PEDIATRICS PERSPECTIVES

Insurance Coverage of Puberty Blocker Therapies for Transgender Youth

Jaime Stevens, MD[a], Veronica Gomez-Lobo, MD[b], Elyse Pine-Twaddell, MD[a,c]

Appropriate medical intervention along with an affirming environment has been shown to result in improved health outcomes for transgender and gender-nonconforming people.[1,2]

Youth whose natural pubertal development would be detrimental to their psychological and general well-being can be treated with "puberty blockers" to prevent irreversible phenotypic changes. In our experience, the most effective medications are the gonadotropin-releasing hormone (GnRH) agonist leuprolide injections (Lupron; AbbVie, Chicago, IL) or histrelin subcutaneous implant (Supprelin, Vantas; Endo Pharmaceuticals, Malvern, PA), and these have been recommended in both the Endocrine Society Guidelines and the World Professional Organization for Transgender Health Standards of Care.[3,4] The safety and efficacy of these regimens have been reported in several populations.[2,5]

GnRH agonist pharmacotherapy can cost thousands of dollars per month. As a result, articles both in the media and in medical literature discuss the difficulty of obtaining insurance coverage for GnRH analogs used for this indication. As Dr Norman Spack stated, "Many, if not most, young adolescent American transgender patients who are deemed appropriate candidates for the recommended medical intervention . . . are unable to obtain the treatment due to insurance denial"; he estimated that insurance had covered blockers for <20% of his clinical cohort since 2007.[6,7] Lupron-Depot (Ped) 3-month shots cost >$6000, whereas the adult version costs $4000; for the histrelin implant, the pediatric brand Supprelin costs >$20 000, whereas the adult brand Vantas costs $3500 (costs are approximate). Supprelin is currently approved by the US Food and Drug Administration (FDA) for puberty suppression, but many providers opt for Vantas, which is the same compound but developed and FDA approved as a treatment for prostate cancer. The higher cost of pharmaceuticals approved for use in youth may be related to the increased complexity and cost of clinical trials in children, the high risk of conducting these trials, the low expectation of return on this investment, and the designation of a new drug that extends patent exclusivity in exchange for trials in children.

Gender-nonconforming and transgender people face many barriers to care, such as lack of access to competent health care providers, lack of

[a]University of Maryland, Baltimore, Maryland; [b]MedStar Washington Hospital Center, Children's National Health System, Washington, District of Columbia; and [c]Chase Brexton Health Care, Baltimore, Maryland

Dr Stevens collected and analyzed data and drafted the initial manuscript; Drs Gomez-Lobo and Pine-Twaddell collected and analyzed data and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

www.pediatrics.org/cgi/doi/10.1542/peds.2015-2849

DOI: 10.1542/peds.2015-2849

Accepted for publication Sep 21, 2015

Address correspondence to Elyse Pine-Twaddell, 1111 N Charles St, Baltimore, MD 21201. E-mail: epine@chasebrexton.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

family or social support, or lack of access to medical care through insurance denial. Insurance denial may result from specific health care exclusions for transgender care, lack of FDA approval for such medications, limited coverage for those <18 years old, or insurance policy claims of lack of evidence supporting safety and efficacy in an adolescent population. The US Department of Health and Human Services has made it clear that transgender people are included in its gender nondiscrimination clause, and as of January 2015, 4 states and the District of Columbia have interpreted nondiscrimination to include the coverage of transition-related care, in both public and private plans. Other states require coverage by either private or public plans, and many have proposed to expand coverage in the last several months.

With increasing medical and media coverage and societal awareness of transgender youth, the patterns of insurance coverage may be shifting. We examined the insurance coverage patterns in 2 university-based practices, 1 a pediatric endocrinology service (PES) and 1 a pediatric and adolescent gynecology referral service (PAG). A total of 36 patients presented for puberty suppression between 2010 and 2015 (9 in the PAG and 27 in the PES). Patients ranged in age from 7 to 17 years, with an average age of 13 years, and presented with a median of Tanner stage 3. One patient had no insurance, 2 had Medicaid, and the remainder carried insurance from 1 of at least 6 different private companies.

In the PAG practice, 9 patients presented for GnRH agonists, and the first 3 received Vantas without insurance requests under the assumption it would not be covered (2010–2012). Subsequently, 2 received Vantas after insurance denial, and 3 received Supprelin after insurance approval. One patient had an insurance denial that was overturned after a state discrimination appeal was filed. In the PES practice, 27 patients presented for GnRH agonists. One patient also had a diagnosis of central precocious puberty. Of the remaining 26 patients, 17 had initial insurance approval for blockers, and 8 were approved on appeal. One patient did not have any insurance coverage and was unable to afford therapy. Although medical therapy was covered by insurance, the copays and deductible were prohibitively expensive for 3 patients who remained without treatment. One family opted to fill the prescription through a Canadian pharmacy rather than through their insurance to save money.

Between the 2 practices, 89% of patients who presented for puberty blockers obtained therapy, and insurance covered the cost in 72% of cases. In the past several years, patient advocates have also found that some insurance companies are changing or have recently changed their policies, which may expand access and reduce the need for appeals. All insurance requests for puberty blockers were eventually approved by insurance for patients presenting since 2015. The appeals process involved phone calls explaining the reasoning for off-label use, letters written with information about the standard of care and published information about safety and efficacy, and peer-to-peer requests with medical directors.

It is also notable that the high costs of these medications are prohibitive without insurance coverage, and the cost differential for adult versus pediatric versions of the same medications raises important questions about the value our society places on access to medical care for children.

Providers may be dissuaded from prescribing and advocating for coverage for these medications because of the perception that denial is routine and multiple publications describing the difficulty of obtaining coverage. However, in our experience GnRH analogs for use in preventing the irreversible changes associated with puberty in transgender and gender-nonconforming youth have in most cases been covered by insurance for patients in our 2 centers, with increasing frequency in recent years. As part of advocating for a very vulnerable patient population, it is important that providers are aware of all options for their patients and also aware that appealing and challenging insurance denials can succeed in procuring necessary medications for their patients.

ABBREVIATIONS

FDA: US Food and Drug Administration
GnRH: gonadotropin-releasing hormone
PAG: pediatric and adolescent gynecology referral service
PES: pediatric endocrinology service

REFERENCES

1. Radix A, Silva M. Beyond the guidelines: challenges, controversies, and unanswered questions. *Pediatr Ann*. 2014; 43(6):e145–e150
2. de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014; 134(4):696–704
3. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al; Endocrine Society. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94(9):3132–3154
4. Coleman E, Bockting W, Botzer M, et al. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *Int J Transgenderism*. 2011;13:165–232
5. Vance SR, Ehrensaft D, Rosenthal DM. Psychological and medical care of gender

nonconforming youth. *Pediatrics*. 2014; 134(6):1184–1192

6. Edwards-Leeper L, Spack NP. Psychological evaluation and medical treatment of transgender youth in an interdisciplinary "Gender Management Service" (GeMS) in a major pediatric center. *J Homosex*. 2012;59(3):321–336
7. Hartocollis A. The new girl in school: transgender surgery at 18. *New York Times*. June 16, 2015. Available at: www.nytimes.com/2015/06/17/nyregion/transgender-minors-gender-reassignment-surgery.html?_r=0. Accessed July 6, 2015

Insurance Coverage of Puberty Blocker Therapies for Transgender Youth

Jaime Stevens, Veronica Gomez-Lobo and Elyse Pine-Twaddell

Pediatrics 2015;136;1029
DOI: 10.1542/peds.2015-2849 originally published online November 2, 2015;

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Insurance Coverage of Puberty Blocker Therapies for Transgender Youth

Jaime Stevens, Veronica Gomez-Lobo and Elyse Pine-Twaddell

Pediatrics 2015;136;1029
DOI: 10.1542/peds.2015-2849 originally published online November 2, 2015;