Medicare Prescription Drug Plan Coverage of Hormone Therapies Used by Transgender Individuals

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Abstract

Purpose: Although pharmacologic hormone therapy represents one of the mainstays of gender-affirming therapy for transgender individuals, there are many access barriers for these therapies, including insurance coverage of these drugs. The purpose of this study was to examine Medicare coverage of hormone therapies used by transgender individuals.

Methods: Using Centers for Medicare and Medicaid Services prescription drug plan formulary files, we determined plan coverage, coverage restrictions, and out-of-pocket (OOP) costs for all 10 drugs recommended in the 2009 and 2017 Endocrine Society treatment guidelines for transgender patients.

Results: For masculinizing therapies, the proportion of plans providing unrestricted coverage ranged from 22% to 79% in 2010 and from 5% to 75% in 2018. For feminizing therapies, the proportion providing unrestricted coverage ranged from 24% to 100% in 2010 and from 13% to 100% in 2018. Median annual OOP costs for masculinizing therapies ranged from \$232 to \$1112 in 2010 and from \$180 to \$2176 in 2018. For feminizing therapies, OOP costs ranged from \$84 to \$2716 in 2010 and from \$72 to \$3792 in 2018.

Conclusion: Our findings highlight the variability in access to guideline-recommended hormone therapies for individuals insured through Medicare.

Keywords: Endocrine Society guideline, gender-affirming therapy, hormone therapy, Medicare prescription drug plans, transgender

Introduction

THE INSTITUTE OF MEDICINE (now called the National Academy of Medicine) identified the transgender adult population as an at-risk group because these individuals face both an increased disease burden and reduced access to health care services.¹ Many transgender individuals are uninsured, do not have a health care provider, or are unable to afford a health care appointment when they need it.² Transgender people also commonly experience discrimination in health care settings, and nearly one quarter of trans-

gender patients report needing to teach their clinician about transgender health care.³ Even after securing access to an appropriately trained clinician, gaining access to guideline-recommended therapies can be challenging for transgender individuals.

The mainstays of treatment for transgender individuals include access to mental health care, pharmacologic therapy to suppress endogenous hormones and/or hormone therapy (HT) to maintain sex hormones within the physiologic range for the patient's affirmed gender, and, for some individuals, gender-affirming surgery. HT is a mainstay of

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gender-affirming therapy because it can induce physical changes consistent with one's affirmed gender identity, because it is safe when managed by a trained clinician, because it is associated with an improvement in mental well-being, and because it is commonly required before undergoing gender-affirming surgery.⁴⁻⁷ Although gender-affirming surgery is clinically indicated for transgender individuals who desire it and meet certain eligibility requirements, HT is more commonly used in practice because many transgender people do not meet the above criteria or are unable to afford surgery.⁶ The Endocrine Society and the World Professional Association for Transgender Health (WPATH) have published evidence-based clinical guidelines on medical treatment and care for transgender individuals.^{6,7} To underscore the medical necessity of these treatments, the Endocrine Society recently issued a position statement emphasizing the need for payers to cover prescribed medical interventions for transgender patients.⁸

However, despite the existence of established clinical guidelines and the medical necessity of these treatments, one U.S. survey of transgender individuals found that 25% reported being denied insurance coverage for hormone therapies.³ There has been no systematic examination of formulary coverage for hormone therapies and it is unknown whether and to what degree health plans for Medicare beneficiaries are providing coverage for these therapies for older transgender adults, a particularly vulnerable subgroup who may face several unique challenges, such as increased identity concealment in health care settings and difficulty identifying clinicians who can manage HT in the setting of medical comorbidities.⁹⁻¹² Accordingly, we examined Medicare prescription drug plan (PDP) formulary coverage and restrictions for those hormone therapies recommended in the 2009 and 2017 Endocrine Society treatment guidelines,^{6,13} including out-of-pocket (OOP) costs associated with hormone therapies. We expect our findings to help provide a better understanding of the cost and access barriers faced by the transgender population.

Methods

Data sources

We used Centers for Medicare and Medicaid Services (CMS) PDP formulary files from the second quarters of 2010, 2014, and 2018. These files provide details about plan structure and coverage for all Medicare Advantage and stand-alone plans, but do not provide information about the Medicare beneficiaries enrolled in each plan. Medicare Advantage PDPs (MA-PDPs) provide drug coverage in addition to benefits for other medical services, whereas stand-alone PDPs solely provide prescription medication coverage. We limited our study to plans that submitted full details about cost-sharing, coverage phase, and tier structures for the drugs in our sample. We excluded special needs plans, which are Medicare advantage plans that restrict enrollment to institutionalized individuals, dual eligibility, and individuals with severe or disabling chronic conditions. We selected the years 2010 and 2018 to allow time for plans to incorporate clinical recommendations from the 2009 and 2017 Endocrine Society guidelines; we selected 2014 because it was the midpoint between 2010 and 2018.^{6,13} As this project used publicly

available data that did not involve human subjects, it was exempt from review by the Yale Human Research Protection Program.

Drug sample

We examined all drugs recommended in the 2009 and 2017 Endocrine Society treatment guidelines for transgender patients,^{6,13} which differed in recommended dosage but were otherwise the same, and included all available generic and brand-name formulations that were available during the entire duration of the study. HT for trans-masculine individuals typically consists of testosterone in patch, gel, or injection form. Trans-feminine individuals may take estrogen monotherapy (available as a pill, patch, injection, or gel) or a multidrug regimen consisting of estrogen and spironolactone. Leuprolide may also be included in multidrug regimens for trans-feminine people.⁶ For medications of the same form of delivery that had multiple generic and brand name formulations available (e.g., multiple versions of oral estradiol), we reviewed all formulations identified in the formulary files, but limited our study to the formulation that had the greatest number of plans offering the drug with unrestricted coverage, as defined below. We report results using the generic or brand name, depending on which formulation was included in our final drug sample.

Outcome measures: plan coverage and coverage restrictions

To examine access to HT, we first determined plan coverage and coverage restrictions for each drug in our sample. Every Medicare PDP has a formulary, which is a list that assigns tiers and coverage restrictions through utilization management strategies for covered medications. Coverage restrictions include prior authorization, step therapy, and quantity limits.¹⁴ Prior authorization requires prescribers to receive approval before prescribing a drug and is intended to ensure that patients meet certain clinical criteria to warrant a particular therapy.¹⁵ Step therapy requires the use of another drug before a particular drug can be approved for reimbursement. Drugs excluded from a formulary are typically not reimbursed by the payer, and beneficiaries are responsible for the full cost of these drugs.

Outcome measures: beneficiary OOP costs

We also determined required beneficiary OOP costs for each drug of interest, adjusted for inflation using June 2018 as the index month and year.¹⁶ Because the frequency of administration varies from daily (for patches and pills) to weekly, biweekly, or monthly (for injections), we used cost information for a 30-day supply of each drug in our sample. In addition, because dose ranges can be highly variable and oral medications of lower dosages can be combined to achieve a higher dose, we used the lowest dose of the dose ranges listed in the 2017 Endocrine Society guideline to calculate costs.⁶ We then chose the least expensive dose-quantity combination to reach the lowest dose of the listed dose range. This approach allowed us to provide the most conservative estimate of OOP costs required of transgender beneficiaries.

Medicare PDPs must set their deductible phase, initial coverage zone, coverage gap, and catastrophic coverage zone within parameters set annually by CMS, but they have flexibility within these limits.¹⁷ For example, some plans may require beneficiaries to enter a deductible phase where beneficiaries typically pay the full cost of the drug before moving into the initial coverage zone. Other plans have a \$0 deductible, thereby immediately sharing in the medication costs of their enrolled beneficiaries. We used each plan's specific coverage structure, rather than the standard Part D benefit, when calculating our main outcomes.

Statistical analyses

For each drug, descriptive statistics were used to determine the percentage of Medicare PDPs providing coverage without any prior authorization requirement, step therapy requirement, or quantity limit (unrestricted coverage); the percentage providing coverage with one or more restrictions (restricted coverage); and the percentage not providing coverage. For each drug, we then used descriptive statistics to calculate median annual OOP beneficiary copayment (using the 30-day supply cost) among all plans offering coverage. We examined annual costs because these medications are typically used on a long-term basis. Results were stratified by feminizing versus masculinizing therapies and by plan type (stand-alone PDP vs. MA-PDP) for each of the years (i.e., 2010, 2014, and 2018) because prior analyses have shown differences in OOP costs between the two plan types.¹⁸ We used the χ^2 test to compare the proportion of plans providing coverage and the Mann-Whitney *U* test to compare median OOP costs in 2010 and 2018, overall and stratified by plan type. We used the Bonferroni correction to adjust for multiple comparisons, using a *p* value of 0.025 as the threshold for statistical significance. All statistical analyses were performed using R Studio version 1.1.423 (RStudio, Inc., Boston, MA).

Results

There were 2978 Medicare PDPs in 2010, 2857 in 2014, and 3052 in 2018 (Table 1). The proportion of MA-PDPs relative to stand-alone PDPs grew over time, from 54.5% (*n*=1622) MA-PDPs versus 45.5% (*n*=1356) stand-alone PDPs in 2010 to 74.4% (*n*=2272) MA-PDPs versus 25.6% (*n*=780) stand-alone PDPs in 2018.

Drug sample

There were 10 drugs recommended in the 2009 and 2017 Endocrine Society treatment guidelines for transgender

TABLE 1. NUMBER OF MEDICARE ADVANTAGE PRESCRIPTION DRUG PLANS AND STAND-ALONE PRESCRIPTION DRUG PLANS IN 2010, 2014, AND 2018

	2010	2014	2018
Total number of PDPs in sample	2978	2857	3052
MA-PDPs, <i>n</i> (%)	1622 (54.5)	1758 (61.5)	2272 (74.4)
Stand-alone PDPs, <i>n</i> (%)	1356 (45.5)	1099 (38.5)	780 (25.6)

MA, Medicare advantage; PDP, prescription drug plan.

TABLE 2. HORMONE THERAPY DRUG SAMPLE AND DOSAGES ANALYZED

Drug name	Dose analyzed
Masculinizing therapies	
Gel (Testim)	50 mg gel packet daily
Transdermal patch (Androderm)	4 mg daily
Parenteral (testosterone-cypionate)	50 mg weekly
Parenteral (testosterone-enanthate)	50 mg weekly
Feminizing therapies	
Oral (estradiol)	2 mg daily
Transdermal patch (estradiol)	0.1 mg daily
Parenteral (estradiol-valerate)	20 mg every other week
Parenteral (Depo-Estradiol)	5 mg weekly
Oral (spironolactone)	100 mg daily
Parenteral (Lupron-Depot)	3.75 mg monthly

patients that met our study inclusion criteria: four masculinizing agents (all testosterone agents) and six feminizing agents (including four forms of estrogen derivatives, one antiandrogen agent, and one gonadotropin-releasing hormone [GnRH] agonist) (Table 2).^{6,13}

Plan coverage

The percentage of plans providing unrestricted, restricted, and no coverage for medications was significantly different between 2010 and 2018 (*p*<0.005). Overall, the proportion of plans providing no coverage or restricted coverage generally increased or stayed the same between 2010 and 2018, whereas the proportion providing unrestricted coverage decreased (Figs. 1 and 2). In addition, the percentage of plans providing unrestricted, restricted, and no coverage was significantly different between MA-PDPs and stand-alone PDPs in 2018 (*p*<0.005) but not in 2010 (*p*=0.28).

For masculinizing therapies, the proportion of plans providing unrestricted coverage ranged from 22% (Androderm) to 79% (testosterone-cypionate and -enanthate) in 2010 and from 5% (Testim) to 75% (testosterone-cypionate) in 2018 (Fig. 1). Notably, for Testim, the proportion of plans providing unrestricted coverage was 29% in 2010, 13% in 2014, and 5% in 2018; and for Androderm, the proportion providing unrestricted coverage was 22% in 2010, 22% in 2014, and 8% in 2018. The proportion of plans providing restricted coverage varied from 19% (testosterone-cypionate) to 66% (Androderm) in 2010 and from 17% (Testim) to 54% (Androderm) in 2018. Finally, the proportion of plans offering no coverage ranged from 1% (testosterone-enanthate) to 28% (Testim) in 2010 and from 0% (testosterone-cypionate) to 78% (Testim) in 2018. In 2010 and 2018, for two of four therapies, plans more often provided restricted as opposed to unrestricted coverage. These results stratified by MA-PDPs and stand-alone PDPs are provided in Table 3.

For feminizing therapies, the proportion of plans providing unrestricted coverage ranged from 24% (Lupron-Depot) to 100% (oral estradiol and spironolactone) in 2010 and from 13% (transdermal estradiol) to 100% (spironolactone) in 2018 (Fig. 2). Notably, for transdermal estradiol, the proportion of plans providing unrestricted coverage was

FIG. 1. Medicare PDP coverage and restrictions for masculinizing hormone therapies in 2010, 2014, and 2018. PDP, prescription drug plan.

49% in 2010, 19% in 2014, and 13% in 2018. Across all plans, the proportion of plans providing restricted coverage for feminizing therapies varied from 0% (oral estradiol, estradiol-valerate, and spironolactone) to 71% (Lupron-Depot) in 2010 and from 0% (estradiol-valerate and spironolactone) to 80% (Lupron-Depot) in 2018. The proportion of plans providing no coverage ranged from 0% (oral estradiol

and spironolactone) to 39% (Depo-Estradiol) in 2010 and from 0% (oral estradiol, spironolactone, and Lupron-Depot) to 40% (Depo-Estradiol) in 2018. Among plans covering the medications, one of six feminizing therapies had more plans providing restricted as opposed to unrestricted coverage in 2010, whereas this was true for three of six medications in 2018. Results by plan type are given in Table 3.

FIG. 2. Medicare PDP coverage and restrictions for feminizing hormone therapies in 2010, 2014, and 2018.

TABLE 3. MEDICARE PRESCRIPTION DRUG PLAN COVERAGE AND RESTRICTIONS FOR HORMONE THERAPIES IN 2010, 2014, AND 2018

Drug name	2010					2014					2018						
	Plan coverage (%)	Plan coverage without any restrictions (%)	Formulary restrictions in place (%)			Plan coverage without any restrictions (%)	Formulary restrictions in place (%)			Plan coverage without any restrictions (%)	Formulary restrictions in place (%)						
			PA (%)	ST (%)	QL (%)		PA (%)	ST (%)	QL (%)		PA (%)	ST (%)	QL (%)				
Testosterone																	
Gel (Testim)	72	29	21	7	18	48	13	32	0	20	22	5	17	0	15		
MA-PDP	78	38	22	7	18	45	14	27	0	19	28	7	20	0	17		
Stand-alone PDP	64	18	21	8	18	50	10	40	0	22	7	0	7	0	7		
Transdermal (Androderm)	88	22	33	0	47	58	22	28	0	26	62	8	39	0	48		
MA-PDP	94	23	35	0	49	54	22	23	1	24	63	10	39	0	46		
Stand-alone PDP	81	21	32	0	44	64	22	35	0	29	60	4	38	0	52		
Parenteral (testosterone-cypionate)	98	79	19	0	0	98	81	17	0	0	100	75	25	0	0		
MA-PDP																	
Stand-alone PDP	96	76	20	0	0	97	79	18	0	0	99	73	26	0	0		
Parenteral (testosterone-enanthate)	100	82	18	0	0	100	85	15	0	0	100	79	21	0	0		
MA-PDP	99	79	20	0	0	99	81	18	0	5	99	71	24	0	6		
Stand-alone PDP	99	77	22	0	0	98	79	19	0	5	99	71	26	0	5		
	100	82	18	0	0	99	84	15	0	6	99	71	20	0	9		
Estrogen																	
Oral (estradiol)	100	100	0	0	0	98	35	64	0	0	100	33	67	0	0		
MA-PDP	100	100	0	0	0	97	30	67	0	0	100	30	70	0	0		
Stand-alone PDP	100	100	0	0	0	100	44	55	0	0	100	42	58	0	0		
Transdermal (estradiol)	98	49	0	0	49	87	19	53	0	44	80	13	48	0	47		
MA-PDP	97	43	0	0	54	84	15	53	0	46	75	14	45	0	39		
Stand-alone PDP	100	56	0	0	43	93	25	47	0	40	98	11	56	0	70		
Parenteral (estradiol-valerate)	72	72	0	0	0	72	55	17	0	0	89	89	0	0	0		
MA-PDP	83	82	1	0	0	81	56	25	0	0	90	90	0	0	0		
Stand-alone PDP	61	61	0	0	0	57	54	3	0	0	89	89	0	0	0		
Parenteral (Depo-Estradiol)	61	60	1	0	0	56	38	20	0	0	60	42	1	0	17		
MA-PDP	68	67	2	0	0	64	40	24	0	0	67	47	2	0	18		
Stand-alone PDP	53	52	0	0	0	44	34	10	0	0	40	27	0	0	13		
Anti-androgen																	
Oral (spironolactone)	100	100	0	0	0	100	100	0	0	0	100	100	0	0	0		
MA-PDP	100	100	0	0	0	100	100	0	0	0	100	100	0	0	0		
Stand-alone PDP	100	100	0	0	0	100	100	0	0	0	100	100	0	0	0		
GnRH agonist																	
Parenteral (Lupron-Depot)	95	24	71	0	10	95	16	72	0	37	100	20	80	0	30		
MA-PDP	95	30	65	0	8	96	23	68	0	37	100	25	74	0	29		
Stand-alone PDP	95	16	79	0	12	94	4	78	0	38	100	4	96	0	33		

All figures are reported as a percentage of total plans available to consumers and meeting inclusion criteria during the relevant year. GnRH, gonadotropin-releasing hormone; PA, prior authorization; QL, quantity limit; ST, step therapy.

OOP costs

For masculinizing therapies, median annual OOP beneficiary costs ranged from \$232 (interquartile range [IQR], \$84–\$437, testosterone-cypionate) to \$1112 (IQR, \$788–\$1205, Testim) in 2010 and from \$180 (IQR, \$114–\$253, testosterone-cypionate) to \$2176 (IQR, \$2103–\$2439, Testim) in 2018 (Fig. 3). In 2010, three of four masculinizing therapies had lower OOP costs when covered by MA-PDPs than by stand-alone PDPs; in 2018, it was two of four (Table 4).

For feminizing therapies, median annual OOP beneficiary costs ranged from \$84 (IQR, \$70–\$97, oral estradiol) to \$2716 (IQR, \$2627–\$3338, Lupron-Depot) in 2010 and from \$72 (IQR, \$12–\$144, spironolactone) to \$3792 (IQR, \$3715–\$3918, Lupron-Depot) in 2018 (Fig. 3). By plan type, in 2010, five of six feminizing therapies had lower OOP costs when covered by MA-PDPs than by stand-alone PDPs; in 2018, it was one of six (Table 4). Between 2010 and 2018, costs were significantly different for stand-alone PDPs ($p < 0.005$), but not for MA-PDPs ($p = 0.027$) (Table 4).

Discussion

In this study of all drugs recommended by the 2009 and 2017 Endocrine Society guidelines for treatment of transgender people,^{6,13} we found substantial variability in Medicare PDP coverage and beneficiary OOP costs associated with medically necessary HT used by transgender individuals. Although several feminizing and masculinizing therapies were generally covered and associated with annual OOP costs under \$500, restricted or no coverage of the therapies

was common. Medicare Advantage plans more commonly offered unrestricted coverage than their stand-alone counterparts for both feminizing and masculinizing therapies. However, while most (8 of 10) therapies were associated with lower OOP costs through MA-PDPs than stand-alone PDPs in 2010, MA-PDPs had higher OOP costs than their stand-alone counterparts (for 7 of 10 therapies) in 2018.

Our formulary coverage analysis showed high rates of formulary restrictions, which are consistent with studies showing high and increasing rates of prior authorization and step therapy required in other drug classes, such as those used to treat rheumatoid arthritis, hepatitis C, hyperlipidemia, and multiple sclerosis.^{19–22} Although formulary restrictions are typically implemented to manage spending and drug utilization,¹⁴ they can negatively impact medication fills and adherence.^{23,24} Our results may provide context to the findings from a U.S. survey of transgender individuals, in which 25% of respondents reported being denied insurance coverage for hormone therapies.³ These access barriers may result in higher OOP costs and lack of adherence to HT. Although we found that a minority of HT medications are commonly provided with unrestricted coverage, this finding may reflect that these medications are most commonly used for other indications and are available in low-cost generic form.

Our OOP cost analysis showed that annual costs for HT can vary widely and are highly dependent on the medication regimen. Given the high rates of poverty and low household income in the transgender population,^{3,25} these costs may be prohibitive for many people. Even for individuals who can afford HT OOP costs, these expenses should be considered

FIG. 3. Median annual required Medicare beneficiary out-of-pocket costs for hormone therapies in 2010, 2014, and 2018.

TABLE 4. MEDIAN ANNUAL OUT-OF-POCKET COSTS OF HORMONE THERAPIES IN MEDICARE PRESCRIPTION DRUG PLANS OFFERING COVERAGE IN 2010, 2014, AND 2018

<i>Drug name</i>	2010 beneficiary OOP cost (\$)			2014 beneficiary OOP cost (\$)			2018 beneficiary OOP cost (\$)		
	<i>All plans (IQR)</i>	<i>MA-PDP only</i>	<i>Stand-alone PDP only</i>	<i>All plans (IQR)</i>	<i>MA-PDP only</i>	<i>Stand-alone PDP only</i>	<i>All plans (IQR)</i>	<i>MA-PDP only</i>	<i>Stand-alone PDP only</i>
Testosterone									
Gel (Testim)	\$1112 (788, 1205)	\$1137 (785, 1199)	\$1033 (796, 1246)	\$1313 (1127, 1598)	\$1309 (1148, 1586)	\$1329 (1102, 1633)	\$2176 (2103, 2439)	\$2133 (2102, 2283)	\$3214 (3053, 3278)
Transdermal (Androderm)	\$799 (652, 1167)	\$722 (633, 1153)	\$930 (687, 1235)	\$1156 (1086, 1508)	\$1130 (1109, 1468)	\$1442 (1081, 1532)	\$1963 (1707, 2306)	\$1953 (1592, 2111)	\$2548 (2092, 2924)
Parenteral (testosterone-cypionate)	\$232 (84, 437)	\$139 (70, 445)	\$264 (167, 436)	\$356 (127, 572)	\$254 (127, 572)	\$405 (254, 526)	\$180 (114, 253)	\$180 (120, 327)	\$157 (72, 215)
Parenteral (testosterone-enanthate)	\$255 (84, 498)	\$167 (70, 510)	\$348 (167, 496)	\$337 (127, 572)	\$216 (102, 572)	\$386 (216, 526)	\$507 (253, 723)	\$564 (180, 1055)	\$480 (399, 524)
Estrogen									
Oral (estradiol)	\$84 (70, 97)	\$84 (70, 100)	\$85 (70, 97)	\$89 (64, 127)	\$114 (70, 153)	\$76 (64, 96)	\$103 (72, 240)	\$131 (74, 372)	\$72 (36, 108)
Transdermal (estradiol)	\$97 (70, 220)	\$84 (70, 111)	\$200 (97, 368)	\$178 (89, 346)	\$127 (102, 229)	\$337 (64, 394)	\$493 (236, 591)	\$504 (195, 650)	\$423 (282, 518)
Parenteral (estradiol-valerate)	\$111 (84, 379)	\$97 (70, 180)	\$251 (97, 443)	\$466 (127, 1018)	\$456 (127, 1208)	\$477 (350, 700)	\$694 (372, 1200)	\$1140 (240, 1240)	\$612 (429, 698)
Parenteral (Depo-Estradiol)	\$394 (139, 974)	\$404 (111, 1030)	\$380 (259, 684)	\$463 (191, 1081)	\$509 (191, 1145)	\$440 (298, 1034)	\$708 (442, 1200)	\$826 (293, 1200)	\$685 (559, 708)
Anti-androgen									
Oral (spironolactone)	\$97 (70, 209)	\$84 (70, 111)	\$190 (97, 353)	\$89 (38, 191)	\$89 (38, 127)	\$89 (13, 251)	\$72 (12, 144)	\$84 (24, 144)	\$72 (12, 135)
GnRH agonist									
Parenteral (Lupron-Depot)	\$2716 (2627, 3338)	\$2656 (2583, 2746)	\$3107 (2719, 3600)	\$4006 (3802, 4198)	\$3968 (3644, 4133)	\$4054 (3980, 4233)	\$3792 (3715, 3918)	\$3782 (3706, 3900)	\$3826 (3729, 3955)

All figures in 2010 and 2014 are adjusted for inflation, using June 2018 as the index month and year. IQR, interquartile range; OOP, out-of-pocket.

in the context of an individual's overall medication regimen. Transgender Medicare beneficiaries more commonly have multiple chronic medical conditions than cisgender beneficiaries,¹⁰ and they have more emergency department visits and hospitalizations.²⁶ These cost and access burdens may explain why nearly 1 in 10 transgender people has acquired HT through nonlicensed sources such as friends or online.³ Our finding that OOP costs remain substantial adds to other access barriers that have been described for this population, including: delayed referrals, long waits before initial visits, shortage of clinicians able and willing to provide gender-affirming care, high rates of discrimination from clinicians, difficulty gaining and understanding insurance coverage, problems with diagnostic coding (e.g., denied reimbursements based on gender markers), and financial barriers to care.^{27–30}

Limitations

Our study has several limitations. First, although our analysis examined for the presence of utilization management restrictions such as prior authorization, our data do not provide information about the specific details of these restrictions and therefore cannot reveal differences in access to HT for gender minority versus non gender minority beneficiaries. Second, because we did not know the number of beneficiaries enrolled in each plan, we could not weigh our results by the number of beneficiaries. Third, because there are no publicly available data about the most commonly used HT regimens and dosages in older transgender adults, our calculations may not be representative of the most commonly used medications and dosages. We selected the lower limits of the ranges provided in the 2017 Endocrine Society guideline to provide the most conservative estimate of coverage and OOP costs.⁶ Finally, because our data were not drawn from insurance claims or patient records, we do not know the actual OOP costs paid by beneficiaries nor do our data reflect costs paid by dual-eligible beneficiaries or low-income subsidy enrollees.

Conclusion

We found substantial variability in Medicare formulary coverage and OOP costs for HT. This is the first published analysis describing formulary coverage and OOP costs for HT used by transgender individuals, and it highlights the substantial access and cost barriers faced by this marginalized population. Further research is needed to understand overall medication costs faced by transgender individuals and the impact of this cost burden on their health and quality of life.

Disclaimer

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