



PREDICTING OPPORTUNITY IN EMERGING THERAPIES

Market Sizing Insights from the
GLP-1 and Metabolic Arena

Jesse Cuaron, PhD, PPM

Abstract

The emergence of novel metabolic markets highlights significant opportunities within previously untapped disease areas. These markets, characterised by unmet clinical needs, have drawn strategic investments from drug manufacturers, leading to substantial returns.

Weight management stands out prominently, particularly with the introduction of glucagon-like peptide (GLP-1) drugs like Novo Nordisk's Wegovy (semaglutide). These drugs have revolutionised the weight management market by offering effective treatment options where previously there were few.

Effective market sizing is essential, encompassing epidemiological data, prescription rates, and access considerations to provide a holistic view of the addressable market size. This comprehensive approach helps identify bottlenecks, key focus areas, and opportunities to expand the addressable patient population, ultimately informing strategic initiatives for drug manufacturers.

Novel Metabolic Markets

Over the past decade, we have observed the emergence of markets within disease areas that have remained largely untapped. These markets, characterised by well-documented unmet needs, have often lacked clinically efficacious treatment options. They represent valuable opportunities for drug manufacturers, who have strategically invested in these areas and enjoyed substantial returns, with weight management serving as a prime example. To capitalise on these opportunity-rich markets, a deep understanding of strategy, research, and market dynamics is essential. Navigating their potential requires meticulous diligence due to the considerable inherent uncertainties.

There are several examples of disease markets that have recently emerged or have displayed significant development due to the arrival of novel pharmaceuticals. This is particularly witnessed in the metabolic category, which is the therapeutic area this paper focuses on. This field can occasionally experience stagnation in treatment advancements due to the maturity of its existing markets. However, there are notable exceptions in the form of novel metabolic disease markets that promise to change the treatment landscape.

These new metabolic markets, which have emerged since 2021, include:

- **Weight management, with the introduction of Novo Nordisk's Wegovy (semaglutide) in 2021; low penetration or efficacy seen with appetite suppressants, lipase inhibitors, and stimulant drugs¹**
- **Metabolic dysfunction-associated steatohepatitis (MASH), with the introduction of Rezdifra (resmetirom) in 2024²**
- **Obstructive sleep apnea (OSA), with an anticipated launch of tirzepatide and AD109 (atomoxetine + oxybutynin) within ~2024³ through 2026⁴**

Nascent Metabolic Disease Markets



Analysing nascent markets through examples in the metabolic space provides valuable insights and clarifies which considerations are most crucial for a drug manufacturer aiming to enter a new or undeveloped disease area. Ipsos has already been actively conducting research in these emerging areas, capturing real-world patient-level data through our Obesity and MASH Therapy Monitors (with CKD, Heart Failure, and Alzheimer's launching shortly).

Market Sizing

For any disease market, but especially for a nascent disease space, market sizing is necessary for determining how many patients could potentially be treated by drug therapy where none exists. Epidemiology, with relevant segmentation considered, sets the foundation for determining market size in a nascent disease market. But it isn't enough to merely look at a market in terms of underlying epidemiology alone; other considerations, e.g. predicting prescription, treatment rate and access, are important to gain a more complete sense of the addressable market size.

This comprehensive approach enables drug manufacturers to better identify and anticipate:

- Potential bottlenecks in diagnosis, testing, awareness, access
- Key areas for focused efforts and budgeting (e.g., targeting specific stakeholders or specialists)
- Opportunities to influence market growth and expand the addressable patient population

Drug manufacturers targeting MASH and OSA should concentrate on enhancing efforts to raise disease awareness and emphasise the urgency of treatment (both examples of bottlenecks that could significantly impact market potential). For instance, this could involve initiatives aimed at earlier disease detection and increased testing. For MASH, this might include recognising and screening for abdominal symptoms and elevated liver enzymes, while for OSA, it could focus on detecting snoring and pauses in breathing during sleep.^{5,6} Such measures could potentially expand the market by increasing both diagnosis rates and subsequent rates of treatment and prescription rates.



How does one estimate market size? A patient-based market sizing model is a valid and commonly used approach. Although publicly available data can provide estimates of disease prevalence, insights into treatment and access components often cannot be obtained through desk research alone. The probable lack of relevant analogues will also exacerbate this issue. Therefore, a primary market research (PMR) component takes on a more pivotal role in opportunity analysis. PMR enables a more exploratory, in-depth analysis, leading to more informed predictions when forecasting nascent disease markets.

The epidemiology of patients by body mass index for weight management is well-documented in many countries. Nevertheless, forecasting the evolution of treatment and prescription rates presents a significant challenge, highlighting the critical need for PMR.

When determining market size, the approach will vary depending on whether the market is already established or new. Existing or mature disease markets benefit from the availability of multiple data sets with actuals and real-world data (RWD) providing a grounded perspective of market realities, which are then complemented by PMR. In nascent disease markets, anchors are typically scarce and secondary data points may be minimal, making the availability of these commodities – and RWD – all the more valuable.

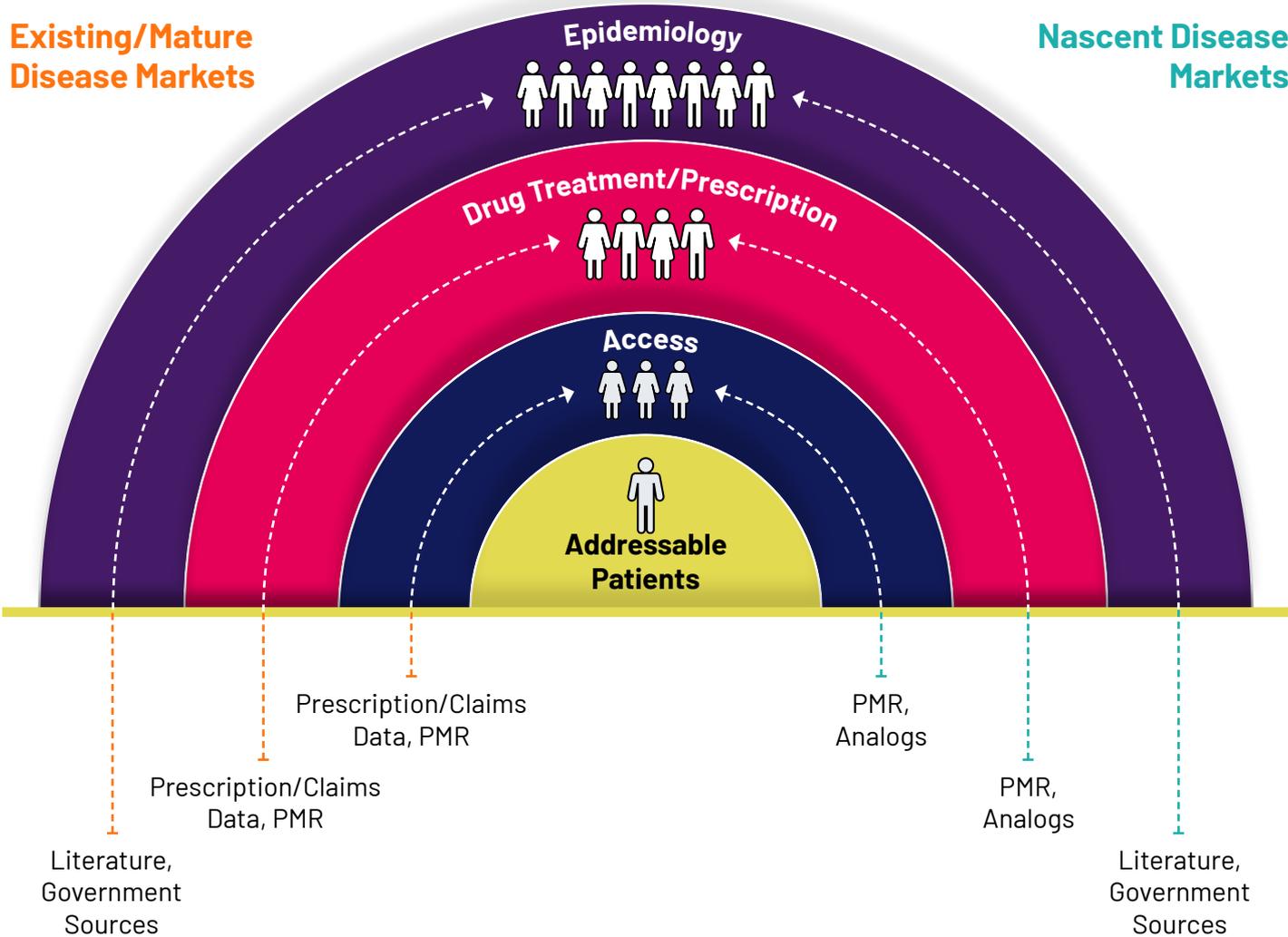


Navigating the potential of nascent markets requires meticulous diligence due to the considerable inherent uncertainties.

Addressable Patient Population

Existing/Mature Disease Markets

Nascent Disease Markets



Research Approach

Conducting research in a drug market that is yet to exist requires a dedicated and tailored approach, necessitating a deep dive into a multitude of secondary data sources and PMR components. In contrast, research in an existing or mature disease market leverages available data and focuses on tracking a drug within a well-defined competitive landscape. The former includes an increased dependence on PMR to inform assumptions and inputs. Effective PMR should encompass a broad range of potential stakeholders and respondents, including healthcare professionals (HCPs), payers, and key opinion leaders such as government officials and academics. Ipsos' Q4 2024 GLP-1 Market Sizing Study is an example of such a PMR methodology, gauging caseload and GLP-1 volume usage across a variety of clinician stakeholders.

In the metabolic arena, a wide range of prescribers, including both primary care doctors and specialists, are well-established and identified. These include, but are not limited to:

- **Endocrinologists and obesity medicine specialists for weight management⁷**
- **Gastroenterologists and hepatologists for MASH⁵**
- **Sleep medicine specialists and otolaryngologists (ENTs) for OSA⁶**

In addition to identifying key players and understanding the role of specialists in disease management, there are other key levers and specific components that should be prioritised when conducting market sizing research. For instance, the lever of diagnosis (captured through epidemiology) is crucial for understanding potential limitations or opportunities for market growth. Although desk research will be employed (primarily for epidemiological purposes), PMR will be required to explore and deep dive into awareness (physician and patient), unmet needs, and patient journey, which all help to paint a picture of market size potential.

Drawing from the metabolic space, it's essential to consider the patient journey. This approach highlights barriers such as the need for biopsies in MASH and polysomnography in OSA.^{5,6} Overlap between metabolic conditions adds a further

layer of complexity to evaluate. It should also be noted that as more patients use GLP-1s for weight management, the incidence of other related conditions and comorbidities, such as MASH and OSA, are likely to decrease. These constricting factors, particularly related to diagnosis rates, illustrate how they can limit market growth.

The focus on which market sizing components are most important varies between mature markets and nascent disease markets, driven by the absence of actuals or RWD in the latter. For instance, in nascent disease markets, significant emphasis should be placed on epidemiology, demographics, and unmet needs. In contrast, while these elements remain important, they are generally less critical or prioritised in existing or mature markets. Again, if good quality RWD is available, it will go some way to comprehensively assess the extent of the aforementioned barriers and complexities in the patient journey of the nascent areas.



Component Focus in Disease Markets

Existing/Mature Disease Markets		Nascent Disease Markets	
Actuals/RWD (Units)			Epidemiology
Access Considerations			Awareness (HCPs and Patients)
Epidemiology			Identifying Unmet Needs
Marketing			Patient Profile/Journey
Regulatory/Competitive Dynamics			Analogs
Unmet Needs			Access/Adoption Barriers

Unique Set of Challenges

It's essential for drug manufacturers to thoroughly understand the potential opportunities and dynamics of a nascent market before deciding to enter. However, several challenges arise due to the lack of anchor points and relevant analogues. Gaining expertise in this area is crucial, as failing to do so could result in missing out on a highly profitable opportunity. The risks and consequences of either underestimating or overestimating a nascent market are numerous.

For any disease market, but especially for a nascent disease space, market sizing is necessary in determining how many patients could potentially be treated by drug therapy where none exists.



Market Sizing Pitfalls and Consequences

Pitfalls in Estimating Market Potential

- 1 Flawed PMR design**
 Skewed results from poorly designed, inadequate sample size, biased survey questions, inappropriate analytical techniques.
- 2 Ignoring external or emerging factors**
 Failing to account for evolving trends such as shifts in healthcare policies, regulatory changes, new technologies, changing patient demographics, disease perception, evolving global economic conditions.
- 3 Insufficiencies and misimplementation of secondary research and datasets**
 Data limitations, choosing wrong analogs, outdated data, inaccurate epidemiology segmentation, and lack of access or ability to pay considerations.

Consequences of Misunderstanding Market Size

- Capacity planning problems
- Incorrect pricing strategies and budgeting
- Losing out, providing opening to competitors
- Misallocate sufficient resources or investment
- Missed sales and revenue opportunities
- Reputational damage among stakeholders and investors, or both
- Shortage or excess of supply (molecule, delivery device)

As observed with the launch of GLP drugs for weight management, Novo Nordisk continues to face supply shortages.⁹ This issue may stem in part from an underestimation of demand and challenges in accurately gauging the addressable population, along with some impact possibly attributed to unforeseen social media influence. Eli Lilly previously faced a similar situation but has since reported an improvement in supply.⁹

To help mitigate the risks associated with misestimating market size, drug manufacturers often employ a combination of secondary data, PMR, and expert consultations.



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Ipsos, with its proven track record, excels in understanding market complexities by staying attuned to stakeholder perceptions, thus providing a more informed and robust approach to market sizing. As one of the leading global market research companies, Ipsos has a unique advantage and excels in understanding society: HCPs, patients, caregivers, payers, consumers, HC systems, government policies and the wider society.

Navigating a nascent disease market requires a comprehensive understanding of all relevant segments and components, including key stakeholders such as HCPs and payers. This challenge is addressed by offering multi-disciplinary healthcare teams specialising in market research, forecasting, epidemiology, and access. These teams are well-versed in multiple therapeutic areas, utilising validated and consistent market research methodologies across various geographies. Additionally, current and emerging market factors and events globally are systematically tracked, and relevant insights drawn from relevant market trends.¹⁰

As touched upon earlier, RWD can more decisively quantify an addressable population but is harder to come by in nascent therapeutic areas. However, as said, sources such as Ipsos' Obesity Therapy Monitor and MASH Therapy Monitor provide current data of this nature. The data can provide the initial building blocks for any PMR, specifically identifying unmet treatment needs and patient journey analysis, as well as patient profiling to help quantify treatment-eligible subsets; visibility of relevant prescriber types and caseload/treatment rate analysis is also possible. Data from longer established real-world datasets, such as Ipsos Therapy Monitors in other areas, can also offer proxies for comparative market analogue analysis. The Ipsos GLP-1 Market Sizing Study, available to multiple clients in Q4 '24, will additionally provide granularity regarding proportional usage contribution of this drug class across several therapeutic areas, including emerging fields beyond metabolic conditions, e.g., Alzheimer's Disease, and alcohol usage disorder.

In summary, some key guidelines for effectively navigating and evaluating a nascent market are as follows:

- 1** **Conduct thorough desk research** from multiple sources like academic literature, government sources, registries, broker reports, and company documents.
- 2** **Identify relevant market analogues** for comparative analysis if possible.
- 3** **Perform customised PMR**, both qualitative and quantitative, informed by therapeutic area expertise.
- 4** **Cross-validate PMR and secondary research findings** to ensure accuracy.
- 5** **Monitor emerging trends** that could impact market dynamics.
- 6** **Utilize scenario planning and modelling** to explore uncertainties and predict potential changes.



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AUTHOR

Jesse Cuaron, PhD, PPM
Associate Vice President
Healthcare
Jesse.Cuaron@ipsos.com

www.ipsos.com

