Identity/ Experienced Gender	One’s internal, deeply held sense of gender. For transgender people, their gender identity does not align with social expectation for their sex designated at birth. Most people have a gender identity of man or woman. For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see above), gender identity is not visible to others.
Gender Role	Behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.
Non-Binary	Describes when a person does not identify exclusively as a man or woman but might feel like they are a mix of genders or have no gender at all
Sex Assigned at Birth	This is usually an assignment of male or female based on genital anatomy.
Sex	Attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, gonads, sex hormones, internal and external genitalia, and secondary sex characteristics.
Sexual Orientation	An individual’s enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same.
Transgender	An umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek gender-affirming care.
Transition	The process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity.

Adapted from the 2017 Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline¹

result of minority stress, which is when discrimination based on identity leads to socioeconomic disenfranchisement and stress that contributes to risk behaviors and health disparities.⁹

Gender-affirming care refers to medical, psychological, and social support provided to individuals to help align their gender identity with their affirmed gender.¹ This has been shown to improve mental health

measures in TGD youth.¹⁰ This may include a combination of support with social transitioning, mental health services, medical therapy, and gender-affirming surgeries. The goal is to enhance the well-being and quality of life for transgender and non-binary individuals by addressing their unique healthcare needs.

It is important for pharmacists to understand the role and responsibility

they have in GAC, as they may have TGD patients or come across gender-affirming medications in inpatient, outpatient, or community settings. It is crucial that they understand the medications, counseling pearls, and implications for care. Pharmacists must also know the importance of respecting their patients' chosen name, pronouns, and their preferred terminology. This responsibility extends to understanding that a person's identity may not match with legal documents. This may, in turn, have implications for filling prescriptions, billing insurance, keeping medical records, and more. Pharmacists must also stay vigilant about changes to legislation that impacts the care that TGD patients can receive. This paper aims to contribute to the ongoing discussion surrounding GAC, discussing pharmacotherapy as a transformative force in enhancing the lives of young individuals navigating the complexities of gender identity.

Puberty Blockers (GnRH-agonists)

Gonadotropin releasing hormone agonists (GnRHa), also known as puberty blockers, act on the hypothalamic-pituitary-gonadal (HPG) axis. Typically, the hypothalamus releases gonadotropin releasing hormone which then binds in the anterior pituitary gland.¹¹ The anterior pituitary gland releases the gonadotropins luteinizing hormone (LH) and follicle-stimulating hormone (FSH). Gonadotropins cause the gonads to secrete hormones; namely estrogen and progesterone in those assigned female at birth and testosterone in those assigned male at birth. GnRHAs reduce the effects of this process by triggering excess gonadotropins and weakening their receptors' response. This then prevents the release of sex hormones and development of secondary sex characteristics, including development of an Adam's apple, hair growth and thickening, facial and jawline definition, and voice deepening in those assigned a male sex at birth and breast development and the onset of menstruation in those assigned a female sex at birth.¹²

The onset of puberty and the associated physical changes can escalate gender dysphoria in adolescents.¹² Puberty suppression aims to relieve some anxiety

and gender dysphoria, offer adolescents more time to evaluate their gender identity, and prevent the development of permanent changes, such as voice pitch, body shape, or patterns of facial and body hair that would require more invasive interventions in the future.¹² Based on data from the use of GnRHa in central precocious puberty, pubertal suppression is reversible as the HPG axis will function normally and puberty will resume if the agent is discontinued without long-term adverse effects.^{11,13} Puberty suppression may be initiated at the onset of puberty and its physical features.¹² In individuals assigned male at birth, the first indication of puberty is testicular growth, usually between the ages of 9 and 14 years.¹¹ In patients assigned female at birth, this is seen typically between the ages of 8 and 13 years with breast development.

There are several options available for formulations and dosing of GnRHa.^{11,12} Histrelin is available as a subcutaneous implant, surgically implanted into the arm. While FDA approved for 12 months in central precocious puberty, this implant has shown equal suppression of luteinizing hormone at 24 months.¹³ Leuprolide is available as a subcutaneous or intramuscular injection, given daily, every month, 3 months, or 6 months. Cost of these medications can play a role in puberty suppression options.¹³ GnRHa can be very expensive for patients, and cost is often determined by insurance coverage. Pharmacists must work with families, providers, and insurers to provide the best options and access.

Some general adverse effects may include fatigue, hot flashes, flushing, or changes in mood.¹¹ While changes in mood or behavior may be reported, GnRHa and puberty suppression have been related to improved psychosocial functioning and mood in transgender youth. Decreased sex hormones can cause decreased bone mineral density (BMD) in some patients; however, BMD was found to normalize after discontinuation of GnRHa when used for limited periods of time. Additionally, BMD can be improved in patients with hormone replacement therapy and supplementation of calcium and vitamin D. Histrelin has been associated with some redness, swelling, or itching after implantation.¹⁴ Leuprolide has been associated with metabolic effects,

including weight fluctuations and elevated lipid levels, and cardiovascular effects, including electrocardiogram changes or increased blood pressure, though it is not clear whether these side effects are expected in transgender youth compared to other populations (such as patients with prostate cancer) that utilize this medication.¹⁵

Patients should be monitored at baseline and regularly after starting treatment with serum LH, FSH, and testosterone or estradiol, depending on the gonads present.^{11,14,15} BMD monitoring is controversial, and recommendations regarding this vary; the Endocrine Society has the most aggressive monitoring guidelines for DEXA scans every 1-2 years.¹¹ Though they are uncommon, providers should also be aware of potential drug-drug interactions. Metabolic effects of GnRHa may decrease the efficacy of antidiabetic agents.^{14,15} Caution should be used with the addition of other potential QTc-prolonging agents, such as macrolides, fluoroquinolones, and some antidepressants or antipsychotics.

Gender-Affirming Hormone Therapy

Feminizing Hormones

Hormone therapy may be considered for gender diverse youth on puberty blockers or those who seek treatment later in puberty. Per Endocrine Society Guidelines, it is recommended to overlap the puberty blocker and the addition of hormone therapy.¹ For patients assigned male at birth on puberty-blocking agents, antiandrogen medications (discussed in a later section) may be introduced when estrogen has been initiated and reaches sufficient serum concentrations. This additional medication aids in the suppression of testosterone for when GnRHa are stopped.

Estrogen is the hormone responsible for feminizing sex characteristics during puberty for those assigned a female sex at birth and during the gender affirmation of TGD youth who were assigned male sex at birth.¹⁷ It also suppresses testosterone production in people with testicles. There are several different formulations of estrogen, including an oral tablet, patch, injection, transdermal gel, and spray. However, the gel and spray are not recommended as they are less likely to reach appropriate serum concentrations.¹⁸

It is also important to note that conjugated equine estrogens and ethinyl estradiol have been used in the past but are no longer recommended in gender-affirming care due to 1) the inability to accurately measure blood estrogen levels; 2) increased risk of thrombogenicity and stroke by altering serum levels of fibrinogen, factor VII, and antithrombin III;^{19,20} and 3) ethical debates regarding how the estrogens are acquired.¹⁹

Estrogens have a variety of side effects, most commonly including migraines, mood swings, hot flashes, and weight gain.^{18,21} Estrogens also have an increased risk associated with venous thromboembolism and breast cancer.^{18,21} There are many medications that estrogens can interact with, most notably are drugs that affect CYP3A4.²¹ Estrogen is a CYP3A4 substrate, one that medications and substances such as macrolides, antifungals, verapamil, or grapefruit juice can inhibit, leading to higher risk of adverse effects. CYP3A4 inducers, such as rifampicin or phenytoin, increase the metabolism of estrogen, leading to lack of clinical effect.

Few studies have been conducted investigating fertility in patients undergoing feminizing therapy,²² relying on very small sample sizes and varying protocols which resulted in incomplete, and occasionally, conflicting results.²³ Prolonged estrogen exposure has resulted in atrophy and impaired or absent spermatogenesis, while normal spermatogenic activity and reversibility have been reported.²⁴⁻²⁷ The lack of consistency and evidence warrants an important discussion about fertility as part of the goals for patient care.

Masculinizing Hormones

In GAC, testosterone may be initiated for pediatric patients on puberty blockers, but can also be initiated after puberty and up to mid-late adulthood.¹⁷ Once initiated, testosterone therapy could be lifelong.^{17,28} However, lifelong therapy is not always needed for TGD youth if the primary goal is voice deepening, in which case it may be discontinued after this is achieved.²⁸

Testosterone, an endogenous androgen that promotes masculinizing sex characteristics, is the primary treatment utilized for patients seeking masculinizing GAC.²⁹ When given exogenously, it maintains and promotes secondary sex characteristics in both androgen deficiency

TABLE 2. Expected Effects of Feminizing Hormone Therapy

<i>Effect</i>	<i>Expected Onset</i>	<i>Expected Max Effect</i>	<i>Reversibility</i>
Decreased libido	1-3 months	1-2 years	Variable
Decreased spontaneous erection	1-3 months	3-6 months	Variable
Stopped scalp hair loss (no regrowth)	1-3 months	1-2 years	Yes
Body fat redistribution	3-6 months	2-5 years	Yes/Variable
Decreased muscle mass	3-6 months	1-2 years	Yes
Softened skin/ decreased oil	3-6 month	Unknown	Yes
Breast growth	3-6 months	2-3 years	No
Decreased testicular volume	3-6 months	2-3 years	Variable
Thinned/slowed growth of facial/ body hair	6-12 months	> 3 years	Yes
Male sexual dysfunction	Variable	Variable	Variable
Decreased sperm production	Variable	Variable	Variable

Adapted from World Professional Association for Transgender Health Standards of Care, Version 7¹⁶

TABLE 3. Expected Effects of Masculinizing Hormone Therapy

<i>Effect</i>	<i>Expected Onset</i>	<i>Expected Max Effect</i>	<i>Reversibility</i>
Acne/Increased Skin Oil	1-6 months	1-2 years	Yes
Cessation of Menses	2-6 months	N/A	Yes
Facial/Body Hair Growth	3-6 months	3-5 years	No
Body Fat Redistribution	3-6 months	2-5 years	Yes/Variable
Clitoral Enlargement	3-6 months	1-2 years	No
Vaginal Atrophy	3-6 months	1-2 years	Yes
Voice Deepening	3-12 months	1-2 years	No
Increased Muscle Mass (with exercise)	6-12 months	2-5 years	Yes
Scalp Hair Loss	> 12 months	Variable	No

Adapted from World Professional Association for Transgender Health Standards of Care, Version 7¹⁶

and masculinizing therapies.³⁰ Dosing is titrated to target serum concentration, similar to the normal physiologic range for cisgender males.³⁰ Several testosterone formulations exist, such as intramuscular or subcutaneous injections, topical gel, transdermal patches, and subcutaneous pellets.²⁹⁻³¹ Testosterone, a C-III medication, is the only controlled substance in GAC.^{1,29} Unlike other controlled substances, there are no dependence concerns associated with

testosterone, and withholding it would likely result in worse social or psychological effects on TGD youth.¹⁷

Side effects are consistent across the IM testosterone, with the most common being acne, which peaks at 6 months.²⁹ Other side effects include alopecia, reduced HDL cholesterol, increased triglycerides, and an increase in systolic blood pressure.²⁹ Of note, current safety data reflects short-term use of testosterone therapy in

masculinizing care, as long-term therapy has limited safety analyses.²⁹ One absolute contraindication to testosterone therapy is pregnancy, as it is teratogenic.¹⁷ Several relative contraindications exist, including severe hypertension, sleep apnea, and polycythemia.¹⁷ Of note, a Risk Evaluation and Mitigation Strategies (REMS) program exists for long-acting IM testosterone undecanoate due to the risk of pulmonary oil microembolus, as this is a rare but deadly adverse reaction.¹⁷ Patients may regain fertility after the discontinuation of testosterone therapy, provided they have not undergone any gender-affirming procedures that would affect fertility;²⁹ however, the long-term impact of testosterone on fertility is not completely understood.³²

Per the 2017 Endocrine Society Guidelines, routine monitoring is recommended 3-4 times in the first year and once or twice yearly thereafter.¹ At these monitoring appointments, it is recommended that hematocrit/hemoglobin be checked to prevent erythrocytosis.¹⁷ Periodic monitoring of weight, blood pressure, and cholesterol is also recommended to minimize cardiovascular risks.¹

Providers should be mindful of potential drug interactions with testosterone. Dehydroepiandrosterone is considered a category X interaction due to increased toxicity with testosterone use.³⁰ Testosterone can increase the risk of hepatotoxicity associated with cyclosporine.³⁰ Additionally, hypertensive effects can occur, especially in patients taking other medications known to increase blood pressure.³⁰ Concomitant use of testosterone with corticosteroids can increase fluid retention.³⁰

Additional Gender-Affirming

Medications

Anti-Androgen Medications

Antiandrogen therapy can be useful for patients seeking feminizing care who may have contraindications or do not desire estrogen or as an adjunct therapy. Androgen blockers are used to help lower testosterone levels and decrease the necessary estrogen doses, which helps reduce adverse effects associated with high doses.¹ The two most common forms of antiandrogen therapy are spironolactone and the 5-alpha reductase inhibitors dutasteride or finasteride. While 5-alpha reductase inhibitors can be considered for transgender male patients to treat hair loss side effects, their use in pediatrics is generally not recommended. Spironolactone is a potassium-sparing diuretic that suppresses testosterone synthesis, has anti-androgen receptor activity, and can contribute to a limited degree of breast development.^{17,18,33}

An alternative agent is bicalutamide, for which there are studies investigating its use in feminizing care of TGD youth as an alternative to GnRHa.^{34,35} Bicalutamide is a non-steroidal androgen receptor inhibitor typically used in prostate cancer to reduce androgenic effects in the body.³⁶ Limited studies show that 80%-90% of patients experience breast development within 6-7 months.³⁵ It is unclear whether the hepatotoxicity risk seen in older populations is a significant concern in pediatric patients, though one case of hepatitis in an adolescent on this medication has been reported.³⁷

Progesterone/Aromatase Inhibitors

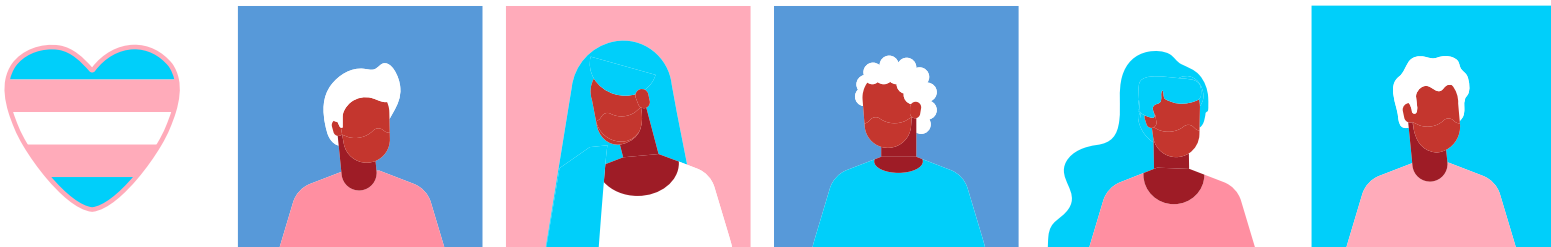
Progestin agents can be used in conjunction with or in the absence of testosterone for menstrual suppression in masculinizing therapy.^{17,38,39} Per 2017 Endocrine Society guidelines, the agents typically used are norethindrone (PO) and medroxyprogesterone (PO and IM), although any progestin only or oral contraceptive pill would also provide a similar effect.¹ Aromatase inhibitors are

alternatives to progestogens for the cessation of menstrual bleeding, in adjunct to testosterone therapy, but use is limited.³⁸ Progestin agents may also be used as components of feminizing therapy to lower testosterone levels and enhance breast development, but clinical evidence and use is limited.¹⁷

Nonpharmacologic Tools for Gender Affirmation

Though medical therapy is often a key component in GAC, there are several facets to consider in the treatment of the transgender/gender diverse individual. These nonpharmacologic interventions include social, legal, and surgical forms of affirmation.⁷

Social affirmation refers to methods taken to affirm one's gender identity through how they express themselves and are perceived in social environments. Under this umbrella includes one's chosen name and pronouns, disclosing their gender identity to their family, friends, and community, and how one presents themselves through their hairstyle, clothing, and speech.⁴⁰ Some may practice methods such as binding (the use of certain materials/garments to create a flat chest contour), packing (the use of objects or prostheses in one's underwear to create a more outward contour), and/or tucking (the practice of moving the testes in the inguinal canal and moving the penis posteriorly to create a smoother contour).⁴¹ Another option that some gender diverse individuals may pursue is voice and communication training to better align their voice, cadence, and communication mannerisms to their gender identity.³⁹ There is no consensus on how to best employ these interventions (e.g. gradually, all at once, etc.); however, support and guidance from the individual's family, primary care provider, and mental health provider are invaluable. By nature, social interventions are completely reversible and



may offer space for exploration for a young person's gender identity.

Legal affirmation, as the name implies, refers to legal actions taken to enhance aspects of social affirmation, including name and gender marker change. The necessary steps and documentation to enact these changes vary widely from state to state and may require documentation from medical and/or mental health providers. These changes are also considered reversible.

Surgical affirmation refers to procedural interventions to affirm one's gender. These are generally reserved until adulthood, but non-genital surgeries may be occasionally considered in some adolescents on a case-by-case basis. There are a wide variety of procedures that range in cost and invasiveness; however, they are all generally considered irreversible. Masculinizing procedures may include phalloplasty (creation of a penis using a flap of one's skin), metoidioplasty (creation of a penis using the clitoris), mastectomy (removal of breast tissue), hysterectomy (removal of the uterus), and oophorectomy (removal of the ovaries). Feminizing procedures may include vaginoplasty (creation of a vagina), breast implants or augmentation, facial feminization, tracheal shave (to reduce the size of the Adam's apple), and orchiectomy (removal of the testes).⁴² Colloquially, procedures involving the chest are often referred to as "top surgery" and those pertaining to the genital organs are often referred to as "bottom surgery." As several of these procedures involve the alteration or removal of reproductive organs, these are not performed before the age of 18, and discussions regarding goals surrounding fertility are critical.

Conclusion

As the number of transgender and gender nonconforming youth in the United States continues to increase, so does the need for comprehensive, quality care for this population.³ Through the overview of medical therapies provided in this paper, pharmacists and other healthcare professionals may better familiarize themselves with the varying modalities used to provide GAC, while recognizing that GAC is a multidimensional entity, with pharmacotherapy as only one aspect of their care. There are various medical options for gender diverse youth depending

on their stage in pubertal development and their readiness to enact change with respect to their gender identity. GnRHa may be offered to those who have begun displaying early signs of puberty, with the goal of suppressing further irreversible undesired pubertal changes. While GnRHa may be helpful in the pubertal years, hormones (estrogen and testosterone) and adjunctive agents (such as androgen blockers and progestins) are the mainstays of long-term gender-affirming pharmacotherapy. With enhanced knowledge of these medications, pharmacists and other healthcare professionals may better counsel and treat their gender diverse patients and may contribute to collaborative, informed, and nonjudgmental care necessary to dismantling the significant health disparities faced by the transgender community.

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PR This article has been peer-reviewed.
The contribution in reviewing is greatly appreciated!

Acknowledgements: We would like to thank Dr. Christi Albert, PharmD, BCPS for her mentorship and guidance throughout the review process.

Disclosure: The authors declare no real or potential conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria.

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