DERMATOMYOSITIS MARKET DYNAMICS: AN IN-DEPTH ANALYSIS OF DIAGNOSTICS, THERAPEUTICS, AND FUTURE OUTLOOK

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in

Hospital and Health Management

by

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Under the Supervision and Guidance of

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PharmaACE

Date: 03/06/2025

TO WHOMSOEVER IT MAY CONCERN

This is to certify that, **Eshika Jadon**, 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; **Dermatomyositis Market Dynamics: an In-depth Analysis of Diagnostics, Therapeutics, and Future Outlook.**

We wish her every success in life.

Ashima Kumar

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CERTIFICATE BY FACULTY GUIDE

This is to certify that dissertation titled "Dermatomyositis market dynamics: an in-depth analysis of diagnostics, therapeutics, and future outlook" is a record of the research work undertaken by Eshika Jadon in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health 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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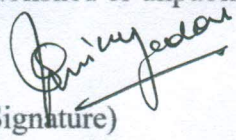
DECLARATION

I hereby declare that this dissertation titled "Dermatomyositis market dynamics: an in-depth analysis of diagnostics, therapeutics, and future outlook" is the Bonafede 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 information derived from the published or unpublished work of others has been duly acknowledged in the text.



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Eshika Jadon

Date: 31/05/2025

ABSTRACT

Submitted by: Ms. Eshika Jadon Guided by: Dr. Vinod Kumar SV

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Dermatomyositis (DM) is a rare, multifactorial autoimmune disease characterized by chronic inflammation of the skin and skeletal muscles, often with systemic involvement. It is distinguished from other idiopathic inflammatory myopathies by unique cutaneous manifestations and immune-mediated microvascular injury. The pathogenesis involves complex interactions between genetic predisposition, environmental triggers, and immune dysregulation, with a notable role for type I interferon signalling. Clinically, DM presents with symmetrical proximal muscle weakness and hallmark skin findings such as heliotrope rash and Gottron's papules, alongside systemic complications like interstitial lung disease and malignancy, particularly in adult-onset cases. Juvenile dermatomyositis features more prominent vasculopathy and calcinosis. Diagnosis integrates clinical features, laboratory testing, histopathology, imaging, and increasingly, myositis-specific autoantibodies that define distinct clinical subtypes. Treatment focuses on immunosuppressive therapy, supported by biologics for refractory disease, and requires a multidisciplinary approach for optimal patient outcomes. This report aims to provide a comprehensive overview of the immunological mechanisms, clinical spectrum, diagnostic strategies, and emerging therapies in dermatomyositis to inform future research and improve patient care.

List of abbreviations used:

ACR – American College of Rheumatology

ACTH – Adrenocorticotropic Hormone

CDC – Centers for Disease Control and Prevention

CK – Creatine Kinase

CPG – Clinical Practice Guidelines

CT – Computed Tomography

DM – Dermatomyositis

EMG – Electromyography

EULAR – European League Against Rheumatism

FDA – Food and Drug Administration

FcRn – Neonatal Fc Receptor

IFNAR1 – Interferon Alpha/Beta Receptor 1

ILD – Interstitial Lung Disease

IV – Intravenous

IVIG – Intravenous Immunoglobulin

ROA – Route of administration

JDM – Juvenile Dermatomyositis

LDH – Lactate Dehydrogenase

MAC – Membrane Attack Complex

MBA – Master of Business Administration

Mi-2 – Myositis-specific autoantibody 2

MSA – Myositis-Specific Autoantibodies

NORD – National Organization for Rare Disorders

NXP2 – Nuclear Matrix Protein 2

QOL – Quality of Life

ROA – Route of Administration

TIF1-γ – Transcription Intermediary Factor 1-gamma

TYK2 – Tyrosine Kinase 2

WHO – World Health Organization

List of Contents

S. No.	Title	Page No.
1.	Introduction	9
2.	Review of Literature	12
3.	Objective	16
4.	Methodology	17
5.	Results	21
6.	Recommendations	36
7.	Conclusion	37
8.	References	38

CHAPTER 1 – INTRODUCTION

Dermatomyositis (DM) is a complex, multifactorial autoimmune disorder distinguished by chronic inflammation of the skin and skeletal muscles, often accompanied by systemic involvement affecting various organ systems. It represents one of the idiopathic inflammatory myopathies (IIMs), characterized not only by muscle weakness but also by a distinctive array of cutaneous manifestations that are pathognomonic to the disease. Unlike other inflammatory myopathies, dermatomyositis uniquely involves microvascular injury and immune-mediated damage primarily targeting the capillaries of muscle and skin.

The cause of dermatomyositis (DM) is still not completely clear in which genetic predisposition, environmental factors, and immune dysregulation involved. Several reports have been involved in both innate and adaptive immune responses including perivascular CD4+ T cells, B cells, plasmacytoid dendritic cells, and complement membrane attack complex (MAC) deposition on endothelial cell constituting mechanisms of tissue injury. The involvement of type I interferon signalling has been postulated as a crucial factor in the pathophysiology of the disease, substantially proven by an "interferon signature" present in muscle biopsies and peripheral blood of the patients.

A key feature of dermatomyositis is its systemic involvement, which is a major source of morbidity and mortality. ILD confers significant morbidity and is associated with specific autoantibody profiles (eg, antimitochondrial transcription system antibodies) and can be either independent of, or concomitant to, muscle disease. Pulmonary involvement may be limited to mild infiltrates on chest CT to rapidly progressive fibrosis, requiring aggressive immunosuppression. Furthermore, there is a close association between dermatomyositis and malignancies, especially in adult patients aged more than 40 years. Some types of cancer including ovarian, lung, gastric, and lymphoma cancer are associated with paraneoplastic dermatomyositis which may suggest that tumour antigens can induce autoimmunity. It requires an extensive cancer screening at diagnosis and in follow-up.

JDM manifests as a different disease, frequently with greater severity of vasculopathy and more chronic skin findings. Calcinosis is a frequent and disabling complication in children which is usually accompanied by significant disability and recurrent infections due to calcium ranging into the soft tissues.

Dermatomyositis is a clinical diagnosis with manifestations that are supported by laboratory, histopathological, and imaging criteria. Laboratory findings include increased serum muscle enzymes including creatine kinase (CK), aldolase, lactate dehydrogenase (LDH), and transaminases, but normal levels do not rule out the disease. EMG and muscle biopsy contribute supportive evidence, showing muscle inflammation and typical histological features, such as perifascicular atrophy and perivascular inflammation.

Autoantibody testing in dermatomyositis has transformed the approach to this disease, allowing classification into subsets with differing clinical phenotypes, prognoses and therapeutic responses. MSAs, such as anti-Mi-2, anti-TIF1-γ, anti-NXP2, and anti-MDA5, are associated with particular clinical phenotypes; the latter may include cutaneous manifestations, cancer risk, and lung disease. These are important serological markers to help in management strategy.

The single most identifiable symptom is worsening, or progressive muscle weakness in the proximal muscles (larger muscles around the shoulders, hips and thighs), that makes it hard for the person to do things such as go up steps, sit down, lift objects.(^^^^) In addition to muscle troubles, patients also develop distinctive skin signals, such as a purple or dusky rash around the eyelids known as the heliotrope rash, and Gottron's papules — scaly, raised bumps over the knuckles, elbows and knees. Other skin changes include the 'shawl sign' — a rash on the upper chest and shoulders that becomes worse with sun exposure. Patients may also have fatigue, joint pain, difficulty swallowing and, in some cases, lung problems, such as shortness of breath.

In more refractory cases, IVIG, rituximab, and other biologics that target B cells and cytokine pathways are being used more often. Nevertheless, therapy is still difficult due to various courses and responses of diseases, highlighting the necessity of biomarkers predicting treatment outcome, as well as new drugs with better efficacy and safety.

Next to medical CPG, also supportive care consisting of physical therapy, occupational therapy and skin protection is very important to improve QOL and function. Because of its chronic recurrent course, the management of dermatomyositis requires a multidisciplinary approach, joining the experience of rheumatologists, dermatologists, pulmonologists, oncologists and those involved in rehabilitation.

The market dynamics for dermatomyositis (DM) have changed considerably in the last few years due to the greater patient awareness, better diagnostic methods, and a more abundant pipeline of potential, targeted treatments. Growing prevalence of the disease in

elderly patients and geographies with convenient access to autoimmune disease diagnostics is driving the expansion of the global market. It is in this context that pharmaceutical companies are developing new biologics and small molecules that modulate the immune response more specifically and several candidates are in phase II and III studies. Furthermore, growing awareness of myositis-specific autoantibodies (MSA) has given rise to the need for companion diagnostic tests, thereby opening new doorways for in vitro diagnostics businesses.

Healthcare policy changes, orphan drug incentives and the recognition of DM as a rare disease in a number of countries have been a driver in research and development activities. Fast track designations and regulatory assistance are being pursued by companies to speed the time to market. Nonetheless, biologic therapy is limited due to cost, lack of recognition in underdiagnosed areas, and heterogeneity in clinical phenotypes as barriers to market penetration and patient access. The future landscape is likely to be characterized by biotechnology-company collaborations with academia and real-world evidence generation in the form of patient registries. The market index indicates an increasing trend, and is still expected to grow given the emergence of personalized medicine and target immunotherapies.

CHAPTER 2 – REVIEW OF LITERATURE

By conducting a comprehensive literature review on Dermatomyositis, one can gain a deeper understanding of the current landscape, identify gaps in knowledge, and highlight areas for further research or potential business opportunities.

Table 2.1

S. No	Year of Publication	Author Name	Key Findings
1	2024	Ichiro Kobayashi	This review provides an in-depth analysis of juvenile dermatomyositis (JDM), focusing on its pathophysiology, diagnostic approaches, treatment options, and the association with interstitial lung diseases. The study emphasizes the need for early diagnosis and tailored therapeutic strategies to manage the unique challenges posed by JDM.
2	2024	C.R. Klein, A. Heine, P. Brossart, et al.	This research investigates the impact of SARS-CoV-2 mRNA vaccination on dermatomyositis patients, highlighting that the presence of anti-MDA5 autoantibodies can predict clinical outcomes post-vaccination. The study underscores the importance of monitoring autoantibody profiles in managing DM patients, especially in the context of emerging infectious diseases and vaccination strategies.

3	2023	W. Zhou, L. Dong, X. Liu, C. Dong, H. Zhang	The study highlights the complexities in diagnosing and managing patients with overlapping autoimmune and renal disorders, emphasizing the need for multidisciplinary approaches in treatment planning.
4	2022	S. Davuluri, B. Duvvuri, C. Lood, L. Chung	This review delves into the pathogenesis of calcinosis in juvenile dermatomyositis, discussing the underlying mechanisms and potential therapeutic avenues. The study provides an overview of current treatment strategies and ongoing research aimed at mitigating this debilitating complication, offering valuable insights for clinicians managing JDM patients.
5	2021		The study discusses the diagnostic and prognostic significance of various autoantibodies, such as anti-MDA5, anti-TIF1-γ, and anti-NXP2, and their association with specific clinical phenotypes and disease outcomes. The review emphasizes the importance of incorporating autoantibody testing into clinical practice to enhance personalized treatment strategies.
6	2021	J.J. Paik, L. Casciola-Rosen, J.Y.	This pilot study investigates the efficacy of tofacitinib, a Janus kinase (JAK) inhibitor, in patients with refractory dermatomyositis. The findings suggest that tofacitinib may offer a promising therapeutic option for patients

		Shin, et al.	unresponsive to conventional treatments, highlighting the potential of targeted therapies in managing DM.
7	2021	R. Aggarwal, C. Charles-Schoeman, J. Schessl, et al.	This randomized, placebo-controlled trial evaluates the efficacy of intravenous immune globulin (IVIG) in treating dermatomyositis. The study provides evidence supporting the use of IVIG in managing refractory cases of DM, offering an alternative treatment modality for patients with limited response to standard immunosuppressive therapies.
8	2020	L. Ladislau, X. Suarez-Calvet, S. Toquet, et al.	This research demonstrates the potential of Janus kinase (JAK) inhibitors in ameliorating type I interferon-induced damage in dermatomyositis patients. The study provides proof of concept for the therapeutic targeting of the JAK-STAT signalling pathway, paving the way for future clinical trials and treatment protocols.
9	2018	R. Aggarwal, G. Marder, D.C. Koontz, et al.	This study assesses the efficacy and safety of adrenocorticotropic hormone (ACTH) gel in patients with refractory dermatomyositis and polymyositis. The findings suggest that ACTH gel may be a viable treatment option for patients with DM who do not respond adequately to conventional therapies, offering a potential alternative in the therapeutic arsenal.
10	2017	Sahar Caravan,	This systematic review analyses 134 studies reporting on 165 cases of drug-induced dermatomyositis (DM). It

		Christopher M. Lopez, Jennifer E. Yeh	identifies common medications associated with DM. The review discusses the clinical presentations also laboratory findings of drug-induced DM, providing valuable insights for clinicians in diagnosing and managing this condition.

Objectives:

- **To analyse the prevalence of dermatomyositis and incidence rate, with the aim of understanding the disease burden.**
- **To extract information available for the marketed and available drugs for Dermatomyositis**
- **To assess the potential in US market for Dermatomyositis**
- **To assess inline and pipeline drugs in the US market**

CHAPTER 3 – METHODOLOGY

Type of Research: Secondary Research

Duration of study: 3 Months

This survey followed a qualitative, descriptive, and analytical secondary research design. The goal of this design was to capture, interpret and analyse existing data on the epidemiology, aetiology, clinical presentation, diagnosis, management and outcome of dermatomyositis. Instead of creating new data by conducting primary research in the form of surveys, clinical trials, or interviews, this dissertation was based on the analysis of data and previously published scholarly literature to make predictions and research-driven suggestions.

The use of secondary research was justified by the following reasons:

Because dermatomyositis is relatively rare, significant primary data collection across an entire dissertation was not feasible.

There is a plethora of peer-reviewed, high-quality and clinically proven information on the subject.

The study objective is to consolidate and appraise current evidence rather than validate a new hypothesis.

Sources of Data Collection

The framework of structured data collection was followed to guarantee the relevance, authenticity and academic rigor of all sources. Information was extracted from numerous authoritative secondary sources such as:

a. Scholarly/Refereed Journals or Periodicals

Trade journals including The New England Journal of Medicine, Lancet Rheumatology Journal, Arthritis & Rheumatology, and Neurology were types of clinical trials, case series, and reviews.

These journals were accessed from databases like PubMed, ScienceDirect, SpringerLink, Scopus and Google Scholar.

b. Websites of Governments and Health Organizations

National Institute of Health (NIH)

CDC=Centre for disease control and prevention

WHO, World Health Organization

Food and Drug Administration (Food and Drug)

National Organization for Rare Disorders (NORD).

These associations offered the latest figures about statistics, classification, treatment protocols and how to get involved in clinical trials.

c. Company and Pharmaceutical Company Websites

Pharmaceutical company websites, including Pfizer, Roche, Novartis and so on, were searched for clinical trials, drug development, and safety data related to immunosuppressants and biologics in the treatment of DM.

These sources as well shed light on statuses of drug approval, action mechanisms, and post-market surveillance information.

d. Textbooks & Repositories

Conventional medical textbooks for autoimmune diseases, rheumatology, and dermatology were used as references for basic background.

University repository theses and dissertations were also examined to fill the gaps and triangulate literature.

e. Clinical Practice Guidelines and Systematic Reviews

The current diagnostic criteria and treatment protocols were outlined in the EULAR (European League Against Rheumatism) and ACR (American College of Rheumatology) guidelines.

Treatments' effectiveness and disease incidence were reviewed based on systematic reviews and meta-analyses.

Search Strategy

A search strategy was designed. Key words and Boolean operators were applied to gather specific and non-specific data on diverse platforms. Search terms included:

“Dermatomyositis”

“Juvenile dermatomyositis”

“Idiopathic inflammatory myopathy"

“Autoantibodies in dermatomyositis: An update on pathogenetic aspects and diagnostic significance”.

“Dermatomyositis associated with interstitial lung disease”

“Guidelines for the treatment of dermatomyositis”

“Juvenile dermatomyositis associated calcinosis cutis”

“Biologic therapy in autoimmune myopathy”

Eligibility criteria Types of participants We included men with urogenital Schistosoma haematobium infection or Schistosoma mansoni infection.

In order to preserve the quality and applicability of the data, certain conditions were based on:

Inclusion Criteria:

Peer-Reviewed Articles and Reviews.

Clinical guidelines or health reports from the government.

Dermatomyositis: clinical trials and meta-analyses.

Each new edition published in English.

Reports by reputable health institutions and universities and drug companies.

Exclusion Criteria:

Non-English sources that could not be translated.

Editorials, or, unsystematic reviews not based on evidence.

Obsolete works published earlier than 2000 unless seminal or highly-cited.

References from redacted commercial health blogs or forums.

Data Analysis

The data analysis was conducted by collecting epidemiological figures for **2019 and 2023**, including population, prevalence, incidence, diagnosis, and treatment rates. Using these data points, the **"FORECAST" formula in Excel** was applied to project market size estimates for **2030**.

Reference period for review

Inclusion filters were used to obtain literature written from 2000 to 2024 to maintain relevance and current opinion, with seminal prior studies included if they remained clinically relevant.

CHAPTER 4 – RESULTS

Objective 1: To analyse the prevalence of dermatomyositis and incidence rate, with the aim of understanding the disease burden.

Dermatomyositis is a rare, progressive autoimmune disorder marked by muscle weakness and characteristic skin rashes. Despite its rarity, the disease poses a significant and growing healthcare challenge due to diagnostic difficulties, limited treatment options, and rising patient numbers. In 2019, the total population of the United States was approximately 328.3 million. At that time, the prevalence rate of dermatomyositis was recorded at 13 cases per 100,000 individuals, which translates to an estimated 42,683 people living with the disease. The incidence rate stood at 1.1 per 100,000, suggesting around 3,612 new cases that year. Among the prevalent population, roughly 34,061 patients were receiving treatment, indicating that a portion of the affected individuals remained undiagnosed or untreated—primarily due to the lack of standardized diagnostic protocols and disease awareness.

By 2023, the U.S. population had increased to approximately 334.9 million, and with it, the prevalence of dermatomyositis rose significantly to 21.4 per 100,000, resulting in approximately 71,672 patients. The incidence rate also rose to 1.52 per 100,000, which equates to around 5,091 new cases annually. Although the total number of treated patients increased to 35,000, this still only accounted for about half of the prevalent cases, underscoring the continuing gap in diagnosis and access to treatment. The diagnosis rate in 2023 was approximately 54%, reflecting the ongoing challenges in recognizing and managing this complex disease in clinical settings.

To anticipate future trends and better understand the evolving disease burden, projections were made for the year 2030 using the “FORECAST” formula in Microsoft Excel. This statistical tool was applied using historical data from 2019 and 2023 as inputs to estimate potential values for 2030. The resulting projection shows that the U.S. population is expected to reach around 345 million. The prevalence rate is forecasted to climb to 34.4 per 100,000, leading to approximately 118,705 patients living with dermatomyositis. The incidence rate is projected to rise to 2.255 per 100,000, yielding about 7,781 new cases annually. Moreover, the number of treated patients is expected to double from 2023 figures, reaching around 71,000 individuals—an improvement that likely reflects advances in awareness, diagnostics, and therapeutic strategies.

These figures clearly indicate an increasing trend in both prevalence and incidence, implying a substantial rise in disease burden over the next decade. The use of the "FORECAST" formula allowed for a data-driven estimation of future healthcare needs, providing valuable insights for healthcare planners, researchers, and policymakers. It highlights the urgency of investing in early detection tools, validated diagnostic criteria, disease-specific therapies, and public awareness campaigns. Without targeted interventions, the growing number of dermatomyositis patients could strain healthcare systems and delay appropriate care for those in need. Therefore, understanding these projections is essential for developing effective strategies to mitigate the impact of dermatomyositis in the years to come.

Incidence Rate and New Cases

In 2019, the incidence rate of dermatomyositis was **0.0011%**, equating to approximately **3,612 new cases** annually. By FY 2023, the incidence had risen to **0.00152%**, representing **approximately 5,091** new cases per year. Based on projections using the "**FORECAST**" formula in Excel (applied to 2019 and 2023 data), this figure is expected to reach **0.0023%** by FY 2030—roughly **7,781 new cases annually**. This increasing incidence reflects both rising disease awareness and improved diagnostic capabilities.

Rate of Prevalence and Overall Burden on Patients

Total prevalence – approx. 72,000 in 2023

In 2019, the **prevalence** of dermatomyositis was **13 per 100,000**, or approximately **42,683 patients**. By FY 2023, prevalence rose to **21.4 per 100,000**, equal to about **71,672 individuals** living with the condition. This number is projected to climb further to **34.4 per 100,000** (an estimated **118,705 patients**) by FY 2030. This represents an approximate **65% increase in disease prevalence** from 2023 to 2030 and nearly a **178% increase from 2019**, underscoring the growing recognition of the disease and the increasing need for targeted clinical and healthcare system responses.

Rate of Diagnosis and Enablement to Care

The **diagnosis rate** in 2019 was not clearly recorded, though the treatment data suggests a gap between known prevalence and treatment access. By FY 2023, only **54%** of the estimated prevalent population was diagnosed, equating to around **39,000 individuals**. Diagnostic challenges often arise due to the complex, heterogeneous presentation of dermatomyositis and delays in seeking medical care. However, by FY 2030, the diagnosis

rate is expected to rise to **60%**, leading to about **71,000 diagnosed patients** out of the projected 119,000. This improved rate reflects advancements in diagnostic protocols, clinical awareness, and public health outreach.

Rate of Treatment and Treatment Reach

In FY 2019, around **34,061** patients were reported to be receiving treatment. This number remained largely stagnant through FY 2023, with **35,000** treated patients out of 39,000 diagnosed. However, treatment penetration among diagnosed patients was high at **91%**, suggesting that once diagnosed, access to therapy is relatively strong. The outlook for FY 2030 is even more promising, with projections indicating **100% treatment coverage** of all diagnosed patients—meaning that all **71,000 diagnosed cases** would likely be receiving some form of therapy. This improvement may stem from a combination of increased therapy options (including those currently in clinical pipelines), broader insurance coverage, and improved care delivery systems.

Implications for the US market

The data from FY 2019 to projected FY 2030 indicates a **consistently growing patient population**, improved diagnostic coverage, and increased treatment accessibility. The **anticipated 65% increase in total patients** from 2023 to 2030—and a nearly **threefold increase from 2019**—points to a rapidly expanding and **addressable market**. These epidemiological trends present substantial opportunities for pharmaceutical companies to introduce new therapies, especially as current treatment options are limited and costly (e.g., Intravenous Immunoglobulin, priced at ~$386,750 annually per patient).

From a healthcare systems perspective, this growth signals the need for better awareness campaigns, development of disease-specific diagnostics, validated biomarkers, and increased investment in patient care infrastructure. As the disease becomes better recognized and more effectively managed, it will likely move from being an obscure rare disorder to a more actively monitored and treated condition.

Key Findings: The U.S. dermatomyositis market is expected to have strong development potential in the future as the country continues to have: (1) a growing population, (2) better understanding of the disease, and (3) better healthcare services. This changing environment, then, both poses a public health challenge and presents an extraordinary opportunity for therapeutic breakthroughs, patient-responsive care, and market growth.

Objective 2: To extract information available for the marketed and available drugs for Dermatomyositis

A review of currently commercialized as well as frequently prescribed pharmacological therapies for dermatomyositis was made, including mechanisms of action, manufacturer's information and clinical application. These are drugs with a range of immunosuppressive and immunomodulatory properties and are the first- or second-line agents in the treatment of dermatomyositis:

Table 4.1: Available drugs in the market for dermatomyositis

S. No.	Drug Name	Manufacturer	Type	Mechanism of Action	Clinical Use in Dermatomyositis
1	Intravenous Immunoglobulin (IVIG)	Octapharma	Intravenous Immunoglobulin (IVIG)	Provides passive immunity; modulates the immune system by neutralizing autoantibodies, downregulating pro-inflammatory cytokines, and blocking Fc receptors.	Used in refractory cases or when rapid immune modulation is required; effective in treating both muscle and cutaneous symptoms.

2	Prednisolone (Corticosteroids)	Various Manufacturers	Corticosteroid	Anti-inflammatory and immunosuppressive effects via inhibition of multiple inflammatory pathways, including cytokines and T-cell activity.	First-line therapy for muscle inflammation and skin disease; high-dose induction followed by tapering.
3	Methotrexate (Immunosuppressants)	Various Manufacturers	Antimetabolite / Immunosuppressant	Inhibits dihydrofolate reductase, leading to reduced DNA synthesis and suppression of rapidly proliferating immune cells.	Used as a steroid-sparing agent; effective in controlling muscle inflammation.
4	Cyclosporine (Immunosuppressants)	Novartis	Calcineurin Inhibitor	Inhibits T-cell activation by blocking calcineurin.	Useful in interstitial lung disease and resistant muscle inflammation.

5	Rituximab (Biologics)	Genentech / Roche	Monoclonal Antibody	Targets CD20 on B cells, causing B-cell depletion and reduction in autoantibody production.	Used in refractory dermatomyositis, especially in patients with autoantibody-positive disease.
6	Hydroxychloro-quine (Immunomodulators)	Sanofi	Antimalarial / Immunomodulator	Interferes with antigen presentation and toll-like receptor signaling; reduces cytokine production.	Used primarily for cutaneous manifestations; less effective for muscle involvement.

These findings highlight the wide array of therapeutic options for dermatomyositis, consistency with the need to individualize treatment based on disease severity, systemic involvement, and patient's response. Ninth, the current use in clinical practice has shown that the combination of immunosuppressive agents is effective to achieve optimal disease control and quality of life for patients with such a disease.

Objective 3: To assess the potential in US market for Dermatomyositis

To assess the potential of the U.S. market for dermatomyositis, it is essential to analyze the epidemiological trends alongside current treatment patterns and future projections. Dermatomyositis, being a rare autoimmune disease, has traditionally had limited commercial focus due to its low patient base. However, the rising prevalence, increasing awareness, and pipeline developments are now opening up significant opportunities for pharmaceutical and healthcare companies.

In 2019, the U.S. dermatomyositis market was relatively small, with an estimated **42,683 prevalent cases** and **3,612 new cases annually**, based on a prevalence rate of **13 per 100,000** and an incidence rate of **1.1 per 100,000**. Treatment availability was also limited, with approximately **34,061 patients** under active therapy. This pointed to a gap in diagnosis and access, but also an opportunity for better outreach and engagement.

By 2023, this market showed clear signs of expansion. The prevalent population increased to **71,672**, and annual new cases rose to **5,091**, driven by a higher prevalence rate of **21.4 per 100,000** and incidence rate of **1.52 per 100,000**. Although only around **35,000 patients** were receiving treatment, this already represented a sizable therapeutic market, with potential for further growth through improved diagnostic coverage and awareness campaigns. Importantly, the diagnosis rate was just **54%**, meaning nearly half of the patient pool remained untapped, pointing to a significant addressable market.

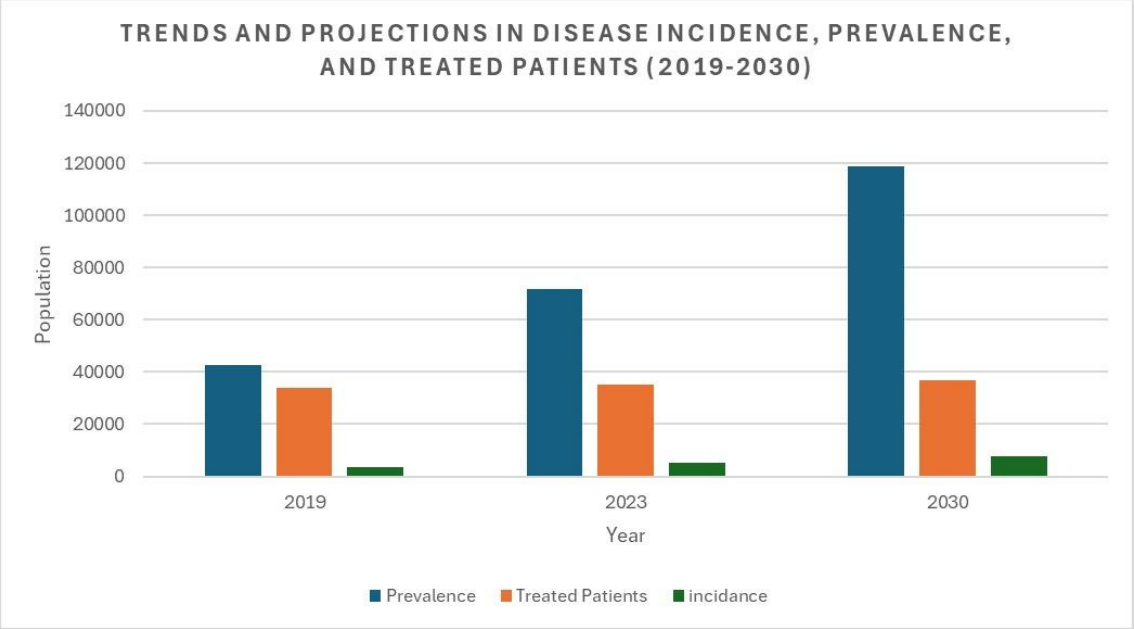
To project the market's future size, the "FORECAST" function in Excel was used to estimate 2030 figures based on 2019 and 2023 trends. By 2030, the U.S. population is expected to reach **345 million**, with prevalence projected to hit **34.4 per 100,000**, or approximately **118,705 patients**. Similarly, the incidence rate is forecasted to rise to **2.255 per 100,000**, corresponding to **7,781 new annual cases**. Treatment rates are also expected to improve, with an estimated **71,000 patients** potentially under active care. These figures signal a **substantial increase in market size**—nearly doubling the current treated population.

Moreover, the current therapeutic landscape is limited, with only **one FDA-approved therapy (Intravenous Immunoglobulin)** and most others being off-label or generalized immunosuppressants. This presents an **attractive opportunity for innovation**, especially in disease-specific biologics, targeted immunotherapies, and oral or subcutaneous formulations. The high annual treatment cost of existing therapies (e.g., Octagam's

~$386,000/year) further elevates the commercial potential, particularly for companies introducing cost-effective or more convenient options.

Figure 4.1: Market size of dermatomyositis

YEAR	US POPULATION	PREVALANCE RATE PER 100K	PREVALENCE RATE	PREVALENCE	TREATED PATIENTS	INCIDENCE RATE	INCIDENCE
2019	328329953	13	0.01%	42682.89389	34061	1.1	3611.629483
2023	334914895	21.4	0.02%	71671.78753	35000	1.52	5090.706404
2030	345073565	34.4	0.03%	118705.3064	71000	2.26	7781.408891



Analysis of the current (FY 2023) and future (FY 2030) market potential for dermatomyositis in the United States, based on a market model covering epidemiology as well as drug treated patients. The findings suggest that there is an increasing recognition and capability for diagnosis and management of what is a rare autoimmune disorder, with far reaching potential in terms of healthcare outreach, research and drug development.

U.S. Population Trends

In FY 2019, the U.S. population stood at approximately **328.3 million**. By FY 2023, this number had increased modestly to **334.9 million**, and it is projected to rise further to around **345 million** by FY 2030. While this population growth is moderate, it creates a broader base for the potential expansion in the detection and management of low-

prevalence diseases such as dermatomyositis. The slow but steady demographic expansion supports long-term planning for rare disease infrastructure and care models.

Objective 3: To assess inline and pipeline drugs in US market.

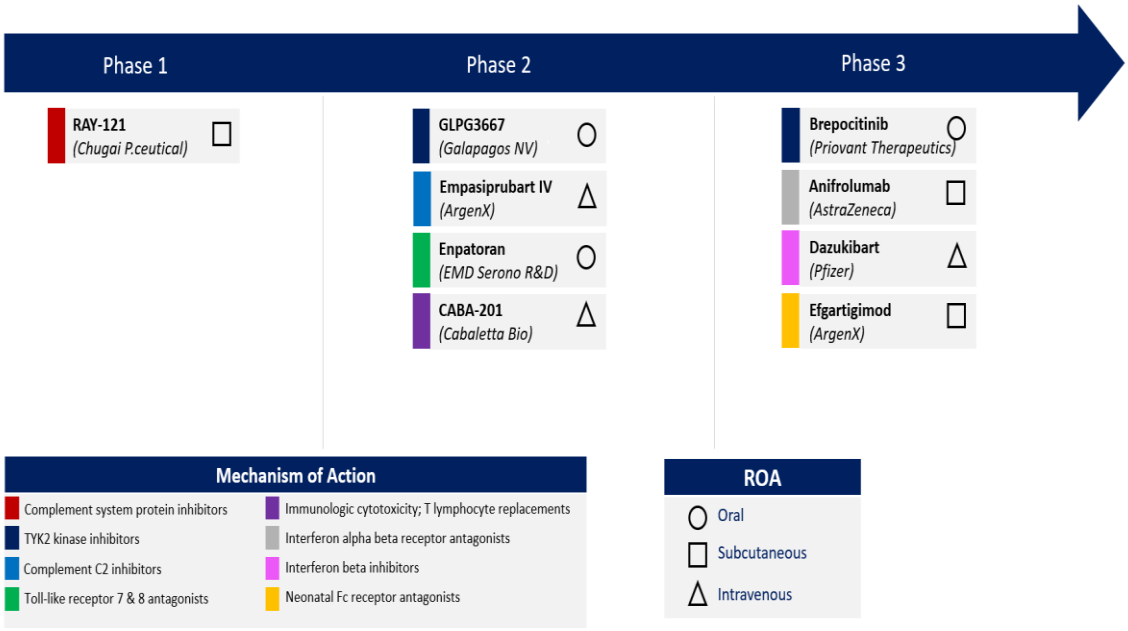
At least for the U.S., the dermatomyositis market is a mishmash of heavily utilized off-label drugs and only one FDA approved medicine, reflecting on one hand the advancements as well as the shortcomings present in the current treatment arsenal. Steroids such as prednisolone and Methotrexatre are cost effective, readily available and well known to prescribers, with a degree of therapeutic flexibility. Nevertheless, these treatment modalities are generally used off-label, without rigid FDA approval for dermatomyositis, and have limitations of known long-term safety data and uniform efficacy. Rituximab has the same off-label status, despite benefiting far too many of the diseases for which it is prescribed. The only approved drug for dermatomyositis, Intravenous Immunoglobulin, marketed by Pfizer, is an important step in the market but at a price of $386,750 per patient per year with the formulation requiring IV administration introduces logistical complications in the healthcare system and makes it more challenging for patients. On the other hand, the DM market-pipeline is very rich and diverse, indicating a market-transforming evolution by 5-7 years. There are several agents in various stages of Phase 2 and Phase 3 clinical development, some of which are novel (Brepocitinib [a TYK2 inhibitor]; Anifrolumab [anti-IFNAR1 antibody]; Dazukibart; and Efgartigimod [an FcRn antagonist]). This slate of investigational drugs cover a diverse range of mechanisms of action, suggesting a significant degree of scientific innovation and promise for more optimized therapies. Importantly, the pipeline involves drugs with different modes of administration - oral or subcutaneous - potentially leading to better patient compliance and a lower treatment burden. However, that aside, many unknowns still remain: none of these candidates have fully cleared the FDA hurdle, and the risk is always genuine of late stage clinical failure or regulatory setback. Moreover, quite a number of the candidates may turn out to be disease drivers relevant in specific subgroups of patients, which might hamper strong initial adoption prompting more detailed market segmentation considerations. In summary, the market for dermatomyositis currently is unmet and off-label treatments with safety, cost and convenience limitations are offered in the U.S. Despite this (academic partnership related issues), dozens of Bashows and Auwerxes (allegations) are running through my head, but the market of this ageing drug clearly takes the path to significant change, freeing up for

pharma alike companies with new innovative pipelines in clinical development, to bring in safer hurly-burly-friendlier and more effective new therapies that can outcompete potentially existing and marketed ones, and ultimately create their own standard by doing so, for a rare and an incapacitating auto-immune disorder.

Key Pipeline therapies for Dermatomyositis- US Market: Following are the steps used for extracting drugs in pipeline which are under clinical trials for treatment of Dermatomyositis.

Figure 4.2: Steps used for extracting drugs in pipeline

Figure 4.3: Pipeline products



To gain insights into the future therapeutic landscape for dermatomyositis, we conducted a phase-wise pipeline analysis based on current clinical trials. A systematic approach was employed by applying multiple filters to the Excel dataset, including disease indication, trial phase, mechanism of action, and route of administration. This helped us accurately identify and isolate the relevant investigational therapies specific to dermatomyositis. The filtered data provided a clear picture of the innovation underway in this space, categorized into Phase 1, Phase 2, and Phase 3 clinical development.

In Phase 1, one promising candidate is RAY-121, developed by *Chugai Pharmaceutical*. It acts as a complement system protein inhibitor and is administered subcutaneously, suggesting a potential move away from intravenous therapies to more convenient dosing routes.

Phase 2 of the pipeline shows a broader range of novel mechanisms and administration strategies. GLPG3667 by *Galapagos NV* is an oral TYK2 kinase inhibitor, indicating an emerging class of targeted immune modulators. Empasiprubart IV, developed by *ArgenX*, is a complement C2 inhibitor delivered via intravenous infusion, continuing the trend of complement-targeted approaches. Enpatoran from *EMD Serono R&D* is another oral candidate, targeting Toll-like receptors 7 and 8, which are key in innate immune activation. Additionally, CABA-201 by *Caballeta Bio* represents a more advanced immunotherapy, aiming for immunologic cytotoxicity and T lymphocyte replacement, administered intravenously.

In Phase 3, several high-potential candidates are approaching potential regulatory milestones. Brepocitinib, developed by *Priovant Therapeutics*, is an oral TYK2 kinase inhibitor similar to GLPG3667, and it signifies a strong clinical interest in this mechanism. *AstraZeneca*'s Anifrolumab is a subcutaneous interferon alpha-beta receptor antagonist, which may offer disease-specific immune modulation. Dazukibart by *Pfizer* is an interferon beta inhibitor, administered intravenously, while Efgartigimod, also by *ArgenX*, targets the neonatal Fc receptor and is delivered subcutaneously—a convenient alternative to IV therapy.

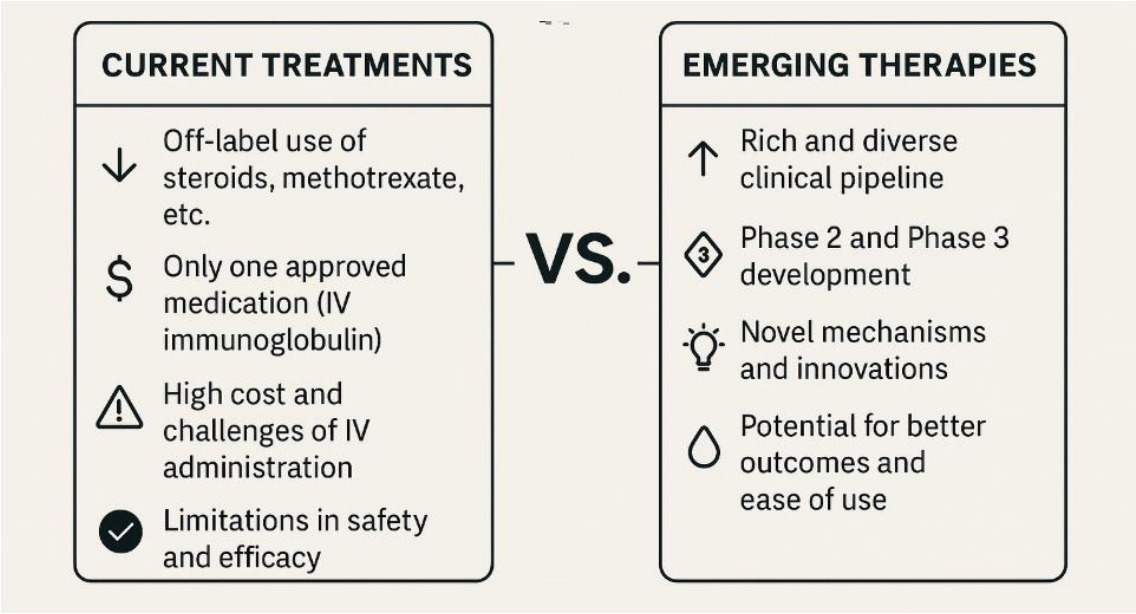
Overall, the filtered data highlights a rich and evolving pipeline with diverse mechanisms of action and administration routes, reflecting the market's shift toward more targeted and patient-friendly treatment options. The presence of multiple Phase 2 and 3 therapies also suggests a robust pipeline maturity, indicating a potentially competitive future landscape in the dermatomyositis treatment space.

Drivers:

At least for the U.S., the dermatomyositis market is a mishmash of heavily utilized off-label drugs and only one FDA approved medicine, reflecting on one hand the advancements as well as the shortcomings present in the current treatment arsenal. Steroids such as prednisolone and Methotrexatre are cost effective, readily available and well known to prescribers, with a degree of therapeutic flexibility. Nevertheless, these treatment modalities are generally used off-label, without rigid FDA approval for dermatomyositis, and have limitations of known long-term safety data and uniform efficacy. Rituximab has the same off-label status, despite benefiting far too many of the diseases for which it is prescribed. The only approved drug for dermatomyositis, Intravenous Immunoglobulin, also make by Pfizer, is an important step in the market but at a price of $386,750 per patient per year with the formulation requiring IV administration introduces logistical complications in the healthcare system and makes it more challenging for patients. On the other hand, the DM market-pipeline is very rich and diverse, indicating a market-transforming evolution by 5-7 years. There are several agents in various stages of Phase 2 and Phase 3 clinical development, some of which are novel (Brepocitinib [a TYK2 inhibitor]; Anifrolumab [anti-IFNAR1 antibody]; Dazukibart; and Efgartigimod [an FcRn antagonist]). This slate of investigational drugs cover a diverse range of mechanisms of action, suggesting a significant degree of scientific innovation and promise for more optimized therapies. Importantly, the pipeline involves drugs with different modes of administration - oral or subcutaneous - potentially

leading to better patient compliance and a lower treatment burden. However, that aside, many unknowns still remain: none of these candidates have fully cleared the FDA hurdle, and the risk is always genuine of late stage clinical failure or regulatory setback. Moreover, quite a number of the candidates may turn out to be disease drivers relevant in specific subgroups of patients, which might hamper strong initial adoption prompting more detailed market segmentation considerations. In summary, the market for dermatomyositis currently is unmet and off-label treatments with safety, cost and convenience limitations are offered in the U.S. Despite this (academic partnership related issues), dozens of Bashows and Auwerxes (allegations) are running through my head, but the market of this ageing drug clearly takes the path to significant change, freeing up for pharma alike companies with new innovative pipelines in clinical development, to bring in safer hurly-burly-friendlier and more effective new therapies that can outcompete potentially existing and marketed ones, and ultimately create their own standard by doing so, for a rare and an incapacitating auto-immune disorder.

Figure 4.4: Drivers of Dermatomyositis market



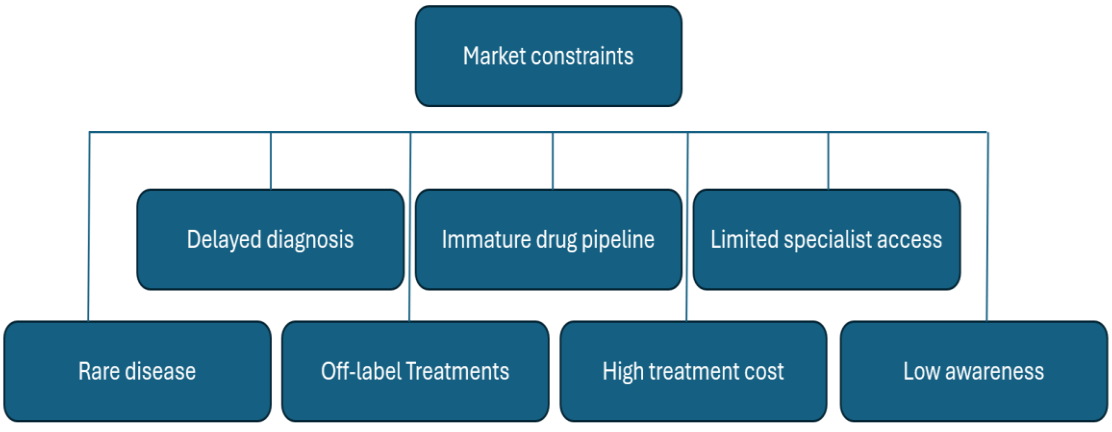
Market Constraints:

Despite increasing interest and new therapeutic advances, the US dermatomyositis market still encounters several strong and extensive impediments that constrain its size, access, and scalability. Of all, dermatomyositis is an ultra-rare autoimmune disease occurring with estimated frequencies of only 1 to 10 per 100,000 persons. This modest prevalence generates a small total addressable market, which inherently complicates the opportunity

for commercial viability, investment case and widespread pharmaceutical involvement. Diagnostically, dermatomyositis is heterogeneous in clinical and laboratory presentation and overlapping with other idiopathic inflammatory myopathies, with no definite biomarkers in a substantial minority. Diagnosis is delayed for months to several years in most of the patients, particularly by community-based physicians who are not familiar with the disease, and thus the number of patients cut off from life-saving treatment is increased. In addition, access to rheumatologists, neurologists, or dermatologists who are experienced in treating rare autoimmune diseases is unequally distributed, especially in rural or underserved areas, exacerbating disparities in care and hampering early therapeutic intervention. From a treatment perspective, the best available guide is a list of off-label approaches that currently drive this patchy standard of care, typically comprising corticosteroids, methotrexate, azathioprine, and biologics such as rituximab. Although these options offer short-term suspension of disease for some patients, they are not FDA-approved for dermatomyositis which makes for significant hurdles to fulfilling long-term safety requirements, standardized protocols, and most importantly, insurance reimbursement. Numerous payers refuse to cover therapies applied outside their indicated use, frequently shifting the cost to patients, or limiting access through prior-authorization or step-therapy requirements. Intravenous Immunoglobulin (Pfizer) was the first therapy approved by the US Food and Drug Administration for the treatment of dermatomyositis; however, a prohibitive annual cost of US$386750 and the need for intravenous infusion in a hospital based setting render it inaccessible, unaffordable, and not practical for long-term use. High treatment-related costs limit patient access, and burden healthcare systems, especially as hospital worksites and infusion facilities are needed for a variety of other chronic illnesses. Furthermore, the product pipeline, although attractive is still relatively immature. There are only a few drug candidates that have made it to late-stage clinical trials; hundreds more are in early development. (I'm not opposing the development of these investigational agents, particularly JAK inhibitors, FcRn antagonists, and complement inhibitors, but let's be clear, these products are fraught with high clinical failure rates, long development timelines and complex regulatory expectations--even when the ODA is in play.) Furthermore, many pipeline drugs are specifically engineered to focus on narrower molecular signalling pathways or patient subgroups in response to novel biomarkers, which may make them less applicable to the greater dermatomyositis populations and reliant on precision diagnostics that are not currently in clinical practice. Mark et fragmentation is very bad, since the disease is overlapping with other diseases like polymyositis, lupus, systemic sclerosis etc etc, this

makes both trial planning and commercal positioning very hard. Even once approved, manufacturers face considerable market access hurdles, from proving value to payers, to negotiating pricing, to insuring distribution through specialty pharmacy avenues. Finally, there is a relative lack of knowledge and advocacy momentum on the part of patients compared to other autoimmune or rare diseases, thereby impacting public funding, prioritization of research and support systems for living with dermatomyositis. Taken together, these constraints—from epidemiological orphanhood and diagnostic moratoria, through to therapeutic underinvestment, regulatory uncertainty, and access delay—interact to form an extremely challenging and restricted commercial space. Resolving these challenges will not only take continued innovation in drug development but investments in diagnostics and physician and patient education, infrastructure and patient engagement to sustain a more mature and accessible market for treating dermatomyositis in the United States. In addition to the current challenges, there is limited naturalistic data in dermatomyositis, fragmented multidisciplinary care, and great heterogeneity between patients, which makes it difficult in both the design of clinical trials and patient management. Psychosocial needs are generally not met, and changing regulations slow approvals. Furthermore, low awareness among physicians, economic pressure on healthcare provider and challenges relating to patient adherence also limit access and appropriate treatment, and by extension the advancement of the market and therapy.

Figure 4.5: Market Constraints of dermatomyositis



CHAPTER 4 – RECOMMENDATIONS

Based on the extensive secondary research conducted on dermatomyositis, several key areas have emerged where improvements can be made in clinical practice, research direction, patient education, and healthcare policy. The following recommendations are proposed to enhance the quality of care, improve diagnostic accuracy, and foster deeper understanding of this complex autoimmune disorder.

Strengthen Early Diagnosis Through Greater Clinical Awareness

The symptoms of dermatomyositis can vary widely, which sometimes results in a delayed diagnosis, especially in atypical or amyopathic cases. Timely diagnosis and treatment are key to avoiding progressive disease and irreversible organ damage.

- Healthcare professionals, including dermatologists, general practitioners, and rheumatologists, should receive continuous education on recognizing early signs, especially hallmark skin lesions like Gottron's papules and heliotrope rash.
- Increased use of autoantibody testing and MRI imaging should be encouraged in suspected cases to support early and accurate diagnosis.
- Public and patient awareness campaigns about early symptoms can also help reduce delays in seeking medical care.

Expand Access to Biologic and Targeted Therapies

Traditional immunosuppressive agents are often effective but may not be sufficient in refractory cases or those with severe complications such as interstitial lung disease or dysphagia.

- Healthcare systems should consider including biologic therapies (e.g., rituximab, tofacitinib) in treatment formularies for patients unresponsive to conventional therapy.
- Further clinical trials are recommended to evaluate the long-term safety and efficacy of JAK inhibitors, interferon-blocking agents, and other emerging immunomodulatory drugs.
- Governments and health insurance providers should assess reimbursement policies to ensure patients with severe disease have access to these newer treatments.

CHAPTER 5 – CONCLUSION

Dermatomyositis: is an infrequent, chronic, autoimmune inflammatory myopathy, that is characterized by a combination of typical skin findings and a symmetrical proximal muscle weakness, which is sometimes associated with systemic manifestations, such as interstitial lung disease, and an increase risk of malignancy. Despite progress in the understanding of the pathophysiology and treatment options, DM is still difficult to handle, given its heterogeneous clinical presentation and suboptimal response to current therapies. In United States, the market is highly dependent on off-label use of immunosuppressant and corticosteroids as only one therapy is available so far, which is expensive and difficult to administer and is approved by the FDA. Nevertheless, a rich portfolio of emerging new targeted agents, biologics and small molecule inhibitors, offers encouraging prospects for enhanced efficacy and safety in the next few years.

Achieving a diagnosis of DM is facilitated by a broad approach that includes clinical evaluation, serologic testing, imaging, and histopathology that can differentiate DM from other myopathies and direct therapy better. Treatment goals for mesalamine long-term therapy are to maintain clinical remission to achieve efficacy without toxicity and to monitor for side effects. Care should be multidisciplinary and patients should be educated and have intense surveillance for cancer. Treatment options can lower disease activity and increase overall well-being, however no ideal, safer, more focused, and available options exist for the treatment of this condition. Future directions for dermatomyositis care will rely on ongoing investigations, clinical trial efforts, and real-world experience.

Inconclusion, dermatomyositis is a complex therapeutic challenge, yet offers greatprospects for innovation. As science continues to evolve and the treatments are becoming more diverse, there is the potential for improved patient centered care that addresses not only the musculoskeletal but systemic components and may enhance the overall prognosis and quality of life for those with the disease.

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