Sexual Medicine Society of North America (SMSNA) Position Statement on Access to Evidence-Based Sexual Medicine Therapies

The Sexual Medicine Society of North America (SMSNA) is dedicated to advancing the highest standards of patient care, research, and education in the field of sexual medicine. As part of this mission, the Society advocates for patient access to medically appropriate, evidence-based therapies for conditions that significantly affect physical health, emotional well-being, interpersonal relationships, and quality of life.

Sexual dysfunctions are medical conditions that can substantially impair mental health, intimate relationships, self-esteem, and overall quality of life.[1] And although they are common sequelae of aging, sexual dysfunctions are no different than other routinely covered age-associated abnormalities such as arthritis, glaucoma, malignancy, and cardiovascular disease, among others. The stigmatization of sexual health conditions has historically contributed to underdiagnosis, undertreatment, and barriers to care.[2] Policies that inappropriately restrict access to evidence-based sexual medicine therapies risk perpetuating these disparities and may ultimately harm patients.

Over recent years, physicians and patients have increasingly encountered insurance denials for established sexual medicine therapies, including penile prosthesis implantation, surgical treatment of Peyronie's disease, FDA-approved intralesional injections such as collagenase clostridium histolyticum (Xiaflex®), and testosterone therapies.[3] These denials often result in suboptimal care, increase patient distress, and interfere with the physician-patient relationship.

The SMSNA recognizes that insurance providers have the authority and responsibility to define the terms, limitations, and structure of insurance coverage policies. Coverage determinations are influenced by many factors, including contractual terms, actuarial considerations, cost analyses, and internal utilization policies. The Society does not contend that every treatment must be universally covered under every insurance plan.

However, the SMSNA believes it is critically important to distinguish between a coverage determination and a scientific or medical determination regarding safety, efficacy, or appropriateness of care. It is inappropriate to characterize well-established sexual medicine therapies as "experimental," "investigational," "unproven," or lacking medical necessity when substantial peer-reviewed evidence, professional society guidelines, FDA approvals, and long-standing clinical experience support their use in properly selected patients.

Penile prosthesis implantation remains the gold standard treatment for men with medically refractory erectile dysfunction who have failed or are intolerant of conservative therapies.[4]

Multiple decades of published literature have demonstrated high rates of patient and partner satisfaction, durable long-term outcomes, and acceptable safety profiles.[5] Similarly, surgical correction of Peyronie's disease through tunical plication or plaque incision/excision with grafting represents established reconstructive procedures supported by contemporary urologic guidelines and extensive published evidence.[6] These procedures are not cosmetic interventions. They are reconstructive operations intended to restore sexual function, reduce deformity, alleviate psychological distress, and improve quality of life in appropriately selected patients.

The Society is particularly concerned by insurance denials involving collagenase clostridium histolyticum (Xiaflex®) in clinical scenarios that are increasingly supported by contemporary scientific evidence and expert consensus. While FDA labeling and initial clinical trials necessarily involved carefully selected patient populations, the practice of medicine evolves as additional evidence becomes available through post-marketing studies, multicenter investigations, and real-world clinical outcomes.

Numerous peer-reviewed studies have now demonstrated the safety and clinical utility of collagenase therapy in men with ventral curvature deformities, active/acute-phase disease, calcified plaques, hourglass/indentation deformities, congenital penile curvature, recurrent Peyronie's disease, and reactivation or de novo plaque formation after prior treatment.[7-12]

Importantly, the existence of these clinical characteristics should not automatically serve as justification for denial of treatment coverage when a treating physician determines that therapy is medically appropriate. Blanket exclusions based solely on plaque calcification, curvature direction, indentation deformities, recurrent disease, or the need for additional treatment cycles are not scientifically justifiable and do not reflect contemporary scientific literature or expert practice patterns.

The SMSNA is also concerned by increasing barriers to medically appropriate testosterone therapy for men with symptomatic low testosterone. Examples include frequent formulary changes, requirements for failure of prior therapies, restricting treatment to narrowly defined indications, imposing testing requirements that exceed established scientific guidelines, or giving preference to treatment modalities without clear, evidence-based rationale. As with the other therapies described, these business-centered policies are not supported medically and can interfere with carefully optimized treatment regimen, reduce adherence, and contribute to subtherapeutic management.

The SMSNA encourages insurers, policymakers, employers, and healthcare stakeholders to ensure that coverage policies accurately reflect contemporary medical evidence,

established professional guidelines, and current standards of care. We believe that coverage determinations should be developed in consultation with clinicians and researchers who possess subject matter expertise in sexual medicine and reconstructive urology.

To that end, the SMSNA welcomes the opportunity to collaborate constructively with insurance providers and healthcare organizations. The Society is prepared to provide expert consultation, educational resources, and clinical guidance to assist payer medical directors and policy committees in understanding the appropriate indications, safety considerations, and evidence base surrounding these therapies.

Our shared goal should be to promote responsible, evidence-based, patient-centered care while ensuring that individuals suffering from sexual health disorders retain access to medically appropriate treatment options. Patients deserve policies grounded in science, fairness, and contemporary clinical understanding.

The Sexual Medicine Society of North America remains committed to advancing education, research, advocacy, and access to high-quality sexual healthcare for all patients.

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