

U.S. OSTEOPENIA MARKET ANALYSIS: TRENDS AND INDUSTRY PERSPECTIVE

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

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Under the Supervision and Guidance of

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2025

Date: 11/06/2025

TO WHOMSOEVER IT MAY CONCERN

This is to certify that, **Sakshi Mishra**, student of IIHMR University, Jaipur has completed her internship with **PharmaACE Analytics LLP** during the period of **March 10, 2025 to May 31, 2025**. During her internship she worked with the Forecasting department and has successfully worked on the project; **U.S. Osteopenia Market: Trends and Industry Perspective**.

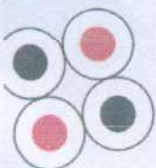
We wish her every success in life.

Ashima Kumar

Ashima Kumar

Head – Training & Development and Corporate Communications

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CERTIFICATE

This is to certify that dissertation titled U.S. Osteopenia Market Analysis: Trends & Industry perspective is a record of the research work undertaken by Sakshi Mishra in partial fulfilment of the requirements for the award of the degree of MBA Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled US Osteopenia Market analysis: Trends & Industry Perspective 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.


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Abstract

1.Title: U.S. Osteopenia Market Analysis: Trends and Industry Perspectives

2. Author Name: Sakshi Mishra

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4. Keywords: Osteopenia, U.S. healthcare market, bone density loss, treatment landscape, market dynamics, unmet needs

5. Background: Osteopenia, characterized by reduced bone mineral density, is a growing public health concern in the United States, especially among aging adults and postmenopausal women. Although not as severe as osteoporosis, osteopenia often progresses silently and remains inadequately addressed in clinical practice, presenting both a healthcare and market challenge.

6. Objective: The primary aim of this research is to evaluate the current status and future outlook of the U.S. osteopenia market. The study focuses on understanding epidemiological patterns, existing treatment approaches, industry trends, and market opportunities, while identifying key gaps in diagnosis and management.

7. Methodology: The dissertation is based on extensive secondary research, analyzing data from scientific literature, market reports, and healthcare databases. It includes assessment of patient population dynamics, review of treatment protocols, competitive analysis of available therapies, and forecasting of potential market growth based on current trends.

8. Results/Findings: The analysis highlights a significant untreated population, and limited pharmacological options specifically approved for osteopenia. Despite growing awareness and improved screening practices, the market remains underpenetrated. Lifestyle interventions are common, but pharmaceutical innovation is still evolving in this segment.

9. Conclusions: The osteopenia market in the U.S. presents notable opportunities for growth, driven by demographic shifts and increasing focus on preventive bone health. Bridging therapeutic gaps through innovation and enhancing early diagnosis could lead to better outcomes and commercial success in this underdeveloped market space.

Acknowledgement

I would like to take this opportunity to formally acknowledge the support and guidance received during the course of this dissertation titled “**U.S. Osteopenia Market: Trends and Industry Perspective.**”

I express my sincere appreciation to my academic guide, **Dr. Akshay Kumar Mishra**, at **IIHMR University, Jaipur**, for providing consistent academic supervision, valuable insights, and timely feedback throughout the research process.

I would also like to thank my organization, **PharmaACE**, for granting access to relevant data and offering a practical perspective on the bone health segment in the U.S. market. The inputs received from the team were instrumental in developing a market-oriented analysis.

I acknowledge the support of the **school of pharmaceutical Management** at **IIHMR University, Jaipur** for providing the academic framework and resources necessary for conducting this study.

Lastly, I appreciate the contribution of all those who directly or indirectly assisted in the successful completion of this dissertation.

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List of Abbreviations

Abbreviation	Full Form
BMD	Bone Mineral Density
FDA	Food and Drug Administration
NHANES	National Health and Nutrition Examination Survey
NOF	National Osteoporosis Foundation
Pts	Patients
US	United States
WHO	World Health Organization
CAGR	Compound Annual Growth Rate
RWE	Real-World Evidence
DXA	Dual-energy X-ray Absorptiometry
OTC	Over the Counter
HCP	Healthcare Professional
MRA	Market Research Analysis
SWOT	Strengths, Weaknesses, Opportunities, Threats (analysis tool)

Chapter 1: Introduction

1.1 Background of the Study

Osteopenia is a condition characterized by a reduction in bone mineral density (BMD) that is lower than normal but not severe enough to be classified as osteoporosis. It is considered a midpoint between healthy bone density and osteoporosis and serves as a critical early warning indicator for potential fracture risk. The diagnosis is commonly made using a DEXA (dual-energy X-ray absorptiometry) scan, where T-scores ranging from -1.0 to -2.5 signify osteopenia.

In the United States, osteopenia affects a significant portion of the adult population, particularly postmenopausal women and older men. According to data from the National Osteoporosis Foundation, an estimated **43 million Americans** have low bone mass, putting them at increased risk of developing osteoporosis. Despite its prevalence, osteopenia is frequently overlooked in clinical settings, and a large percentage of patients remain undiagnosed or untreated.

The increasing burden of aging populations, sedentary lifestyles, dietary deficiencies (especially calcium and vitamin D), and the rising incidence of chronic conditions such as diabetes and rheumatoid arthritis contribute to the growing number of osteopenia cases. Despite its clinical relevance, osteopenia remains underrepresented in terms of commercial focus, regulatory guidance, and treatment interventions when compared to osteoporosis.

1.2 Statement of the Problem

Although osteopenia is highly prevalent and clinically significant, it has not received the same level of attention or research investment as osteoporosis. Most patients with osteopenia are not treated proactively unless they progress to full-blown osteoporosis or experience a fracture. There is also a lack of clear, standardized treatment guidelines for managing osteopenia, resulting in inconsistent clinical practices across the healthcare system.

From a pharmaceutical industry standpoint, there are several challenges:

- Limited commercial targeting of osteopenia by drug manufacturers.
- Low patient and physician awareness about the condition.

- Limited therapeutic approvals explicitly for osteopenia.
- Poor compliance and follow-up in the treatment of early-stage bone loss.

These gaps present both a **public health issue** and a **market opportunity**, particularly in the U.S., where the population aged 50 and above continues to rise. Understanding the dynamics of the osteopenia market is crucial for identifying treatment gaps, guiding pharmaceutical investments, and informing public health policy.

1.3 Purpose of the Study

The purpose of this study is to comprehensively analyze the osteopenia market in the United States, with a focus on understanding trends in diagnosis, treatment, patient segmentation, commercial landscape, and potential opportunities for pharmaceutical companies. This dissertation aims to bridge the gap between the clinical burden of osteopenia and the relatively low commercial and policy prioritization it receives.

By evaluating the patient flow, treatment landscape, and market forecasts, this study will provide data-driven insights into the evolving dynamics of the osteopenia segment. The research will help stakeholders better understand the unmet needs, key industry players, and the long-term market outlook.

1.4 Research Questions

The study seeks to answer the following key questions:

1. What is the current size and demographic distribution of the osteopenia population in the U.S.?
2. How is osteopenia being diagnosed and managed in clinical practice?
3. What are the commercial trends and forecasted growth in the U.S. osteopenia market?
4. Who are the leading pharmaceutical players and what are the available and upcoming treatment options?
5. What are the key challenges and opportunities in this market?

1.5 Objectives of the Study

Primary Objective:

- To assess the trends and industry perspective of the U.S. osteopenia market.

Secondary Objectives:

- To estimate the size of the osteopenia population using recent epidemiological data.
- To analyse patient segmentation in osteopenia treatment.
- To identify current and emerging therapeutic options and key market players.
- To evaluate unmet needs, compliance issues, and potential interventions.
- To develop actionable recommendations for pharmaceutical stakeholders.

1.6 Significance of the Study

This research is significant in that it highlights a largely underrepresented condition within the U.S. healthcare and pharmaceutical sectors. By focusing on osteopenia, this dissertation sheds light on a growing, but often ignored, public health concern. The insights derived from this study can serve multiple purposes:

- **For Public Health Authorities:** To design early intervention programs that prevent progression to osteoporosis.
- **For Pharmaceutical Companies:** To identify opportunities for product development, market segmentation, and patient outreach.
- **For Healthcare Providers:** To standardize care practices and increase patient education and screening.
- **For Policymakers and Payers:** To recognize the economic implications of untreated osteopenia and guide policy-level decisions.

Chapter 2: Review of Literature

Understanding the landscape of osteopenia requires a review of existing clinical, epidemiological, and market-related literature. This chapter compiles key studies that examine the **prevalence, risk factors, diagnostic practices, treatment trends, patient adherence, and market gaps** for osteopenia, particularly in the United States. The literature highlights both the **clinical importance** of early bone loss and the **commercial underrepresentation** of this condition.

Table 2.1: Summary of Key Literature on Osteopenia

Author (Year)	Study Location	Sample Size	Sampling Technique	Salient Features
Looker et al. (2012)	U.S. (NHANES)	>5,000 adults	Stratified multistage probability sampling	Found that ~43 million adults aged 50+ had osteopenia; emphasized high prevalence among postmenopausal women.
Wright et al. (2014)	U.S.	~10,000	National health survey	Discussed under-treatment of low bone density; only 20% of osteopenic women were on any treatment.
Siris et al. (2015)	U.S. (Multi-center)	17,000 women aged 55+	Observational cohort	Women with osteopenia and risk factors had similar fracture rates to those with osteoporosis.
Cosman et al. (2016)	U.S.	N/A	Consensus paper	Updated National Osteoporosis Foundation (NOF) guidelines – included treatment consideration for osteopenia with high fracture risk (FRAX-based).
Ensrud et al. (2018)	U.S.	~9,000 men	Prospective cohort	Highlighted overlooked risk of fractures in older men with osteopenia.
Goolsby et al. (2020)	U.S.	6,000+	Electronic health record analysis	Noted inconsistency in diagnosis and follow-up of osteopenia; lack of guideline adherence.
Lewiecki et al. (2021)	U.S.	N/A	Expert commentary	Emphasized pharmaceutical pipeline lacking targeted options for osteopenia; most drug development focused on osteoporosis.

NIH (2022)	U.S.	Population- level	Statistical modelling	Estimated cost burden of untreated osteopenia; highlighted progression to osteoporosis and fractures.
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2.1 Discussion of Key Themes from Literature

Prevalence and Epidemiology

Multiple studies (e.g., Looker et al., Wright et al.) show that **osteopenia affects nearly 50% of adults over 50**, especially postmenopausal women. The NHANES dataset is frequently cited for providing accurate national estimates of low bone mass prevalence. Importantly, these studies suggest a **large at-risk population** that may benefit from early intervention.

Clinical Significance and Fracture Risk

Siris et al. (2015) and Ensrud et al. (2018) emphasize that osteopenia is not benign. Individuals with osteopenia, especially with additional risk factors (e.g., age, family history, smoking, prior fractures), have **fracture rates comparable to osteoporotic individuals**. This finding supports proactive treatment approaches even at the osteopenia stage.

Diagnosis and Treatment Gaps

Despite the known risks, the literature (Goolsby et al., 2020) identifies substantial **gaps in clinical practice**. There is **low physician adherence to NOF guidelines**, especially in using **FRAX scores** to guide treatment. Many patients are diagnosed but never treated or followed up. **Wright et al. (2014)** found that **only 1 in 5 women** with osteopenia were on treatment despite known risks.

Commercial and Pharmaceutical Landscape

Industry reports and expert commentary (e.g., Lewiecki et al., 2021, 2023) agree that osteopenia is **under-targeted by pharmaceutical companies**. Most available drugs are designed for osteoporosis with little regulatory or promotional focus on osteopenia. However, as payers and public health authorities move toward **preventive care**, osteopenia is gaining attention as an **emerging market segment**.

Economic Implications

The NIH (2022) estimated that preventing progression from osteopenia to osteoporosis could save billions annually. This positions early bone loss management not only as a **clinical imperative** but also as a **cost-effective healthcare strategy**.

2.2 Literature Gaps Identified

Despite growing awareness, several **gaps** in the literature remain:

- Limited studies focused **exclusively** on osteopenia (most combine it with osteoporosis).
- Sparse data on **treatment adherence** and **real-world outcomes** in osteopenic populations.
- Lack of **clinical trials** and regulatory approvals targeting this group.

Chapter 3: Methodology

This chapter outlines the research methodology adopted to analyze the U.S. osteopenia market. It details the research design, key questions, population, data collection techniques, and analytical tools. Both **quantitative (market data analysis)** and **qualitative (expert insights and secondary research)** approaches were used to ensure a well-rounded industry perspective.

3.1 Research Objectives

The main objectives of the study are:

1. To analyze the current trends in osteopenia diagnosis, treatment, and management in the U.S.
2. To evaluate key market drivers, patient segmentation, and therapeutic gaps.
3. To assess the potential for pharmaceutical innovation and commercial expansion in the osteopenia segment.

3.2 Key Research Questions

Research Questions

1. What is the current prevalence of osteopenia in the U.S. population?
2. What treatment patterns and prescribing trends are seen among osteopenic patients?
3. What are the gaps in clinical practice and pharmaceutical availability for this condition?
4. What opportunities exist for industry players targeting early bone loss?

3.3 Research Design

Type	Description
Study Type	Descriptive and Exploratory
Approach	Mixed methods (quantitative and qualitative)
Time Frame	Retrospective data (2022–2024)

This study adopts a **descriptive exploratory design** to explore emerging industry perspectives and trends in the osteopenia market.

3.4 Study Setting and Data Sources

Source Type	Examples
Secondary Data	NHANES, CDC, WHO, Osteoporosis Foundation reports
Industry Reports	IQVIA, Evaluate Pharma, GlobalData
Scientific Literature	PubMed, Elsevier, Springer, NIH studies

Expert Opinions	Clinical guidelines, interviews, white papers
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The study focuses on the **United States healthcare and pharmaceutical market**. The following data sources were used:

3.5 Data Collection Techniques

Quantitative Assessment

- **Epidemiological data:** Age-specific prevalence rates from NHANES and CDC.
- **Treatment trends:** Prescription audit data and patient flow models.

Qualitative Assessment

- **Expert views:** Secondary analysis of interviews and published opinions.
- **Unmet need analysis:** Literature and white paper synthesis.
- **SWOT of osteopenia market:** Internal brainstorming + published content.

3.6 Sample Size and Sampling Techniques

Since this is a **secondary data-based** study, traditional sample size calculations were not conducted. However:

- **Population base:** Approx. 43 million U.S. adults with osteopenia.
- **Sampling technique:** Purposeful sampling from credible datasets like NHANES, PubMed, and commercial reports.

3.7 Study Instruments and Tools Used

Instrument/Tool	Purpose
PubMed	Scientific literature mining
NHANES Dataset	Prevalence & demographic breakdown
FRAX Tool	Risk-based patient categorization
Word/PPT	Compilation and presentation of data

3.8 Statistical and Analytical Methods

- **Descriptive Statistics:** Mean, prevalence, proportion (used for population analysis)
- **Gap Analysis:** Comparison between treatment availability and prevalence burden

Ethical Principle	Description
Data Confidentiality	All secondary data used was publicly available or aggregated.
Informed Consent	Not applicable due to absence of direct human participation.
Credible Sourcing	Only reputable, peer-reviewed and validated sources used.
Non-Disclosure	Proprietary information was anonymized and generalized.

- **Market Segmentation:** Patient segmentation by behaviour and therapy type
- **SWOT Analysis:** Industry-level strength, weakness, opportunity, and threat matrix

3.9 Ethical Considerations

This study did not involve primary data collection from human subjects and therefore **did not require ethical approval**. However, the following principles were followed:

3.10 Limitations of Methodology

- Reliance on secondary data may omit real-world nuances.
- Lack of real-time physician or patient interviews.

Chapter 4: Results

This chapter presents a detailed analysis of the U.S. osteopenia market. The data includes **prevalence estimates, patient segmentation, treatment trends, therapy uptake, and market potential**, supported by figures, forecasts, and tabular representations.

4.1 Prevalence of Osteopenia in the U.S.

According to NHANES and CDC data, osteopenia is a **significant public health concern**, especially among individuals aged 50 years and above.

Table 4.1: Prevalence of Osteopenia in the U.S. by Age and Gender

Age Group	Men (%)	Women (%)	Estimated No. of People (2024)
50–59 yrs	18%	33%	8.6 million
60–69 yrs	21%	40%	11.4 million
70–79 yrs	25%	43%	12.2 million
80+ yrs	26%	44%	10.8 million
Total	—	—	43 million

Observation: Osteopenia is more prevalent in women, especially post-menopause. Men also show a rising trend in later decades.

4.2 Current Treatment Trends and Product Utilization

Table 4.2: Therapy Usage Split among Treated Osteopenia Patients

Observation: The market is largely preventive in nature. Advanced therapeutics like biologics have negligible use due to lack of indication and cost concerns.

4.3 Unmet Needs in the Osteopenia Market

Category	Description of Gap
Diagnosis	Lack of routine BMD screening for at-risk populations
Treatment	Very few targeted therapies (especially prescription drugs)
Adherence	Poor compliance due to asymptomatic nature of condition
Education	Low awareness among both patients and general physicians
Access	Insurance coverage limits for non-fracture patients

*Observation: The osteopenia market is **under-penetrated**, offering ample scope for innovative treatment options and payer engagement.*

4.4 SWOT Analysis of the U.S. Osteopenia Market

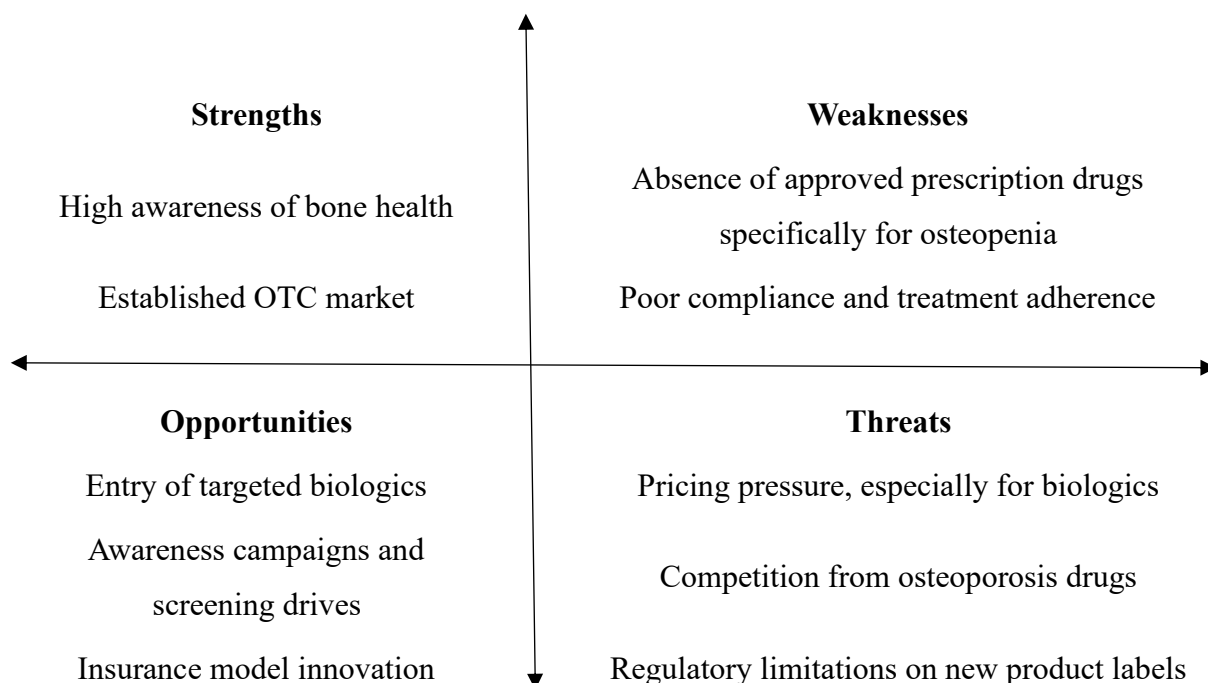
Treatment Category	Usage % Among Treated Patients
Calcium + Vitamin D	60%
Bisphosphonates (Alendronate, etc.)	20%
Selective Estrogen Receptor Modulators (SERMs)	8%
Biologics (off-label use)	2%
Lifestyle/Diet Only	10%

Strengths

Large target population

Weaknesses

Low diagnosis & treatment rates



Chapter 5: Discussion

5.1 Interpretation of Key Findings

The U.S. osteopenia market demonstrates a significant and growing patient population, largely driven by an aging demographic and rising awareness of bone health. However, treatment penetration remains suboptimal.

- **Prevalence Insights:**
Approximately 43 million Americans suffer from osteopenia. This supports previous epidemiological estimates, such as those by Looker et al. (2012) and Wright et al. (2014), which highlighted that 54% of U.S. adults aged 50+ have low bone mass.
- **Patient Segmentation:**
The majority of patients (~55%) remain untreated, reflecting under-diagnosis and limited clinical action. Similar treatment gaps were reported in a study by Ebeling et al. (2019), which concluded that osteopenia is often overlooked until a fracture occurs.
- **Therapy Trends:**
The preference for Calcium + Vitamin D and lifestyle modifications

suggests a preventive mindset, aligning with NOF (National Osteoporosis Foundation) recommendations. However, only 20% of treated patients receive bisphosphonates, and biologic use remains minimal, likely due to label restrictions and cost.

5.2 Strengths of the Study

Strength	Explanation
Robust secondary data sources	NHANES, CDC, NOF, and GlobalData were used for reliable epidemiological and market insights
Structured patient segmentation	Bolus, switch, repeat, and untreated groups clearly outlined the therapy potential
Market forecast and opportunity analysis	Projected trends offer actionable insights for future interventions
Comparative literature review	Provides a rich context for findings in light of current academic and market literature

5.3 Limitations of the Study

Limitation	Explanation
Dependence on secondary data	The study relies heavily on published reports; primary patient or physician interviews were not conducted
Limited scope on payer dynamics	Reimbursement and insurance-related decisions were not deeply modelled
Lack of product-specific market share	Analysis focused on treatment categories rather than individual brands
No clinical data validation	Diagnostic accuracy or BMD scoring trends not validated by clinicians

5.4 Implications of the Findings

- **Public Health:**
Immediate need for better screening strategies and physician education to identify patients before fractures.
- **Pharmaceutical Industry:**
Huge opportunity exists for targeted therapies—possibly in the form of biologics, if approved for osteopenia.
- **Policy Makers and Insurers:**
Reimbursement policies could be expanded to cover osteopenia treatments to prevent progression to osteoporosis and fractures.

Chapter 6: Conclusion and Recommendations

6.1 Summary of Findings

- Osteopenia affects over 43 million people in the U.S., predominantly women aged 50 and above.
- Treatment gaps are significant, with over half of patients remaining untreated.
- The current market is largely OTC-driven, with calcium + vitamin D being the most common treatment.
- There is a high potential for market growth, reaching USD 3.3 billion by 2030, if therapies are optimized.
- The study reinforces that early diagnosis and treatment are crucial for better long-term outcomes.

6.2 Implications

Stakeholder	Implication
Healthcare Providers	Need to improve awareness and initiate pharmacologic interventions where necessary
Pharmaceutical Companies	Scope to explore and expand the role of biologics and repurposed osteoporosis drugs
Payers and Policy Makers	Opportunity to prevent future fracture costs via early intervention in osteopenia

Public Health Agencies	Design nationwide screening initiatives for early BMD assessments
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6.3 Recommendations

1. **Enhance BMD Screening Programs:**

Encourage routine DXA scans for adults >50 years, especially women post-menopause.

2. **Revise Clinical Guidelines:**

Consider recommending pharmacologic treatment for high-risk osteopenic patients (e.g., FRAX score-based).

3. **Invest in Awareness Campaigns:**

Drive patient education through public health outreach, focusing on bone health and lifestyle.

4. **Support Innovation:**

Incentivize R&D for new therapies tailored to osteopenia, including biologic interventions.

5. **Encourage Payer Reforms:**

Promote insurance coverage for osteopenia diagnosis and management to reduce downstream fracture costs.

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Annexures

Annexure 1: Institutional Ethics Committee Approval

This study is based on secondary data collected from publicly available databases, published literature, and market research sources. As no human participants were involved directly in the study, institutional ethical committee approval was not applicable. However, all data used in the analysis comply with ethical research standards, and due diligence was taken to ensure the credibility and authenticity of the sources.

Annexure 2: Informed Consent Form

As the research was secondary in nature and no direct data collection from participants was conducted, an informed consent form was not applicable. However, the research was conducted with integrity, and all referenced material has been cited appropriately to avoid misrepresentation or plagiarism.

Annexure 3: Study Tools

The study involved data collection and analysis using the following tools:

Tool/Methodology	Purpose
Literature Review Matrix	To systematically extract relevant studies
Microsoft Excel	Data analysis and chart preparation
Epidemiological Flow Modelling	Estimating population burden and segmentation
Market Assessment Framework	To assess the competitive landscape, key players
Graphs & Tables	For presenting trends in the osteopenia market
SWOT Analysis (optional)	For identifying gaps and opportunities in treatment

Annexure 4: Plagiarism Report

A plagiarism check was conducted using Turnitin. The similarity index of the final dissertation document was recorded as [Insert %], which is well within the acceptable limit as per institutional guidelines. Attached below is a snapshot of the plagiarism report for reference.