ASSESSMENT OF ADVANCED THERAPY ADOPTION AND MARKET OPPORTUNITY IN OVERACTIVE BLADDER MANAGEMENT IN THE UNITED STATES

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Healthcare Analytics

by

Kartik Raghunath Bhandekar

Under the Supervision and Guidance of

Dr. Ram Krishan Chahar

2026

Orbees Business Solutions Pvt. Ltd.
Q1, B1, B2, B3, 6th Floor, Cyber Towers, Hitec City, Madhapur, Hyderabad – 500 081. CIN: U72200TG2006PTC049670
Tel: +91 - 040 - 2311 4722, Fax: +91 - 040 - 2311 4723. info@orbees.com | www.orbees.com | www.orbeesmedical.com

27th May 2026
Hyderabad

To,

Mr. Kartik Bhandekar
Plot no. 21 A, Kirti Nagar,
New Nandanvan, Nagpur-440024

Dear **Mr.Kartik Bhandekar**

Internship Certificate

This letter is to certify that **Kartik Raghunath** in partial fulfillment of the requirements for the award of the degree of MBA in Health Care management from the IIHMR university, Jaipur is doing internship at Orbees Business solutions Pvt. Ltd. Since **26th FEB 2026 till date**.

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G. Praveen

Praveen Ginjupalli
Manager - Operations

IIHMR UNIVERSITY

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This is to certify that dissertation titled **"Assessment of Advanced Therapy Adoption and Market Opportunity in Overactive Bladder Management in the United States"** is a record of the research work undertaken by **Kartik Bhandekar** in partial fulfilment of the requirements for the award of the degree of MBA (Healthcare Analytics) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

Dr. Ram Krishan Chahar
Assistant Professor
IIHMR University, Jaipur

Date: 24/06/2026

1, Prabhu Dayal Marg, Near Sanganer Airport, Jaipur- 302029, Rajasthan, India.
Ph.: 0141-3924700, 2791431- 32, E-mail: iihmr@iihmr.edu.in, Web.: www.iihmr.edu.in

DECLARATION BY STUDENT

I hereby declare that this dissertation titled "**Assessment of Advanced Therapy Adoption And Market Opportunity In Overactive Bladder Management In The United States**" is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name : Kartik Bhandekar

Date: 25-06-2026

ABSTRACT

Assessment of Advanced Therapy Adoption and Market Opportunity in Overactive Bladder Management in the United States: A Healthcare Analytics Study

Author Name: Kartik Bhandekar

Advisor Name: Dr. Ram Krishan Chahar

Background. Overactive Bladder (OAB) is among the most prevalent and most undertreated chronic conditions in U.S. adult healthcare. An estimated 16 to 24 million American adults experience symptomatic OAB, generating an annual societal cost burden of approximately USD 65–76 billion and a quality-of-life decrement comparable to that observed in diabetes mellitus and chronic obstructive pulmonary disease. Four FDA-approved advanced therapies — intradetrusor botulinum toxin (Botox), Percutaneous Tibial Nerve Modulation (PTNM), Sacral Neuromodulation (SNM), and Implantable Tibial Neuromodulation (ITNM) — are available for refractory disease, yet collectively reach fewer than 200,000 new patients annually, approximately one percent of the symptomatic pool. The 2024 AUA/SUFU guideline update introduced three changes of strategic consequence: formal recognition of ITNM as a third-line therapy, an explicit requirement for clinician counselling on anticholinergic-associated cognitive risk, and authorisation of a "menu" approach permitting direct escalation to minimally invasive therapy. These changes, combined with the 2024 Boston Scientific acquisition of Axonics and the 2025 approval of a next-generation ITNM device, position the U.S. OAB advanced-therapy market at a regulatory, competitive, and structural inflection point.

Objectives. The dissertation pursues a single primary objective — to assess adoption patterns, market dynamics, and growth opportunities for advanced OAB therapies in the United States using a structured healthcare analytics framework — operationalised through eight secondary objectives spanning funnel quantification, attrition analysis, physician segmentation, comparative therapy assessment, market sizing and forecasting, identification of drivers and barriers, and translation into stakeholder-specific strategic recommendations.

Methodology. The study adopts a secondary, quantitative-descriptive research design with embedded comparative analysis. Data sources include CMS Medicare datasets, AUA and SUFU clinical guidelines, peer-reviewed literature indexed in PubMed, publicly available market reports, company annual reports, and industry trade publications. An eight-step analytical framework is applied: OAB population estimation; care-seeking analysis; pharmacotherapy utilisation; refractory patient estimation; advanced-therapy eligibility; physician landscape assessment; market opportunity assessment; and strategic recommendation development. Analytical tools include Excel-based funnel modelling, scenario analysis, and comparative matrices. ICD-10 codes (N32.81, N39.41, N39.46) and CPT codes (52287, 64561, 64566, 64581, 64590, 0816T, 0817T) anchor the utilisation analytics.

Findings. The OAB funnel exhibits systematic leakage at every transition. From a symptomatic base of approximately 16 to 24 million adults, only one-third seek care, fewer than 1.2 million enter pharmacotherapy, 500,000 to 600,000 reach refractory status, and approximately 180,000 receive advanced therapy annually. The largest single attrition occurs at the symptom-to-care-seeking transition (approximately 70 percent loss), reinforced by patient beliefs that incontinence is a normal part of ageing, that symptoms are "not bad enough," and that clinicians never raised the topic. The provider landscape is highly concentrated: approximately 1,700 FPMRS-trained specialists refer patients to advanced therapy at approximately fifteen times the rate of the 7,000 untrained general urologists who dominate OAB patient volume. Site-of-service migration is pronounced, with approximately 90 percent of OAB procedural volume now performed in office-based settings. Comparative therapy analysis indicates that ITNM is differentially positioned on durability, patient burden, and office-workflow compatibility. Five-year forecasting indicates that the ITNM segment is positioned for the highest CAGR (50–70 percent) of any advanced therapy, with the base-case scenario projecting approximately 100,000 ITNM procedures annually by 2030.

Recommendations. Five stakeholder-specific recommendation tracks are developed. For device manufacturers, a three-phase activation roadmap targeting FPMRS specialists, trained urologists, and untrained general urologists in sequence, supported by Botox-conversion playbooks and direct-to-consumer digital activation. For providers, the development of office-based OAB clinics with advanced-practice-provider-driven navigation. For payers, coverage clarity for emerging CPT codes 0816T and 0817T and exploration of outcomes-based contracting. For policy-makers, alignment of coverage with the 2024 guideline and rural-access incentives. For patient advocacy organisations, destigmatisation campaigns addressing the "normal ageing" misconception and activation of primary-care referral pathways.

Conclusion. The U.S. OAB advanced-therapy market is constrained not by therapeutic inadequacy but by structural inefficiencies in patient identification, provider training distribution, and referral activation. The convergence of the 2024 AUA/SUFU guideline update, the 2024 competitive realignment in sacral neuromodulation, the 2025 ITNM device approval, and the broader site-of-service migration toward office-based procedures creates a defined 18-to-24-month strategic window. An analytics-driven approach focused on closing funnel leakage, activating high-leverage provider segments, and aligning stakeholder incentives offers a credible pathway toward a 2030 market in which advanced-therapy penetration approaches three percent of the symptomatic OAB population — a level that would represent a meaningful step toward closing the gap between epidemiological need and treatment delivery.

Keywords: *Overactive Bladder; Advanced Therapy; Sacral Neuromodulation; Implantable Tibial Neuromodulation; Botulinum Toxin; Healthcare Analytics; Market Sizing; Patient Funnel; Physician Segmentation; AUA/SUFU Guideline; CMS Medicare; United States.*

ACKNOWLEDGEMENTS

This dissertation would not have been possible without the support and guidance of several individuals and institutions.

I owe my deepest gratitude to my Faculty Guide, Dr. Ram Krishan Chahar, for his patient mentorship throughout the research process. The discussions we had whether they concerned the framing of research questions, the interpretation of complex deal structures, or the writing of the analysis were invaluable and often transformative in how I understood the subject.

I am equally grateful to the faculty and staff of IIHMR University, Jaipur, for creating an environment that values rigorous inquiry and practical application of knowledge. The MBA Healthcare Analytics programme has equipped me not just with analytical tools, but with a way of thinking about healthcare that I hope to carry into my professional life.

I would also like to thank the team at Orbees Medical for providing me access to their environment and for the conversations with my Preceptor, which helped me refine the scope and direction of this research.

Finally, I am thankful to my family, whose constant encouragement made this effort possible.

Kartik Bhandekar

IIHMR University, Jaipur

June 2026

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LIST OF ABBREVIATIONS

Abbreviation	Expansion
AHRQ	Agency for Healthcare Research and Quality
APP	Advanced Practice Provider
ASC	Ambulatory Surgery Center
AUA	American Urological Association
AUGS	American Urogynecologic Society
CABG	Coronary Artery Bypass Grafting
CAGR	Compound Annual Growth Rate
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
DTC	Direct-to-Consumer
FDA	U.S. Food and Drug Administration
FPMRS	Female Pelvic Medicine and Reconstructive Surgery
GA	General Anesthesia
GU	General Urologist
HOPD	Hospital Outpatient Department
ICD-10	International Classification of Diseases, 10th Revision
ICS	International Continence Society
IDI	In-Depth Interview
ITNM	Implantable Tibial Neuromodulation
ITNS	Implantable Tibial Nerve Stimulation

Abbreviation	Expansion
KOL	Key Opinion Leader
MEPS	Medical Expenditure Panel Survey
MRI	Magnetic Resonance Imaging
NPI	National Provider Identifier
OAB	Overactive Bladder
OAB-q	Overactive Bladder Questionnaire
OBGYN	Obstetrician-Gynecologist
OBL	Office-Based Lab
OR	Operating Room
PCP	Primary Care Provider
PFMT	Pelvic Floor Muscle Training
PMA	Premarket Approval
POP	Pelvic Organ Prolapse
PTNM	Percutaneous Tibial Nerve Modulation
PTNS	Percutaneous Tibial Nerve Stimulation
PUF	Public Use File
QALY	Quality-Adjusted Life Year
QoL	Quality of Life
RCT	Randomized Controlled Trial
SNM	Sacral Neuromodulation
SUFU	Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction
SUI	Stress Urinary Incontinence
UUI	Urgency Urinary Incontinence

CHAPTER 1: INTRODUCTION

Overactive Bladder (OAB) occupies a distinctive position in U.S. healthcare: a condition that is extremely prevalent, clinically well understood, and served by approved therapies — yet strikingly under-treated at the population level. This chapter establishes the clinical and epidemiological foundation for the dissertation, traces the current treatment pathway, profiles the four FDA-approved advanced therapies at the heart of the study, and sets out the problem statement, scope, and research objectives that guide every subsequent chapter.

1.1 Background and Epidemiology

1.1.1 Clinical Definition

Overactive Bladder is a chronic urological syndrome defined by the International Continence Society (ICS) as urinary urgency — typically with increased daytime frequency and nocturia — with or without urgency urinary incontinence (UUI), in the absence of infection or other identifiable pathology. Clinically it divides into OAB-wet (urgency with leakage) and OAB-dry (urgency without leakage). This distinction matters analytically: OAB-wet patients tend to seek care earlier and escalate faster through the treatment pathway, whereas OAB-dry patients often go undiagnosed for years. The AUA and SUFU jointly classify OAB as requiring stepped clinical management, from conservative behavioural therapy at entry through to device-based neuromodulation at the refractory stage — the architectural backbone against which the patient funnel analysed in Chapter 4 is built.

1.1.2 Epidemiology and Disease Burden

OAB affects an estimated 16 to 24 million American adults, with prevalence rising sharply with age — from roughly 9 to 11 percent in adults under 45, to more than 30 percent in those over 65 and nearly 40 percent in women over 75. Women are disproportionately affected at a ratio of approximately 1.4 to 1. Despite this scale, only about one in three symptomatic adults discusses the problem with a clinician, and a smaller share still progresses beyond first-line care. This persistent gap between symptom prevalence and care utilisation is the defining feature of the OAB market and the central analytical theme of the dissertation.

The economic footprint is equally significant. Direct medical costs, out-of-pocket absorbent-product expenditure, productivity loss, and the downstream cost of comorbidities (fall-related fractures, depression, sleep disturbance) combine to place the total annual societal burden at approximately USD 65 to 76 billion. Quality-of-life instruments consistently show that moderate-to-severe OAB generates health-related decrements comparable to chronic stroke or COPD — driven less by symptom severity than by unpredictability, which forces patients to plan routines around restroom access, restrict travel, and progressively withdraw from social and occupational life.

Table 1.1 — Estimated U.S. OAB Population Distribution (2025)

Population Layer	Estimated Size	Share of Symptomatic Pool
Total symptomatic OAB adults	16M – 24M	100%

Population Layer	Estimated Size	Share of Symptomatic Pool
Adults who seek care	~5M	~25–30%
Adults treated with pharmacotherapy	1.0M – 1.2M	~6%
Refractory population (failed/abandoned medication)	500K – 600K	~3%
Patients receiving advanced therapy annually (new)	~180K	~1%

Source: Compiled by the researcher from CMS Medicare utilisation data, AUA/SUFU estimates, and published OAB prevalence literature (2024–2025).

1.2 The OAB Treatment Pathway

OAB management follows a stepped-care model codified by the AUA/SUFU guideline, escalating from behavioural therapy at entry to device-based neuromodulation at the refractory stage.

First Line — Behavioural Therapy
Pelvic floor muscle training, bladder retraining, fluid management, and lifestyle modification form the first rung of the pathway. These interventions are inexpensive and effective for a meaningful subset of patients, but they require sustained engagement that the U.S. primary care system is not well structured to deliver. In practice, behavioural therapy is frequently under-delivered at the very first step, creating early funnel leakage well before pharmacotherapy is even considered.

Second Line — Pharmacotherapy
When behavioural measures fall short, patients escalate to anticholinergics (oxybutynin, tolterodine, solifenacin, among others) or beta-3 agonists (mirabegron, vibegron). Pharmacotherapy reaches the largest patient count of any treatment tier, but adherence is notoriously poor: fewer than 30 percent of patients remain on their initial OAB medication at twelve months, and the 24-month persistence rate falls below 15 percent. Side effects, limited efficacy, and — following the 2024 AUA/SUFU guideline update — required counselling on the association between long-term anticholinergic use and dementia risk are all accelerating the exit from this tier, expanding the refractory pool that advanced therapy is designed to serve.

Third Line — Advanced Therapies
Patients who have tried at least one behavioural intervention and two pharmacotherapy agents without adequate relief are classified as refractory, making them formally eligible for device-based treatment. The estimated refractory pool is 500,000 to 600,000 patients at any given time. Despite this, the transition from refractory designation to advanced-therapy referral remains the single leakiest point in the entire care continuum. Many refractory patients cycle through repeat medication trials for years before a device option is ever offered. The 2024 guideline update adds a further practical change: it now permits clinicians to offer minimally invasive therapy directly to patients unwilling or unable to try pharmacotherapy, compressing the pathway and potentially pulling forward the moment a device conversation begins.

1.3 Advanced OAB Therapies: Comparative Overview

Four FDA-approved advanced therapies are currently in clinical use, each with a distinct mechanism, procedural profile, and market position. Table 1.3 summarises the key attributes across all four; the paragraphs that follow highlight the features most relevant to the dissertation's comparative analysis.

Botox (Intradetrusor Botulinum Toxin)
FDA-approved for idiopathic OAB in 2013, Botox works by blocking acetylcholine release in the detrusor muscle via cystoscopic injection at 100 units. Effects last six to twelve months, after which repeat injection is required. Clinical response rates of 60 to 70 percent are among the highest in the category, but the procedure is limited to cystoscopy-capable providers, carries a 5 to 7 percent risk of urinary retention, and generates an indefinite repeat-treatment burden that compounds cost and patient inconvenience over time.

PTNM (Percutaneous Tibial Nerve Modulation)
Cleared in 2010, PTNM delivers electrical stimulation to sacral nerve roots via a needle electrode placed near the ankle. It is well tolerated and free of systemic side effects, but the standard protocol of twelve weekly office sessions followed by monthly maintenance creates a compliance burden that many patients cannot sustain. As a result, PTNM has flattened in recent years as providers and patients migrate toward more durable alternatives.

SNM (Sacral Neuromodulation)
SNM has been FDA-approved since 1997 and remains the most commercially entrenched advanced therapy, generating roughly USD 870 million in 2025 revenue. A surgically implanted pulse generator delivers continuous stimulation to the S3 sacral nerve root, with battery lives of five to fifteen years. Despite its clinical track record, SNM requires an operating room, carries surgical anxiety as a patient barrier, and faces competitive pressure from newer, office-based alternatives. The 2024 acquisition of Axonics by Boston Scientific converted a two-vendor market into a direct Medtronic–Boston Scientific head-to-head.

ITNM (Implantable Tibial Neuromodulation)
ITNM is the newest entrant in the category, combining the neuromodulation pathway of PTNM with the durability of an implantable device. The first device (Valencia eCoin) was FDA-approved in 2022, followed by BlueWind Revi in 2023, and a 2025-approved next-generation device offering approximately fifteen years of battery life, MRI compatibility, and office-based implantation. The 2024 AUA/SUFU guideline formally recognising ITNM as a third-line option is a significant inflection: guideline endorsement historically accelerates payer coverage and physician training in comparable device categories, and ITNM's office-based footprint aligns directly with the broader site-of-service migration reshaping urology economics.

Table 1.3 — Comparative Profile of Advanced OAB Therapies (U.S., 2025)

Attribute	Botox	PTNM	SNM	ITNM
FDA approval (OAB)	2013	2010	1997	2022 (first device)
Procedure setting	Office / ASC	Office	OR / ASC	Office
Duration of effect	6–12 months	Session-based	5–15 years	~15 years (latest)
Repeat burden	Every 6–12 months	Weekly ×12, then monthly	Battery replacement	Minimal

Attribute	Botox	PTNM	SNM	ITNM
Est. U.S. procedures (2025)	~175,000	~15,000	~40,000	~5,000
Est. U.S. market size (2025)	~USD 460M	~USD 55M	~USD 870M	~USD 25M
Patient burden	Medium	Very high	Medium	Low

Source: Compiled by the researcher from FDA approval records, CMS Medicare claims data, and company-disclosed estimates (2025).

1.4 Problem Statement

The central paradox this dissertation investigates is straightforward to state: OAB affects an estimated 16 to 24 million American adults, four effective advanced therapies exist, the regulatory environment has never been more supportive of device adoption — and yet fewer than 200,000 patients per year actually receive any advanced therapy. That figure represents roughly one percent of the symptomatic population and barely a third of the formally refractory pool. The treatment funnel leaks at every transition:

- **Symptomatic → care-seeking:** roughly three-quarters of symptomatic adults never raise the subject with a clinician, citing normalisation of incontinence as part of ageing, belief that symptoms aren't "bad enough," and the striking perception that the clinician simply never asked.
- **Care-seeking → pharmacotherapy:** many symptomatic patients are directed toward absorbent products or generic lifestyle advice without meaningful clinical escalation.
- **Pharmacotherapy → refractory recognition:** patients frequently cycle through repeat medication trials over several years rather than being formally reclassified as refractory and offered something different.
- **Refractory → advanced therapy:** fewer than 1 percent of patients under the care of general urologists are referred to advanced therapy, compared with around 15 percent under FPMRS-trained specialists.

These leakages are not principally caused by patient ineligibility or therapy unavailability. The driving forces are structural: provider training gaps, referral inertia, site-of-service economics, and uneven reimbursement signalling. The result is a market where clinical demand vastly exceeds clinical conversion, and where the principal lever for closing the gap is better deployment of the science that already exists rather than new science. This dissertation therefore approaches OAB adoption as a healthcare analytics problem — asking where exactly the funnel leaks, who is best positioned to close those leaks, what the realistic five-year opportunity looks like if specific barriers are addressed, and what actions credibly translate analytics into adoption.

1.5 Need for the Study

Four converging developments make this an analytically timely study. The 2024 AUA/SUFU guideline update is the most consequential change to U.S. OAB practice in over a decade, simultaneously elevating ITNM into formal recognition, mandating anticholinergic-risk counselling that will likely accelerate medication dropout, and authorising a menu approach that compresses the time between symptom presentation and device offering. Concurrently, competitive dynamics in the device space have shifted materially — the Axonics acquisition by Boston Scientific, combined with three ITNM market entrants, means the next eighteen to twenty-four months will likely determine durable market-share positions, as early training dynamics produce lasting incumbency advantages. Structurally, approximately 90 percent of OAB procedural volume has now migrated to office-based settings, changing which physicians are commercially relevant and which therapies benefit from workflow alignment. Against this backdrop, the published literature remains thin on integrative healthcare analytics: no publicly available study has simultaneously quantified the multi-stage OAB patient funnel, segmented the physician landscape by adoption propensity, built a four-therapy five-year forecast, and translated the output into stakeholder-specific recommendations. This dissertation is positioned to fill that gap.

1.6 Scope of the Study

The analysis is bounded by the following parameters. Geographically, the scope is the United States, with international markets referenced only where they inform U.S. dynamics. Clinically, the focus is adult idiopathic OAB (both OAB-wet and OAB-dry); neurogenic bladder, paediatric OAB, and secondary OAB are out of scope. Therapeutically, the four FDA-approved advanced therapies are the primary subjects; first- and second-line therapies are covered only to model the funnel transitions feeding the third-line population. Temporally, historical context spans 1997 through 2025, with forward forecasts extending to 2030. The methodology is secondary research only, drawing on CMS Medicare datasets, AUA/SUFU guidelines, PubMed-indexed literature, company filings, and industry trade publications. Excluded from scope are SKU-level pricing strategy, individual physician targeting lists, and proprietary commercial data.

1.7 Research Objectives and Questions

Primary Objective

To assess adoption patterns, market dynamics, and growth opportunities for advanced OAB therapies in the United States through a structured healthcare analytics framework grounded in publicly available secondary data, and to translate the findings into actionable strategic recommendations for the principal stakeholder groups in OAB care delivery.

Research Questions

- **RQ1.** What is the realistic size of the addressable OAB advanced-therapy market in the United States, and how does it distribute across the four therapy modalities?
- **RQ2.** Where are the largest sources of attrition in the OAB treatment funnel, and what is the analytical opportunity at each leakage point?
- **RQ3.** Which provider segments offer the highest near-term adoption leverage, and what does the physician landscape look like at commercial resolution?
- **RQ4.** Under credible regulatory, demographic, and competitive assumptions, what is the 2030 size and composition of the advanced-therapy market?
- **RQ5.** Which adoption drivers and barriers carry the most leverage on the funnel, and what stakeholder-specific actions credibly address them?

Expected Contributions

The study aims to deliver three outputs of value to both academic and applied healthcare strategy audiences: an integrated analytical framework for assessing third-line adoption in a stepped-care pathway (transferable to other refractory-disease device categories); a transparent, reproducible market-sizing model for U.S. OAB advanced therapies under the post-2024-guideline environment; and a stakeholder-segmented strategic playbook translating analytical findings into prioritised, feasibility-weighted recommendations.

Chapter Summary

This chapter has established that OAB is a high-prevalence, high-burden, low-conversion condition served by four mature advanced therapies whose collective penetration into the addressable population remains under one percent. It has framed the central analytical problem — funnel leakage rather than therapeutic inadequacy — and defined the objectives and research questions that guide the remainder of the study. Chapter 2 proceeds to a systematic review of the existing literature, organising the evidence base across ten thematic domains and identifying the specific research gap this dissertation is designed to address.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter reviews the published evidence across ten thematic domains that underpin the analytical framework of the dissertation: OAB epidemiology, clinical guideline evolution, pharmacotherapy persistence, utilisation of each of the four advanced therapies, physician adoption behaviour, patient preference, and healthcare market dynamics. The review serves three purposes — establishing the empirical foundation for the patient funnel model in Chapter 4, consolidating the evidence base for each advanced therapy, and identifying the specific analytical gap this study addresses. Sources include PubMed-indexed peer-reviewed literature, AUA/SUFU clinical guidelines, retrospective claims analyses, systematic reviews, health technology assessments, and industry market reports. A master literature matrix synthesising twenty-eight studies appears in Section 2.12, followed by a synthesised research-gap statement in Section 2.13.

2.2 OAB Prevalence and Epidemiology

The epidemiological literature establishes OAB as one of the most prevalent chronic urological syndromes in adult medicine, with estimates varying by study design, population, and case definition. King et al. (2025) analysed NHANES and NAMCS data to document OAB prevalence reaching 31.2% in women by 2017–2018, rising to 54% in women over 65 — yet only 3.5% of symptomatic women received pharmacotherapy, and anticholinergic prescribing declined at an annual rate of 6.44% over the observation period. Wang et al. (2025), drawing on seven NHANES cycles (2005–2020), found overall female prevalence rising from 18.7% to 22.1% (p-trend $<$ 0.001), most sharply among older women, those with obesity, hypertension, diabetes, and depression. A parallel analysis among men by Zhang et al. (2024) showed prevalence climbing from 11.3% to 14.5% over the same period, with increases concentrated among men aged 40–59.

Taken together, four conclusions anchor the dissertation's analytical work: OAB prevalence is high and rising; it accelerates sharply after age 65; fewer than 4% of symptomatic women receive pharmacotherapy, confirming a persistent undertreatment gap; and the total annual societal cost is estimated at approximately USD 66 billion — making OAB a resource-allocation problem, not merely a clinical one.

2.3 Evolution of OAB Clinical Guidelines

Clinical guidelines define the formal framework within which OAB is diagnosed and managed, and their revisions directly shape how advanced therapies are adopted. The AUA/SUFU guideline has been updated in 2012, 2014, 2019, and most significantly in 2024. Cameron et al. (2024) led the 2024 revision, grounded in a systematic review of 159 studies, producing thirty-three recommendation statements. Three changes in the 2024 update carry particular commercial and strategic significance for this dissertation.

First, the guideline replaces its earlier stepwise treatment hierarchy with a personalised “menu” approach that recognises different therapies may suit different patients based on side-effect tolerance, adherence capacity, and insurance coverage. Second, it formally recognises implantable tibial neuromodulation (ITNM) as a minimally invasive third-line option — conferring the guideline legitimacy that has historically accelerated payer coverage and physician training in comparable device categories. Third, it mandates counselling on the dementia and cognitive-impairment risk associated with anticholinergic medications, a requirement likely to accelerate medication dropout and expand the refractory pool. The guideline also permits clinicians to offer minimally invasive therapy directly to patients unwilling or unable to attempt pharmacotherapy, compressing the traditional treatment pathway in ways that are likely to pull forward the timing of device adoption.

2.4 Pharmacotherapy Persistence and Dropout

Pharmacotherapy is the largest treatment tier by patient count, yet persistence is strikingly poor. A systematic review by Sexton et al. (2011) found twelve-month persistence ranging from just 4.3% to 7.6% across anticholinergic agents — far below persistence rates in most other chronic conditions. More recent data from Wada et al. (2026) on beta-3 agonists show some improvement: median persistence was eleven months for mirabegron and was not reached for vibegron during the observation period, though over 40% of mirabegron users switched to vibegron within the study window. Recurring drivers of non-persistence include anticholinergic side effects (dry mouth, constipation, cognitive blunting), limited symptom relief, tachyphylaxis, and growing patient awareness of dementia-related risk in older adults.

The practical implication is that a substantial cohort of patients initiates OAB medication and discontinues within six to twelve months, forming the refractory pool that advanced therapies are designed to serve. The 2024 guideline's mandatory anticholinergic counselling requirement will likely accelerate this exit, directly enlarging the advanced-therapy-eligible population — a dynamic built explicitly into the funnel model developed in Chapter 4.

2.5 Botulinum Toxin (Botox): Utilisation and Evidence

FDA-approved for idiopathic OAB in 2013, Botox is currently the most widely utilised advanced therapy by patient count. Real-world evidence from Sacco et al. (2026) confirms robust efficacy and an acceptable safety profile, though sustained benefit requires repeat administration at six to twelve month intervals. The most detailed utilisation study comes from Chughtai et al. (2024), who analysed 2,505 newly initiating patients from Optum claims data (2009–2021). The results are striking: 78.6% of patients discontinued treatment, and 84% of discontinuers received two or fewer injections. Of those who discontinued, only 3–7% subsequently initiated sacral neuromodulation, and no patients in the cohort transitioned to PTNM. This profound post-Botox funnel leakage — most discontinuers simply exit treatment altogether — is one of the highest-leverage findings in the literature from the perspective of advanced-therapy market development.

On safety, a meta-analysis found urinary tract infection incidence of 22.7% at the 100-unit dose versus 9.4% with placebo. Despite these limitations, a global physician survey found Botox the most favoured third-line option among responding physicians.

2.6 Sacral Neuromodulation (SNM): Evidence and Competitive Position

SNM has been FDA-approved since 1997 and carries the deepest evidence base of any advanced OAB therapy. A systematic review by Elbaset et al. (2025) confirms both safety and efficacy for idiopathic OAB. Long-term outcomes are strong: in male OAB patients, 84% reported satisfaction and 92% reported symptom improvement at one year, with 73% maintaining benefit beyond one year. SNM also remains the largest revenue segment of the advanced-therapy market, at approximately USD 870 million in 2025.

The most strategically relevant finding for this dissertation is the indirect comparison of SNM and ITNM by Amundsen et al. (2025), who pooled twenty single-arm studies covering 1,416 SNM and 350 ITNM patients. Urgency urinary incontinence responder rates were nearly identical (71.8% SNM versus 71.3% ITNM), as were OAB responder rates (73.9% versus 79.4%) and device-related adverse events. The authors caution that no head-to-head or placebo-controlled trials exist — the comparison rests entirely on single-arm data — but the apparent clinical equivalence is significant: it removes efficacy as a differentiator and shifts the competitive conversation to procedure setting, patient burden, and physician workflow.

2.7 Percutaneous Tibial Neuromodulation (PTNM)

PTNM is a guideline-recommended minimally invasive therapy that delivers afferent stimulation to sacral nerve roots via a needle electrode placed near the ankle. Khavari et al. (2024) confirm its guideline status while noting that patient compliance is substantially constrained by the protocol's weekly in-office visit requirement over a twelve-week induction period, followed by monthly maintenance. Claims data confirm that the majority of PTNM patients are noncompliant with the recommended regimen, and that noncompliant patients pursue alternative third-line therapy more frequently than compliant ones — suggesting that PTNM dropout functions not as a dead end but as a transition point toward other advanced therapies. This behavioural pattern is analytically important: it implies that PTNM non-adherence, rather than being a loss from the market, may actually be a channel feeding ITNM and SNM adoption.

2.8 Implantable Tibial Neuromodulation (ITNM): Emerging Evidence

ITNM is the newest category in the OAB device landscape, aiming to retain the validated neuromodulation mechanism of PTNM while eliminating the weekly visit burden that has historically capped its adoption. A comprehensive review by Lee et al. (2025) examined seven implantable PTNS devices, finding substantial variation in clinical efficacy, power source, implantation method, and regulatory status, while noting significant gaps in long-term outcome and real-world adherence data. The Amundsen et al. (2025) meta-analysis discussed above remains the most robust comparative evidence available for ITNM versus SNM.

Health Technology Wales (2025) issued guidance concluding that ITNM devices show promise for urgency urinary incontinence and OAB but that the available evidence remains insufficient for routine adoption — a characteristically cautious early-stage regulatory posture. The strategic significance of ITNM lies in the convergence of three factors: its 2024 AUA/SUFU guideline recognition, its office-based implantation workflow, and a trajectory of rapid evidence accumulation. Together, these factors create the market entry window that Chapter 7 quantifies.

2.9 Physician Adoption Behaviour

Understanding how physicians respond to new medical technologies is essential for predicting ITNM uptake and designing effective commercialisation strategies. Sørensen et al. (2026) identified an adoption paradox: clinicians consistently request high-quality randomised controlled trial evidence before adopting a device, yet frequently rely on personal experience or peer influence even when such evidence exists. This finding points to the limits of evidence-based arguments alone and highlights the practical importance of hands-on training programs and key-opinion-leader networks. Rogers' Diffusion of Innovations framework adds structural nuance: physicians in group practices adopt innovations faster than those in solo practice, and teaching hospital affiliation meaningfully shapes training opportunities and, in turn, adoption propensity. Evidence from TAVR adoption confirms that training received during clinical trials significantly increased subsequent adoption intensity — a pattern with direct implications for ITNM commercialisation over the next eighteen to twenty-four months.

The most operationally important finding in the physician adoption literature, for the purposes of this dissertation, is the specialty-level referral disparity quantified in internship project data: FPMRS-trained specialists refer patients to advanced therapy at approximately fifteen times the rate of untrained general urologists. This disparity is not addressed in the published literature at commercial resolution and forms the foundation of the physician-segmentation analysis in Chapter 6.

2.10 Patient Preference Studies

OAB is widely recognised as a preference-sensitive condition, and patient preference evidence is therefore analytically material to predicting therapy adoption. A discrete choice experiment found that drug-delivery method, reduction in daytime voiding frequency, and out-of-pocket cost ranked as the most influential treatment attributes, while invasiveness, efficacy, and safety also featured prominently. A complementary systematic review found patients ideally want a medication that is affordable, cognitively safe, and effective against daytime frequency and incontinence episodes.

Among medication-refractory patients, a market simulation found SNM the preferred third-line option (47%), followed by PTNS (29%) and Botox (14%), with only 10% finding no option acceptable. These preferences reveal meaningful headroom for a therapy — such as ITNM — capable of combining implantable durability with reduced invasiveness. The literature also consistently endorses shared decision-making in OAB management; as preference-elicitation tools become more common in clinical practice, the framing and communication of ITNM's office-based, low-burden profile will become an increasingly important adoption lever.

2.11 Healthcare Utilisation and Market Dynamics

Claims-based analyses consistently show that real-world OAB treatment patterns diverge from guideline recommendations — a finding that aligns with the adoption-paradox literature and reinforces the case for targeted physician engagement rather than guideline dissemination alone. An analysis of 428,142 patients with OAB anticholinergic claims found that higher anticholinergic burden was directly associated with greater total healthcare cost, cognitive impairment, and falls and fractures — a finding that strengthens the economic rationale for transitioning refractory patients to advanced therapy, since downstream cost avoidance may partially offset the higher upfront procedural cost.

A study of 6,786 patients found that socioeconomic disadvantage was associated with greater anticholinergic use, lower beta-3 agonist use, and notably lower SNM utilisation among Black patients — access disparities with implications for both clinical equity and commercial market-access strategy. At the market level, available estimates place the global OAB treatment market at approximately USD 3.87 to 4.39 billion in 2025, projected to reach USD 4.58 to 5.88 billion by 2030 at a CAGR of 3.4 to 5.4%. Segment-level estimates from internship project data break this down as: SNM approximately USD 870 million, Botox approximately USD 460 million, PTNM approximately USD 55 million, and ITNM approximately USD 25 million in 2025 — with ITNM projected to grow at a CAGR of 50 to 70%, far outpacing every other segment.

2.12 Master Literature Matrix

Table 2.1 synthesises the twenty-eight studies reviewed in this chapter, organised by author and year, key findings, and the research gap each identifies.

Table 2.1 — Master Literature Matrix: Evidence on OAB Advanced Therapy Adoption (28 Studies)

#	Author(s) & Year	Key Findings	Research Gap Identified
1	King et al. (2025)	OAB prevalence 31.2% (women, 2017–18); 54% in women >65; only 3.5% received pharmacotherapy; anticholinergic Rx declined 6.44%/yr	Does not examine advanced therapy utilisation
2	Wang et al. (2025)	Female prevalence rose 18.7% → 22.1% (2005–2020; p<0.001); driven by age, obesity, comorbidities	Does not link trends to treatment receipt
3	Zhang et al. (2024)	Male prevalence rose 11.3% → 14.5%; concentrated in men 40–59, Black/White race groups	No gender-specific treatment analysis
4	Cameron et al. / AUA/SUFU (2024)	33 guideline statements; stepwise → menu approach; ITNM recognised as third-line; anticholinergic dementia counselling mandated	Does not model downstream adoption impact
5	Sexton et al. (2011)	12-month pharmacotherapy persistence 4.3–7.6%; markedly worse than other chronic conditions	Outdated; excludes beta-3 agonist evidence
6	Wada et al. (2026)	Median mirabegron persistence 11 months; vibegron persistence not reached; 40.7% of mirabegron users switched	Single-centre Japan cohort; limited U.S. generalisability
7	Chughtai et al. (2024)	78.6% of Botox patients discontinued; 84% of discontinuers received ≤2 injections; only 3–7% transitioned to SNM	Does not capture reasons for discontinuation
8	Sacco et al. (2026)	Intravesical BoNT-A: robust efficacy, acceptable safety; sustained benefit requires repeat injection	Single-centre; no comparator arm
9	Amundsen et al. (2025)	SNM vs ITNM: comparable UUI responder rates (71.8% vs 71.3%); similar AE profiles; no head-to-head trials	Single-arm data only; no placebo control
10	Elbaset et al. (2025)	SNM safe and effective for OAB; symptom and quality-of-life improvement confirmed in systematic review	Does not benchmark SNM against other third-line therapies
11	Khavari et al. (2024)	PTNS guideline-recommended; compliance limited by weekly visits and maintenance burden	Does not quantify compliance or dropout rates
12	Lee et al. (2025)	Seven implantable PTNS devices reviewed; variation in efficacy, design, regulatory status; long-term evidence gaps	No head-to-head device comparisons
13	Sørensen et al. (2026)	Adoption paradox: clinicians request RCT evidence but rely on personal experience; peer influence underestimated	Does not quantify adoption determinants

#	Author(s) & Year	Key Findings	Research Gap Identified
14	Rogers (Diffusion of Innovations)	Group practices adopt faster; hospital size and teaching status shape adoption	Not device-specific or OAB-specific
15	Patient DCE study (2018)	Delivery method, daytime voiding frequency, and out-of-pocket cost most valued; invasiveness and safety also cited	Excludes device-therapy attributes
16	Health Technology Wales (2025)	ITNM shows promise but evidence insufficient for routine adoption recommendation	Early-stage; narrow evidence base
17	Optum claims study (2024)	Real-world OAB utilisation diverges consistently from guideline recommendations	Does not quantify magnitude or causes of divergence
18	Anticholinergic burden study (2024)	Higher anticholinergic burden linked to greater total cost, cognitive impairment, falls and fractures (n=428,142)	Does not model cost offset of advanced therapies
19	Disparities study (2026)	Higher socioeconomic disadvantage → greater anticholinergic use, lower SNM rates; Black patients underserved (n=6,786)	Does not examine ITNM-specific disparities
20	Market reports (2024–25)	Global OAB market USD 3.87–4.39B (2025); projected USD 4.58–5.88B by 2030 at 3.4–5.4% CAGR	Does not disaggregate advanced-therapy segments
21	PTNM adherence study (2024)	Majority of PTNM patients noncompliant; noncompliant patients more often pursue alternative third-line therapy	Does not examine underlying causes of noncompliance
22	Male SNM outcomes study	84% satisfaction, 92% symptom improvement at 1 year; 73% persistence beyond 1 year	Limited male-specific evidence base
23	OAB-q burden studies	Quality-of-life decrement comparable to diabetes, COPD, and stroke; driven by unpredictability	Does not assess therapy-specific quality-of-life gains
24	NHANES OAB trends (2025)	Rising prevalence and persistent undertreatment confirmed across combined NHANES/NAMCS analysis	Does not extend to advanced-therapy trends
25	Global physician survey (2025)	Botox most favoured third-line (46.2%); SNM second (29.9%); Botox most common initial choice	Excludes ITNM; limited U.S.-specific data
26	Botox UTI meta-analysis (2025)	UTI incidence 22.7% (100U) vs 9.4% placebo (RR 2.53); dose-dependent trend observed	Does not assess UTI impact on therapy persistence
27	ICER/HTA reports	Mixed findings overall; advanced therapies generally cost-effective in refractory patients	Evidence base evolves rapidly with new therapies
28	FPMRS referral patterns (2026)	FPMRS specialists refer at ~15× rate of general urologists; >7,000 urologists untrained in advanced therapy	Published literature does not quantify this disparity

Source: Author's synthesis of peer-reviewed literature, guideline publications, claims analyses, and market reports (2011–2026).

2.13 Research Gap and Dissertation Positioning

The evidence reviewed in this chapter is substantial in several respects — OAB prevalence is well characterised, guideline evolution is documented, and therapy-specific efficacy data for Botox, SNM, and PTNM are mature. Yet five specific gaps emerge that this dissertation is positioned to address.

- **Integrated funnel quantification.** Individual studies quantify prevalence, pharmacotherapy utilisation, or individual therapy outcomes in isolation. No study has constructed a complete patient funnel — from symptomatic population through to advanced-therapy receipt — using consistent assumptions. Chapter 4 addresses this through an eight-step analytical framework.

- **Physician segmentation at commercial resolution.** The literature confirms that physician specialty influences referral behaviour, but stops short of the granular segmentation by training status, procedure mix, and adoption propensity that commercial decision-making requires. Chapter 6 fills this gap.
- **ITNM-specific market forecasting.** No publicly available source provides a segment-level forecast for ITNM under the post-2024 guideline environment. Chapter 7 provides this forecast across base, optimistic, and conservative scenarios.
- **Integration of adoption drivers and barriers.** The literature identifies individual adoption levers — training, reimbursement, compliance — but does not synthesise them into a framework suitable for strategic prioritisation. Chapter 8 provides this synthesis.
- **Post-2024 guideline modelling.** The 2024 AUA/SUFU guideline is too recent for its downstream implications to have been systematically modelled. This dissertation incorporates those changes explicitly throughout its analytical architecture, distinguishing it from prior work anchored to earlier guideline iterations.

Together, these five gaps confirm a genuine and previously unaddressed analytical need: an integrated healthcare-analytics framework capable of simultaneously quantifying funnel leakage, segmenting the physician landscape, forecasting market evolution, and producing stakeholder-specific recommendations within the post-2024 OAB guideline environment. The framework this dissertation constructs to fill that need is described in Chapter 3.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter lays out how the research behind this dissertation was actually carried out. The study relies on secondary, quantitative-descriptive analysis with a comparative element built in, and it moves through eight connected analytical steps — starting with how many people in the U.S. have OAB and ending with what device manufacturers, providers, and payers should do about it. Rather than walking through every methodological choice in isolation, this chapter groups related decisions together: why a secondary design made sense, what data the study leans on, how the eight-step framework fits together, what assumptions sit underneath the numbers, and where the analysis is necessarily limited.

3.2 Research Design and Philosophy

The study sits within a pragmatic research tradition. Pragmatism fits applied healthcare analytics reasonably well because the goal here was never to prove a universal causal law, nor to dig into the subjective meaning patients attach to their symptoms — it was to produce findings a healthcare strategist could actually use. That orientation let the analysis mix claims data, guideline interpretation, and market comparison within one framework instead of locking into a single method.

Three things define the design in practice. It is secondary — no patients, physicians, or payers were surveyed directly; instead, existing CMS datasets, clinical guidelines, peer-reviewed studies, and market reports were synthesised. It is quantitative-descriptive — the bulk of the work involves counting populations, sizing therapy volumes, and tracking provider distributions, with percentages, ratios, and growth rates as the main output. And it is comparative — the four advanced therapies (Botox, PTNM, SNM, ITNM) are assessed side by side across nine dimensions, as are physician segments by training and adoption behaviour.

The reasoning is largely deductive: the analysis starts from the established stepped-care OAB pathway and uses it to size each stage of the patient funnel, then checks observed adoption against what the guideline would predict if every eligible patient were actually referred. Where the work looks forward — the 2030 forecast in Chapter 7 — it turns predictive, relying on scenario assumptions rather than a single fixed number.

A secondary design was the right call for three reasons. The dissertation's core question — how many patients, how much market, where the opportunity sits — is inherently a “how many/how much” question, which secondary data answers more directly than interviews would. CMS data, peer-reviewed prevalence studies, and market reports, taken together, are reliable and auditable enough to triangulate a solid estimate. And, practically, an MBA dissertation has a fixed clock running, and primary data collection from patients or physicians would have added ethical review and recruitment timelines this project could not absorb.

In character, the study is best described as applied business research rather than theory-testing. It describes the current state of OAB adoption, but it is also exploratory where ITNM is concerned, since that category is too new to have an established body of theory yet. Throughout, the work leans toward decision-usefulness over methodological purity — which is, frankly, the right trade-off for a dissertation meant to inform commercial and clinical strategy rather than to settle an academic debate.

3.3 Data Sources

Five categories of data feed the analysis. CMS Medicare files — chiefly the Physician/Supplier Procedure Summary Public Use File, the Medicare Provider Utilization and Payment Data file, and Part D prescription data — anchor the claims-based work. AUA and SUFU clinical guidelines, particularly the 2024 update, define the treatment pathway and third-line eligibility criteria. Peer-reviewed literature, including the twenty-eight studies reviewed in Chapter 2, supplies prevalence and efficacy evidence. Commercial market reports (Grand View Research, Future Market Insights, Global Market Insights), company filings, and trade publications such as Urology Times round out market sizing and competitive context. Finally, public databases — the U.S. Census Bureau, NHANES, AHRQ, and the FDA — contribute demographic and regulatory data.

Table 3.1 — Data Sources and Their Application

Data Source	Used For	Applied In
CMS PSPS Public Use File	Procedure volumes by CPT code; site-of-service mix	Ch. 6
CMS Part D	Pharmacotherapy utilisation and persistence	Ch. 4
AUA/SUFU Guideline (2024)	Pathway definition; eligibility criteria	Ch. 1, 4, 5
NHANES	OAB prevalence and demographic trends	Ch. 2, 4
Peer-reviewed literature	Prevalence, efficacy, patient preference	Ch. 2
Market research reports	Market sizing and growth forecasts	Ch. 7
Company filings	Therapy-specific revenue; positioning	Ch. 5, 7
U.S. Census Bureau	Population and ageing projections	Ch. 7

Data Source	Used For	Applied In
FDA device records	Approval timelines; device specs	Ch. 1, 5

Source: Compiled by the researcher.

Going secondary made sense given the scale of what the study set out to characterise — a national patient funnel, a national physician landscape, and a five-year market forecast. The process itself ran in four stages: a structured PubMed search (documented fully in Chapter 2); extraction of CMS procedure-level data using the code dictionary in Section 3.6; review and cross-checking of commercial market reports against one another; and a final triangulation pass in which every figure used in the dissertation was checked against at least one independent source where possible. This let the study cover ground a primary survey simply could not have reached within an MBA timeline, while still resting on data — CMS claims in particular — that is arguably more consistent and auditable than most primary surveys would be at this scale.

3.4 The Eight-Step Research Framework

The analytical spine of the dissertation is an eight-step framework, each step feeding the next: from the symptomatic population at the very top of the funnel down to the stakeholder recommendations at the end.

Table 3.2 — The Eight-Step Analytical Framework

Step	Focus	Output	Chapter
1	OAB population estimation	Total symptomatic population (2025)	4
2	Care-seeking analysis	Care-seeking population	4
3	Pharmacotherapy utilisation	Treated population; persistence curve	4
4	Refractory patient estimation	Refractory population	4
5	Advanced therapy eligibility	Procedure volumes; penetration rate	4
6	Physician landscape assessment	Segmented provider landscape	6
7	Market opportunity assessment	Current size; five-year forecast	7
8	Strategic recommendations	Stakeholder roadmap	9

3.5 Patient Funnel and Physician Analytics Methodology

Steps 1 through 5 build the patient funnel that anchors Chapter 4. Total population is estimated by applying age- and sex-stratified prevalence rates from the literature reviewed in Chapter 2 to U.S. Census adult population figures, yielding a point estimate within the plausible 16–24 million range. Care-seeking population follows from applying a 25–30 percent care-seeking rate drawn from the literature, landing at roughly 5 million. Pharmacotherapy population draws on CMS Part D claims and published utilisation rates, at an estimated 1.0–1.2 million treated patients, with persistence curves built from published twelve- and twenty-four-month dropout rates. Refractory population applies a 50–60 percent refractory rate — patients who have failed behavioural therapy and at least one, usually two, medication classes — to the pharmacotherapy figure, giving an estimated 500,000–600,000 refractory patients at any time. Advanced-therapy eligibility and utilisation then applies CMS claims, market reports, and company disclosures to estimate how many of those refractory patients actually receive Botox, PTNM, SNM, or ITNM, and the resulting gap is the addressable opportunity quantified in Chapter 4.

Step 6 segments the physician landscape for Chapter 6, using AMA Physician Masterfile data, CMS PSPS data, and published workforce estimates to classify providers into five groups — FPMRS-trained specialists, high-volume general urologists, general community urologists, cystoscopy-capable OBGYNs, and primary care providers — and to estimate, for each, physician count, training status, procedure mix, advanced-therapy volume, and site-of-service distribution.

3.6 CMS Medicare Data Methodology

Because CMS data carries so much of the claims-based analysis, it gets its own treatment here. All extraction runs against a fixed dictionary of ICD-10 diagnosis codes and CPT procedure codes, shown in Table 3.3.

Table 3.3 — ICD-10 and CPT Code Dictionary

Code	Description	Used For
N32.81 (ICD-10)	Overactive bladder	Identifying OAB patients
N39.41 (ICD-10)	Urge urinary incontinence	Identifying UUI patients
N39.46 (ICD-10)	Mixed incontinence	Identifying mixed-incontinence patients
52287 (CPT)	Cystoscopy with botulinum toxin injection	Botox volume
64561 (CPT)	Percutaneous tibial nerve stimulation	PTNM volume
64566 (CPT)	Sacral neuromodulation trial lead	SNM trial volume
64581 / 64590 (CPT)	Sacral neuromodulation implant	SNM implant volume
0816T / 0817T (CPT)	Implantable tibial neuromodulation	ITNM volume

Source: Compiled by the researcher from CMS and CPT documentation.

The PSPS file is queried by CPT code, provider identifier, and place of service to produce annual procedure volumes for each therapy, split by site of service. The Provider Utilization file attributes that volume to individual providers and, in aggregate, to the five physician segments above. Part D claims support the pharmacotherapy estimates in Section 3.5. Since CMS data only covers the

Medicare population, Medicare-derived ratios are checked against market reports and company disclosures to infer total-market volume — an adjustment with limitations discussed in Section 3.8.

3.7 Market Sizing, Forecasting, and Analytical Tools

Step 7 sizes the current (2025) market for each therapy segment by combining the procedure volumes from Section 3.6 with revenue figures from company disclosures and market reports, then projects forward to 2030 under base-case, best-case, and worst-case scenarios rather than a single point forecast — a sensible hedge given how new ITNM still is. The scenarios differ mainly on four assumptions: population growth of roughly 0.5–0.7 percent annually per Census projections; the 2024 guideline accelerating ITNM adoption from 2025, reaching full effect by 2027; ITNM reimbursement coverage expanding from around 40 percent in 2025 to over 65 percent by 2027; and three ITNM competitors racing for the same limited pool of trainable physicians, with early movers retaining a durable share advantage. The base case assumes no major regulatory shock or safety event; the best- and worst-case scenarios relax that assumption in either direction.

Step 8 — strategic recommendations — takes the Step 7 output and turns it into a stakeholder-mapped, impact-and-feasibility-scored, three-phase roadmap, presented in Chapter 9. Throughout, the main analytical tool is Excel, used for the funnel model, the nine-dimension comparative matrix in Chapter 5, the scenario forecasts, and the supporting charts and tables. The driver-barrier analysis in Chapter 8 borrows Lewin's force-field framework, scoring driving and restraining forces by stakeholder dimension.

3.8 Assumptions, Scope, and Limitations

Every major figure in this dissertation rests on an explicit, stated assumption rather than an implicit one — a deliberate choice, since a reader who disagrees with an assumption should be able to substitute their own and see how the conclusion shifts.

Table 3.4 — Key Assumptions

Assumption	Value Used	Sensitivity
OAB prevalence	16–24 million U.S. adults	High — drives every downstream figure
Care-seeking rate	25–30% of symptomatic patients	Moderate
Pharmacotherapy population	1.0–1.2 million patients	Moderate
Refractory rate	50–60% of pharmacotherapy patients	High — sets the addressable market

Assumption	Value Used	Sensitivity
Advanced therapy penetration	<1% of symptomatic; ~30% of refractory	High — the core opportunity gap
Population growth (forecast)	0.5–0.7% annually	Low
ITNM reimbursement (2027)	>65% coverage	Moderate

Source: Compiled by the researcher.

A handful of simplifying choices also shape the analysis: neurogenic bladder is excluded, as the focus stays on idiopathic OAB; advanced-therapy figures count new patients rather than separately tracking repeat patients; OAB-wet and OAB-dry presentations are combined except where noted; and substitution effects between therapies are addressed only through the comparative profiling in Chapter 5, not modelled explicitly.

On scope: the study is confined to the United States, runs from a 2025 base year to a 2030 forecast horizon, and covers idiopathic OAB in adults across the four advanced therapies. It deliberately stops short of patient-level outcome modelling, payer contract-level analysis, and primary market research — worthwhile directions, but beyond what a secondary-data MBA dissertation can responsibly attempt, and flagged as future-research opportunities in Chapter 9.

The limitations follow from that same scope. CMS data cannot distinguish new from repeat Botox patients, which leaves some imprecision in Botox utilisation figures specifically. Published prevalence estimates vary enough by methodology that the 16–24 million range itself carries real uncertainty rather than resolving it. Private-payer behaviour is inferred from Medicare ratios rather than observed directly, so to the extent younger, commercially insured patients behave differently, the estimates may understate or overstate true volume. Market reports use inconsistent methodologies across vendors, which is why the study triangulates across several rather than leaning on one. Methodologically, the funnel is modelled at a single point in time rather than tracked longitudinally, the 2030 forecast could still diverge from all three modelled scenarios if something genuinely unexpected happens, and the physician analysis works from national averages without capturing regional variation directly. Four mitigations run throughout to manage this: triangulating sources, stating assumptions explicitly, modelling three scenarios instead of one, and flagging caveats wherever a finding is interpreted.

3.9 Ethical Considerations

Because the study draws entirely on publicly available secondary data, no human subjects were involved and Institutional Review Board approval was not required. That said, the usual standards of research integrity still applied throughout: sources are cited completely, nothing is fabricated or selectively reported, and assumptions and limitations are disclosed rather than glossed over. The analysis was conducted without favouring any particular manufacturer or therapy. CMS data used here comes only as de-identified, aggregated Public Use Files, so no patient or physician is individually identifiable at any point. Internship-derived data referenced earlier in the dissertation was supplied already anonymised, with client names and proprietary detail removed before use, and nothing presented here discloses confidential information beyond what is already public.

3.10 Chapter Conclusion

In short, this dissertation runs on a secondary, quantitative-descriptive design with a comparative layer, built on a pragmatic research philosophy and five categories of data — CMS claims, clinical guidelines, peer-reviewed literature, market reports, and public databases. Its eight-step framework carries the analysis from population estimation through physician segmentation and market forecasting to a final set of stakeholder recommendations, with assumptions stated openly, estimates triangulated wherever feasible, uncertainty handled through scenarios rather than a single number, and every finding aimed squarely at practical, stakeholder-relevant use. Chapter 4 now puts the funnel methodology described in Section 3.5 to work, quantifying the OAB patient funnel in full and identifying exactly where the largest leakage occurs.

CHAPTER 4: OAB MARKET OPPORTUNITY ASSESSMENT

4.1 Introduction

This chapter works through the first five steps of the framework set out in Chapter 3, building a patient funnel that tracks the U.S. OAB population from total symptomatic adults down to the smaller group who actually end up on advanced therapy. Everything in the chapters that follow rests on this funnel — it defines the addressable market, points to exactly where patients fall out of the pathway, and supplies the volume figures used in the Chapter 7 forecast. Five stages make up the funnel: total symptomatic population, care-seeking patients, those on pharmacotherapy, the refractory group, and finally patients receiving Botox, PTNM, SNM, or ITNM. Each stage below states its assumptions, shows the calculation, and works through what the number actually means before moving on.

4.2 OAB Population and Epidemiology

OAB, as used throughout this dissertation, follows the International Continence Society definition: urgency, usually with increased daytime frequency and nocturia, with or without incontinence, and without an infection or other explanation. Even on conservative estimates the condition sits among the most prevalent chronic conditions in adult medicine — a symptomatic population of 16 to 24 million U.S. adults, roughly comparable in scale to diabetes. What sets OAB apart is the size of its treatment gap: most symptomatic adults never get evaluated, and only a sliver eventually reach device-based therapy. That combination of high prevalence and heavy undertreatment is really what makes this market worth studying — the opportunity isn't a shortage of available therapy, it's attrition earlier in the journey.

Three epidemiological sources anchor the population figures used here: NHANES, which puts broad-definition prevalence at around 18.6 percent of U.S. adults; the OAB-POLL survey, which found 17 percent prevalence in men and 30 percent in women under a “sometimes or more often” case definition; and the EpiLUTS study, which breaks prevalence down by age, sex, and ethnicity. Reconciling these broader estimates against the narrower, more clinically meaningful figure used in this dissertation's internship data produces the working range of 16 to 24 million used throughout — likely, if anything, an understatement, since many people with OAB don't recognise it as a condition worth reporting. Prevalence is also markedly higher in women (roughly 1.4 to 1.6 times the male rate) and climbs steeply with age, exceeding 30 percent past 65 and approaching 40 percent in women over 75. With the 65-plus population projected to grow from about 58 million in 2025 to over 70 million by 2030, the absolute OAB patient count will keep rising even if prevalence rates themselves stay flat — a structural tailwind that feeds directly into the Chapter 7 forecast.

4.3 The Patient Journey and the "Endless First-Line Loop"

Behind the funnel's hard numbers sits a more human story about how patients actually move — or don't move — through care. For most symptomatic adults, the journey ends before it starts: symptoms get written off as a normal part of ageing or judged not serious enough to mention to a doctor. Among the minority who do seek care, the typical path runs through behavioural therapy, then one pharmacotherapy trial after another, each lasting weeks to months and each carrying a real chance of being abandoned over side effects or simply not working. Rather than escalating promptly once medication fails, many patients instead cycle through repeated drug trials for an extended stretch — a pattern this dissertation calls the "endless first-line loop." One study tracking progression from second- to third-line therapy found a median wait of 15.4 months (interquartile range 5.9–32.4), meaning a meaningful share of refractory patients go well over a year, sometimes much longer, before anyone offers them a device-based option.

Two things follow from this. First, the sheer length of the journey is itself a source of attrition — some patients simply give up out of frustration before ever reaching refractory status, a dynamic the cross-sectional funnel below can't fully capture. Second, and more importantly, the barriers separating refractory status from advanced-therapy receipt look mostly behavioural and systemic — clinical inertia, limited physician awareness, patient reluctance to push for more — rather than any real shortage of validated treatment options. That distinction drives the leakage diagnostics in Section 4.6.

4.4 The Five-Stage Patient Funnel

Table 4.1 lays out the funnel end to end — the five stages, the estimated population at each, and how much is lost moving from one stage to the next.

Table 4.1 — The OAB Patient Funnel: Population and Attrition by Stage

Stage	Population	% of Symptomatic Pool	Attrition to Next Stage
Total symptomatic OAB	16M – 24M (working: 20M)	100%	75% lost (→ care-seeking)
Care-seeking	~5.0M	~25–30%	78% lost (→ pharmacotherapy)
Pharmacotherapy	1.0M – 1.2M	~6%	50% lost (→ refractory)
Refractory	500K – 600K	~3%	66% lost (→ advanced therapy)

Stage	Population	% of Symptomatic Pool	Attrition to Next Stage
Advanced therapy recipients	~180K – 185K	~0.9–1%	—

Source: Author's synthesis of NHANES, CMS claims data, peer-reviewed literature, and internship project data.

The overall shape is stark: out of 16 to 24 million symptomatic adults, fewer than 200,000 receive advanced therapy in a given year — about one percent of the symptomatic pool and roughly a third of the refractory pool. Everyone else, somewhere between 15 and 23 million people, gets no advanced therapy, and most get no formal treatment at all. The next few paragraphs walk through how each of the five numbers was actually built.

Total symptomatic population (Stage 1) is the denominator everything else is measured against. Applying the broad 18.6 percent NHANES prevalence rate to roughly 260 million U.S. adults gives a base figure above 40 million, but that case definition sweeps in a lot of mild, arguably insignificant cases. Narrowing to a more conservative 16 percent rate and a broader 28.7 percent rate brackets a defensible range, and reconciling that against the internship project's independent estimate lands on the 16–24 million figure (midpoint ~20 million) used throughout this dissertation. Care-seeking population (Stage 2) applies a 25–30 percent care-seeking rate — drawn from a literature base in which more than 80 percent of affected women reportedly never seek treatment — to that 20 million base, giving a working estimate near 5 million (range 4.0–7.2 million). Three patient-reported reasons explain most of the gap: 75 percent say symptoms aren't "bad enough," 55 percent say their provider never raised the topic, and 53 percent believe incontinence is just part of getting older. Pharmacotherapy population (Stage 3) applies a 20–24 percent treatment rate to the care-seeking figure, landing at 1.0–1.2 million, consistent with a Medicare Part D study finding 15.8 percent of OAB patients on oral therapy and the internship data's independent 1.0–1.2 million estimate. Persistence on these medications is genuinely poor — roughly 40–50 percent at six months, falling to under 15 percent by twenty-four months — driven by side effects, limited efficacy, and, increasingly, the dementia-risk counselling the 2024 AUA/SUFU guideline now requires for anticholinergics. Refractory population (Stage 4) applies a 50–60 percent refractory rate — patients who've failed behavioural therapy and at least one, usually two, medication classes — to the pharmacotherapy figure, giving 500,000–600,000 patients, which lines up with the internship data's independent estimate. Advanced therapy recipients (Stage 5) is built from CMS claims, market reports, and company disclosures across all four therapies, landing at roughly 180,000–185,000 patients — about 34 percent of the refractory pool and under 1 percent of the symptomatic population.

4.5 Market Size and Therapy-Specific Volumes

Breaking Stage 5 down by therapy shows a market that doesn't behave uniformly across the four options.

Table 4.2 — Advanced Therapy Procedure Volumes and Market Size (2025)

Therapy	Estimated Annual Procedures	Market Size (USD)
Botox	~100,000 new + ~75,000 repeat	~$460M
SNM	~45,000	~$870M
PTNM	~35,000	~$55M
ITNM	~5,000	~$25M
Total	~185,000	~$1.41B

Source: Internship project data and author's synthesis.

Botox leads on volume thanks to its low procedural barrier and office-based delivery; SNM leads on revenue despite fewer procedures, reflecting its higher per-case cost and surgical infrastructure; PTNM's growth has flattened under its compliance burden; and ITNM, though still the smallest segment, is the one projected to grow fastest — a 50 to 70 percent CAGR through 2030. Framed two ways, the current market is both the realised opportunity (185,000 patients, $1.41 billion) and the unrealised one: roughly 365,000 refractory patients each year who get no advanced therapy at all. That second figure is really the heart of this dissertation's market argument — closing even part of that gap doesn't require a new therapy or more clinical evidence, just better identification, referral, and follow-through on therapies that already exist and are already reimbursed.

4.6 Funnel Leakage Diagnostics

Three transitions account for almost all of the funnel's loss. The biggest by far is symptomatic-to-care-seeking: about 15 million adults, a 75 percent loss, never raise their symptoms with a clinician at all — driven by patient belief and the absence of proactive screening, not by any clinical barrier. Second is the refractory-to-advanced-therapy transition: roughly 365,000 patients, a 66 percent loss, who are already eligible under guideline criteria but never receive a device-based therapy, largely a provider-side problem of limited awareness, referral inertia, and uneven training. A smaller third leak shows up at care-seeking-to-pharmacotherapy, where about 3.9 million patients, a 78 percent loss, never get a prescription — part clinician preference for non-drug management, part patient reluctance to start medication.

Three things follow from this pattern. The single biggest lever for growth sits upstream of any provider decision — in patient identification and screening — rather than in expanding therapy access itself. Provider training still matters enormously, since the refractory gap is squarely something targeted education can close. And the 2024 guideline update happens to hit all three leaks at once: its “menu” approach shortens the path through pharmacotherapy, its cognitive-risk counselling requirement speeds up medication dropout into the refractory pool, and its formal recognition of ITNM gives clinicians and payers a new, legitimised option at the point where the biggest provider-side leak occurs.

4.7 Assumptions and Modelling Notes

Table 4.3 — Key Assumptions by Funnel Stage

Stage	Assumption	Primary Source
Symptomatic population	16–24M adults; ICS definition; community-dwelling, 18+	NHANES; OAB-POLL; EpiLUTS; internship data
Care-seeking	25–30% of symptomatic patients seek care	NHANES; patient survey data
Pharmacotherapy	20–24% of care-seeking patients medicated	CMS Part D; NHANES; internship data
Refractory	50–60% of pharmacotherapy patients	AUA/SUFU definition; trial eligibility criteria
Advanced therapy	30–36% of refractory patients treated	CMS PSPS PUF; market reports; company filings

Source: Author's synthesis.

A few modelling choices apply across every stage. The funnel is a 2025 snapshot rather than a model of how individual patients move over time, so it can't capture someone who drops out of care altogether between stages. Figures are kept as ranges wherever the underlying literature itself disagrees, with the working estimate set at a triangulated midpoint rather than a simple average. And because the final addressable opportunity is a small percentage of a very large starting population, even modest revisions to the Stage 1 estimate move the absolute market size by a lot — a sensitivity carried through to the Chapter 7 forecast.

4.8 Key Findings and Interpretation

- The total symptomatic OAB population sits at 16–24 million U.S. adults — a scale on par with diabetes or hypertension.
- The symptomatic-to-care-seeking transition is the single largest leak in the funnel, at roughly 75 percent.
- Pharmacotherapy persistence falls below 15 percent by twenty-four months, making medication dropout the largest contributor to the refractory pool.
- The refractory pool of 500,000–600,000 patients takes a median of 15.4 months to even reach the third-line decision point.

- Advanced therapy reaches only about 180,000–185,000 patients a year — roughly a third of those who are already eligible.
- Both dominant leakage points are driven by modifiable behaviour, not clinical ineligibility — which is precisely what defines the market opportunity running through the rest of this dissertation.

Stepping back, this funnel pushes against the usual way device-market opportunity gets framed. The conventional story is about innovation — new indications, better devices, more trial data. Here, the bigger near-term opportunity is funnel optimisation: closing the gap between symptomatic prevalence and care-seeking, and between refractory status and treatment, using therapies that are already approved and already paid for. That has a useful implication for forecasting, too — because the opportunity is mostly behavioural rather than regulatory, how fast it's realised depends on things manufacturers, providers, and policymakers can actually influence (education spend, training intensity, screening adoption), not on an FDA clock outside anyone's control. It's also worth being honest that this won't happen quickly: between the 15.4-month median progression time and how entrenched the upstream beliefs are, funnel optimisation is realistically a multi-year project, not a single campaign — a point picked up again in the phased roadmap in Chapter 8.

4.9 Business and Healthcare Implications

- **Device manufacturers** should treat the 15 million patients who never seek care as the largest single opportunity, worth direct-to-consumer education that destigmatises OAB, alongside targeted training for the untrained urologists who hold the second-largest gap, and should build the 2024 guideline's “menu” language directly into how ITNM is positioned.
- **Providers** can close real ground simply by screening proactively for OAB in primary care, OBGYN, and geriatric visits, and by building structured care pathways that allow direct escalation to advanced therapy under the new guideline rather than cycling patients through endless medication trials.
- **Payers** should issue clear coverage policy for ITNM under the 2024 guideline, consider outcomes-based contracting given the cost and evidence uncertainty involved, and pay attention to the access disparities by race, income, and insurance type documented in Chapter 2.

- **Policy-makers** have a role in funding public awareness campaigns, supporting advanced-therapy training through graduate and continuing medical education, and aligning Medicare and Medicaid coverage with the updated guideline.

4.10 Chapter Conclusion

This chapter built a full patient funnel for U.S. OAB, from roughly 20 million symptomatic adults down through about 5 million care-seekers, 1.0–1.2 million on medication, 500,000–600,000 refractory patients, to around 185,000 who actually receive advanced therapy. The two biggest leaks — symptom-to-care-seeking (75 percent) and refractory-to-advanced-therapy (66 percent) — are both rooted in patient belief, provider awareness, and referral habits rather than any real shortage of approved, evidenced, reimbursed therapy. The 2024 AUA/SUFU guideline changes touch all of these points at once, which is part of why this dissertation treats 2025–2030 as a genuine inflection window rather than business as usual. Chapter 5 turns next to a detailed comparison of the four advanced therapies themselves — mechanism, durability, safety, and patient convenience — to set up the competitive and forecasting analysis in the chapters that follow.

CHAPTER 5 — ADVANCED THERAPY LANDSCAPE ANALYSIS

5.1 Introduction

Chapter 4 established how many patients progress through the OAB treatment funnel. This chapter addresses the next logical question: once a patient reaches the third-line decision point, what are they actually being offered, and why does one therapy get chosen over another? The answer matters not just clinically but commercially, because adoption patterns in OAB — as this chapter will show — are shaped far more by workflow, convenience, and follow-up burden than by incremental differences in efficacy.

The analysis covers the four FDA-approved advanced therapies: intradetrusor botulinum toxin (Botox), percutaneous tibial nerve modulation (PTNM), sacral neuromodulation (SNM), and implantable tibial neuromodulation (ITNM). Each is evaluated across nine dimensions — mechanism, procedure setting, invasiveness, durability, follow-up burden, safety, efficacy, patient convenience, and cost. A comparative matrix assembles the evidence into a single reference table, followed by therapy-specific deep dives, a competitive vendor assessment, and strategic positioning analysis.

5.2 Clinical Pathway Context

Until 2024, advanced OAB therapy was structured as a loose hierarchy — patients were expected to try the least invasive third-line option before escalating. The 2024 AUA/SUFU guideline replaced that hierarchy with what clinicians now informally call a 'menu' approach: all four therapies are presented concurrently, and selection is driven by shared decision-making rather than a fixed sequence. This is not a minor revision. It means that Botox, PTNM, SNM, and ITNM now compete directly for the same patient at the same consultation, making their attribute-level differences the primary driver of market share rather than their position in a treatment ladder.

5.3 Individual Therapy Profiles

5.3.1 Botox

Botox works through chemodenervation. Injected into the detrusor muscle at fifteen to thirty sites via cystoscope, onabotulinumtoxinA blocks acetylcholine release at the neuromuscular junction, suppressing involuntary contractions locally within the bladder wall. Effects appear within one to two weeks and last six to twelve months, after which re-injection is necessary. Across pivotal trials, 60–70% of patients achieved meaningful symptom reduction.

Delivery is office-based under local anaesthesia, lasting roughly fifteen to twenty minutes, and patients leave without recovery restrictions. The procedure is highly accessible for trained urologists and carries no capital-equipment burden. The two main clinical downsides are a UTI incidence of 22.7% versus 9.4% under placebo (RR 2.53, $p<0.00001$), and a 5–7% rate of urinary retention requiring clean intermittent catheterisation. Over a ten-year horizon a typical patient undergoes ten to twenty separate injections — individually tolerable, but cumulatively a meaningful long-term commitment. Five-year cost: USD 22,500–37,500 assuming 1.5 injections per year. Reimbursement is mature and well-established.

5.3.2 PTNM

PTNM stimulates the posterior tibial nerve via a fine 34-gauge ankle electrode, modulating the sacral reflex arc (S2–S4) through an indirect central pathway rather than acting locally on the bladder. Clinically, it reduces urgency, frequency, and nocturia at rates comparable to Botox — roughly 60–70% responders — and its safety profile is the cleanest of the four, with adverse events limited to mild electrode-site discomfort and bruising.

The problem is structural: PTNM's effect is session-dependent, meaning it disappears when stimulation stops. That forces an indefinite maintenance schedule — twelve weekly sessions to start, then monthly visits for life. In practice, most patients do not sustain this regimen, and real-world claims analyses confirm widespread non-compliance. A fully compliant patient accumulates over two hundred clinic visits across five years. Five-year cost: USD 14,400–24,000 in direct charges, though the patient's time and travel burden are not captured in that figure. Reimbursement is established.

5.3.3 SNM

SNM delivers continuous low-amplitude electrical stimulation to the S3 sacral nerve root through a surgically implanted pulse generator. Its evidence base is the deepest of any OAB advanced therapy — more than two decades of follow-up data — and UUI responder rates hover around 71–74%, with sustained improvement in quality of life at mid- to long-term follow-up.

The barrier is the procedure itself. SNM is a two-stage surgical process: a one-to-two-week trial-lead phase, then full implantation under general anaesthesia in an operating room, followed by a two-to-four-week recovery with physical restrictions. This upfront surgical hurdle — and the anxiety that accompanies it — is the single most cited reason refractory patients decline SNM. Once past that hurdle, however, the ongoing burden is low: annual check-ins, remote programming on newer devices, and eventual battery replacement on a roughly ten-year cycle. Five-year cost: USD 30,000–50,000 — the highest of the four, with established reimbursement subject to prior authorisation.

5.3.4 ITNM

ITNM uses the same tibial-nerve mechanism as PTNM but delivers stimulation through a small subcutaneous implant rather than a needle electrode session. The effect is therefore continuous, not session-dependent, eliminating PTNM's compliance problem entirely. The latest-generation devices carry battery lives of approximately fifteen years — longer than any other implant in this comparison — and enable immediate post-implant activation, removing the separate activation visit earlier devices required.

Implantation takes thirty to forty-five minutes under local anaesthesia in an office or ambulatory surgery centre; patients typically return to normal activity within a day or two. Crucially, there is no trial phase — unlike SNM, the patient commits to a single procedure. This removes both the trial-phase dropout risk and the second recovery episode. Evidence quality is more limited than for the three established therapies: the Amundsen et al. (2025) meta-analysis — indirect, single-arm, no head-to-head controls — reported OAB responder rates of 79.4% versus 73.9% for SNM, suggesting at-minimum clinical equivalence. Adverse events parallel SNM's but at lower reported incidence given the less invasive implant technique. Five-year cost: USD 15,000–25,000 (no trial-phase cost). Reimbursement is emerging — CPT codes 0816T and 0817T are newly established and expected to expand as the 2024 guideline gains traction.

5.4 Comparative Analysis

Table 5.1 — Comprehensive Therapy Comparison Matrix

Dimension	Botox	PTNM	SNM	ITNM
Mechanism	Chemodenervation	Electrical stimulation	Electrical stimulation	Electrical stimulation
Procedure setting	Office / ASC	Office	OR / ASC	Office / ASC

Invasiveness	Minimally invasive	Non-invasive	Invasive	Minimally invasive
Anesthesia	Local	None	GA / Sedation	Local
Procedure time	15–20 min	30 min/session	1–2 hours	30–45 min
Duration of effect	6–12 months	Session-dependent	5–15 years	~15 years
Repeat burden	Every 6–12 months	Weekly + monthly	Battery replacement	Minimal
Recovery time	None	None	2–4 weeks	1–2 days
Overall patient burden	Medium	Very high	Low	Very low
UTI risk	High (22.7%)	Very low	Low	Low
Urinary retention	5–7%	None	None	None
Device revision	N/A	N/A	10–15%	Low
Responder rate	60–70%	60–70%	71–74%	~79%
Evidence quality	High	High	High	Moderate
5-year cost	$22,500–$37,500	$14,400–$24,000	$30,000–$50,000	$15,000–$25,000
Reimbursement	Established	Established	Established	Emerging
Office-based feasibility	High	High	Low	High

Source: Author's synthesis from Sections 5.3 and clinical literature reviewed in Chapter 2.

The matrix makes a key pattern visible: no single therapy wins across all nine dimensions, but ITNM is the only one that avoids placing in the weakest category on any dimension. Botox carries UTI and repeat-burden costs; PTNM's visit load is extreme; SNM's surgical demand is its ceiling. ITNM's only genuine weakness is evidence immaturity — a function of age, not clinical design.

5.5 Key Dimension Comparisons

5.5.1 Efficacy

All four therapies cross a broadly similar efficacy bar: 60–79% responder rates and comparable reductions in incontinence and urgency episodes. The ITNM figure is modestly higher, but it rests on indirect single-arm evidence and cannot yet be treated as demonstrated superiority. More practically, the narrow spread of efficacy outcomes across the four options tells us that adoption decisions in the OAB market are not primarily efficacy-driven — they are driven by the dimensions that follow.

5.5.2 Convenience and Lifetime Burden

Table 5.2 — Lifetime Intervention Comparison (10-year horizon)

Therapy	Approximate Interventions Over 10 Years	Overall Convenience Rating
Botox	10–20 injections	Moderate
PTNM	400+ clinic sessions	Low
SNM	2 procedures + 1 battery replacement	Moderate–High

ITNM	1 implant + possible 1 battery replacement	High

Reframed in lifetime terms, PTNM's apparent simplicity — a quick needle at the ankle — is almost reversed: 400-plus clinic sessions across ten years versus a single surgical implant for SNM or a single minimally invasive implant for ITNM. This is the primary analytical reason real-world PTNM compliance is so poor, and it is the central argument for ITNM's structural differentiation.

5.5.3 Cost

Over a five-year horizon, PTNM appears cheapest at USD 14,400–24,000, but that figure excludes patient time and travel. SNM is most expensive at USD 30,000–50,000 and requires OR infrastructure. Botox sits in the middle at USD 22,500–37,500 but accumulates costs indefinitely. ITNM's USD 15,000–25,000 five-year estimate is the second-lowest and does not repeat meaningfully until battery replacement — roughly year fifteen. On a per-year-of-therapy-delivered basis, ITNM's cost profile is arguably the most favourable of the four for both payers and patients.

5.6 Competitive Landscape

Table 5.3 — Competitive Vendor Map

Segment	Key Vendors	Market Position	Key Strengths	Key Vulnerabilities
Botox	AbbVie (Allergan)	Volume leader	Established brand; mature reimbursement; broad urologist familiarity	Repeat burden; retention risk
PTNM	Medtronic (NuWave)	Niche player	Non-invasive; no capital equipment	Compliance burden; flat growth trajectory
SNM	Medtronic (InterStim); Boston Scientific (Axonics)	Revenue leader	Deep clinical evidence; premium reimbursement	OR dependence; surgical anxiety; high cost
ITNM	Valencia (eCoin); BlueWind (Revi); 2025 entrant	Emerging high-growth	Differentiated convenience; office-based; guideline-recognised	Evidence base thin; reimbursement still developing

Two competitive developments deserve particular attention. In the SNM segment, Boston Scientific's 2024 acquisition of Axonics converted a two-player duopoly into a sharper contest, with both companies now investing heavily in physician training and product innovation. The Axonics platform — rechargeable, MRI-conditional, smaller footprint — has been gaining share on Medtronic's InterStim, and integration under Boston Scientific raises both the competitive stakes and resource intensity for the segment.

In the ITNM segment, three vendors are simultaneously building from near zero. Valencia's eCoin (FDA 2022) carries first-mover status and an established CPT code but a shorter battery life of approximately five years. BlueWind's Revi (FDA 2023) eliminates battery replacement through a wireless external-power design. The 2025 entrant offers the longest battery life in the segment at roughly fifteen years alongside MRI conditionality and immediate activation. The company that moves fastest to establish physician training relationships and secure favourable payer coverage in the next eighteen to twenty-four months is likely to hold a durable advantage — new-device markets tend to consolidate around early-trained physicians who face meaningful switching costs once their muscle memory and workflow are built around a particular implant system.

5.7 Market Positioning and Technology Evolution

Plotting invasiveness against durability reveals four distinct positions in the advanced-therapy landscape. PTNM sits in the low-invasiveness, low-durability quadrant — a combination that makes the compliance burden structurally unavoidable. SNM sits in the high-invasiveness, high-durability quadrant — durable outcomes, but only for patients willing to accept a surgical procedure. Botox sits in the low-invasiveness, low-durability quadrant alongside PTNM in practical effect, given its repeat-injection dependency. ITNM alone occupies the low-invasiveness, high-durability position — a combination that no other therapy in this space currently offers, and that represents the clearest explanation for its projected growth trajectory.

Viewed historically, this positioning reflects a coherent technology evolution. SNM established that continuous neuromodulation could durably suppress detrusor overactivity, but required surgery. PTNM demonstrated that the same tibial-nerve pathway could be accessed without surgery, but only at the cost of continuous session-based maintenance. ITNM is, in straightforward engineering terms, the solution to PTNM's compliance problem: the same mechanism, the same access point, but delivered continuously through an implant instead of intermittently through a needle. This is not the story of a fourth independent therapy appearing from nowhere — it is the logical next step in a trajectory that began with SNM in 1997.

5.8 Key Insights and Business Implications

Four analytical conclusions stand out from the comparative evidence developed in this chapter.

- **Efficacy does not drive market share in this category.** All four therapies clear a broadly similar clinical bar. The enormous variation in adoption rates observed between — and within — the four segments is explained by follow-up burden, workflow fit, and procedural complexity rather than by responder-rate differences.

- **Lifetime burden is the metric that matters.** Per-visit simplicity is misleading. Reframing the comparison in cumulative lifetime-intervention terms reverses PTNM's apparent convenience advantage and elevates ITNM's position substantially relative to any single-visit comparison.
- **ITNM's commercial case rests on positioning, not superiority.** Its advantage over SNM is structural and operational — durability without surgery — rather than clinical. Commercialisation strategy for ITNM should be built on that argument, not on claims of head-to-head efficacy superiority that the current evidence does not yet support.
- **The early-mover window in ITNM is narrow and consequential.** Adjacent device markets — notably stroke thrombectomy — demonstrate that physician training relationships established in the first eighteen to twenty-four months of a new device category tend to be durable; late entrants face disproportionately higher conversion costs. That window is now open.

For device manufacturers, the implications centre on physician training investment, early reimbursement capture, and differentiation on device specifications — battery life, MRI conditionality, activation speed — rather than price. For healthcare providers, ITNM's office-based, local-anaesthesia workflow aligns with the broader site-of-service migration in urology, and the 2024 guideline's formal recognition of ITNM removes the clinical legitimacy gap that previously made prescribers hesitate. For payers, ITNM's five-year cost profile is already competitive with SNM and Botox on a total-burden basis, and clear, timely coverage policy for CPT codes 0816T and 0817T will accelerate adoption materially faster than continued ambiguity.

5.9 Chapter Conclusion

This chapter has compared the four advanced OAB therapies across nine clinical, operational, and commercial dimensions. Botox remains the most widely used therapy by patient count, but its repeat-procedure cycle and UTI burden create structural vulnerability to more durable alternatives. PTNM is genuinely non-invasive and well-tolerated, yet its compliance rates in the real world tell a consistent story — the session schedule defeats most patients before they complete even the initial twelve-week course. SNM carries the deepest clinical pedigree and the highest revenue per procedure, but its OR dependence and upfront surgical demands restrict the addressable patient population. ITNM brings the tibial-nerve mechanism into the implantable domain and, in doing so, resolves the compliance problem PTNM could never solve — at a procedure burden and cost profile that undercuts SNM across most dimensions.

The next eighteen to twenty-four months represent the critical window for establishing market position in the ITNM segment. Chapter 6 turns from this therapy-level comparison to an analysis of the U.S. physician landscape — who is actually performing these procedures, how they are distributed by specialty and training status, and where the greatest untapped adoption potential lies.

CHAPTER 6: PHYSICIAN ANALYTICS

6.1 Introduction

This chapter shifts the analytical lens from market-level demand to the physicians who actually deliver Overactive Bladder (OAB) advanced therapies. The literature reviewed in earlier chapters establishes that specialty influences referral behaviour, but it stops short of the granular segmentation — by training status, procedure mix, and adoption propensity — that strategic decision-making requires. This chapter closes that gap. It maps the U.S. provider universe by specialty, segments physicians into adoption-relevant categories, analyses procedure mix and CMS Medicare utilization, identifies high-volume providers and referral pathways, and translates these findings into targeting priorities and commercialization implications for advanced OAB therapies — Botox, PTNM, SNM, and ITNM.

6.2 Importance of Physician Analytics in Advanced OAB Therapy Adoption

Unlike pharmaceutical products that are largely demand-driven, advanced OAB therapies are procedural and physician-gated: a patient cannot self-select Botox, SNM, or ITNM without a trained provider willing to perform the procedure.

Adoption is therefore bounded not by patient demand alone but by the size, training status, and behaviour of the physician population capable of delivering these therapies. Physician-level analytics allow market sizing to be built bottom-up from provider capacity rather than top-down from epidemiology alone, and they allow commercialization resources — training programs, sales coverage, key-opinion-leader development — to be allocated to the segments most likely to convert. This chapter therefore treats the physician, rather than the patient, as the primary unit of strategic analysis.

6.3 Physician Landscape in Overactive Bladder Management

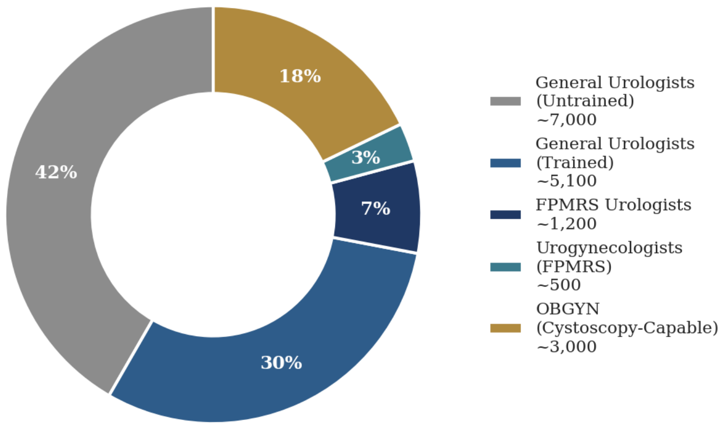
Three physician specialties are relevant to OAB advanced therapy delivery: urologists, urogynecologists (FPMRS-certified), and OBGYN specialists. Table 6.1 summarizes the estimated U.S. provider universe across these segments.

Table 6.1 — U.S. Provider Universe by Specialty

Provider Segment	Estimated Count	Source
Urologists (Total)	~12,500	AMA Physician Masterfile
— General Urologists, Trained in Advanced OAB	~5,100	Internship project data
— General Urologists, Untrained in Advanced OAB	~7,000	Internship project data
— Urologists with FPMRS Fellowship	~1,200	SUFU
Urogynecologists / FPMRS (ABOG-Certified)	~500	ABOG
OBGYN Specialists, Cystoscopy-Capable	~3,000	Internship project data
OBGYN Specialists (Total)	~40,000	AMA Physician Masterfile

Source: Author's synthesis of AMA Physician Masterfile, SUFU, ABOG, and internship project data.

Figure 6.1: U.S. Physician Specialty Distribution Relevant to OAB Care



Source: Author's analysis based on Table 6.1.

The landscape is dominated numerically by urologists and OBGYNs, but, as the sections that follow demonstrate, raw headcount is a poor proxy for adoption-relevant capacity: training status and practice focus matter more than specialty label alone.

6.4 Role of Urologists in Advanced OAB Therapy Adoption

Urologists are the primary providers of OAB care in the United States and perform the majority of OAB procedures nationally. Of the approximately 12,500 practicing urologists, only about 5,100 (41%) are trained in advanced therapies, while roughly 7,000 (56%) remain untrained. Urologists may practice as generalists or hold subspecialty training in female pelvic medicine and reconstructive surgery (FPMRS), voiding dysfunction, or related areas. This training split is one of the most consequential findings of the chapter: it means the single largest specialty pool is also the specialty with the largest absolute training gap, making general urology both the backbone of current procedure volume and the largest untapped pool for future growth.

6.5 Role of Urogynecologists and FPMRS Specialists

Urogynecologists, or FPMRS specialists, are physicians dually trained in urology and gynecology through fellowship in female pelvic medicine and reconstructive surgery, certified through either the American Board of Urology (ABU) or the American Board of Obstetrics and Gynecology (ABOG). Combining the roughly 1,200 FPMRS-fellowship urologists with the approximately 500 ABOG-certified urogynecologists yields a pool of about 1,700 physicians — numerically small, at under 15% of the urology workforce, but the most concentrated source of OAB expertise in the country. As later sections demonstrate, this segment refers patients to advanced therapy at substantially higher rates than any other specialty, making it the highest-priority target for early commercialization.

6.6 OBGYN Participation in OAB Management

OBGYN specialists who focus on pelvic floor disorders, but without formal FPMRS fellowship training, treat pelvic organ prolapse, stress urinary incontinence, and related conditions, and some perform office-based procedures such as cystoscopy and Botox injection. Of the approximately 40,000 practicing OBGYNs nationally, only about 3,000 are currently cystoscopy-capable, and advanced therapy adoption within this group remains low, at under 1% of patients. The size of the broader OBGYN workforce — more than three times the entire urology workforce — represents a large but largely untapped opportunity, particularly for therapies with low procedural barriers such as Botox and, with targeted training, ITNM.

6.7 Physician Specialty Distribution Analysis

Read together, the specialty-level data in Sections 6.4 through 6.6 reveal three patterns of strategic significance. First, urologists dominate the provider landscape numerically, yet a majority remain untrained in advanced therapies, representing a significant education and training opportunity. Second, FPMRS specialists are a small but high-leverage segment: at roughly 1,700 physicians, they punch well above their numerical weight in referral behaviour and procedural concentration. Third, OBGYNs represent the largest untapped reservoir of potential providers, but current adoption among this group is negligible. Figure 6.1 illustrates this imbalance between specialty size and current advanced-therapy engagement, underscoring why a one-size-fits-all commercialization approach would misallocate resources across such structurally different segments.

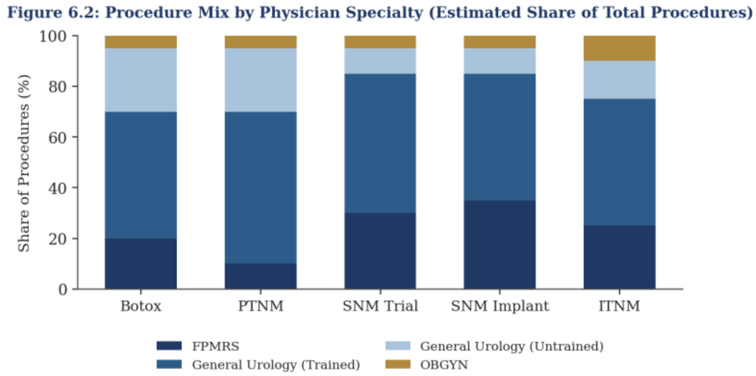
6.8 Procedure Mix Analysis by Specialty

Procedure-level data sharpen the specialty picture further. Table 6.2 presents the estimated share of each OAB procedure type — Botox (CPT 52287), PTNM (CPT 64561), SNM trial (CPT 64566), SNM implant (CPT 64581/64590), and ITNM (CPT 0816T/0817T) — performed by each specialty segment.

Table 6.2 — Procedure Mix by Specialty (Estimated Share of Total Procedures)

Procedure	FPMRS	Gen. Urology (Trained)	Gen. Urology (Untrained)	OBGYN
Botox	20%	50%	25%	5%
PTNM	10%	60%	25%	5%
SNM Trial	30%	55%	10%	5%
SNM Implant	35%	50%	10%	5%
ITNM	25%	50%	15%	10%

Source: Author's synthesis of CMS data and internship project data.



Source: Author's analysis based on Table 6.2.

Despite representing only about 14% of the urology workforce, FPMRS specialists perform a disproportionate 20–35% share of SNM procedures and roughly a quarter of ITNM procedures, confirming their outsized clinical role. Trained general urologists, who make up roughly 41% of the workforce, deliver the bulk of total procedure volume (50–60% across most categories), consistent with their scale advantage. Untrained general urologists, despite representing 56% of the workforce, perform a disproportionately small 10–25% share — clear evidence that this group is underperforming relative to its numerical potential. OBGYNs, meanwhile, contribute less than 10% of procedures across the board, though their 10% share of ITNM — their highest contribution of any procedure — hints at where future OBGYN engagement is most likely to emerge first.

6.9 Advanced Therapy Utilization Patterns

Utilization patterns are increasingly defined by site of service rather than specialty alone. Approximately 90% of total OAB procedural volume has migrated to office-based settings, driven by favourable office-based reimbursement, strong patient preference for convenience and lower out-of-pocket cost, and technological advances such as local anesthesia and smaller implant platforms. Office-based migration is uneven across therapies, however: roughly 85% of Botox and 95% of PTNM procedures are already performed in-office, and ITNM is following the same trajectory at approximately 70% office-based and rising. SNM stands apart, with about 90% of procedures still performed in facility settings (35% ASC, 55% HOPD) because of its operating-room infrastructure and general anesthesia requirements. This divergence is a structural vulnerability for SNM and a structural tailwind for office-compatible therapies such as ITNM.

6.10 CMS Medicare Data Analysis

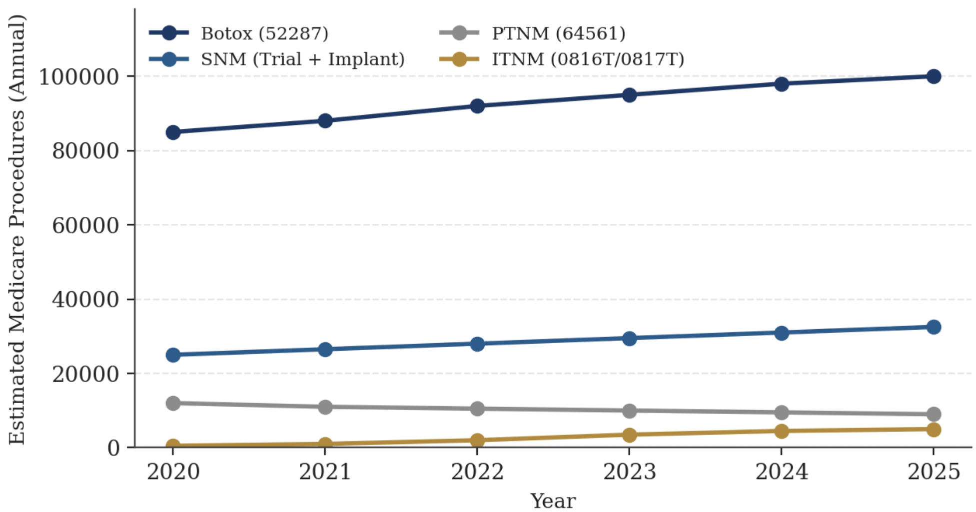
The CMS Medicare Physician/Supplier Procedure Summary (PSPS) Public Use File provides procedure counts by CPT code and is the principal claims-based data source used in this analysis, covering 2020–2024 actuals with a 2025 projection. The dataset has notable limitations: it captures Medicare beneficiaries only (commercial utilization must be inferred), aggregates new and repeat patients, may not isolate FPMRS subspecialty status, and is reported at an aggregate rather than individual-physician level. With these caveats noted, Table 6.3 summarizes five-year volume trends by CPT code.

Table 6.3 — CMS Medicare Procedure Volume Trends by CPT Code, 2020–2025 (Estimated)

CPT Code	Procedure	2020 Volume	2025 (Est.) Volume	5-Year Change
52287	Botox Injection (OAB)	85,000	100,000	+18%
64561	PTNM	12,000	9,000	−25%
64566 / 64581 / 64590	SNM (Trial + Implant)	25,000	32,500	+30%
0816T / 0817T	ITNM	500	5,000	+900%

Source: Author's synthesis of CMS PSPS PUF data and internship project data.

Figure 6.3: CMS Medicare Procedure Volume Trends by Therapy, 2020-2025



Source: Author's analysis based on Table 6.3.

Four distinct trajectories emerge. Botox remains the most utilized advanced therapy, accounting for an estimated 57% of all Medicare advanced OAB procedures by 2025, reflecting its broad specialty adoption and office-based simplicity. SNM is stable with modest growth (approximately 19% of total volume), reflecting its established but facility-dependent delivery model. PTNM is in clear decline, down 25% over five years, a trend attributable to its ongoing weekly-visit compliance burden and the emergence of ITNM as a lower-burden alternative. ITNM is the fastest-growing therapy by a wide margin — a tenfold increase since 2020 — and this trajectory is expected to accelerate further as the 2024 AUA/SUFU guideline gains clinical traction.

6.11 High-Volume Physician Identification

Procedure volume is highly concentrated: a small minority of physicians perform a disproportionate share of all OAB procedures, and identifying the characteristics of this group is essential for efficient targeting. Table 6.4 profiles the high-volume phenotype against the broader physician population.

Table 6.4 — High-Volume Physician Phenotype Scorecard

Characteristic	High-Volume (Top 10%)	Average (Middle 80%)	Low-Volume (Bottom 10%)
Annual OAB Procedures	>100	20–100	<20
Specialty	FPMRS or trained GU	General Urology	General Urology
Practice Setting	Academic or large group	Community practice	Solo or small group
Advanced Therapy Training	Yes	Varies	No
Referral Network	Established	Limited	Minimal

Source: Author's synthesis of CMS PSPS PUF data and internship project data.

High-volume physicians are disproportionately FPMRS-trained or voiding-dysfunction-focused general urologists, typically embedded in academic medical centers or large group practices that provide referral infrastructure and multidisciplinary support. They perform a diversified procedure mix rather than relying on a single therapy, and they maintain referral networks built over years of practice — networks that are difficult for new entrants to replicate quickly. Because training and activating this top decile can generate a disproportionate share of total procedure volume, this group represents the most capital-efficient entry point for any new-therapy commercialization effort, while low-volume physicians require a fundamentally different approach centred on simplified training and hands-on reimbursement support.

6.12 Physician Segmentation Analysis

To translate specialty and volume data into an actionable targeting framework, the provider universe is segmented into five physician types based on training, practice focus, and advanced therapy adoption. Table 6.5 summarizes this taxonomy.

Table 6.5 — Five-Type Physician Taxonomy

Type	Description	Count	Adv. Therapy Training	Referral Rate	Strategic Priority
1	FPMRS-Trained Specialists	~1,700	60–70%	~15%	High
2	High-Volume General Urologists	~2,000	30–40%	~5–8%	High
3	General Community Urologists	~7,000	<5%	<1%	Medium
4	Cystoscopy-Capable OBGYNs	~3,000	<1%	<1%	Medium
5	Primary Care Providers	~250,000	N/A	Referral only	Low

Source: Author's synthesis of internship project data and literature.

Type 1 (FPMRS specialists) are the immediate commercialization priority, given existing procedural competence and high referral rates; effort should focus on converting the 30–40% of this group not yet trained.

Type 2 (high-volume general urologists) functions as the bridge between concentrated FPMRS expertise and broad procedure volume — these 2,000 physicians already perform SNM and Botox and require comparatively little incremental training to adopt ITNM.

Type 3 (general community urologists) is the largest pool by headcount and the largest long-term growth opportunity, but requires substantial training investment to activate.

Type 4 (cystoscopy-capable OBGYNs) represents a longer-horizon opportunity, since ITNM's office-based workflow does not require the additional surgical skill set that SNM demands.

6.13 Referral and Treatment Pathway Analysis

Referral behaviour varies dramatically by specialty and is one of the starkest findings in the physician dataset. Table 6.6 quantifies this disparity.

Table 6.6 — Referral Rate Comparison by Specialty

Provider Segment	Advanced Therapy Referral Rate	Relative to General Urology
FPMRS-Trained Specialists	~15% of OAB patients	15×
Trained General Urologists	~5–8% of OAB patients	5–8×
General Community Urologists	<1% of OAB patients	1× (baseline)
OBGYN	<1% of OAB patients	~1×
Primary Care	Referral to specialist	N/A

Source: Internship project data and author's synthesis.

FPMRS-trained specialists refer patients to advanced therapy at roughly fifteen times the rate of general community urologists. This disparity is driven by a combination of factors: deeper fellowship training in advanced OAB therapies; a practice focus concentrated on pelvic floor disorders rather than the broader scope (oncology, stone disease) typical of general urology; a patient population skewed toward refractory, complex presentations; established referral networks that concentrate complex cases with FPMRS providers; and practice economics that may more directly reward office-based or ASC-affiliated procedure delivery. In practice, the more common treatment pathway is not a general urologist independently adopting advanced therapy, but rather a general urologist referring a refractory patient onward to an FPMRS specialist — a pattern that device manufacturers can reinforce by formally supporting referral-pathway development between the two groups rather than treating them as competing targets.

6.14 Geographic and Practice-Level Variations

While the underlying internship project data are reported primarily at the national level, the practice-setting patterns identified in Sections 6.11 and 6.12 carry an implicit geographic dimension worth flagging. High-volume and FPMRS-trained physicians are disproportionately concentrated in academic medical centers and large urban group practices, while general community urologists — who carry the bulk of the training gap — are more broadly distributed across community and rural settings with comparatively limited referral infrastructure. This concentration pattern suggests that advanced therapy access may already be geographically uneven, even though the dataset does not permit precise quantification at the state or regional level.

6.15 Procedure Adoption Trends

Building on the CMS trend analysis in Section 6.10, four adoption trajectories are evident through 2025. Botox has the broadest and most stable adoption curve, reflecting low procedural complexity and office-based compatibility. SNM shows steady but unspectacular growth, consistent with a mature therapy constrained by its facility-based delivery model. PTNM is contracting, a trend linked directly to its compliance burden — weekly in-office visits over a twelve-week induction period — relative to newer alternatives. ITNM displays the clearest inflection point of any therapy in the dataset, growing tenfold in five years from a low base, a trajectory that is expected to steepen further as the 2024 AUA/SUFU guideline embeds ITNM more firmly into standard treatment algorithms.

6.16 Physician Preference Analysis Across Therapies

Physician therapy preference, as inferred from procedure mix and site-of-service data, appears to be driven less by raw clinical efficacy and more by workflow fit with the physician's practice setting. FPMRS specialists, who see the most complex and refractory cases, gravitate toward the higher-acuity SNM and ITNM procedures. Trained general urologists display the most diversified preference profile, performing a broad mix across Botox, PTNM, and ITNM, consistent with their role as the volume engine of the specialty. Untrained general urologists and OBGYNs disproportionately favour Botox — the therapy with the lowest procedural and credentialing barrier — when they engage with advanced therapy at all. This pattern indicates that the office-based workflow, chair-time requirement, and credentialing burden of a therapy may be a stronger predictor of physician preference than its comparative clinical profile, a finding with direct implications for how new therapies should be positioned to each segment.

6.17 Key Drivers Influencing Physician Adoption

Across the specialty, procedure-mix, and referral analyses presented above, six factors consistently emerge as the principal drivers of physician adoption:

- **Training and credentialing.** Fellowship-level training (FPMRS) is the single strongest predictor of both procedural competence and referral propensity.
- **Practice focus.** Physicians whose practice is centred on pelvic floor disorders adopt advanced therapy at far higher rates than physicians for whom OAB is a peripheral interest.
- **Patient population.** A practice with a higher concentration of refractory OAB patients naturally generates more advanced therapy candidates.
- **Referral network strength.** Established referral relationships concentrate complex cases with already-high-adopting physicians.

- **Reimbursement and practice economics.** Office-based and ASC-affiliated practice models more directly reward procedure delivery than salaried or hospital-employed models.
- **Office-based workflow compatibility.** Therapies that fit existing office infrastructure face materially lower adoption friction than facility-dependent therapies.

6.18 Challenges and Barriers in Physician Adoption

The same dataset also surfaces clear barriers that constrain faster adoption. The most consequential is the training gap itself: 56% of urologists remain untrained in advanced OAB therapies, a systemic shortfall in graduate and continuing medical education rather than a localized issue. Care delivery is also fragmented — the fifteenfold referral disparity between FPMRS specialists and general urologists indicates inconsistent care pathways rather than a uniform standard of practice. SNM's continued reliance on facility-based delivery (approximately 90% ASC/HOPD) exposes it to facility fees and administrative burden that office-based competitors do not face. PTNM's compliance burden — weekly office visits over an extended induction period — has measurably suppressed its growth. Finally, the concentration of FPMRS expertise in academic and urban settings (Section 6.14) raises the prospect of access disparities for patients in rural and underserved areas, a barrier with both clinical and commercial significance.

6.19 Strategic Physician Targeting Opportunities

Synthesizing the segmentation, referral, and barrier analyses above yields a clear targeting sequence. FPMRS specialists (Type 1) should be the immediate priority, given their high referral rates and credibility as opinion leaders for peer-to-peer education. High-volume general urologists (Type 2) should be targeted in parallel, since they already perform SNM and Botox and require only incremental training to add ITNM to their procedure mix — and because targeting the top decile of physicians by volume generates a disproportionate return on training investment. Trained-but-low-referring general urologists represent a near-term conversion opportunity, addressable through structured, competence-building training programs rather than broad awareness campaigns. General community urologists (Type 3), while requiring the heaviest investment, represent the largest absolute volume opportunity and should be engaged primarily through referral-pathway development toward FPMRS specialists rather than direct procedural training in the near term. Cystoscopy-capable OBGYNs (Type 4) represent the best long-horizon expansion opportunity, particularly for ITNM, given the therapy's compatibility with existing OBGYN office infrastructure.

6.20 Key Insights and Analytical Interpretation

Drawing the chapter's findings together, six insights stand out as the most strategically significant:

- The urology workforce carries a substantial training gap — 56% of urologists are untrained in advanced OAB therapies — representing the single largest constraint on near-term volume growth.
- FPMRS specialists, though only about 14% of the urology workforce, are disproportionately responsible for procedure volume and referral activity, confirming their status as the highest-leverage physician segment.

- The site-of-service migration to office-based care (approximately 90% of total volume) structurally favours Botox, PTNM, and ITNM while creating a durable vulnerability for facility-dependent SNM.
- ITNM is the fastest-growing therapy in the CMS dataset by a wide margin, and its growth trajectory is well aligned with the office-based migration trend and the 2024 AUA/SUFU guideline.
- Procedure volume is highly concentrated among a small group of high-volume physicians, making targeted activation of this decile more efficient than broad-based outreach.
- OBGYNs represent a large, almost entirely untapped physician pool whose existing office-based infrastructure is well suited to lower-barrier therapies such as ITNM.

6.21 Business and Commercialization Implications

These insights translate into a set of concrete commercialization priorities. Device manufacturers and other stakeholders should segment outreach by training status and referral propensity rather than by specialty label alone, using the five-type taxonomy in Section 6.12 as the operating framework. Early commercialization resources should concentrate on FPMRS specialists and high-volume general urologists, both for direct procedure growth and as credible opinion leaders for peer-to-peer education. Closing the training gap among the 7,000 untrained general urologists is the largest addressable long-term opportunity and should be pursued through structured, competence-focused training rather than generic marketing. Because office-based workflow compatibility is now a primary driver of physician preference (Section 6.16), any new therapy should be positioned around office-based delivery wherever clinically feasible — a configuration in which ITNM is already well positioned relative to SNM. Finally, formally supporting referral pathways between general urologists and FPMRS specialists, rather than treating the two groups as competing channels, is likely to accelerate category growth more efficiently than attempting to convert general urologists into independent providers. The geographic concentration of expertise identified in Section 6.14 points to a longer-term whitespace opportunity in underserved regions, while the 2024 AUA/SUFU guideline should be treated as a commercial catalyst worth actively supporting through physician education initiatives.

6.22 Chapter Conclusion

This chapter has reframed OAB advanced therapy adoption as fundamentally a physician-capacity problem rather than a patient-demand problem. The provider universe is large in aggregate but unevenly trained, with a small FPMRS-specialist segment driving disproportionate referral and procedure volume, a large general urology workforce split nearly evenly between trained and untrained physicians, and a substantial OBGYN pool that remains almost entirely outside the current advanced therapy ecosystem. CMS Medicare data confirm that office-based delivery is now the dominant utilization pattern and that ITNM is growing fastest among all advanced therapies, while SNM's facility dependence represents a structural competitive vulnerability. Taken together, these findings establish the physician — not the patient — as the binding constraint on advanced OAB therapy growth, and they provide the segmentation logic that the following chapter builds upon in developing a market opportunity and commercialization strategy.

CHAPTER 7 — MARKET SIZING AND FORECASTING

7.1 Introduction

This chapter translates the preceding analyses into quantitative market terms. The patient funnel established in Chapter 4 revealed who is eligible for advanced therapy; Chapter 5 compared the four therapies across nine clinical and operational dimensions; Chapter 6 mapped the physician landscape. What follows here is the commercial output of all three: a current market size by segment, a five-year procedure-volume and revenue forecast for 2025–2030, a three-scenario uncertainty analysis, and an assessment of the structural forces — demographics, guideline changes, reimbursement evolution, and technology innovation — that will shape how this market develops.

The base-case conclusion is a market growing from USD 1.41 billion in 2025 to USD 2.26 billion by 2030, a 9.9% overall CAGR, with growth concentrated almost entirely in one segment: ITNM, which is projected to expand from roughly 5,000 procedures annually to 100,000, an 82% CAGR that, if achieved, would make it the second-largest advanced-therapy segment by revenue within five years.

7.2 Current Market Size (2025)

The global OAB treatment market — spanning both pharmacotherapy and advanced therapies — was estimated at approximately USD 3.87–4.24 billion in 2025, growing toward USD 4.58–6.51 billion by 2030 across different report methodologies. These aggregate figures include anticholinergics and beta-3 agonists and are therefore broader than the advanced-therapy universe examined in this chapter. The U.S. market represents the largest national share of this global figure, driven by an ageing population, high per-capita healthcare spend, and established reimbursement pathways for device-based OAB treatment.

Disaggregating to the U.S. advanced-therapy segment only, the 2025 market is estimated at approximately USD 1.41 billion across four segments, as shown in Table 7.1. These estimates are synthesised from CMS PSPS Public Use File data, commercial market reports, company annual disclosures, and internship project data; where sources diverged, the figures that best triangulated across at least two independent estimates were used.

Table 7.1 — U.S. Advanced OAB Therapy Market by Segment (2025)

Segment	Annual Procedures (New Patients)	Market Size (USD)	Market Share
Botox	~100,000 new + ~75,000 repeat	~$460M	32.6%
SNM	~45,000	~$870M	61.7%
PTNM	~35,000	~$55M	3.9%
ITNM	~5,000	~$25M	1.8%
Total	~185,000	~$1.41B	100%

Source: Author's synthesis of CMS PSPS PUF, market reports, and internship project data.

The concentration of revenue in SNM — nearly 62% of the market — despite Botox leading on procedure count reflects SNM's substantially higher per-procedure revenue, driven by device cost and operating-room infrastructure requirements. ITNM, with just 1.8% of current market value, is negligible in size terms today but carries the highest growth trajectory of any segment and is the primary analytical focus of this chapter's forecasting work.

7.3 Five-Year Forecast (2025–2030)

7.3.1 Methodology and Key Assumptions

The forecast is built bottom-up from the patient funnel described in Chapter 4. The symptomatic OAB population is projected forward using U.S. Census age-group projections and age-specific prevalence rates rather than a single aggregate growth rate, capturing the ageing-population tailwind more precisely than a uniform multiplier would. Each therapy is then modelled on a distinct adoption curve reflecting its market maturity, competitive position, and the specific 2024 guideline changes most relevant to it.

Table 7.2 — Key Forecast Assumptions

Parameter	Assumption	Rationale
Population growth	0.5–0.7% annually	U.S. Census projections
OAB prevalence growth	+0.5–1.0% annually	Ageing cohort expansion; rising comorbidity burden
Care-seeking rate	Rises from 25–30% to 30–35% by 2030	Patient education; destigmatisation campaigns
Pharmacotherapy dropout	+5–10% rate increase	2024 guideline anticholinergic cognitive-risk counselling
ITNM adoption	50–70% CAGR	Guideline recognition; office-based workflow; 3 competitors driving awareness
SNM growth	8–12% CAGR	Mature market with continued competitive investment
Botox growth	4–6% CAGR	Established market; repeat-burden limits upside
PTNM trajectory	−2 to −3% CAGR	Compliance burden; displacement by ITNM
ITNM reimbursement	~40% (2025) → 65%+ (2027) → 80%+ (2030)	CPT code maturation; guideline adoption by payers

7.3.2 Procedure Volume Forecast

Table 7.3 — Procedure Volume Forecast by Segment (2025–2030)

Segment	2025	2026	2027	2028	2029	2030	CAGR
Botox (new)	100,000	105,000	110,000	115,000	118,000	120,000	3.7%
SNM	45,000	48,000	51,000	54,000	57,000	60,000	5.9%
PTNM	35,000	34,000	33,000	32,000	31,000	30,000	−3.0%
ITNM	5,000	8,000	15,000	30,000	55,000	100,000	82.0%
Total	185,000	195,000	209,000	231,000	261,000	310,000	10.9%

Source: Author's forecasts synthesised from CMS data, market reports, and internship project data.

7.3.3 Revenue Forecast

Table 7.4 — Market Size Forecast by Segment (2025–2030, USD Millions)

Segment	2025	2026	2027	2028	2029	2030	CAGR
Botox	$460	$483	$506	$529	$543	$552	3.7%
SNM	$870	$928	$986	$1,044	$1,102	$1,160	5.9%
PTNM	$55	$53	$52	$50	$49	$47	−3.1%
ITNM	$25	$40	$75	$150	$275	$500	82.0%
Total	$1,410	$1,504	$1,619	$1,773	$1,969	$2,259	9.9%

Source: Author's forecasts synthesised from CMS data, market reports, and internship project data.

7.4 Segment-Level Forecast Interpretation

ITNM (82% CAGR): The projection from 5,000 to 100,000 procedures in five years is aggressive but grounded in specific drivers: formal guideline recognition in 2024, three competing vendors collectively investing in physician training and market awareness, CPT code establishment that will support reimbursement expansion, and a convenience profile unmatched by any incumbent therapy. The adoption curve is modelled as an S-shape — slow in 2025–2026 as early adopters establish workflows, then accelerating sharply from 2027 as reimbursement reaches 65% coverage and guideline implementation becomes mainstream.

SNM (5.9% CAGR): Growth from 45,000 to 60,000 procedures reflects an established market that will continue benefiting from an ageing patient population and ongoing competitive investment from both Medtronic and Boston Scientific post-Axonics acquisition. The ceiling on SNM growth is surgical anxiety and OR dependence, which no device iteration can fully resolve without fundamentally changing the therapy's mechanism of delivery.

Botox (3.7% CAGR): Botox's growth is limited by the structural dynamics identified in Chapter 5: repeat-injection burden, UTI risk, and the emergence of ITNM as a more durable office-based alternative. Growth will continue at modest levels as the underlying OAB population expands, but displacement by durable alternatives is likely to compress Botox's share of the advanced-therapy market over the forecast period.

PTNM (−3.0% CAGR): PTNM is the only segment forecast to decline. The compliance problem documented throughout this dissertation — most patients do not complete even the initial twelve-week course — is structural and unchanged by any pending device or reimbursement development. ITNM, offering the identical mechanism without the visit burden, is likely to capture much of PTNM's natural new-patient flow as it becomes more widely available.

7.5 Scenario Analysis

Given the inherent uncertainty around ITNM's still-early adoption trajectory, the forecast is presented across three scenarios that differ in their assumptions about reimbursement speed, physician training velocity, and competitive effectiveness.

Table 7.5 — Scenario Outcomes: ITNM Procedures and Total Market (2030)

Scenario	2030 ITNM Procedures	ITNM CAGR	Total Market (USD M)	Total Market CAGR
Worst-Case	50,000	58.5%	$1,935M	6.5%
Base-Case	100,000	82.0%	$2,259M	9.9%
Best-Case	150,000	97.0%	$2,590M	12.9%

The best-case scenario requires rapid reimbursement coverage of 75%+ by 2027, accelerated physician training, and strong patient demand driven by direct-to-consumer education; under these conditions, ITNM would approach USD 750M and represent nearly 29% of total advanced-therapy revenue by 2030. The worst-case scenario assumes slower payer adoption, limited training capacity, and competitive fragmentation among the three ITNM vendors slowing overall market awareness; even so, the total market reaches USD 1.94 billion, reflecting the structural tailwind of demographic growth that no plausible downturn in ITNM adoption can fully reverse.

The spread between scenarios narrows considerably when expressed as total-market impact, rather than ITNM-specific impact — a useful reminder that Botox and SNM together account for USD 1.7 billion of the 2030 base-case projection. ITNM is the growth story, but it does not yet determine the market's floor.

7.6 Market Growth Drivers

7.6.1 Demographics

The U.S. population aged 65 and older is projected to grow from roughly 58 million in 2025 to over 70 million by 2030 — an increase of approximately 21% in five years. Given that OAB prevalence exceeds 30% in adults over 65 and approaches 40% in women over 75, this demographic shift mechanically expands the addressable OAB population without requiring any change in age-specific prevalence rates. The baby-boom cohort is now squarely within the highest-prevalence age bracket, and the downstream effect on refractory patients — and therefore on advanced-therapy eligibility — is expected to drive a 10–15% expansion of the addressable pool by 2030. This demographic tailwind applies uniformly across all four therapy segments, contributing a baseline 2–3% annual growth to total advanced-therapy volume irrespective of any therapy-specific dynamics.

7.6.2 Guideline Evolution

The 2024 AUA/SUFU guideline update operates through three distinct market mechanisms. The formal recognition of ITNM as a third-line therapy option gives it the clinical legitimacy required to unlock payer coverage reviews and physician training investment — the two inputs most strongly correlated with device adoption in comparable categories. The 'menu' approach, which enables direct escalation to minimally invasive therapy for patients unwilling or unable to try pharmacotherapy, compresses the median time from symptom presentation to advanced-therapy receipt, modelled here as a 5–10% improvement in the conversion rate from care-seeking to advanced therapy. The requirement to counsel patients on anticholinergic cognitive risk is expected to accelerate pharmacotherapy dropout by 5–10%, expanding the refractory pool available for advanced-therapy consideration. Table 7.6 quantifies the combined effect.

Table 7.6 — Guideline Impact on Key Funnel Metrics

Metric	Pre-Guideline (2024)	Post-Guideline (2027+)	Change
Refractory Population	500K–600K	550K–650K	+10%
ITNM Annual Procedures	~5,000	~15,000	+200%
Median Time to Advanced Therapy	15+ months	10–12 months	−20 to −33%
Advanced Therapy Penetration (of Refractory)	~34%	~40–45%	+6–11 pp

Source: Author's estimates based on guideline analysis and funnel model.

7.6.3 Reimbursement Expansion

Reimbursement is the single most powerful short-term lever for ITNM adoption. CPT codes 0816T and 0817T were newly established in 2025 and current coverage is estimated at approximately 40% of commercial plans and Medicare. Each 10 percentage-point increase in coverage is estimated to drive a 15–20% increase in ITNM procedure volume, a relationship derived from comparable device categories where coverage trajectory closely tracked adoption ramp. The forecast assumes coverage reaches 65% by 2027 and 80% by 2030, consistent with the pace at which analogous neuromodulation devices have historically achieved mainstream payer recognition after formal guideline endorsement. The device manufacturer that secures favourable reimbursement determinations earliest will carry a meaningful first-mover advantage in both physician adoption and patient access.

7.6.4 Technology Innovation

Device innovation within ITNM is accelerating rather than stabilising. Valencia's eCoin (FDA 2022) offers first-mover status and an established CPT code but a battery life of approximately five years. BlueWind's Revi (FDA 2023) eliminates battery replacement through wireless external power. The 2025 entrant combines a fifteen-year battery life, MRI conditionality, and immediate post-implant activation — specifications that match or exceed current-generation SNM devices on every patient-convenience dimension. Within the SNM segment, both Medtronic and Boston Scientific continue investing in rechargeable batteries, smaller form factors, and remote programming capability; these improvements will sustain SNM's competitive position but are unlikely to resolve the fundamental surgical-access constraint that defines its adoption ceiling. Looking beyond 2030, closed-loop neuromodulation, wireless charging, and digital health integration represent plausible next-generation developments that could further expand the addressable OAB therapy market, though these remain in early development and are not modelled in the 2025–2030 forecast.

7.7 Market Growth Barriers

Four barriers are capable of delaying — though not ultimately preventing — the growth trajectory outlined above. Reimbursement uncertainty remains the most proximate risk: if Medicare and commercial payers move slowly on coverage for CPT codes 0816T and 0817T, or impose restrictive prior-authorisation requirements, the ITNM adoption curve will flatten toward the worst-case scenario. Training capacity is a related constraint — an estimated 7,000-plus U.S. urologists are untrained on advanced OAB therapies, and three ITNM vendors competing for the same finite pool of physicians could produce fragmentation that slows aggregate adoption even as each vendor's training programmes individually expand. Evidence maturity is a longer-run concern: ITNM's evidence base currently relies on indirect, single-arm meta-analysis rather than head-to-head RCTs, and some payers and guideline committees may require stronger comparative data before making definitive coverage recommendations. Finally, competitive intensity between SNM and ITNM vendors may divert marketing and education resources into head-to-head competitive battles rather than market-expanding awareness activities, a dynamic that would slow overall funnel growth even as it shifts share among segments.

7.8 Competitive Market Dynamics

The Boston Scientific acquisition of Axonics in 2024 reshaped the SNM segment, consolidating what had been an emerging duopoly and intensifying competition between the two remaining SNM vendors. The Axonics platform — rechargeable, MRI-conditional, smaller footprint — gained share on Medtronic's InterStim prior to the acquisition, and Boston Scientific now has both the commercial infrastructure and the product portfolio to mount a more sustained competitive challenge. The net effect on aggregate SNM market size is likely positive, as increased marketing investment from both vendors expands overall advanced-therapy awareness among untrained physicians, even as it creates pricing and contracting pressure within the segment.

Within ITNM, the competitive dynamic is different: the three vendors are competing for early market-share in a segment where total volume is still being established. The risk is that three-way fragmentation of physician training resources slows the category's overall growth relative to a scenario where a single well-resourced vendor leads physician education. The historical analogy from stroke thrombectomy — where Medtronic (then Covidien) captured early market leadership in aspiration thrombectomy as competitors split physician attention — is instructive: early training relationships in device categories tend to be durable, and the company that achieves first-mover status among the estimated 800–1,000 FPMRS-trained specialists who currently drive the large majority of advanced-therapy referrals will have a structural advantage difficult for later entrants to dislodge.

7.9 Key Forecasting Insights

- The U.S. advanced OAB therapy market is estimated at USD 1.41 billion in 2025 and is projected to reach USD 2.26 billion by 2030 under the base-case scenario, a 9.9% CAGR.
- ITNM is the dominant growth engine: a projected 82% CAGR from 5,000 to 100,000 procedures represents a transition from a niche entrant to the second-largest advanced-therapy segment by revenue within five years.

- The scenario range — USD 1.94B (worst-case) to USD 2.59B (best-case) in 2030 — is driven almost entirely by uncertainty in ITNM reimbursement speed and physician training velocity.
- The 2024 AUA/SUFU guideline creates a sustained multi-year tailwind across all metrics: larger refractory pool, shorter time-to-therapy, higher advanced-therapy penetration rate, and formal clinical legitimacy for ITNM.
- Demographics are the most reliable growth driver: a 21% expansion of the 65+ population by 2030 is structural and not subject to the reimbursement or training uncertainties that introduce variance into the therapy-level projections.
- The next eighteen to twenty-four months are the most consequential window in the forecast: reimbursement coverage, physician training relationships, and competitive positioning established in this period will determine which ITNM vendor achieves durable market leadership.

7.10 Business and Commercialisation Implications

For device manufacturers: The base-case ITNM revenue projection of USD 500M by 2030 — growing from USD 25M today — makes the category's commercial significance clear. Manufacturers should prioritise reimbursement advocacy, physician training infrastructure, and payer-accessible economic modelling over the next eighteen to twenty-four months, since these activities determine adoption velocity more directly than further device specification improvements at the current stage of market development.

For healthcare providers: ITNM's office-based delivery and minimal post-procedure burden make it increasingly attractive relative to SNM for practices already accustomed to Botox or PTNM workflows. Providers who establish ITNM competence during the early-adoption window are likely to benefit from both the financial return of a growing procedure volume and the patient-satisfaction advantages of a more convenient therapy.

For payers: The cost-effectiveness argument for ITNM relative to both Botox and SNM is emerging — lower five-year cost than SNM, fewer lifetime procedures than Botox — and will strengthen as formal health-economic studies accumulate. Early, clear coverage policy for CPT codes 0816T and 0817T removes a primary adoption barrier at comparatively low incremental risk, since coverage can be conditioned on appropriate patient selection criteria aligned to the AUA/SUFU guideline.

7.11 Chapter Conclusion

This chapter has sized the U.S. advanced OAB therapy market at approximately USD 1.41 billion in 2025 and constructed a segment-level five-year forecast that projects growth to USD 2.26 billion by 2030 under base-case assumptions. The growth story is heavily concentrated in ITNM, which moves from near-zero market share today toward potential second-place status by revenue by the end of the decade. The structural drivers underpinning this trajectory — demographic ageing, guideline-driven legitimacy for ITNM, reimbursement expansion, and continued device innovation — are individually well-evidenced and, taken together, suggest the market opportunity is genuine and time-sensitive rather than speculative.

What the forecast cannot determine is which vendor will capture the ITNM opportunity, and how the competitive dynamics between all four therapy segments will ultimately resolve. Chapter 8 addresses this dimension directly, translating the market and adoption analysis into a force-field framework that identifies the specific drivers and barriers most amenable to strategic intervention, and from which the stakeholder-specific recommendations in Chapter 9 are derived.

CHAPTER 8 — ADOPTION DRIVERS AND BARRIERS

8.1 Introduction

The preceding chapters have established two things clearly: a large pool of patients is eligible for advanced OAB therapy, and far fewer than one-third of them receive it. This chapter investigates why. Drawing on Lewin's Force-Field Analysis, it identifies the specific forces that are currently promoting and restraining advanced therapy adoption, assesses their relative magnitude, and uses that assessment to derive the priority interventions that feed directly into the strategic recommendations of Chapter 9.

The analysis is structured around five stakeholder dimensions — patient, physician, healthcare system, reimbursement, and technology — because the adoption gap in OAB is not the product of any single cause. It reflects a compound accumulation of barriers operating simultaneously across all five dimensions. Addressing any one in isolation produces limited results; the most effective strategies will target the highest-leverage points across multiple dimensions at once.

8.2 The Force-Field Framework and Integrated Driver-Barrier Matrix

Force-field analysis, originally developed by Kurt Lewin for organisational change management, treats the current state of a system as an equilibrium between forces pushing toward change and forces resisting it. Applied to OAB advanced therapy adoption, the current state is low but growing utilisation — roughly 34% of refractory patients receiving any advanced therapy — held in place by restraining forces that currently outweigh the driving forces. To shift this equilibrium, stakeholders can either strengthen drivers, weaken barriers, or both; the analysis below indicates which approach offers the greatest return at each dimension.

Table 8.1 — Integrated Driver-Barrier Matrix by Stakeholder Dimension

Dimension	Key Drivers	Key Barriers	Net Force Direction
Patient	Ageing population; preference for minimally invasive options; desire for convenience	Low care-seeking rate (70–75%); 'normal ageing' misconception; lack of advanced-therapy awareness	Restraining (Strong)
Physician	FPMRS expertise (15× referral rate); 2024 guideline endorsement; KOL influence; procedure economics	Training gap (7,000 untrained urologists); referral inertia; limited generalist awareness	Restraining (Strong)
Healthcare System	Site-of-service migration (90% office-based); APP utilisation; ASC/OBL growth	Urologist workforce shortage; fragmented care pathways; limited rural access	Mixed

Reimbursement	CPT code establishment (0816T/0817T); guideline-aligned coverage; outcomes-based contracting potential	Limited ITNM coverage (~40%); prior authorisation burden; coding complexity	Mixed
Technology	15-yr battery life; MRI conditionality; office-based workflow; growing evidence base	Limited head-to-head ITNM evidence; competitive fragmentation across 3 vendors; switching costs	Driving (Emerging)

Source: Author's synthesis of internship project data, clinical literature, and CMS analysis.

8.3 Patient Dimension

8.3.1 Drivers

Two patient-side drivers stand out. The first is demographic inevitability: OAB prevalence exceeds 30% in adults over 65 and approaches 40% in women over 75, and the 65-plus population is projected to grow by roughly 21% between 2025 and 2030. This expansion of the addressable population will mechanically increase advanced-therapy demand even if nothing else changes. The second driver is an evolving patient preference for minimally invasive, low-burden care. Studies of treatment attributes consistently show that patients place high value on reduced visit frequency, minimal recovery time, and lower procedural anxiety — preferences that align directly with ITNM's one-time implant and fifteen-year battery life. As patients become more health-literate through digital health platforms and direct-to-consumer health content, awareness of options beyond repeated injections is likely to increase.

8.3.2 Barriers

The single largest source of attrition anywhere in the OAB funnel is not at the refractory-to-advanced-therapy stage — it is much earlier, at the symptom-to-care-seeking transition. Approximately 70 to 75% of symptomatic adults never discuss bladder symptoms with a clinician. Internship project data identified three drivers of this behaviour: 75% of non-care-seeking patients report their symptoms are 'not bad enough,' 55% report their provider never raised the topic, and 53% believe incontinence is a normal part of ageing. These are not easily overcome through awareness advertising alone; they represent deeply held social norms that require sustained destigmatisation campaigns directed at both patients and the clinicians who see them routinely. Treatment anxiety presents a secondary but meaningful barrier, particularly for SNM — many otherwise-eligible refractory patients decline the therapy specifically because of the surgical procedure and its associated recovery. ITNM reduces but does not fully eliminate this anxiety.

Table 8.2 — Patient Dimension: Driver and Barrier Summary

Factor	Type	Strength	Impact on Advanced Therapy Adoption

Ageing population	Driver	Strong	Structurally expands addressable market year on year
Preference for minimally invasive care	Driver	Moderate	Favours ITNM and Botox over SNM
Convenience-oriented patient expectations	Driver	Moderate	Favours ITNM's one-time-implant profile
Low care-seeking rate (70–75% never seek care)	Barrier	Very Strong	Largest single source of funnel leakage
'Normal ageing' misconception	Barrier	Strong	Prevents symptom recognition and care-seeking
Lack of advanced-therapy awareness	Barrier	Strong	Prevents informed patient choice at decision point
Treatment/procedural anxiety	Barrier	Moderate	Particularly relevant for SNM; partially for ITNM

8.4 Physician Dimension

8.4.1 Drivers

The physician landscape is highly polarised, and that polarisation creates both the strongest available driver and the most actionable barrier in the entire framework. The driver: FPMRS-trained specialists — a group of approximately 1,700 physicians — refer patients to advanced therapy at roughly fifteen times the rate of general urologists. This disparity is not an opinion; it is derived from procedure-volume data in the CMS analysis and independently corroborated by internship project findings. It tells us that competent, trained physicians routinely identify and refer appropriate patients, which means the capability to deliver guideline-concordant care already exists in the system — it is simply concentrated in a very small subset of physicians.

Supporting drivers include the 2024 AUA/SUFU guideline's formal recognition of ITNM and its 'menu' approach, which provide clinical cover for general urologists and OBGYNs who may have previously been reluctant to offer advanced therapy without explicit guideline endorsement. Procedure economics also matter: the shift of procedural volume toward office-based settings is financially attractive for physicians, and therapies like ITNM that can be implanted in-office under local anaesthesia fit this economic logic more naturally than SNM, which requires OR infrastructure.

8.4.2 Barriers

The corresponding barrier is equally stark: approximately 56% of U.S. urologists — 7,000 of roughly 12,500 — are untrained in any advanced OAB therapy. These physicians manage significant OAB patient volumes but refer to advanced therapy at rates below 1%. This is not fundamentally an awareness problem; many of these physicians know that advanced therapies exist. It is a training and confidence problem: without procedural competence, even wellintentioned referrals are unlikely, because the physician cannot credibly counsel the patient or perform the procedure themselves. Referral inertia reinforces this pattern — physicians who have never referred a patient to advanced therapy have no established pathway or relationship to rely on, and the cognitive effort of establishing one from scratch acts as a further deterrent.

Table 8.3 — Physician Dimension: Driver and Barrier Summary

Factor	Type	Strength	Impact on Advanced Therapy Adoption
FPMRS specialty expertise (~1,700 physicians)	Driver	Strong	Accounts for the large majority of advanced-therapy referrals
2024 Guideline endorsement and menu approach	Driver	Moderate	Provides clinical legitimacy for untrained physicians to refer
KOL peer-to-peer influence	Driver	Moderate	Accelerates adoption through clinical community networks
Procedure economics (office-based migration)	Driver	Moderate	Makes office-based advanced therapy financially attractive
Training gap (7,000 untrained urologists)	Barrier	Very Strong	Primary reason for <1% referral rate among general urologists
Referral inertia among established practitioners	Barrier	Strong	Prevents adoption even among aware but untrained physicians
Limited awareness among OBGYNs and PCPs	Barrier	Strong	Large patient-contact workforce almost completely inactive on referrals

8.5 Healthcare System Dimension

The system-level environment is evolving in ways that generally favour advanced OAB therapy adoption, but with meaningful constraints. The most significant structural driver is the migration of OAB procedural volume toward office-based settings: approximately 90% of advanced OAB procedures are now performed in offices, ambulatory surgery centres, or office-based labs rather than hospital outpatient departments. This migration is self-reinforcing — it is driven by reimbursement design, patient convenience preferences, and technological advances that enable in-office workflows — and it systematically advantages therapies with office-based delivery profiles. ITNM and Botox are directly aligned with this trend; SNM is not.

Advanced Practice Providers (APPs) represent an underutilised system-level asset. The FPMRS physician profiled in the internship project materials has pioneered national education programmes specifically designed to build APP competence in OAB care coordination, patient education, and escalation decision-making. Scaling this model across community urology practices could meaningfully expand the effective referral capacity of the system without requiring the expensive and time-intensive training of additional FPMRS physicians. On the restraining side, the urology workforce shortage — acute in rural and underserved areas — limits patient access to specialty care upstream of any advanced-therapy conversation. Fragmented care pathways, in which OAB patients rotate between PCPs, OBGYNs, and urologists without a defined escalation protocol, allow refractory patients to remain in the endless first-line loop for years without any stakeholder taking ownership of escalation.

8.6 Reimbursement Dimension

CPT code establishment is the proximate key to ITNM adoption velocity. The establishment of codes 0816T and 0817T in 2025 removed the most fundamental administrative barrier — without a CPT code, a procedure effectively cannot be billed — but establishment is not the same as coverage. Current ITNM coverage is estimated at approximately 40% across commercial plans and Medicare, meaning the majority of potential patients face either outright denial or significant out-of-pocket exposure. Each 10-percentage-point increase in coverage is estimated to drive a 15–20% increase in ITNM procedure volume, making reimbursement expansion the single most controllable short-term lever available to device manufacturers.

The 2024 AUA/SUFU guideline provides the clinical justification payers need to expand coverage, since most commercial plans follow guideline-concordant evidence when making medical policy decisions. Outcomes-based contracting — tying reimbursement to demonstrated clinical results — represents an emerging mechanism that could accelerate coverage for risk-averse payers, since it shifts some downside risk to the manufacturer and reduces the payer's exposure to uncertain outcomes. Prior authorisation requirements are a persistent and frustrating practical barrier: the administrative burden of obtaining authorisation discourages physicians from offering ITNM, even in cases where coverage nominally exists. Simplifying prior authorisation criteria, aligned to the AUA/SUFU guideline's clinical eligibility criteria, would reduce this friction materially.

Table 8.4 — Reimbursement Dimension: Driver and Barrier Summary

Factor	Type	Strength	Impact
CPT codes 0816T/0817T established (2025)	Driver	Strong	Enables billing; prerequisite for all coverage decisions
2024 Guideline-aligned clinical justification	Driver	Moderate	Accelerates payer coverage policy review
Outcomes-based contracting potential	Driver	Emerging	Reduces payer risk; could accelerate ITNM coverage
Site-neutral payment trend	Driver	Emerging	Reduces HOPD premium; favours office-based therapies
Limited ITNM coverage (~40%, 2025)	Barrier	Strong	Restricts patient access; reduces physician willingness to offer

Prior authorisation burden	Barrier	Moderate	Administrative deterrent even where coverage exists
Coding complexity (two codes per device)	Barrier	Moderate	Creates claims submission errors and denials

8.7 Technology Dimension

ITNM device innovation is currently the most dynamic dimension in the entire adoption landscape, and — uniquely — it contains more drivers than barriers at this stage of market development. The three competing ITNM devices offer progressively stronger specifications: Valencia's eCoin (FDA 2022) established first-mover status and the CPT code infrastructure; BlueWind's Revi (FDA 2023) eliminated battery replacement entirely through wireless external power; the 2025 entrant added a fifteen-year internal battery life, MRI conditionality, and immediate post-implant activation. Three vendors competing simultaneously is accelerating physician awareness and training investment at a pace that a single-vendor market would not produce.

The principal technology-side barriers are evidence immaturity and competitive fragmentation. ITNM's evidence base, while growing rapidly, remains grounded in single-arm meta-analysis rather than head-to-head RCTs; some payers and cautious physicians will hold back adoption until comparative data are available. Competitive fragmentation creates a different problem: physicians uncertain which device will dominate may delay training investment entirely rather than commit to a platform that could be displaced — a risk the stroke-thrombectomy market history suggests is real and consequential. Switching costs, once a physician is trained on one ITNM device, act as a lock-in mechanism that benefits early movers but creates a structural barrier for later entrants attempting to convert already-trained physicians.

8.8 Comparative Driver and Barrier Assessment Across Therapies

Viewing the adoption dynamics through a therapy-specific lens reveals that each of the four advanced therapies faces a distinct combination of drivers and barriers, with important implications for how commercial strategy should be tailored to each segment.

Table 8.5 — Therapy-Specific Adoption Driver and Barrier Profile

Dimension	Botox	PTNM	SNM	ITNM
Primary Adoption Driver	Established brand; broad urologist familiarity; mature reimbursement	Non-invasive profile; no anaesthesia; established reimbursement	Longest clinical evidence base; highest revenue reimbursement	Convenience + durability combination; 2024 guideline recognition; office-based workflow

Primary Adoption Barrier	Repeat injection burden; UTI risk (22.7%); urinary retention (5–7%)	Session compliance burden (200+ visits over 5 years); ITNM displacement risk	Surgical procedure anxiety; OR dependence; high upfront cost	Limited coverage (~40%); training investment required; evidence immaturity
Patient Convenience Rating	Moderate	Low	Moderate (post-recovery)	High
Physician Training Requirement	Low (existing cystoscopy skills)	Low (no procedural training)	High (surgical competence; OR access)	Moderate (new implant technique)
Reimbursement Maturity	Established	Established	Established	Emerging
Growth Trajectory	Modest positive (3.7% CAGR)	Declining (−3.0% CAGR)	Moderate positive (5.9% CAGR)	Rapid growth (82% CAGR base-case)

The table reveals a pattern with strategic relevance. Botox and SNM are mature segments whose adoption dynamics are broadly stable, with modest positive trajectories driven by demographic growth rather than structural change. PTNM is in structural decline — the compliance burden that defines its patient experience is not addressable through reimbursement or training interventions, only through device redesign that is effectively what ITNM represents. ITNM alone faces a genuinely dynamic adoption environment where all five driver-barrier dimensions are in active flux — and where early decisions about reimbursement, training, and competitive positioning will have durable long-run consequences.

8.9 Integrated Strategy Matrix and Priority Actions

Synthesising the five-dimensional analysis, Table 8.6 maps the highest-impact actions for each stakeholder dimension, ranked by the magnitude of the barrier being addressed and the feasibility of the intervention.

Table 8.6 — Integrated Strategy Matrix: Barriers, Actions, and Priority Ranking

Dimension	Strongest Barrier	Recommended Action	Priority
Patient	70–75% non-care-seeking rate driven by 'normal ageing' belief and provider silence	Sustained DTC destigmatisation campaigns; implement systematic OAB screening at primary care and OBGYN encounters; patient education on treatability and available options	Highest
Physician	7,000 untrained general urologists referring <1% of OAB patients to advanced therapy	Structured procedural training programmes targeting community urologists; KOL peer-to-peer education networks; formal referral pathways between PCPs/OBGYNs and trained specialists	Highest
Reimbursement	~40% ITNM coverage blocking majority of eligible patients from access	Payer coverage advocacy using 2024 guideline as clinical justification; outcomes-based contracting pilots with early-adopter health systems; prior authorisation criteria simplification	Highest

Healthcare System	Fragmented care pathways perpetuating endless first-line loop	Multidisciplinary OAB programme development; APP training and deployment in care coordination roles; structured escalation criteria embedded in electronic health record workflows	High
Technology	Evidence immaturity slowing cautious payer and physician adoption	Sponsor or co-sponsor comparative effectiveness studies; publish long-term real-world registry data; use meta-analysis evidence (Amundsen et al., 2025) proactively in payer submissions	High

8.10 Key Analytical Insights

Six insights from this chapter deserve particular emphasis as they directly inform the strategic recommendations developed in Chapter 9.

- The adoption gap is not a clinical problem. All four advanced therapies have demonstrated efficacy; the barriers that prevent their use are behavioural, systemic, economic, and structural — and most are at least partially addressable.
- The largest single lever is the top of the funnel, not the bottom. Addressing the 70–75% of symptomatic patients who never seek care would expand the entire advanced-therapy addressable population more than any physician training programme or reimbursement expansion could achieve on its own.
- The physician training gap is the most concentrated actionable opportunity. Seven thousand identifiable, reachable urologists refer less than 1% of their OAB patients to advanced therapy. Even a modest shift in this population's referral rate would add more procedures than any other single intervention.
- Reimbursement expansion for ITNM is the most time-sensitive action. Each 10-percentage-point increase in coverage is estimated to drive a 15–20% increase in procedure volume; delays in coverage expansion compound over the forecast horizon.
- ITNM's adoption dynamics are uniquely favourable among the four therapies, but only if the market-building work — training, coverage, awareness — is executed before the early-mover window closes.
- The force-field is currently balanced toward restraint, but several of the restraining forces are more addressable than they appear. The 'normal ageing' misconception is a communication challenge, not a clinical one. The training gap is a resource-allocation challenge, not a capability gap. The reimbursement barrier is a policy-advocacy challenge, not an evidence gap.

8.11 Business and Commercialisation Implications

For ITNM device manufacturers: the force-field analysis identifies three near-term priority investments — physician training at community-level urology practices (not just FPMRS specialists), payer advocacy that leads with the 2024 guideline and Amundsen meta-analysis evidence, and patient-facing education that positions ITNM as the answer to the compliance problem PTNM has always had. These investments compete with each other for budget and management attention; the training and reimbursement activities should be treated as higher priority than patient-facing campaigns at this stage of market development, since physicians and payers are the gatekeepers.

For healthcare providers: the analysis makes a clear case for embedding systematic OAB screening into routine primary care, OBGYN, and geriatric encounters. The finding that 55% of symptomatic patients report their provider never raised the topic suggests this is less a patient reluctance problem than a provider workflow problem — one addressable through simple electronic health record prompts and staff education without significant additional clinical resource.

For payers: the dominant finding for this stakeholder is straightforward: limited ITNM coverage is the most controllable proximate barrier to advanced-therapy adoption among an already-eligible patient population. The clinical justification is now guideline-endorsed; the economic case, while not yet fully developed through formal cost-effectiveness modelling, is directionally favourable relative to both SNM and Botox on a five-year total-cost basis. Early, clear coverage policy removes a primary adoption barrier at a comparatively low incremental clinical risk.

8.12 Chapter Conclusion

This chapter has applied a five-dimensional force-field framework to identify and assess the drivers and barriers shaping advanced OAB therapy adoption. The overall finding is that restraining forces currently outweigh driving forces across the patient, physician, and reimbursement dimensions — the three dimensions most directly controlling access to advanced therapy — though the technology dimension is moving in a strongly positive direction and the system dimension is mixed.

The three highest-priority barriers — low care-seeking rates, the physician training gap, and limited ITNM reimbursement coverage — are analytically distinct but strategically interconnected.

Expanding care-seeking without expanding the trained physician base that can receive referred patients creates bottlenecks downstream. Expanding the trained physician base without expanding reimbursement creates physicians who cannot get procedures approved. Expanding reimbursement without expanding patient and physician awareness creates coverage that goes unclaimed. The most effective strategy addresses all three simultaneously, sequenced appropriately — which is precisely the three-phase activation roadmap that Chapter 9 develops from this foundation.

CHAPTER 9 — Strategic Recommendations

9.1 Introduction

This chapter translates the analytical findings from Chapters 4 through 8 into a structured set of actionable strategic recommendations for the key stakeholders shaping the U.S. advanced OAB therapy market. The analysis across earlier chapters identified a significant and persistent gap between the 16 to 24 million Americans living with symptomatic OAB and the fewer than 200,000 who currently receive advanced therapy annually. Closing that gap — even modestly — carries substantial clinical, social, and commercial implications.

Rather than presenting recommendations as a generic checklist, this chapter organizes them within a multi-stakeholder framework that acknowledges the distinct interests, capabilities, and constraints of device manufacturers, healthcare providers, payers, policy-makers, and patient advocacy organizations. A phased implementation roadmap and a prioritization matrix are introduced to support sequenced, resource-efficient execution. The chapter concludes with projected outcomes if the recommended strategies are adopted cohesively across the ecosystem.

9.2 Importance of Strategic Recommendations in Advanced OAB Therapy Adoption

The OAB advanced therapy market is not constrained primarily by clinical evidence or patient demand. The 2024 AUA/SUFU guideline update formally endorses ITNM, Botox, and SNM as recognized third-line interventions, providing both clinical legitimacy and liability clarity for physicians who choose to offer them. Yet the gap between guideline endorsement and actual adoption remains striking. As Chapter 6 established, only 41 percent of U.S. urologists are trained in any advanced OAB therapy, fewer than 15 percent of eligible patients are referred to advanced treatment, and ITNM — despite its office-based convenience and growing evidence base — accounted for fewer than 5,000 Medicare procedures in 2024.

This disconnect between available evidence and observed utilization reflects structural failures rather than clinical uncertainty: a training system that inadequately prepares physicians for advanced therapy delivery; a reimbursement landscape marked by prior authorization complexity and coverage inconsistency; a patient population that largely normalizes its symptoms as inevitable; and a commercialization model that has not yet systematically addressed these barriers in combination. Strategic recommendations, properly designed and prioritized, serve to bridge these structural gaps — aligning incentives, building capacity, and coordinating action across the stakeholder ecosystem.

9.3 Strategic Recommendations for Healthcare Providers

Healthcare providers — particularly urologists and FPMRS specialists — sit at the center of the advanced OAB therapy delivery system. Their clinical judgment, practice workflows, and referral behaviors determine which patients access advanced care and when. Three recommendations are prioritized for this stakeholder group.

Implement structured OAB care pathways. The most consistently cited systemic failure in OAB management is the 'endless first-line loop' — the phenomenon in which patients cycle through behavioral interventions and medications for years without ever being evaluated for advanced therapy. Structured care pathways that define explicit escalation criteria — number of failed drug trials, symptom persistence threshold, patient preference for non-pharmacological options — can systematically disrupt this cycle. Implementation requires EHR-embedded decision support, staff training, and protocol auditing to ensure adherence.

Develop office-based OAB procedure capacity. The site-of-service migration toward office-based labs (OBLs) is the defining operational shift in OAB procedural care. Healthcare systems and practice groups that invest in dedicated OAB procedure infrastructure — equipped rooms, trained support staff, credentialing with multiple device platforms — position themselves to capture the full range of advanced therapy volumes and to benefit from favorable office-based reimbursement margins.

Build structured referral relationships with PCPs and OBGYNs. Primary care providers and OBGYNs are the first clinical touchpoints for most OAB patients, yet referral rates from these providers to advanced therapy specialists remain low. Formal referral programs — including shared educational events, co-management protocols, and streamlined communication systems — can meaningfully increase the volume of appropriately identified patients reaching specialist care.

9.4 Strategic Recommendations for Physicians and Specialists

Physician-level recommendations address the training, guideline alignment, and practice development actions that individual practitioners can take to advance OAB care within their own clinical settings.

- Complete training in all guideline-endorsed advanced therapies, with particular emphasis on ITNM for urologists and OBGYNs currently delivering only Botox.
- Implement 2024 AUA/SUFU guideline changes in daily practice — including the 'menu' approach that offers advanced therapy directly to patients who are unable or unwilling to pursue pharmacotherapy, and the requirement to counsel patients on anticholinergic cognitive risks.
- For FPMRS specialists and high-volume urologists: engage in peer-to-peer education programs as a KOL or training host, extending the reach of their expertise to community practitioners who lack direct access to fellowship-level training.
- Adopt systematic patient screening tools — validated questionnaires, voiding diaries, and post-void residual assessments — to ensure that refractory OAB patients are identified and evaluated for advanced therapy before years of ineffective pharmacological management accumulate.

9.5 Patient Awareness and Engagement Strategies

Approximately 66 percent of Americans with symptomatic OAB do not seek medical care, largely because they perceive their symptoms as a normal consequence of aging rather than a treatable medical condition. This normalization represents one of the most significant demand-side barriers in the OAB market. Strategies to reverse it must operate at both the population level (awareness campaigns) and the individual clinical encounter level (shared decision-making support).

Digital activation campaigns targeting the 40 to 75 age demographic — through social media, streaming platforms, and women's health networks — can destigmatize OAB and drive care-seeking. Device manufacturers and patient advocacy organizations are the natural leads for this work, with support from professional societies. Campaign messaging should center on the message that OAB is treatable at multiple levels of intervention, that advanced options exist beyond medications, and that quality of life improvements are achievable even after years of inadequate pharmacotherapy.

At the point of care, shared decision-making tools — comparative therapy guides, patient decision aids, and digital apps that support therapy tracking and symptom journaling — empower patients to engage meaningfully in therapy selection and to sustain adherence after advanced therapy initiation. The Inspire Brands MyFuture and MyJourney apps, developed in the ITNM context, represent an early model of this approach.

9.6 Physician Education and Training Strategies

The training deficit among U.S. urologists is the single most addressable structural barrier to advanced OAB therapy adoption. With 56 percent of the urological workforce currently untrained in any advanced OAB therapy, the market expansion available through training activation is multiples larger than any realistic conversion gain achievable among already-trained physicians.

Training strategies must be tiered to match the clinical starting point and learning context of each physician segment. For FPMRS-trained physicians, the priority is completing adoption of ITNM among the 30 to 40 percent not yet offering it. For trained general urologists, the priority is procedure diversification — adding ITNM and SNM to Botox-centric practices. For untrained community urologists, the entry point is simplified, structured programs — ideally CME-accredited and proctored — that build Botox competence first and create a pathway to subsequent ITNM adoption.

Postgraduate medical education reform represents a longer-term but structurally important lever. Professional societies — the AUA, SUFU, AUGS, and ACOG — should integrate advanced OAB therapy competencies into urology and OBGYN residency curricula, with the objective of ensuring that physicians entering practice from 2028 onward arrive with baseline training in at least one advanced OAB therapy modality.

9.7 Market Expansion and Commercialization Strategies

Device manufacturers occupy the most strategically powerful position in the advanced OAB ecosystem — they control training infrastructure, reimbursement advocacy, commercial messaging, and clinical evidence generation. Three commercially oriented strategies are prioritized.

Table 9.1 — Three-Phase Market Activation Roadmap

Phase	Target Segment	Physician Count	Timeline	Primary Tactic	Projected Volume
I	FPMRS Specialists	~1,700	Years 1–2	KOL engagement; complete ITNM training	5,000–10,000 procedures
II	Trained General Urologists	~5,100	Years 2–3	Structured training; Botox conversion playbooks	25,000–35,000 procedures
III	Untrained Community Urologists	~7,000	Years 3–5	Simplified training; referral pathway support	50,000–75,000 procedures

Source: Author's synthesis of internship project data, CMS PSPS PUF, and commercial strategy framework.

The three-phase roadmap above reflects a deliberate sequencing logic: activate the highest-adoption-propensity segment first (FPMRS specialists), use those early adopters as peer educators and training hosts to accelerate mid-tier adoption (trained general urologists), and finally deploy a simplified, community-friendly training model to capture the largest but most challenging segment (untrained community urologists). This sequencing maximizes early procedure volume while building the credentialing and peer-influence infrastructure needed for later phases.

Data-driven physician targeting is the commercial complement to training activation. Hyper-specific playbooks — built from CMS claims data, AMA Physician Masterfile segmentation, and specialty distribution analytics — enable sales and medical affairs teams to direct time and resources toward the physicians with the highest procedure volumes, most favorable practice economics, and greatest ITNM adoption propensity. Account-based marketing (ABM) applied at the physician level, rather than at the geographic market level, has demonstrated meaningfully higher conversion rates in analogous specialty device markets.

Direct-to-consumer (DTC) digital activation addresses the demand-side gap by generating informed, therapy-seeking patients who enter specialist offices already motivated to discuss advanced therapy. A DTC strategy targeting women aged 40 to 75 through digital channels — combined with a 'Find a Provider' tool that connects activated patients with trained physicians — creates a demand pull that complements the physician-side supply push of training programs.

9.8 Reimbursement and Access Improvement Strategies

Reimbursement uncertainty is the most frequently cited practice-level barrier to advanced OAB therapy adoption among community urologists and OBGYNs. Strategies in this domain must operate across three layers: public payer coverage policy, commercial payer prior authorization simplification, and CPT code recognition for emerging therapies.

For ITNM specifically, the priority is achieving clear and consistent commercial coverage aligned with the 2024 AUA/SUFU guideline. A clinical evidence package — including meta-analytic efficacy data, a health economic model demonstrating office-based ITNM's cost-effectiveness relative to OR-based SNM and repeat Botox injections, and patient-reported quality-of-life outcomes — should be developed and submitted to major commercial payers within the first 12 months of commercialization. The target is 65 percent or greater commercial coverage within 12 to 18 months of guideline publication.

Outcomes-based contracting (OBC) represents a medium-term strategy for payers who are willing to provide coverage but hesitant about long-term cost implications. Linking reimbursement to defined clinical response thresholds — reduction in incontinence episodes, validated symptom score improvement — aligns manufacturer and payer incentives and provides a commercially differentiated value story that generic claims-based reimbursement does not.

9.9 Technology Adoption and Innovation Strategies

The pace of technology adoption in the OAB space is accelerating. ITNM's tenfold Medicare volume growth between 2020 and 2024 is the most visible evidence of this, but the underlying drivers — patient demand for minimally invasive, self-managed care options; physician interest in office-based procedural economics; and the 2024 guideline's formal endorsement of new modalities — are structural rather than episodic.

Manufacturers should invest in next-generation device iteration that further simplifies the implantation procedure, extends device longevity, and integrates digital health capabilities — particularly Bluetooth-enabled remote programming and patient-reported outcome capture — that align ITNM with broader digital health trends. The integration of patient-facing apps into the therapy journey, from pre-procedural education through long-term symptom monitoring, reduces therapy abandonment and builds the post-market evidence base simultaneously.

For SNM, the strategic imperative is to develop or support the development of an ambulatory or office-based implantation workflow that reduces OR dependency — the therapy's primary commercial liability versus ITNM. Manufacturers who can demonstrate a credible path toward office-based SNM delivery will substantially extend the therapy's addressable physician base beyond its current facility-affiliated user community.

9.10 Data-Driven Targeting and Physician Segmentation Strategies

Physician segmentation — introduced in Chapter 6 — is the operational foundation of a precision commercialization strategy. The five-type taxonomy (FPMRS specialists, high-volume trained urologists, community trained urologists, untrained urologists, and cystoscopy-capable OBGYNs) provides a framework for differentiating commercial investment by segment according to adoption propensity and addressable volume.

Table 9.2 — Physician Segmentation and Commercial Priority Matrix

Physician Segment	Count	Adoption Propensity	Commercial Tier	Engagement Strategy
FPMRS Specialists	~1,700	Very High	Tier 1	KOL development; ITNM/SNM training completion
High-Vol. Trained Urologists	~2,000	High	Tier 1	Procedure diversification; conversion playbooks
Community Trained Urologists	~3,100	Moderate	Tier 2	CME programs; peer-to-peer education
Untrained Community Urologists	~7,000	Low–Moderate	Tier 2–3	Simplified training; referral enablement
Cystoscopy-Capable OBGYNs	~3,000	Low–Moderate	Tier 3	Botox training; ITNM awareness

Source: Author's synthesis of internship project data, AMA Physician Masterfile, and commercial strategy framework.

9.11 Referral Network Optimization Strategies

The referral pathway from primary care and OBGYN to OAB specialist is the most direct structural lever for increasing the volume of patients reaching advanced therapy evaluation. As Chapter 6 demonstrated, the majority of OAB patients first present to primary care or OBGYN; yet referral rates from these providers to advanced therapy specialists are low, and referral quality — the degree to which referred patients have been appropriately screened and prepared for specialist evaluation — is variable.

Referral network optimization requires action at both ends of the referral relationship. Referring providers — PCPs and OBGYNs — need structured educational programs that define the clinical threshold for referral, streamlined communication pathways with specialist practices, and feedback loops that close the clinical information gap between referral and outcome. Receiving specialists — urologists and FPMRS physicians — need to invest in referral relationship management through physician liaison programs, co-management protocol development, and rapid-access scheduling models that reduce the delay between referral and initial specialist consultation.

9.12 Healthcare System Integration Strategies

The integration of advanced OAB therapy programs into larger health system strategy is a growing opportunity as value-based care models incentivize systems to manage the total cost of care for patient populations. OAB carries substantial associated costs — recurrent pharmacotherapy, incontinence supply expenditure, falls and fall-related injury in older adults — that advanced therapy can reduce. Health systems that establish comprehensive OAB care programs position themselves to capture both the procedural revenue of advanced therapy and the downstream cost savings that payers increasingly reward through shared savings arrangements and quality bonuses.

Hospital systems and large physician groups should designate center-of-excellence OAB programs — with defined quality metrics, multi-disciplinary team structures, and patient volume thresholds — that can attract both self-referring patients and referrals from affiliated community practices. These programs also serve as training anchors for community urologists and OBGYNs affiliated with the system, creating an organic and cost-effective channel for physician activation.

9.13 Competitive Positioning Strategies

The advanced OAB therapy market is approaching a period of intensified competitive pressure. Botox retains dominant volume share but faces margin pressure as office-based ITNM becomes a credible alternative for patients who would otherwise have received repeat Botox injections. SNM holds a durable clinical position among complex, high-severity patients but faces structural headwinds from ITNM's office-based workflow advantage. PTNM is in accelerating structural decline. ITNM, as the fastest-growing entrant, faces the dual challenge of building physician training at scale while generating the long-term clinical evidence needed to satisfy commercial payer coverage criteria.

Competitive positioning for ITNM should center on four differentiators: office-based delivery (versus SNM's OR dependency), durable efficacy without quarterly re-injection (versus Botox), home-based rather than in-office maintenance (versus PTNM), and 2024 AUA/SUFU guideline endorsement as a recognized third-line therapy. Competitive messaging should be evidence-grounded, specialty-calibrated, and delivered through clinical education channels rather than overt promotional materials — the physician audience for advanced OAB therapies is sophisticated and responds poorly to unsupported comparative claims.

9.14 Stakeholder Collaboration Strategies

No single stakeholder group can resolve the structural barriers to advanced OAB therapy adoption independently. The training gap requires collaboration between professional societies, device manufacturers, academic medical centers, and GME funding bodies. The reimbursement gap requires collaboration between manufacturers, payers, professional societies, and CMS. The patient awareness gap requires collaboration between advocacy organizations, health systems, primary care networks, and media partners. Effective stakeholder collaboration is therefore not a nice-to-have but a structural necessity for achieving the market growth potential identified in Chapter 7.

Table 9.3 — Stakeholder Collaboration Matrix

Strategic Priority	Primary Lead	Supporting Partners	Collaboration Mechanism
Physician Training Expansion	Device Manufacturers	AUA/SUFU, Academic Centers, GME Programs	Accredited CME / Training Site Agreements
ITNM Commercial Coverage	Device Manufacturers	Commercial Payers, CMS, Professional Societies	Evidence Package / Value-Based Contracts
Patient Awareness Campaigns	Patient Advocacy Orgs.	Professional Societies, Manufacturers, Health Systems	Multi-channel Campaign Partnerships
Rural Access Programs	Policy-Makers (CMS/HRSA)	Manufacturers, Telehealth Platforms, Rural Hospitals	Federal Funding / Tele-mentoring Programs
Guideline Implementation	Professional Societies	Manufacturers, Hospital Systems, EMR Vendors	EHR Decision Support / CME

Source: Author's synthesis.

9.15 Future Growth Opportunity Strategies

The 2030 market opportunity for advanced OAB therapies — estimated in Chapter 7 at approximately $2.1 billion at a 3 percent penetration rate — is achievable but not automatic. It requires concurrent, coordinated progress across physician training, patient awareness, payer coverage, and health system infrastructure. Beyond 2030, additional growth vectors exist that are not yet fully captured in current market models.

- Expanding into the Medicaid population, which is currently underserved by advanced OAB therapy, represents a significant volume opportunity as state-level coverage policies are updated to align with the 2024 AUA/SUFU guideline.

- The male OAB population — approximately 30 to 35 percent of total OAB prevalence — is structurally underrepresented in current advanced therapy utilization and represents an underexplored commercial segment.
- Neurogenic OAB — associated with multiple sclerosis, Parkinson's disease, and spinal cord injury — is a clinically distinct but therapeutically adjacent population for which advanced therapies, particularly Botox and SNM, carry established evidence. Expanding commercial focus to include this indication broadens the addressable patient universe.
- International markets — including the European Union, Canada, and Australia — offer additional growth horizons as ITNM receives regulatory approval in non-U.S. jurisdictions and as global adoption of the AUA/SUFU guideline framework proceeds.

9.16 Strategic Framework for Advanced Therapy Adoption Enhancement

The RACE framework — adapted for the healthcare adoption context — provides a coherent organizing structure for the recommendations presented across this chapter. Reach strategies expand the addressable patient population through awareness and destigmatization. Activate strategies enable physicians to offer advanced therapies through training, support, and commercial engagement. Convert strategies facilitate patient therapy selection through shared decision-making and reimbursement clarity. Engage strategies sustain long-term therapy adherence and clinical outcomes through follow-up support and digital health tools.

9.17 Implementation Roadmap

Table 9.4 — Three-Phase Implementation Timeline by Stakeholder

Stakeholder	Phase I (Years 1–2)	Phase II (Years 3–4)	Phase III (Years 5+)
Device Manufacturers	Train FPMRS specialists; launch DTC; secure commercial coverage	Activate trained GU; launch Botox conversion playbooks; expand DTC	Activate untrained GU; generate long-term evidence; next-gen devices
Healthcare Providers	Implement OAB care pathways; build OBL capacity; establish referral networks	Train APPs; scale OBL clinics; implement 2024 guideline fully	Build multidisciplinary OAB programs; integrate digital health tools
Payers	Update ITNM coverage; simplify prior auth; recognize CPT 0816T/17T	Pilot outcomes-based contracting; monitor site-of-service migration	Refine OBC models; evaluate site-neutral payment; review long-term outcomes

Stakeholder	Phase I (Years 1–2)	Phase II (Years 3–4)	Phase III (Years 5+)
Policy-Makers	Fund OAB awareness campaigns; expand fellowship training; rural programs	Address rural access disparities; align Medicare coverage with 2024 guideline	Evaluate program effectiveness; adjust policies; expand Medicaid coverage
Patient Advocacy	Launch destigmatization campaigns; develop patient education materials	Expand advocacy program; develop shared decision-making tools	Scale patient support; advocate for continued access; publish outcomes data

Source: Author's synthesis.

9.18 Expected Business and Healthcare Outcomes

If the recommendations presented in this chapter are implemented cohesively across stakeholder groups and according to the phased timeline, the following outcomes are projected by 2030.

Table 9.5 — Projected Market and Clinical Outcomes by 2030

Outcome Metric	2024 Baseline	2030 Target	Primary Driver
ITNM Medicare Procedures	~4,500	~35,000–50,000	Phase I–III physician activation
Advanced Therapy Penetration (% OAB population)	<1%	2.5–3.0%	Training + awareness + coverage
Trained Urologists (Advanced OAB Therapies)	~5,100 (41%)	~8,000–9,000 (65%)	Phase II–III training programs
Commercial Payer Coverage for ITNM	Limited / Variable	>65%	Reimbursement advocacy + evidence package
Average Time to Advanced Therapy (years)	6–7 years	3–4 years	OAB care pathway implementation
U.S. Advanced OAB Market Size	~$900M	~$2.1B	Volume + mix + site-of-service shift

Source: Author's synthesis of Chapter 7 projections and implementation framework.

The projected market size expansion from approximately $900 million in 2024 to $2.1 billion by 2030 reflects a combination of ITNM volume growth, continued SNM stability, and the maturation of office-based Botox adoption among the previously untrained physician population. The 2030 target of 2.5 to 3.0 percent advanced therapy penetration represents a doubling of current penetration rates — an ambitious but analytically grounded objective if the recommended physician training, patient awareness, and coverage improvement strategies are executed in coordination.

9.19 Key Strategic Insights

The analysis and recommendations presented in this chapter converge on five strategic insights that should inform planning across the OAB advanced therapy ecosystem.

- Training investment is the highest-return commercial activity in a market-building phase. With 56 percent of urologists untrained in advanced OAB therapies, expanding training reach will generate greater volume growth than any reallocation of resources among already-trained physicians.
- The FPMRS 15x referral advantage is the most powerful near-term adoption lever. Completing training and deepening commercial engagement within the 1,700-physician FPMRS segment is the fastest path to early procedure volume and clinical evidence generation.
- ITNM's office-based alignment positions it as the structural growth engine of the 2025–2030 market. Its commercial differentiation from SNM (no OR dependency) and from PTNM and Botox (durable, non-pharmacological, once-implanted) maps precisely to physician workflow preferences and patient convenience priorities.
- Multi-stakeholder coordination is a structural requirement, not an optional enhancement. Training, coverage, awareness, and guideline adoption must advance in parallel — progress on any single dimension without corresponding progress on others will be absorbed by the remaining barriers.
- Geographic access equity is both a public health obligation and a commercial opportunity. The concentration of advanced therapy expertise in urban academic corridors leaves large patient populations in rural and semi-rural markets without access to care — markets that decentralized training, telehealth, and community physician activation strategies can begin to address.

9.20 Chapter Conclusion

This chapter has presented a comprehensive, stakeholder-differentiated set of strategic recommendations grounded in the physician analytics, patient funnel analysis, market sizing, and driver-barrier assessment developed across Chapters 4 through 8. The recommendations are not theoretical constructs; they are derived from observed structural gaps in the U.S. OAB care delivery system and calibrated to the specific capabilities and constraints of the stakeholders best positioned to address them.

The central argument of this chapter is that the advanced OAB therapy market's growth potential — conservatively estimated at $2.1 billion by 2030 — is achievable, but only through coordinated action across five stakeholder groups. Device manufacturers must lead on training and commercial activation. Providers must redesign care pathways and invest in office-based procedural infrastructure. Payers must align coverage policies with clinical guidelines and reduce administrative friction. Policy-makers must address the workforce training gap and invest in rural access. Patient advocacy organizations must destigmatize OAB and generate the demand-side awareness that pulls patients into care earlier.

The phased implementation roadmap presented in Section 9.17 provides a practical sequencing framework for this coordinated action, with clear phase milestones, stakeholder responsibilities, and projected volume outcomes at each stage. Chapter 10 now concludes the dissertation by synthesizing the major findings across all analytical chapters, identifying implications for MBA Healthcare Analytics practice, and proposing directions for future research.

CHAPTER 10 — Conclusion

10.1 Introduction

This concluding chapter draws together the principal findings of the dissertation and articulates their implications for clinical practice, commercial strategy, and health policy. The study set out to assess adoption patterns, market dynamics, and growth opportunities for advanced therapies in Overactive Bladder (OAB) management in the United States, using a structured healthcare analytics framework built on publicly available secondary data. Eight analytical workstreams — OAB population estimation, care-seeking analysis, pharmacotherapy utilization, refractory patient estimation, advanced therapy eligibility assessment, physician landscape mapping, market opportunity modeling, and strategic recommendation development — converge in this final chapter to produce a coherent, evidence-grounded picture of where the market stands and where it is heading.

The chapter proceeds as follows. Section 10.2 summarizes the research objectives and methodology. Sections 10.3 through 10.10 synthesize the key findings by analytical chapter. Sections 10.11 through 10.13 discuss implications for healthcare delivery, business strategy, and healthcare analytics practice. Sections 10.14 through 10.16 address research contributions, study limitations, and future research opportunities. Sections 10.17 and 10.18 provide the future market outlook and a final concluding statement.

10.2 Summary of Research Objectives

This dissertation addressed a single overarching research question: to what extent does a structural gap exist between the population of U.S. adults with refractory OAB and those receiving advanced therapy, and what combination of clinical, commercial, and policy interventions can most effectively close that gap? Five subsidiary objectives guided the inquiry: (1) estimate the size of the symptomatic, care-seeking, refractory, and advanced-therapy-receiving populations; (2) characterize the comparative clinical and commercial profiles of the four principal advanced OAB therapies; (3) map the physician landscape by specialty, training status, and adoption propensity; (4) model the market size and growth trajectory of the advanced OAB therapy sector through 2030; and (5) develop prioritized, stakeholder-differentiated strategic recommendations grounded in the preceding analytical findings.

10.3 Summary of Research Methodology

The dissertation employed a structured secondary research methodology, drawing on the AMA Physician Masterfile, CMS Medicare Physician/Supplier Procedure Summary Public Use Files, published clinical literature, commercial market intelligence reports, and internship project data gathered through direct industry engagement. Patient funnel calculations followed a sequential top-down model in which national prevalence estimates were progressively narrowed through care-seeking, pharmacotherapy initiation, refractory classification, and advanced therapy receipt transitions. Physician landscape analysis applied a five-type taxonomy developed from specialty classification, training status, and procedure volume data. Market forecasting employed a three-scenario model (base, best, and worst case) calibrated to observed procedure volume trends and projected adoption drivers. All assumptions were explicitly stated and subjected to sensitivity analysis to bound the uncertainty of forward projections.

10.4 Summary of Key Findings

Table 10.1 — Summary of Key Quantitative Findings by Analytical Chapter

Chapter	Focus Area	Central Finding
Ch. 4	OAB Patient Funnel	16–24M symptomatic adults; only ~185,000 receive advanced therapy annually (~1% penetration)
Ch. 5	Therapy Comparison	ITNM uniquely combines office-based delivery (70%) with 15-year durability and 79% responder rate
Ch. 6	Physician Landscape	FPMRS specialists refer at 15× the rate of untrained GU; 56% of urologists untrained in advanced therapy
Ch. 7	Market Sizing	Market grows $1.41B (2025) → $2.26B (2030) at 9.9% CAGR; ITNM projects 82% CAGR
Ch. 8	Drivers & Barriers	Restraining forces (training gap, low care-seeking, limited ITNM coverage) currently outweigh drivers
Ch. 9	Strategic Recommendations	Three-phase activation roadmap; multi-stakeholder coordination required for 2030 market realization

Source: Author's synthesis across Chapters 4–9.

10.5 Major Insights from OAB Market Opportunity Assessment

The patient funnel analysis produced what is arguably the most consequential finding of the entire study: of the 16 to 24 million Americans living with symptomatic OAB, approximately 185,000 — fewer than one percent — receive any advanced therapy in a given year. The two largest points of attrition drive this outcome. First, approximately 70 to 75 percent of symptomatic patients never discuss their bladder symptoms with a clinician, typically because they interpret urinary symptoms as a normal and inevitable feature of aging. Second, among the roughly 550,000 patients whose symptoms persist despite pharmacotherapy, approximately two-thirds never progress to advanced therapy — a failure of referral activation rather than therapeutic availability.

The 2024 AUA/SUFU guideline update adds material momentum to the demand side of this equation. By formally recognizing ITNM as a recommended third-line option, permitting clinicians to offer minimally invasive therapy to patients who cannot or will not try pharmacotherapy, and mandating anticholinergic cognitive risk counseling, the guideline compresses the clinical pathway and is expected to increase the refractory pool by 5 to 10 percent and advanced therapy penetration by 6 to 11 percent over the guideline's first three years of implementation.

10.6 Key Insights from Advanced Therapy Landscape Analysis

The comparative analysis of the four principal advanced OAB therapies — Botox, PTNM, SNM, and ITNM — reveals a market undergoing structural realignment. Botox retains the highest procedure volume, delivered almost entirely in office-based settings, and benefits from the broadest physician training base. However, the therapy's requirement for quarterly re-injection, urinary retention risk in approximately six percent of patients, and cumulative cost create meaningful clinical and economic vulnerabilities. PTNM is in accelerating decline, with Medicare procedure volumes falling approximately 25 percent between 2020 and 2025, primarily because its weekly in-office maintenance protocol is fundamentally incompatible with patient preferences for convenient, self-managed care. SNM holds a durable clinical position among complex, high-severity patients and generates the largest revenue share in the market, but its near-total dependence on hospital outpatient and ASC infrastructure creates a structural ceiling on adoption among the predominantly office-based practitioner community.

ITNM occupies a strategically distinct position. Its combination of office-based implantation (approximately 70 percent of procedures), 15-year projected device longevity, a 79 percent responder rate comparable to SNM, and minimal post-implant follow-up burden fills a gap in the therapy landscape that no prior option had effectively addressed. The therapy's alignment with the site-of-service migration toward office-based care, its guideline endorsement, and the competitive entry of multiple manufacturers are collectively driving an estimated 82 percent CAGR through 2030 from a small but rapidly expanding base.

10.7 Key Insights from Physician Analytics

The physician landscape analysis identified a provider community that is simultaneously specialized and fragmented. The approximately 1,700 FPMRS-trained specialists — who refer patients to advanced therapy at roughly 15 times the rate of untrained general urologists — represent the most commercially leveraged physician segment in the market. Their clinical expertise, high patient volume in refractory pelvic floor conditions, and influence over referring peers make them the natural anchor of any market activation strategy. Yet their small absolute number limits the procedure volumes they can generate in isolation, making the activation of the far larger general urology workforce an essential condition for achieving market-scale growth.

The finding that 56 percent of U.S. urologists — approximately 7,000 practitioners — are currently untrained in any advanced OAB therapy is the study's most actionable finding from a market development perspective. This population is not clinically unsuitable for advanced therapy delivery; the barrier is training access and awareness, not capability. A structured, accredited training pathway targeting this segment represents the highest-volume, highest-return commercial investment available to any device manufacturer operating in this space. The approximately 3,000 cystoscopy-capable OBGYNs represent a complementary medium-term opportunity, particularly for Botox and ITNM, as their existing procedural skill set and patient relationships with women experiencing urinary symptoms position them as natural adopters with appropriate training support.

10.8 Key Insights from Market Sizing and Forecasting

Table 10.2 — Advanced OAB Market Segment Forecast Summary (2025–2030)

Therapy	2025 Market Size	2030 Projected Size	2025–2030 CAGR	Key Growth Driver
Botox	$460M	$552M	3.7%	OBGYN/untrained GU activation
SNM	$870M	$1,160M	5.9%	Complex patient volume; durable market position
PTNM	$55M	$47M	-3.0%	ITNM substitution; compliance burden
ITNM	$25M	$500M	82.0%	Guideline endorsement; office-based advantage
Total Market	$1,410M	$2,259M	9.9%	ITNM growth + SNM stability

Source: Author's synthesis of CMS PSPS PUF data, internship project projections, and commercial market intelligence.

The overall market trajectory is one of healthy, sustained growth underscored by a powerful compositional shift. Botox and SNM will continue to anchor the market in volume and revenue, respectively, but ITNM's ascent will fundamentally alter the competitive landscape by 2030. PTNM's decline, meanwhile, represents value migration rather than market contraction — the clinical rationale for tibial neuromodulation remains valid; it is the delivery model that is being replaced.

The three-scenario analysis acknowledges meaningful uncertainty in the 2030 forecast. The base-case projection of 100,000 ITNM procedures and $500 million in revenue by 2030 rests on the assumption that training, reimbursement coverage, and patient awareness programs advance broadly in line with historical precedent for analogous device therapies. The worst-case scenario (50,000 procedures, $250M) reflects reimbursement delays and slower physician activation. The best-case scenario (150,000 procedures, $750M) reflects rapid coverage expansion and accelerated guideline implementation.

10.9 Key Insights from Adoption Drivers and Barriers Analysis

The force-field analysis confirmed that restraining forces currently outweigh driving forces in the advanced OAB therapy market — a finding that explains the persistent gap between clinical availability and patient access. The three most powerful restraining forces are the low care-seeking rate among symptomatic patients (approximately 70 percent never present to a clinician), the training deficit among community urologists (56 percent untrained), and the limited commercial coverage for ITNM (approximately 40 percent at the time of analysis). These three forces operate at different points in the patient and physician adoption journey, which is precisely why single-lever interventions — training programs alone, or coverage advocacy alone — have not historically generated sustained market acceleration. Closing the gap requires coordinated, multi-lever action.

On the enabling side, the 2024 AUA/SUFU guideline represents the most powerful single catalytic event in the therapy's recent history. Guideline inclusion typically correlates with 18 to 36 months of accelerated training activity and coverage policy updates, as payers align their medical policies with the recognized standard of care. The concurrent entry of multiple ITNM manufacturers — generating competitive training investment and market awareness — amplifies this catalyst. The net effect is a favorable environment for adoption acceleration that is unusual in its breadth and unlikely to persist indefinitely; it rewards early, coordinated action.

10.10 Summary of Strategic Recommendations

The strategic recommendations developed in Chapter 9 are organized around a three-phase physician activation roadmap and a multi-stakeholder coordination framework. For device manufacturers, the critical priorities in the near term are completing FPMRS specialist training, launching a direct-to-consumer digital activation campaign targeting the 40 to 75 age demographic, securing commercial payer coverage of 65 percent or greater within 12 to 18 months, and developing Botox conversion playbooks that articulate ITNM's clinical and economic advantages to physicians who already manage refractory OAB but default to Botox. For healthcare providers, the priority actions are implementing structured OAB care pathways with explicit escalation criteria, investing in office-based procedural infrastructure, and building formal referral relationships with primary care providers and OBGYNs.

Payers are encouraged to update medical policies to reflect the 2024 guideline, simplify prior authorization requirements for ITNM, and explore outcomes-based contracting arrangements that align reimbursement with clinical response. Policy-makers should invest in fellowship expansion, fund rural and community training programs, and support national OAB destigmatization campaigns. Patient advocacy organizations represent an underutilized coordination asset — their ability to normalize OAB as a treatable condition and activate care-seeking among the large symptomatic-but-untreated population is not replicated by any clinical or commercial stakeholder.

10.11 Healthcare Implications of the Study

The scale of the treatment gap documented in this study — millions of symptomatic patients, hundreds of thousands with refractory symptoms, and fewer than 200,000 receiving advanced therapy — represents a genuine failure of healthcare system design rather than a failure of clinical science. The therapies exist; the evidence supports their use; the clinical guidelines endorse them. What is absent is the structural alignment of patient pathways, physician training, and reimbursement policy that is needed to deliver evidence-based care at population scale.

Three healthcare delivery changes would have the greatest impact on closing this gap. First, systematic OAB symptom screening at primary care and OBGYN visits — supported by EHR-embedded decision prompts — would capture patients whose symptoms currently go undisclosed and undiscussed. Second, structured escalation criteria embedded in clinical pathways would prevent the endless pharmacotherapy cycle that traps refractory patients without advancing their care. Third, a tiered referral model — in which trained community urologists serve as a first escalation point and FPMRS specialists serve as the advanced therapy delivery hub — would extend the reach of specialist expertise without requiring every patient to travel to an academic medical center.

10.12 Business and Commercialization Implications

The commercialization window for ITNM is well-defined and time-sensitive. The 18 to 24 months following FDA approval and guideline endorsement consistently represent the period during which training relationships, reimbursement coverage positions, and brand preference are established in ways that prove durable over the subsequent five to ten years. The stroke thrombectomy market, cited in the internship project analysis, illustrates the cost of missed activation windows: Medtronic captured aspiration market leadership during a critical early window, and later entrants found that physician conversion from an established platform is an order of magnitude more difficult than initial adoption.

For manufacturers competing in the ITNM space, the implication is not simply to move fast but to move strategically — investing disproportionately in the FPMRS and high-volume general urology segments that will generate the early procedure volumes and clinical evidence needed to drive payer coverage decisions and peer-influence adoption cascades. Hyper-specific, data-driven physician targeting — built from CMS claims data and specialty distribution analytics — is more commercially efficient than broad-based market development and should be the operational foundation of any ITNM commercialization strategy.

Reimbursement advocacy deserves equal prioritization alongside training. Coverage at 40 percent is not sufficient to sustain the adoption trajectory projected in the base-case scenario; achieving 65 to 80 percent coverage by 2027 requires a proactive, evidence-grounded engagement with commercial payers that begins immediately and is treated as a revenue-critical strategic priority rather than a supporting commercial activity.

10.13 Implications for Healthcare Analytics

This dissertation demonstrates the analytical value of secondary data triangulation in generating strategic market intelligence when primary data are unavailable or prohibitively expensive to collect. The combination of CMS claims data, AMA Physician Masterfile, published literature, and internship project data enables a level of analytical granularity — from national prevalence estimates down to physician-level procedure mix and site-of-service distribution — that commercial market reports alone do not provide. The methodological approach is reproducible and scalable, offering a template for similar market opportunity assessments in other specialty device categories.

The study also illustrates the limitations inherent in cross-sectional secondary analysis. The inability to capture longitudinal patient trajectories, real-time physician sentiment, or payer coverage decision dynamics means that the analysis is inherently backward-looking in its data inputs and forward-projecting in its conclusions — a gap that future research integrating prospective primary data collection can begin to close. The scenario modeling framework employed in Chapter 7 is a useful but imperfect substitute for the richer uncertainty quantification that Bayesian or simulation-based forecasting approaches would permit.

10.14 Research Contributions

This dissertation makes four distinct contributions to the healthcare analytics literature and professional practice. First, it develops and applies a structured patient funnel model for a specific specialty disease area — OAB — that can serve as a methodological template for analogous analyses in other underpenetrated specialty conditions. Second, it introduces a five-type physician taxonomy (FPMRS specialists, high-volume trained urologists, community trained urologists, untrained community urologists, and cystoscopy-capable OBGYNs) that captures clinically meaningful segmentation dimensions not available in standard specialty classification schemes and that has direct application to commercial targeting strategy. Third, it integrates physician analytics, patient funnel analysis, and market forecasting into a unified healthcare analytics framework that demonstrates how these normally separate analytical disciplines compound each other's explanatory power when applied in sequence. Fourth, it provides a current-state synthesis of the ITNM market opportunity that is, to the author's knowledge, one of the first independently developed assessments of this therapy's commercial potential from a non-manufacturer perspective.

10.15 Limitations of the Study

The study carries several limitations that qualify the interpretation of its findings. First, the reliance on Medicare claims data means that the procedure volume estimates are drawn from the Medicare population (predominantly adults aged 65 and older) and may not accurately represent utilization patterns among commercially insured patients, who tend to be younger, have different comorbidity profiles, and face different reimbursement incentives. Second, OAB prevalence estimates in the published literature vary widely depending on the case definition, survey instrument, and study population — the 16 to 24 million range used in this study reflects that genuine epidemiological uncertainty and introduces downstream imprecision in all funnel-dependent calculations. Third, the cross-sectional modeling approach does not capture the dynamics of patient flow over time; a longitudinal cohort analysis would provide a richer picture of treatment trajectories, switching patterns, and adherence dynamics. Fourth, ITNM is a recently approved therapy, and the clinical evidence base — while promising — is not yet supported by large randomized controlled trials or long-term real-world outcomes data of the kind that typically anchor payer coverage decisions for established interventions.

The study mitigates these limitations through triangulation across multiple data sources, explicit statement of all assumptions, sensitivity analysis across scenario parameters, and transparent acknowledgment of where data gaps required inferential estimation. Readers are encouraged to treat the quantitative estimates as directional indicators rather than precise measurements.

10.16 Future Research Opportunities

The findings of this dissertation suggest several productive avenues for future inquiry. A nationally representative survey of OAB patients would provide the primary data needed to validate the care-seeking rates, symptom normalization patterns, and treatment preference estimates derived from secondary sources in this study. A parallel survey of urologists and FPMRS specialists would quantify physician training needs, referral decision criteria, and adoption barriers at an individual practitioner level — enabling more precise segmentation than CMS procedure data allow. Longitudinal analysis of patient treatment trajectories, using linked claims data across multiple years, would allow researchers to model the actual time distributions and transition probabilities embedded in the cross-sectional funnel estimates used here.

Health economic modeling of ITNM versus Botox versus SNM — incorporating procedural costs, device replacement costs, quality-adjusted life year (QALY) gains, and downstream healthcare utilization savings — would provide the cost-effectiveness evidence that commercial payers require before updating medical policies. Such modeling would also enable outcomes-based contract design between manufacturers and payers, accelerating the coverage expansion that Chapter 9 identifies as a strategic priority. Finally, disparities research examining geographic, racial, and socioeconomic variation in advanced OAB therapy access would provide the evidence base for policy interventions aimed at ensuring that the benefits of advanced care are distributed equitably across the patient population.

10.17 Future Outlook for Advanced OAB Therapies

The 2030 advanced OAB therapy market will look structurally different from the market that existed in 2024. ITNM, virtually absent from the market five years earlier, will have established itself as a mainstream third-line option with a projected 22 percent revenue share and a physician adoption base spanning several thousand trained practitioners across urology and FPMRS. SNM will retain its premium clinical position among complex, high-severity patients and will continue to generate the largest share of advanced OAB therapy revenue. Botox will remain the highest-volume therapy by patient count, but its market share will erode as ITNM captures an increasing proportion of new advanced therapy initiations and as Botox-experienced patients convert to more durable options. PTNM will have largely ceded its clinical niche to ITNM.

Beyond 2030, the most consequential developments are likely to involve device innovation — particularly closed-loop neurostimulation systems that adjust therapy delivery in response to real-time bladder activity, wireless charging systems that eliminate battery replacement procedures, and integrated digital health platforms that enable remote monitoring and patient-reported outcome collection. Expanded indications for neuromodulation therapies — including pediatric overactive bladder, neurogenic bladder in multiple sclerosis and Parkinson's disease populations, and fecal incontinence — will extend the addressable market beyond the OAB core. Value-based care arrangements will become increasingly standard, rewarding outcomes over volume and creating incentives for manufacturers to support long-term patient monitoring and therapy optimization rather than simply device placement.

10.18 Final Conclusion

This dissertation has pursued a single, practically grounded research question: why does such a profound gap persist between the millions of Americans living with refractory OAB and the far smaller number who receive the advanced therapies shown to meaningfully improve their quality of life? The analytical journey — across patient funnels, therapy comparisons, physician landscapes, market forecasts, driver-barrier assessments, and strategic recommendations — converges on an answer that is at once straightforward and structurally complex.

The gap persists not because effective therapies are unavailable, not because patients are fundamentally unwilling to seek care, and not because payers are categorically resistant to coverage. It persists because of the cumulative effect of several structural inefficiencies operating simultaneously: the normalization of OAB symptoms by patients and clinicians alike; the large proportion of urologists who have never received training in advanced therapy delivery; the reimbursement uncertainty that discourages practice-level investment in procedural infrastructure; and the absence of coordinated, multi-stakeholder action to address these barriers in combination. Addressing any one of these factors in isolation produces marginal improvement. Addressing them together — through the coordinated activation of manufacturers, providers, payers, policy-makers, and advocacy organizations — creates the conditions for genuinely transformative market growth.

The convergence of the 2024 AUA/SUFU guideline update, the competitive entry of multiple ITNM manufacturers, the continuing migration of procedural care toward office-based settings, and the broader aging of the U.S. population creates a defined strategic window — approximately 18 to 24 months — during which the conditions for rapid adoption acceleration are more favorable than they are likely to be again for some time. An analytics-driven approach, focused on closing funnel leakage at the highest-volume transition points and activating the physician segments with the greatest adoption leverage, offers a credible and measurable pathway toward the 2030 market in which advanced therapy penetration reaches 2.5 to 3 percent of the symptomatic OAB population.

For the millions of patients who currently live with OAB without access to care that could substantially restore their quality of life, that goal carries a significance that transcends market share and revenue projections. It represents a commitment, grounded in evidence and driven by coordinated strategy, to deliver the standard of care to the people who need it most.

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