

Addressing Health-Care System Inequities in the Management of Erectile Dysfunction: A Call to Action

American Journal of Men's Health
September-October 1–10
© The Author(s) 2020
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/1557988320965078
journals.sagepub.com/home/jmh


Arthur L. Burnett, MD¹, Natalie C. Edwards, MSc² , Tonya M. Barrett, RHIT³,
Krista D. Nitschelm, COC, PAHM³, and Samir K. Bhattacharyya, PhD⁴

Abstract

Erectile dysfunction (ED) is a common, burdensome, and costly urologic condition strongly related to all aspects of general health, from physical to mental. ED has profound consequences as it may interfere physical well-being, quality of life (QoL), self-esteem, relationships, self-worth, and productivity. It is therefore important to ensure that all types of effective ED treatments are consistently accessible to patients. While federal and state mandates ensure access to treatment for women's breast health, female-factor infertility, and gender affirmation to ensure that these individuals do not experience a diminished QoL, there are no comparable mandates for men's sexual and reproductive health. The burden of ED necessitates a call to action to improve the accessibility of ED treatments. The call to action steps include: (a) coverage for pharmacological, surgical, and other ED treatments should be viewed in the same way as coverage for other health issues, whether male or female and regardless of the stages of treatment, physical dysfunction, or physical changes; (b) American Urological Association (AUA) guidelines for the management of ED should be followed, including implementation of templates in electronic medical records (EMRs) to support adherence to the guidelines; and (c) coverage criteria should explicitly state that the criteria are intended to support gender equity for sexual and reproductive health care and should not be used to prevent men from receiving medically necessary ED treatments. This call to action offers a pathway to support every man who seeks treatment for ED as a medically necessary intervention by removing systemic health-care barriers.

Keywords

erectile dysfunction, sexuality, medically necessary, policy, gender equity, access to care, health-care issues

Received May 29, 2020; revised September 10, 2020; accepted September 16, 2020

Burden of Erectile Dysfunction

Erectile dysfunction (ED) is a common, burdensome, and costly urologic condition with increasing prevalence as men age. It is estimated that more than half of men between ages 40 and 70 experience partial or complete ED, and approximately 10% have severe or complete ED (Feldman et al., 1994; Goldstein, Goren, Li, Tang, et al., 2019). Recent research has identified that there is a high prevalence of ED in young men (8% in men 20–30 years of age; Kessler et al., 2019).

Organic ED results from physical impairment caused by vascular, endocrine, or neurological damage from illnesses such as cardiovascular disease, diabetes, vascular insufficiency, prostate cancer, Peyronie's disease, and traumatic events such as pelvic or spinal cord trauma (Mushtaq et al., 2018; Nguyen et al., 2017; Potharaju

et al., 2015; Raza et al., 2019). Most men with ED have at least one major cardiovascular or endocrine disease

¹Department of Urology, James Buchanan Brady Urological Institute, Johns Hopkins University School of Medicine, Baltimore, MD, USA

²Health Economics and Outcomes Research, Health Services Consulting Corporation, Boxborough, MA, USA

³Global Health Economics & Market Access, Women's Health & Prosthetic Urology-Men's Health, Boston Scientific Corporation, Urology Pelvic Health Division, Marlborough, MA, USA

⁴Health Economics and Market Access, Boston Scientific Corporation, Marlborough, MA, USA

Corresponding Author:

Arthur L. Burnett, MD, Department of Urology, James Buchanan Brady Urological Institute, Johns Hopkins University School of Medicine, 600 North Wolfe Street, Marburg 407, Baltimore, MD 21287, USA.

Email: aburnet1@jhmi.edu



risk factor such as hypertension, hypercholesterolemia, or diabetes (Hackett, 2009). Many men with ED are prostate cancer survivors where more than 70% of men undergoing radical prostatectomy report some degree of ED 1 year following surgery (Haglund et al., 2015).

Due to the association of ED with comorbid conditions, screening and treatment of ED may aid as a predictor and allow for earlier detection and treatment of undiagnosed comorbid diseases (Burnett et al., 2018). For example, in a study involving 147 patients with coexisting ED and coronary artery disease (CAD), 67% of patients reported that symptoms of ED were clinically evident before symptoms of CAD (Montorsi et al., 2003). The mean time interval between the onset of ED and CAD was 38.8 months (range 1–168; Montorsi et al., 2003). Another study reported a prevalence of undiagnosed diabetes of 11.5% in men with ED compared with only 2.8% in men without ED (Skeldon et al., 2015).

Sexual dysfunction and ED are also related to infertility and the relationship can be reciprocal (Berger et al., 2016). ED, evaluated with validated tools, has a prevalence of approximately one in six in infertile men (Lotti & Maggi, 2018) and can be the cause of infertility in some instances (Berger et al., 2016; Lotti & Maggi, 2018). ED can lead to impaired fertility through natural conception when a severe problem is present, such as absent erection or insufficient erection for penetration (Lotti & Maggi, 2018). One study of men without comorbidities with primary or secondary infertility reported an association between ED and depressive symptoms independent of age, body mass index (BMI), and duration of marriage (Sahin et al., 2017). In addition, among infertile men, ED is an independent risk factor for a reduced frequency of sexual intercourse with an obvious negative effect on fertility (Perlis et al., 2013). A significant association between ED and semen quality impairment was observed in a study after adjusting for age, comorbidities, and psychological and prostatitis-like symptoms (Lotti et al., 2016).

ED poses a considerable burden with profound psychological consequences as it may interfere with a man's overall quality of life (QoL), including but not limited to well-being, self-esteem, relationships, and self-worth—not only personally but also in the workplace (Goldstein, Goren, Li, Maculaitis, et al., 2019). Sexuality is an integral part of an individual's well-being and QoL. Not surprisingly, men often report their QoL as being greatly impacted as a result of their ED. The Impotence Association (now the Sexual Dysfunction Association) reported that 62% of participants in their online survey felt that ED reduced their self-esteem; 29% said their relationships had been affected; and 21% reported that their relationship had ended as a direct consequence (The Impotence Association [now the Sexual Dysfunction

Association], 1997). Men with ED have significantly lower Short-Form 36 (SF-36) Mental Component Summary scores (MCS; 46.7 vs. 51.2), Physical Component Summary scores (PCS; 48.3 vs. 53.0), and health state utilities (Short-Form 6 [SF-6D]: 0.693 vs. 0.778; all $p < .001$) compared to men without ED (Goldstein, Goren, Li, Maculaitis, et al., 2019). Workplace productivity impairment and absenteeism is prevalent in men with ED. Men with ED have significantly higher rates of absenteeism, presenteeism, overall work productivity impairment, and activity impairment compared to men without ED (Goldstein, Goren, Li, Maculaitis, et al., 2019). It is therefore important to ensure that all types of effective ED treatments are consistently accessible to patients with documented medical necessity.

Treatment Options for ED

Specialty society consensus guidelines and position statements created by the American Urological Association (AUA) and the Sexual Medicine Society of North America (SMSNA) outline treatment options for ED, which include oral medications, vacuum erection devices (VEDs), intraurethral suppositories, intracavernosal injections (ICIs), and a penile prostheses (PPs), as described in Table 1 (American Urological Association, 2018; Burnett et al., 2018; Sexual Medicine Society of North America [SMSNA], 2019). The opinion of the SMSNA is that ED is recognized as the most commonly treated problem within the realm of sexual dysfunction disorders (Sexual Medicine Society of North America [SMSNA], 2019). Appropriate treatment of ED may be informed by the cause of a man's ED. Customary practice is to treat ED in a stepwise fashion, starting with pharmacological therapy options and then proceeding to surgical treatment. Several treatment guidelines worldwide, including the current 2019 AUA guideline for the management of ED, outline techniques for assessing the extent and severity of the ED problem, and options for how to best proceed with treatment options for ED that will optimize success and satisfaction for the patient and partner. The AUA guideline states that shared decision-making is the cornerstone of the treatment and management of ED (American Urological Association, 2018; Burnett et al., 2018). The patient and the clinician together determine the best course of therapy based on a discussion of the risks, benefits, and desired outcome. The patient should be informed of all treatment options that are not contraindicated to determine the most appropriate treatment (American Urological Association, 2018; Burnett et al., 2018).

ED patients' needs and expectations vary widely and the treatment approach should always be individualized

Table 1. ED Treatment Options.

Treatment	Description
Oral medications	Orally administered phosphodiesterase type 5 inhibitors (PDE5i) are taken to increase the flow of blood to the penis to induce an erection.
Vacuum erection device	A vacuum device draws blood into the penis, a constriction band around the base of the penis keeps the blood inside the penis to produce an erection.
Intraurethral suppositories	Delivery of medication as a small pellet using an applicator (suppository) into the meatus of the urethra to induce an erection.
Intracavernosal injections	Delivery of medication by injection directly into the penis to produce an erection.
Penile prosthesis	Surgically implanted device within the penis. Two types of penile prosthetics are currently available; an inflatable or malleable (non-inflatable)

Sources: American Urological Association (2018); Burnett et al. (2018); Sexual Medicine Society of North America (SMSNA) (2019).

according to their preferences (Burnett et al., 2018). While the principles underlying the treatment of ED are the same for all men—restoring sexual function, improving overall physical health, and optimizing QoL and well-being for a man and his partner—every man who presents with ED is unique. Each man brings to the clinical encounter not only his symptoms, but his degree of distress, his associated health conditions, his partner’s concerns and issues of relationship quality, and his sociocultural, educational, and spiritual context (Burnett et al., 2018).

ED Treatment and Health Plan Coverage

Rising health-care costs pose significant concerns to health-care systems’ viability. Health-care payers currently employ several mechanisms to counter rising costs, such as excluding some treatments from coverage, imposing significant limitations, or requiring higher copayments through tiered pharmaceutical coverage structures (Fendrick, 2000; Klein & Sturm, 2002). Failure to clearly differentiate the value and clinical and economic benefits of new treatments or technologies may result in a denial of coverage. The economic evaluation of phosphodiesterase-5 inhibitors, particularly sildenafil, has been well described (Rezaee et al., 2019). However, to date, there is inadequate research to assess the cost-effectiveness of ICIs, intraurethral suppositories, PP surgery, VED, and other emerging therapies in men with ED (Rezaee et al., 2019). Therefore, the net economic impact of adoption of these treatments is unclear.

Treatment for ED is widely considered “medically necessary” by health-care insurers. Nearly all commercial insurers (e.g., Blue Cross Blue Shield, Aetna, Anthem, Cigna, HCSC) and Medicare have published coverage policies detailing when ED treatment (whether medical, pharmacological, or other) is medically necessary. Health insurance plan coverage is provided in most cases for ED of organic etiology and covers a spectrum of ED treatments included in Table 1.

Supplemental Table S1 summarizes some of the current ED treatment coverage policies of several commercial health insurance plans and Medicare, including their characteristics, coverage, definition of medical necessity, codes, and so on.

Approximately two-thirds of Americans (67.5%) have commercial or private health insurance coverage, of which 55.7% are insured under an employer-based health plan, accounting for 320,775,014 lives (US Census Bureau, 2017). A sampling of commercial or private health insurance coverage policies state that ED treatments are “medically necessary.” Medically necessary treatments may include pharmacological treatments, external PPs, surgically implanted PPs, or other appropriate treatments. The health plan coverage policies include many of the same treatment options as the AUA treatment guidelines for the treatment of ED, ranging from oral medications, external devices, surgically implanted devices, and so on.

The disparity in reimbursement coverage for ED treatment, despite health insurance plan coverage and published coverage policies and professional society guidelines, is that many employer-sponsored health plans actually do not include coverage benefits for ED treatment. Employers often have specific medical benefit exclusion language written within the employer’s summary of plan benefits for ED treatment options, and evidence shows that this situation has existed for a number of years. A number of government mandates address specific health plan coverage exclusions. For example, the U.S. Government Accountability Office (GAO) published a report in 2011 to demonstrate compliance of the Mental Health Parity and Addiction Equality Act of 2008 (MHPAEA; U.S. Government Accountability Office [GAO], 2011). While the focus of the report was to ensure employer-sponsored health plans were in compliance with the mandate, the report also provides direct insight to the fact that employers excluded access to medically necessary ED treatment options. In employer-sponsored health benefit plans from 2010 or 2011, 23%

of employers reported a medical benefit exclusion for sexual dysfunction treatment. One example of the sexual dysfunction treatment exclusion within the report stated, “any service, supplies, medications, or drugs for the treatment of male or female sexual dysfunction such as, but not limited to, treatment of erectile dysfunction (including penile implants), anorgasmia, and premature ejaculation” (U.S. Government Accountability Office [GAO], 2011).

Studies published in 2018–2019 have confirmed that this practice has continued. Several studies and reports exist on the topic of employer-sponsored health plan benefit exclusions; however, none describes the basis for the overall barrier resulting from an employer's health plan benefit exclusions for ED treatment. A study evaluating trends in health plan insurance coverage of inflatable penile prostheses (IPPs) among patients at the University of Miami between 2016 and 2017 reported that among men seeking IPP with commercial health plan, 48.0% were unable to obtain the device due to an exclusion in their employer-sponsored health plan benefit (Masterson et al., 2019). Regardless of meeting “medical necessity,” the appeal process to request coverage is a long and difficult process for a patient or provider because, in an employer-sponsored health plan, the member's benefit plan actually determines coverage, not the health plan itself. Some employer-sponsored health plans exclude coverage for services or supplies that a health plan considers medically necessary. If there is a discrepancy between the health plan's coverage policy and a member's plan of benefits, the member's benefits plan will govern. A sample analysis of ED management and IPP coverage obtained from a database that focuses on health plan medical benefit verification prior to treatment concluded that of men whose providers determined ED treatment with a PP was medically necessary, 18% had an employer-sponsored health plan benefit exclusion (Mazur et al., 2018).

Implications of Employer Exclusion of ED Treatment

There are notable implications of excluded ED treatments by employer-sponsored health plans excluding medical benefits for medical injections, external devices, and implantable devices that are medically necessary that are covered under a health plans medical policy and are the nuance in this situation. Prescription drug therapy, whether it is excluded or not, is a pharmacy benefit and not addressed under a medical plan policy. The employer-sponsored health plan policy exclusions create confusion and frustration for clinicians because they usurp the clinicians' determination of medical necessity under the health plans medical policy. Although patients

may be able to pay for lower cost generic pharmacological ED therapies out-of-pocket, advanced ED treatments such as ICIs, intraurethral suppositories, PP surgery, and VEDs may not be as accessible to them. AUA Treatment Guidelines American Urological Association (2018) state:

All men should be informed of all treatment options that are not medically contraindicated to determine the appropriate treatment. Although many men may choose to begin with the least invasive option, the Panel notes that it is valid for men to begin with any type of treatment, regardless of invasiveness or reversibility.

These inconsistencies make it difficult for health-care providers to implement ED treatment guidelines appropriately and to provide medically necessary treatment for patients with ED. Consequently, some patients are more disadvantaged than others based on variations in clinicians' advocacy along with coverage variation. The net effect is that some patients cannot access required treatments and clinicians cannot ensure patient access to recommended evidence-based care due to reimbursement and out-of-pocket costs.

In addition to the burden placed on clinicians when implementing management for patients with ED, these exclusions for ED have implications for employee satisfaction and retention. According to recent research on employer benefits and employee engagement, 61% of employees reported that health was a bigger concern than wealth or career, whereas only 14% of employers cited health and well-being as a talent-management priority (Mercer Marsh, 2018). Health and wellness benefits were reported to be more important to employees than job role, colleagues, or organizational culture when it came to loyalty, recruitment, and retention (Mercer Marsh, 2018). Evidence has reported that a healthy and engaged workforce correlates with exceptional company financial performance (Fabius et al., 2013; Goetzel et al., 2016; Grossmeier et al., 2016). Allowing access to medically necessary health benefits such as ED treatment could benefit employers through increased productivity, loyalty, and retention as well as decreased absenteeism and presentism rates (Fabius et al., 2013; Goetzel et al., 2016; Goldstein, Goren, Li, Maculaitis, et al., 2019; Grossmeier et al., 2016).

Policy Interventions for Enabling Access to ED Treatment

Policy interventions could help in alleviating the confusion and bring parity between health plan coverage in a medical policy and employer-sponsored health plan coverage enabling medically necessary nonsurgical and

surgical ED therapies of patients and employees with ED access to treatments. Another instance illustrative of the need for benefits parity and policy intervention is the case of contraceptive coverage. Employers were once reluctant to cover contraception, arguing that the role of health insurance was to treat illness and provide a safety net between health disasters and destitution, thus excluding pregnancy since it was not an illness or a disaster (“Contraceptive equity bills continue to gain,” 2000). Contraceptive equity laws, which started to be introduced in the United States in 2014, prevent insurers from using medical management techniques like cost-sharing, prior authorization, prescription requirements, gender restrictions, or quantity limitations to erect access barriers to contraceptives.

Health-Care Coverage Equality for Men’s Health

Another important consideration is health-care coverage parity and health-care equality for men’s sexual and reproductive health. Although shortfalls in women’s reproductive health have been addressed, medically necessary men’s sexual and reproductive health coverage has lagged. Disparities and inequality in health care have led to changes in federal and/or state mandates such as Women’s Health and Cancer Rights, Reproductive Rights, and Transgender Rights. It is well known that QoL has become one of the important parameters in the evaluation of treatment and assessment of medical conditions. Federal and state mandates ensure access to effective treatment for women’s breast health, female-factor infertility, and gender affirmation to ensure these individuals do not experience a diminished QoL. However, to our knowledge, there are no comparable Federal and state mandates that address men’s sexual and reproductive health inequalities, including sexual dysfunctions such as ED.

The Women’s Health and Cancer Rights Act (WHCRA) mandates that insurers offer breast reconstruction after a mastectomy in a manner determined by the physician and the patient. The WHCRA requires access to and coverage for all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses, and treatment of physical complications of the mastectomy, including lymphedema. A common misconception is that the WHCRA is limited to breast cancer but despite the title, “nothing in the law limits entitlement of benefits to cancer patients.”

Historically, male sexual and reproductive health has not received the same attention as female reproductive health for various reasons. A study by Le et al. (2017)

investigated the degree of transparency surrounding policies of 84 popular U.S. health insurance plans regarding ED and hypogonadism, using breast reconstruction following mastectomy as a control (Le et al., 2017). The authors identified publicly available policies for advanced ED treatment (i.e., ICIs, intraurethral suppositories, PP surgery, and VEDs) in only 39% of the plans examined, while breast reconstruction policies were publicly available for 94% of the plans. Men’s health is increasingly being recognized as a unique and important aspect of public health (Bhasin, 2016). Transformative changes in societal attitudes toward men’s sexual health, body image, and gender identity, and in the economics of reproductive health-care services offer extraordinary opportunities for translational science that is patient-focused, mechanism-based, and integrated with health care (Bhasin, 2016).

Gender affirmation surgery and transgender equity considerations have led to new distinct policies that connect with treatment options. LGBT individuals are protected by Federal non-discrimination laws prohibiting doctors, hospitals, and insurance companies to discriminate against people based on gender. Additional protection exists in State laws (nearly half of the U.S. states) that prohibit employers from having exclusions or limitations in the coverage in health benefits and requires the removal of all transgender exclusions from insurers. Approximately half (52%) of the LGBT population lives in states that prohibit transgender exclusions in health insurance service coverage (Movement Advancement Project [MAP]). The U.S. gender reassignment surgery market was valued at 97.23 million US\$ in 2017 and projected to exceed 968 million by 2024. Of these gender reassignment surgeries, over 30% are female-to-male transition (Global Market Insights, 2018); however, the proportion of female-to-male transitions that proceed with genital surgery may be small. In the instance where a PP is used to create a penis in a female-to-male gender affirmation surgery, health-care benefit coverage under some state laws would be protected from exclusion within an employer-sponsored health plan.

Considerations for coverage for sexual and reproductive health are supported in current state mandates addressing female-factor infertility and reproductive rights requiring health plans by law to offer coverage in 16 states; however, it is unclear within the law if male infertility is addressed adequately (National Conference of State Legislators, 2019). The distribution of infertility due to male factor ranges from 20% to 70% globally (Agarwal et al., 2015). Male-factor infertility is the result of a disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the male reproductive tract, which prevents the conception of a child (American Society for Reproductive Medicine [ASRM],

2020). ED and premature ejaculation are the most common sexual dysfunctions (Hatzimouratidis, 2007; McCabe et al., 2016; Mialon et al., 2012; Papaharitou et al., 2006) and may contribute to infertility in some instances.

The Equal Employment Opportunity Commission (EEOC) mandates that employers who provide health benefits must do so without regard to the race, color, sex, national origin, or religion of the insured. The employer cannot provide different coverage to men and women. Where both men and women are, or could be, affected by the same condition (e.g., infertility) or helped by the same treatment (e.g., PP), the employer will be liable for sexual discrimination if it provides different coverage to employees based on gender. Without federal or state protections or enforcements, the differences between laws and health-care coverage related to men's sexual and reproductive health are vague and often not transparent representing marked disparities within the U.S. health care (Table 2).

Call to Action to Improve Consistency and Accessibility of ED Treatment

The burden of ED necessitates a call to action to improve the consistency and accessibility of all types of ED treatments. This call to action outlines steps that can be taken to remove some of the obstacles faced by men who, depending on the cause and severity of their ED, want to take steps to address their health condition. The call to action steps include: (a) coverage for medical, surgical, and other ED treatments should be viewed in the same way as coverage for other health issues, whether male or female and regardless of the stages of treatment, physical dysfunction, or physical changes; (b) AUA guidelines for the management of ED should be followed including the implementation of templates in electronic medical records (EMRs) to support adherence to the guidelines; and (c) coverage criteria should explicitly state that the criteria are intended to support gender equity for sexual and reproductive health care and should not be used to prevent men from receiving medically necessary ED treatment (Figure 1).

ED is a recognized medical condition that is strongly related to all aspects of general health, from physical to mental health. Men with ED have suffered a physical impairment caused by vascular-, endocrine-, or neurological-related damage from illnesses such as hypertension, hypercholesterolemia, diabetes, prostate cancer, and Peyronie's disease, and from traumatic events such as pelvic or spinal cord trauma (Chung et al., 2013;

Hackett, 2009; Haglind et al., 2015; Nguyen et al., 2017). ED poses a considerable burden with profound consequences as it may interfere with a man's physical well-being, QoL, self-esteem, relationships, self-worth, and productivity (Goldstein, Goren, Li, Maculaitis, et al., 2019).

The AUA guideline states that shared decision-making is the cornerstone of the treatment and management of ED (American Urological Association, 2018). Once it is determined that the cause of the ED is chronic and organic in nature, the patient and the clinician together determine the best course of therapy based on a discussion of the risks, benefits, and desired outcome. The patient is informed of all treatment options that are not contraindicated to determine the most appropriate treatment. Implementation of templates in EMRs can be used to support adherence to the AUA guidelines.

While federal and state mandates ensure access to effective treatment for women's breast health, female-factor infertility, and gender affirmation to ensure these individuals do not experience a diminished QoL, there are no comparable mandates for men's sexual and reproductive health. Employer-sponsored insurers with a benefit exclusion for ED treatment undercut the determination of medically necessary treatment made by licensed medical professionals and the medical policies developed and published by the health insurance companies that administer their benefits. The exclusions for ED treatment ultimately negatively affect employers as they have implications for employee satisfaction and retention (Fabius et al., 2013; Goetzel et al., 2016; Goldstein, Goren, Li, Maculaitis, et al., 2019; Grossmeier et al., 2016). Policy wording that facilitates health-care providers' implementation of treatment guidelines supports gender equity for reproductive health care by enabling access to medically necessary ED treatment. The AUA guidelines provide a recognized structure for creating a cohesive policy for ED treatment.

Conclusions

With this call to action, we offer a pathway to support every man who seeks treatment for ED as a medically necessary intervention by removing systemic health-care barriers. ED constitutes a large but often hidden burden on society given its high prevalence and impact on QoL. In addition to the medical need, men's ability to express the male gender has profound effects on their feelings of worth to themselves, their partners, and in other areas of their lives. It is therefore important to make sure that all types of effective ED treatments are consistently accessible to patients with documented medical necessity.

Table 2. Disparities and Inequalities in Women’s, Men’s, and Transgender Health Addressed With Federal and State Mandates.

	Mandate Summary		Access for Women	Access for Men
Breast (Federal mandate) Women’s Health and Cancer Rights Act (WHCRA) Sexual and reproductive health (SRH) and Sexual and reproductive rights (SRR; state mandate)	Female: Treatment to replace a missing breast as well as the remaining breast for cosmetic reasons is mandated after medical necessity is documented. States that mandate laws related to infertility treatments: 16 states: Arkansas, California, Connecticut, Delaware, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Texas, and West Virginia detail the mandate to cover or offer coverage for infertility diagnosis; however, male ED diagnosis as part of this is not mentioned. Note: The Affordable Care Act (ACA) left the topic of infertility up to the decision of the states.	Male: Treatment to restore function to a malfunctioning penis is not protected by a mandate. Medical necessity and other reasons remain ambiguous due to exclusions.	Mandate assures access	Absence of a mandate that address access to ED. Dysfunction treatments creates variation and disparity.
Gender reassignment (state mandate)	Maine covers transition services under Medicaid. Judges in Wisconsin, Minnesota, and California ruled that health-care providers in those states cannot discriminate based on gender identity. Twenty-two states and Washington, D.C. have specific prohibitions against discriminating in health care on the basis of gender identity.		Varies by states that provide coverage but is the same for individuals are who female or male at birth	Some language is generalized and does not describe gender, but describes coverage for infertility; Louisiana, for example, which prohibits the exclusion of coverage for the diagnosis and treatment of a medical condition solely because the condition results in infertility.
Equal Employment Opportunity Commission (EEOC) Federal	This law makes it illegal to discriminate against someone on the basis of race, color, religion, national origin, or sex.		Varies by states that provide retirement benefits; profit-sharing and bonus plans; leave; and other terms, conditions, and privileges of employment. (a) “Fringe benefits,” as used herein, includes medical, hospital, accident, life insurance, and retirement benefits; profit-sharing and bonus plans; leave; and other terms, conditions, and privileges of employment. (b) It shall be an unlawful employment practice for an employer to discriminate between men and women with regard to fringe benefits	For males: the law and language regarding coverage for infertility is unclear and some language refers to married couples. The language among all the states is silent on a male infertility diagnosis and there is no mention of prior infertility or ED treatments. Some language is generalized and does not describe gender, but describes coverage for infertility; Louisiana, for example, which prohibits the exclusion of coverage for the diagnosis and treatment of a medical condition solely because the condition results in infertility. Varies by states that provide coverage but is the same for individuals are who female or male at birth

Note. ED, erectile dysfunction.

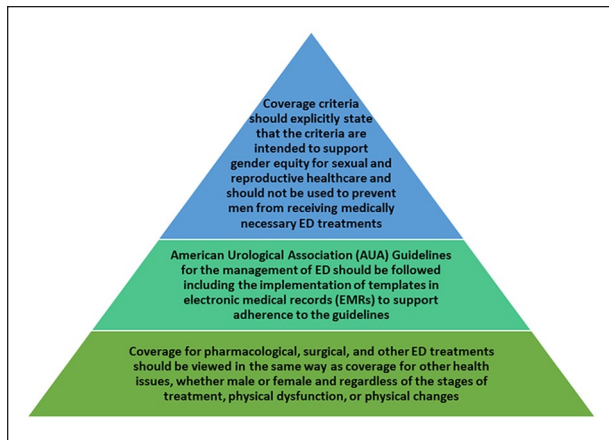


Figure I. Call to action to improve the consistency and accessibility of ED treatments.

Target Journal

American Journal of Men's Health (Special Collection on Male Sexual and Reproductive Health)

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by Boston Scientific.

Ethical Approval and Informed Consent

Ethics approval from an Institutional Review Board and Informed Consent were not required for this work as it does not include patient data.

ORCID iD

Natalie C. Edwards  <https://orcid.org/0000-0002-8501-1467>

Supplemental Material

Supplemental material for this article is available online.

References

Agarwal, A., Mulgund, A., Hamada, A., & Chyatte, M. R. (2015). A unique view on male infertility around the globe. *Reproductive Biology and Endocrinology: RB&E*, *13*(37), 1–9. <https://doi.org/10.1186/s12958-015-0032-1>

American Society for Reproductive Medicine (ASRM). (2020). *Infertility*. Retrieved September 8, from <https://www.asrm.org/topics/topics-index/infertility/>

American Urological Association. (2018). *Erectile dysfunction: AUA guideline (2018)*. [https://www.auanet.org/guidelines/erectile-dysfunction-\(ed\)-guideline](https://www.auanet.org/guidelines/erectile-dysfunction-(ed)-guideline)

Berger, M. H., Messore, M., Pastuszak, A. W., & Ramasamy, R. (2016). Association between infertility and sexual dysfunction in men and women. *Sexual Medicine Reviews*, *4*(4), 353–365. <https://doi.org/10.1016/j.sxmr.2016.05.002>

Bhasin, S. (2016). A perspective on the evolving landscape in male reproductive medicine. *Journal of Clinical Endocrinology and Metabolism*, *101*(3), 827–836. <https://doi.org/10.1210/jc.2015-3843>

Burnett, A. L., Nehra, A., Breau, R. H., Culkin, D. J., Faraday, M. M., Hakim, L. S., Heidelbaugh, J., Khera, M., McVary, K. T., Miner, M. M., Nelson, C. J., Sadeghi-Nejad, H., Seftel, A. D., & Shindel, A. W. (2018). Erectile dysfunction: AUA guideline. *The Journal of Urology*, *200*(3), 633–641. <https://doi.org/10.1016/j.juro.2018.05.004>

Chung, E., Solomon, M., DeYoung, L., & Brock, G. B. (2013). Comparison between AMS 700 CX and Coloplast Titan inflatable penile prosthesis for Peyronie's disease treatment and remodeling: Clinical outcomes and patient satisfaction. *The Journal of Sexual Medicine*, *10*(11), 2855–2860. <https://doi.org/10.1111/jsm.12009>

Contraceptive equity bills continue to gain. (2000). *Reproductive Freedom News*, *9*(2), 8.

Fabius, R., Thayer, R. D., Konicki, D. L., Yarborough, C. M., Peterson, K. W., Isaac, F., Loeppke, R. R., Eisenberg, B. S., & Dreger, M. (2013). The link between workforce health and safety and the health of the bottom line: tracking market performance of companies that nurture a “culture of health”. *Journal of Occupational and Environmental Medicine*, *55*(9), 993–1000. <https://doi.org/10.1097/JOM.0b013e3182a6bb75>

Feldman, H. A., Goldstein, I., Hatzichristou, D. G., Krane, R. J., & McKinlay, J. B. (1994). Impotence and its medical and psychosocial correlates: Results of the Massachusetts Male Aging Study. *The Journal of Urology*, *151*(1), 54–61. [https://doi.org/10.1016/s0022-5347\(17\)34871-1](https://doi.org/10.1016/s0022-5347(17)34871-1)

Fendrick, A. M. (2000). Access to innovative treatment of erectile dysfunction: Clinical, economic, and quality-of-life considerations. *The American Journal of Managed Care*, *6*(12 Suppl), S632–S638.

Global Market Insights. (2018). *Sex reassignment surgery market size by gender transition [male to female {facial, breast, genitals}, female to male {facial, chest, genitals}] industry analysis report, regional outlook, application potential, price trends, competitive market share & forecast, 2018–2024*. Retrieved March 5, Implications of Employer Exclusion of ED Treatment.

Goetzl, R. Z., Fabius, R., Fabius, D., Roemer, E. C., Thornton, N., Kelly, R. K., & Pelletier, K. R. (2016). The stock performance of C. Everett Koop award winners compared with the standard & poor's 500 index. *Journal of Occupational and Environmental Medicine*, *58*(1), 9–15. <https://doi.org/10.1097/JOM.0000000000000632>

Goldstein, I., Goren, A., Li, V. W., Maculaitis, M. C., Tang, W. Y., & Hassan, T. A. (2019). The association of erectile dysfunction with productivity and absenteeism in eight countries globally. *International Journal of Clinical Practice*, *73*(11), e13384. <https://doi.org/10.1111/ijcp.13384>

Goldstein, I., Goren, A., Li, V. W., Tang, W. Y., & Hassan, T. A. (2019). Epidemiology update of erectile dysfunction in

- eight countries with high burden. *Sexual Medicine Reviews*, 8(1), 48–58. <https://doi.org/10.1016/j.sxmr.2019.06.008>
- Grossmeier, J., Fabius, R., Flynn, J. P., Noeldner, S. P., Fabius, D., Goetzel, R. Z., & Anderson, D. R. (2016). Linking workplace health promotion best practices and organizational financial performance: tracking market performance of companies with highest scores on the HERO scorecard. *Journal of Occupational and Environmental Medicine*, 58(1), 16–23. <https://doi.org/10.1097/jom.0000000000000631>
- Hackett, G. (2009). The burden and extent of comorbid conditions in patients with erectile dysfunction. *International Journal of Clinical Practice*, 63(8), 1205–1213. <https://doi.org/10.1111/j.1742-1241.2009.02088.x>
- Haglund, E., Carlsson, S., Stranne, J., Wallerstedt, A., Wilderang, U., Thorsteinsdottir, T., Lagerkvist, M., Damber, J. E., Bjartell, A., Hugosson, J., Wiklund, P., & Steineck, G. (2015). Urinary incontinence and erectile dysfunction after robotic versus open radical prostatectomy: a prospective, controlled, nonrandomised trial. *European Urology*, 68(2), 216–225. <https://doi.org/10.1016/j.eururo.2015.02.029>
- Hatzimouratidis, K. (2007). Epidemiology of male sexual dysfunction. *American Journal of Men's Health*, 1(2), 103–125. <https://doi.org/10.1177/1557988306298006>
- Kessler, A., Sollie, S., Challacombe, B., Briggs, K., & Van Hemelrijck, M. (2019). The global prevalence of erectile dysfunction: a review. *BJU International*, 124(1), 587–599. <https://doi.org/10.1111/bju.14813>
- Klein, R., & Sturm, H. (2002). Viagra: a success story for rationing? *Health Affairs (Millwood)*, 21(6), 177–187. <https://doi.org/10.1377/hlthaff.21.6.177>
- Le, B., McAchrans, S., Paolone, D., Gralnek, D., Williams, D. t., & Bushman, W. (2017). Assessing the variability in insurance coverage transparency for male sexual health conditions in the United States. *Urology*, 102(1), 126–129. <https://doi.org/10.1016/j.urology.2016.12.031>
- Lotti, F., Corona, G., Castellini, G., Maseroli, E., Fino, M. G., Cozzolino, M., & Maggi, M. (2016). Semen quality impairment is associated with sexual dysfunction according to its severity. *Human Reproduction*, 31(12), 2668–2680. <https://doi.org/10.1093/humrep/dew246>
- Lotti, F., & Maggi, M. (2018). Sexual dysfunction and male infertility. *Nature Reviews Urology*, 15(5), 287–307. <https://doi.org/10.1038/nrurol.2018.20>
- Masterson, J. M., Kava, B., & Ramasamy, R. (2019). Commercial insurance coverage for inflatable penile prosthesis at a tertiary care center. *Urology Practice*, 6(3), 155–158. <https://doi.org/10.1016/j.urpr.2018.07.002>
- Mazur, D. J., Gondokusumo, J. C., McBride, J. A., Pastuszak, A. W., & Lipshultz, L. I. (2018). PD18-03 doomed to impotence: Analysis of Erectile Dysfunction (ED) and Inflatable Penile Prosthesis (IPP) insurance coverage from verification benefits databases. *Journal of Urology*, 199(4S), e390–e391. <https://doi.org/10.1016/j.juro.2018.02.980>
- McCabe, M. P., Sharlip, I. D., Lewis, R., Atalla, E., Balon, R., Fisher, A. D., Laumann, E., Lee, S. W., & Segraves, R. T. (2016). Incidence and prevalence of sexual dysfunction in women and men: A consensus statement from the Fourth International Consultation on Sexual Medicine 2015. *The Journal of Sexual Medicine*, 13(2), 144–152. <https://doi.org/10.1016/j.jsxm.2015.12.034>
- Mercer Marsh. (2018). *Creating employee benefits that drive engagement* (Point of View, Issue. file:///C:/Users/owner/Downloads/gl-2018-creating-employee-benefits-that-drive-engagement-pov.pdf
- Mialon, A., Berchtold, A., Michaud, P. A., Gmel, G., & Suris, J. C. (2012). Sexual dysfunctions among young men: Prevalence and associated factors. *Journal of Adolescent Health*, 51(1), 25–31. <https://doi.org/10.1016/j.jadohealth.2012.01.008>
- Montorsi, F., Briganti, A., Salonia, A., Rigatti, P., Margonato, A., Macchi, A., Galli, S., Ravagnani, P. M., & Montorsi, P. (2003). Erectile dysfunction prevalence, time of onset and association with risk factors in 300 consecutive patients with acute chest pain and angiographically documented coronary artery disease. *European Urology*, 44(3), 360–364; discussion 364–365. [https://doi.org/10.1016/s0302-2838\(03\)00305-1](https://doi.org/10.1016/s0302-2838(03)00305-1)
- Mushtaq, S., Khan, K., Abid, S., Umer, A., & Raza, T. (2018). Frequency of hypogonadism and erectile dysfunction in type-II diabetic patients. *Cureus*, 10(5), e2654. <https://doi.org/10.7759/cureus.2654>
- National Conference of State Legislators. (2019). *State laws related to insurance coverage for infertility treatment*. Retrieved March 5, from <https://www.ncsl.org/research/health/insurance-coverage-for-infertility-laws.aspx>
- Nguyen, H. M. T., Gabrielson, A. T., & Hellstrom, W. J. G. (2017). Erectile dysfunction in young men—a review of the prevalence and risk factors. *Sexual Medicine Reviews*, 5(4), 508–520. <https://doi.org/10.1016/j.sxmr.2017.05.004>
- Papaharitou, S., Athanasiadis, L., Nakopoulou, E., Kirana, P., Portseli, A., Iraklidou, M., Hatzimouratidis, K., & Hatzichristou, D. (2006). Erectile dysfunction and premature ejaculation are the most frequently self-reported sexual concerns: Profiles of 9,536 men calling a helpline. *European Urology*, 49(3), 557–563. <https://doi.org/10.1016/j.eururo.2005.09.023>
- Perlis, N., Lo, K. C., Grober, E. D., Spencer, L., & Jarvi, K. (2013). Coital frequency and infertility: Which male factors predict less frequent coitus among infertile couples? *Fertility and Sterility*, 100(2), 511–515. <https://doi.org/10.1016/j.fertnstert.2013.04.020>
- Potharaju, M., Subramaniam, R., Venkataraman, M., Perumal, K., Ramakrishnan, B., Vangara, R., & Reddy, S. (2015). A report on the clinical outcome after High-Dose Rate (HDR) brachytherapy as monotherapy in early prostate cancer. *Cureus*, 7(8), e303. <https://doi.org/10.7759/cureus.303>
- Raza, M. T., Sharif, S., Khan, Z. A., Naz, S., Mushtaq, S., & Umer, A. (2019). Frequency of hypogonadism in type 2 diabetes mellitus patients with and without coronary artery disease. *Cureus*, 11(12), e6500. <https://doi.org/10.7759/cureus.6500>
- Rezaee, M. E., Ward, C. E., Brandes, E. R., Munarriz, R. M., & Gross, M. S. (2019). A review of economic evaluations of erectile dysfunction therapies. *Sexual Medicine Reviews*, 8(3), 497–503. <https://doi.org/10.1016/j.sxmr.2019.06.001>

- Sahin, A., Urkmez, A., Verit, A., Yuksel, O. H., & Verit, F. (2017). Psychologic and sexual dysfunction in primary and secondary infertile male patients. *Archivio Italiano di Urologia e Andrologia*, *89*(2), 120–124. <https://doi.org/10.4081/aiua.2017.2.120>
- Sexual Medicine Society of North America (SMSNA). (2019). *Surgical and non-surgical treatments of sexual dysfunction should be standard benefits of all medical insurance programs*. Retrieved July 23, from <https://www.smsna.org/V1/images/PDF/sms-position-statement-re-surgical-and-non-surgical-treatments.pdf>
- Skeldon, S. C., Detsky, A. S., Goldenberg, S. L., & Law, M. R. (2015). Erectile dysfunction and undiagnosed diabetes, hypertension, and hypercholesterolemia. *Annals of Family Medicine*, *13*(4), 331–335. <https://doi.org/10.1370/afm.1816>
- The Impotence Association (now the Sexual Dysfunction Association). (1997). Impotence Association Survey.
- US Census Bureau. (2017). *Health insurance coverage in the United States: 2016*. <https://www.census.gov/library/publications/2017/demo/p60-260.html>
- U.S. Government Accountability Office (GAO). (2011). *Employers' insurance coverage maintained or enhanced since parity act, but effect of coverage on enrollees varied*. Retrieved March 1, from <https://www.gao.gov/products/gao-12-63>