

INDUSTRY OVERVIEW

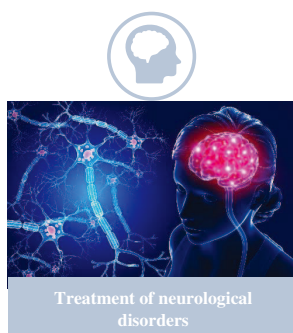
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GLOBAL AND CHINA MODIFIED NEW DRUGS MARKET

Overview

Modified new drugs are pharmaceutical products that, without altering the active pharmaceutical ingredient (API) of an already marketed pharmaceutical product, employs advanced drug delivery technologies and dosage form innovations to achieve significant improvements in efficacy, safety, patient compliance and other key aspects. Consequently, it is approved as a “new drug” by regulatory authorities (e.g., FDA, EMA, NMPA).

Modified new drugs have shown broad application prospects in multiple therapeutic areas and lifestyle health. By utilizing diverse drug delivery technologies, such drugs aim to achieve precise, safe, and efficient treatment experiences, meeting the dual demands of modern medicine for improved efficacy and patient compliance. Their main application scenarios include: treatment of neurological diseases, chronic disease management, large-molecule drug delivery.



- sprays bypass the BBB (Blood-Brain Barrier) for rapid treatment of Parkinson's, Alzheimer's, and epilepsy, with products like diazepam nasal spray and midazolam nasal spray. Compared with conventional oral or injectable formulations, intranasal delivery offers advantages including non-invasive administration and timely symptom control in acute or episodic settings.



- Microneedle patches provide a minimally invasive, painless, and user-friendly drug delivery option for daily chronic care, improving treatment adherence compared with conventional injections. Their ease of self-administration and reduced reliance on medical professionals make them particularly suitable for elderly and pediatric populations, as well as for long-term management of chronic conditions.



- Modified new drugs are enabling broader clinical applications beyond traditional injections. Innovations such as transdermal or intranasal systems are being developed to overcome challenges of poor stability, limited permeability, and frequent dosing. These technologies can protect macromolecules from degradation, enhance absorption or enable localized targeting, and support more convenient, patient-friendly, at-home administration.

The Characteristic of Modified New Drugs

The core value of modified new drugs lies not in the discovery of new molecules, but in reshaping the pharmacokinetic profiles of known active ingredients through innovative dosage forms to achieve new clinical benefits or maximize therapeutic potential. With the rise of precision medicine and patient-centric care, innovative drug products with new drug delivery system are transforming drug development. Drug delivery technologies like microneedles, nasal sprays, and controlled-release systems overcome limitations of traditional drugs by enabling targeted delivery, enhanced absorption, and improved patient compliance. These advances not only boost treatment outcomes but also improve patient experiences. Widely applicable in fields such as neurology, chronic diseases management, oncology, and skincare, these modified new drugs with new drug delivery system or new route of administration are reshaping the pharmaceutical value chain.

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Administration Route	Typical Indications	Bioavailability	Patient Comfort/ Compliance	Typical Use Cases & Settings	Advantages	Limitations
Intravenous	Acute critical illnesses, drugs requiring rapid onset	100%	Low comfort	Hospitalized patients, preoperative/intraoperative, emergency rescue	Fastest onset, precise dosing, no first-pass effect, controllable blood concentration	Highly invasive, requires professional operation, potential vascular damage
Oral	Common chronic diseases (e.g., hypertension, diabetes, chronic inflammation)	<100%	Highest	Outpatient preoperative preparation, long-term management	Convenient, low cost, suitable for long-term management	Affected by gastric pH, enzymes, motility; significant first-pass effect for some drugs; contraindicated for patients with gastrointestinal disorders
Transdermal Patch (Non-Microneedle)	Continuous pain management, hormone replacement, chronic disease management	Higher bioavailability than oral	High	Outpatient preoperative preparation, long-term management	Bypasses first-pass metabolism, provides stable blood concentration	Limited by drug lipophilicity, dosage limitations, requires a longer time (hours to days) to achieve steady-state
Transdermal Patch (Microneedle)	Preoperative sedation, adult type 2 diabetes, and weight management	Superior to oral, comparable to or better than subcutaneous injection	High	Outpatient preoperative preparation, long-term management	Solves injection pain and subcutaneous tissue damage, efficient delivery	Complex manufacturing process, high stability requirements for drugs, limited comfort for long-term wear
Nasal Spray (Local Nasal Indications)	Allergic rhinitis, nasal congestion, nasal polyps	Extremely low, mainly local effect	High	Outpatient preoperative/preventive use, high frequency in children	Rapid onset, high local concentration, avoids systemic side effects	Dose limited by small volume, affected by nasal clearance mechanisms, long-term use may cause mucosal atrophy
Nasal Spray (Systemic CNS Indications)	Central analgesia, sedation, migraine, depression/anxiety requiring systemic CNS absorption	Varies; generally superior to oral	High	Outpatient preoperative/preventive use, high frequency in children	Rapid onset, bypasses blood-brain barrier, avoids gastrointestinal degradation	Dose limited, difficult to deliver large protein molecules, requires specific formulations (e.g., liposomes, nanoparticles)
Nasal Spray (Nose-to-Brain/Intranasal CNS Indications)	Chemotherapy-related nausea and vomiting, traumatic brain injury, alzheimer's disease, parkinson's disease ("Off" episodes)	Superior to other systemic routes, can directly deliver to brain tissue	High; suitable for long-term chronic disease patients	Used for long-term management in outpatients (e.g., chronic pain, cognitive disorders)	Direct delivery to CNS, rapid and targeted, minimal systemic side effects	Dose limited, drug stability issues, delivery efficiency limited by mucosal absorption and neural pathway utilization

Source: Literature Review, Frost & Sullivan

Challenges and threats of the modified new drugs market

Market Access and Commercialization Challenges.

Although the market for improved drugs holds considerable promise, it encounters several significant challenges during actual implementation. Firstly, despite the capacity of technological innovations to overcome traditional delivery barriers, the development of new delivery platforms (such as microneedles and nasal sprays) involves high R&D costs and complex manufacturing processes, resulting in a protracted and uncertain commercialization pathway. Secondly, the market education cycle is lengthy; both patients and healthcare institutions often exhibit low acceptance of these novel dosage forms, and their willingness to pay is constrained by drug pricing and healthcare insurance policies. Lastly, uncertainties in regulatory approvals and ongoing technological iterations require companies to possess exceptional technical expertise and substantial capital, thereby creating high barriers to market entry.

Regulatory Compliance and Market Access Barriers

Although regulatory bodies such as the FDA, EMA, and NMPA have categorized improved drugs under the “new drug” classification, their approval processes remain stringent and uncertain. Companies must provide comprehensive clinical evidence, demonstrating significant improvements in efficacy, safety, or patient adherence due to the new delivery technology, without altering the active pharmaceutical ingredient (API). Furthermore, regulatory agencies maintain high long-term safety standards for innovative delivery platforms (e.g., microneedles and nasal sprays), which not only extends clinical trial timelines but also adds to post-market regulatory responsibilities. Failure to meet these rigorous regulatory criteria can lead to substantial R&D resource loss and potential reputational damage.

Capital Return and Commercialization Balance

The development of improved drugs and the optimization of manufacturing processes typically demand significant capital investment. The production of modified new drugs with new drug delivery system such as microneedle patches requires specialized equipment and high-purity excipients, thereby imposing heightened technical and financial demands on scaling up production. While these new dosage forms can significantly enhance patient experiences, their relatively higher development and manufacturing costs may be reflected in the final pricing to a certain extent.

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Additionally, the scope of healthcare coverage and reimbursement levels directly influence patients’ willingness to pay. If insurance reimbursement proves challenging, the market penetration of these products may encounter certain constraints.

Drivers and Entry Barrier in Modified New Drugs Market

The development of modified new drugs are being synergistically driven by multiple factors, generating sustained growth momentum. The aging population and rising prevalence of chronic diseases are fueling sustained demand for long-acting, safe, and convenient dosage forms, particularly products suitable for home management, such as transdermal systems (including innovative forms like microneedle patches) and nasal sprays.

Concurrently, increasing patient focus on minimally invasive and personalized medication experiences is driving the rapid development of formulations tailored for specific populations, such as pediatric, geriatric, and neurological patients. Technologically, innovative delivery platforms are continuously breaking through delivery barriers for challenging drugs, accelerating industry advancement. Furthermore, policy encouragement and capital investment form a dual engine of “innovation substitution” and “high-barrier investment,” significantly shortening product development cycles. Under the promotion of the national innovation substitution strategy, regulatory agencies guide resources towards the field of innovative formulations through accelerated approval and incentives for generic drug innovation. The capital market favors pharmaceutical companies with long-term return characteristics. With the increasing demand for long-term safe medication among chronic disease patients, high barrier investment not only guarantees research and development funds, but also shortens the research and development cycle, accelerates the launch of improved new drugs, and quickly meets the actual needs of patients.

Overall, modified new drugs are currently in a phase of multi-factor resonance, characterized by “demand pull, technological drive, policy support, and capital backing,” indicating promising future growth prospects.

Modified new drugs face multiple market barriers. On one hand, their high technical barriers involve deep integration across multiple disciplines such as pharmaceuticals, medicinal chemistry, and biotechnology, making R&D highly challenging. Simultaneously, the process scale-up and quality control of high-end formulations present significant difficulties, demanding stringent production capabilities and technological expertise. Furthermore, the lengthy market education cycle, coupled with relatively low acceptance and willingness to pay for new dosage forms among patients and healthcare institutions, also limits market penetration to some extent.

Future Trend in Modified New Drugs Market

1. Policy Drivers and Market Expansion

The National Medical Products Administration (NMPA) is improving approval efficiency and creating fast-track pathways for innovative drugs. Healthcare insurance policies and volume-based procurement mechanisms are increasingly favoring genuinely innovative products. China’s “14th Five-Year Plan” encourages the development of original new drugs and breakthroughs in advanced delivery technologies. Over the next 5–10 years, sustained policy support is expected to drive robust and sustainable market growth.

2. International Collaboration and Industry Chain Integration

Chinese modified new drugs are accelerating their “going global” strategies by monetizing innovation through license-out agreements and expanding global reach, supported by international clinical trials. Mergers, acquisitions, and technical collaborations (e.g., overseas technical alliances or joint R&D) are helping to bridge innovation gaps. The localization of supply chains for key excipients and equipment is reducing costs and enhancing resilience.

3. Technological Iteration and Differentiated Competition

Technological iteration for modified new drugs is evolving from macroscopic controlled release to microscopic precision delivery, with microneedles and nasal sprays being prime examples. Microneedle formulations create a minimally invasive transdermal channel, enabling efficient delivery of macromolecular drugs such as ADCs, nucleic acids, and proteins/peptides. Their differentiation lies in converting injectable drugs into self-administerable patch forms, significantly enhancing patient compliance. Nasal sprays leverage the nose-to-brain pathway to bypass the blood-brain barrier, offering targeted therapy for central nervous system disorders. Both technology platforms feature flexible manufacturing characteristics, enabling adaptation to individual dosing needs through adjustments in microneedle array density, drug loading combinations, or nasal spray formulations, thereby advancing personalized medicine and ultimately creating unique competitiveness in the fields of biologics delivery and precision medicine.

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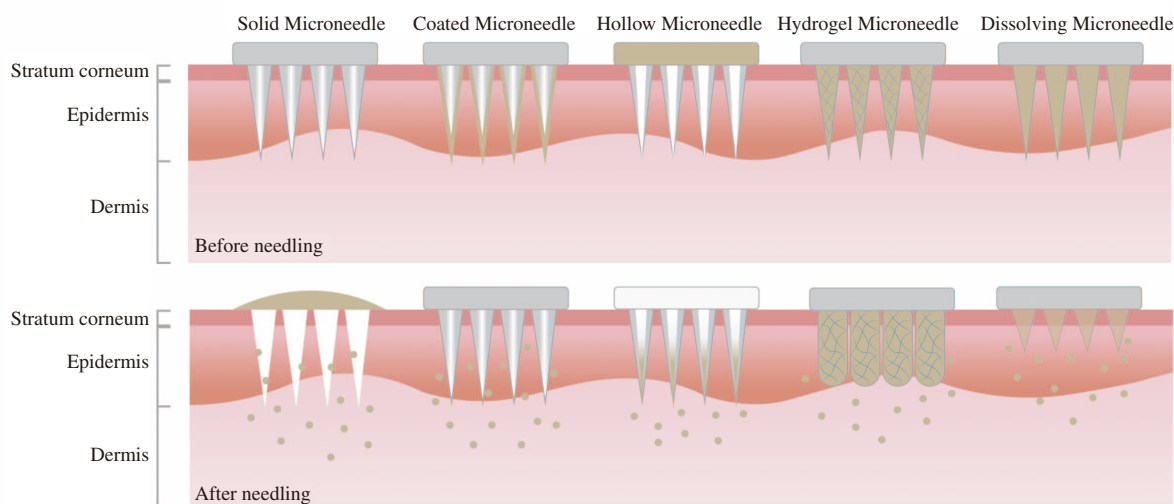
4. Clinical Needs and Untapped Market Opportunities

The aging population and increasing burden of chronic diseases are creating urgent demand for safer, more convenient therapies. Future priorities include: 1) Developing precision platforms such as nose-to-brain delivery and targeted formulations for traditionally difficult-to-treat areas such as brain disorders and cancer; 2) Providing efficient and minimally invasive delivery solutions (e.g., microneedles) for biologics (e.g., proteins, nucleic acid drugs) to enhance patient compliance; 3) Enabling personalized dosing through flexible dosage form design. Ultimately, modified new drugs will transcend their role as mere “delivery tools” and become a core driver in addressing critical clinical challenges and pioneering new treatment paradigms.

GLOBAL AND CHINESE MICRONEEDLE FORMULATION MARKET

Overview

Microneedle formulations significantly enhance skin permeability by creating micron-sized channels on the skin surface, enabling effective transdermal delivery of large-molecule drugs. Microneedles typically have a diameter of several micrometers and lengths ranging from hundreds of micrometers to the millimeter scale. They can instantly establish drug delivery channels, enabling drugs to rapidly reach subcutaneous tissue and enter the bloodstream. With advancements in materials science, microneedles can be manufactured from various materials such as silicon, polymers, and metals, and can be designed to be biodegradable, exhibiting excellent biocompatibility and supporting diverse formulation formats. This delivery system offers an alternative to traditional transdermal drug administration, particularly suited for the minimally invasive administration of large-molecule biopharmaceuticals, vaccines, and poorly absorbable drugs, representing an important development direction for modified new drugs.



Challenges and Threats in the Global, U.S. and China Microneedle Market

The global microneedle market is constrained by high costs of precision manufacturing, divergent regulatory standards across countries, and insufficient long-term safety validation.

- **Manufacturing and Technical Barriers:** The production process of microneedles is extremely sophisticated, involving micrometer-scale structural processing that is complex and costly to manufacture, requiring companies to invest substantial resources in process control and product consistency.
- **Regulatory and Market Access Challenges:** Microneedles are typically classified as medical devices, with significant variations in regulatory policies across different countries. The stringent global regulatory approval systems present companies with difficulties in cross-border market access, high compliance costs, and ongoing regulatory risks.

The U.S. market presents even greater challenges due to stringent FDA reviews, high-end pricing competition, and tariff-driven supply chain restructuring pressures.

- **High Market Entry Costs:** The United States imposes extremely strict regulations on microneedle products, particularly those involving drug delivery, which must undergo rigorous FDA review with lengthy approval processes and substantial costs.

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- **Geopolitical and Supply Chain Risks:** Affected by U.S. tariff policies, exports of microneedle raw materials and finished products from China and other countries face surging cost risks, creating significant pressure for supply chain restructuring and requiring companies to reconfigure their global supply chains to address uncertainties.

The Chinese market is constrained by fragmented regulatory pathways for borderline products, clinical translation bottlenecks, and intense domestic cost competition.

- **Regulatory Classification and Attribute Definition Risks:** In China, microneedle products often cross the boundaries of cosmetics, medical devices, and pharmaceuticals. The National Medical Products Administration (NMPA) has continuously tightened its classification definitions and review standards, presenting companies with prolonged registration cycles, high compliance costs, and shifting regulatory hurdles.
- **Clinical Translation and Local Supply Chain Bottlenecks:** The transition of microneedles from laboratory prototypes to large-scale industrial manufacturing remains a major bottleneck. The domestic supply chain still faces limitations in localized high-precision micro-machining equipment and medical-grade raw materials, which restricts companies' ability to maintain product consistency and scale production efficiently.

Drivers and entry barriers

The growth of global market microneedle market is expected to continue being driven by the following factors:

- **Expanding Healthcare and Aesthetic Demands for Minimally Invasive Delivery:** The global market is heavily propelled by a widespread clinical and consumer shift toward minimally invasive therapies. This is characterized by surging demands in dermatology and cosmetic treatments, a rapidly growing market for transdermal drug delivery systems, rising needs for infectious disease vaccine platforms, and heightened public awareness regarding homebased self-medication and self-health monitoring.
- **Technological and Material Innovations Coupled with Macro Policy Support:** Rapid breakthroughs in manufacturing and material sciences including 3D printing, nanotechnology, smart microneedles, and advanced soluble materials which are evolving microneedles into sophisticated composite systems. This technological leap is heavily reinforced by rising global healthcare expenditures, economic growth.

New entrants to the microneedle market primarily face the following barriers:

- **Divergent Global Regulatory Standards and High Compliance Costs:** Cross-border market access remains highly complex due to significant variations in how different nations classify and evaluate microneedles (often crossing lines between medical devices, cosmetics, and pharmaceuticals). This fragmentation subjects companies to prolonged registration cycles, immense regulatory risks, and redundant, high-cost compliance hurdles.
- **Extreme Sophistication in Precision Manufacturing and Structural Consistency:** The production of microneedles requires intricate, micrometer-scale structural processing that is exceptionally complex to scale. Transitioning from laboratory prototypes to automated, large-scale industrial manufacturing demands massive initial capital and deep technical expertise to guarantee strict product consistency, quality control, and long-term safety validation.

The growth of U.S. market microneedle market is expected to continue being driven by the following factors:

- **Robust Market Expansion and Diverse Therapeutic Applications:** The U.S. firmly commands the largest global market share, fueled by surging domestic and global demands for clinical microinfusing platforms. This growth is sustained across diverse specialized medical sectors, including widespread commercial adoption in high-volume vaccine deployment, rapidly growing pipelines for dissolvable transdermal drug delivery systems, and expanding aesthetic and clinical dermatological therapies.
- **Favorable FDA Environment Coupled with Mature Institutional R&D Investment:** The market benefits from active regulatory backing, highlighted by a notable increase in FDA recognized transdermal patch approvals, which directly signals higher regulatory acceptance. This predictable framework encourages massive R&D capital injection from mature, leading North American pharmaceutical and biotechnology enterprises into non-invasive and minimally invasive medical delivery technologies.

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New entrants to the microneedle market primarily face the following barriers:

- **Exorbitant Financial Commitments and High-Risk R&D Environments:** Developing clinically viable formulations creates a severe financial hurdle, with typical product development costs highly prior to regulatory submission with no guarantee of final approval. These staggering capital requirements and prolonged investment cycles effectively exclude cash constrained small to medium enterprises, consolidating market dominance among a small circle of well-funded, top pharmaceutical and medical device giants. Stringent FDA Regulatory Pathways and Dense Competitive Intellectual Property Webs: New types of combination products must navigate a complex and high-stakes regulatory classification system in the United States. The rules within this system vary widely --some only require demonstrating that the product is similar to an existing one, while others demand extremely detailed proof of safety and biocompatibility. Furthermore, established leading companies in the field, leveraging their carefully arranged core technology barriers and cost advantages from large-scale production, create significant challenges for new entrants. These include the constant risk of facing patent infringement lawsuits and the substantial difficulty of actually penetrating the market.

The growth of China’s microneedle market is expected to continue being driven by the following factors:

- **Patient compliance and medication experience requirements continue to rise:** With the intensification of population aging and the expansion of chronic disease patients, traditional injection therapy has become an important means of chronic disease management. Micro needle technology, with its “minimally invasive” characteristics, has become an important solution in this field. Research has shown that the penetration ability of microneedle drugs far exceeds that of ordinary skin administration methods. Due to its depth of action only reaching the superficial dermis, the vast majority of patients experience minimally invasive during the treatment process, significantly improving their medication adherence. Traditional injectable formulations have limitations in terms of pain sensation, operational complexity, and feasibility for home administration. Microneedles offer advantages such as minimally invasive procedures, low pain levels, and ease of use, thereby enhancing patient compliance.
- **Policy direction is clear:** Under the backdrop of national incentive policies, microneedle technology, as one of the key forms of transdermal drug delivery, aligns with the development trend toward patient-friendly administration methods and enjoys robust policy support. The ‘Opinions on Encouraging Drug Innovation and Implementing Priority Review and Approval’ proposes that drug registration applications should incorporate alternative formulations technologies, innovative therapeutic approaches, and demonstrate significant therapeutic advantages. Based on the macro policy direction of the 2026 Government Work Report, which elevated biomedicine to a strategic emerging pillar industry, and the relevant detailed industry documents, microneedle technology, as a disruptive innovation in the fields of biomedicine and high-end medical devices, is receiving a series of targeted policy benefits.
- **Unmet clinical needs drive the adoption of novel drug delivery methods:** In certain therapeutic areas, traditional oral or injectable drug delivery methods face limitations regarding onset time, first-pass effect, patient compliance, or long-term tolerability. Microneedle drug delivery systems offer a novel alternative for relevant indications and demonstrate significant potential for clinical application. Microneedles are not only drug delivery tools, but also innovative solutions to break through the bottleneck of drug delivery. Large molecule drugs and vaccines are difficult to orally absorb due to their large volume, susceptibility to gastric acid damage, or first pass effects. Microneedles achieve efficient transdermal absorption of difficult to deliver drugs by physically penetrating the stratum corneum, expanding the routes of medication.

New entrants to the microneedle market primarily face the following barriers:

- **High technical development requirements:** Microneedle products involve multidisciplinary integration, placing high demands on R&D. The transition from laboratory development to large-scale production requires a lengthy accumulation of technical expertise.
- **The collaborative development of drugs and microneedle drug delivery systems presents significant challenges:** Microneedle drug requires a high degree of compatibility between the drug formulation and the microneedle delivery system, imposing stringent demands on drug stability, loading efficiency, release kinetics, and intradermal absorption characteristics.

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- **Indications require stringent screening criteria:** Microneedles are not suitable for all drugs or indications; they require targeted development based on the physicochemical properties of the drug, administration frequency, and clinical needs. Companies must possess the ability to comprehensively assess clinical requirements, market size, and payment capacity.

Future Development Trend

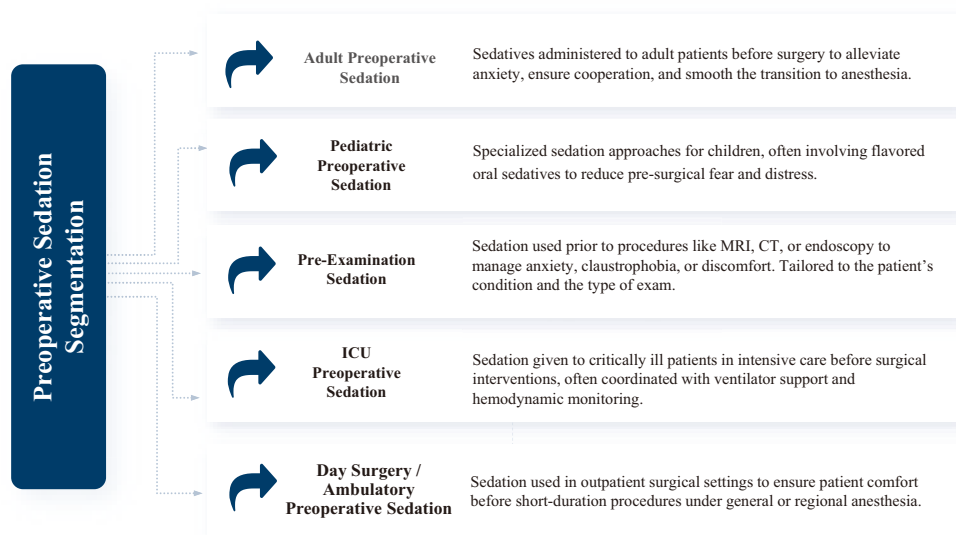
Microneedle technology is breaking through the limitations of traditional transdermal formulations through systematic upgrades in drug penetration capacity, delivery precision, and release control, providing more efficient, safer, and more user-friendly treatment solutions for multiple indications.

1. **Achieving iterative development in the treatment approach for traditional transdermal formulations:** Traditional transdermal formulations (such as patches and gels) are constrained by the barrier function of the skin’s stratum corneum, limiting their delivery to small-molecule drugs. They exhibit slow transdermal rates and low bioavailability, restricting their clinical applications. In contrast, microneedle technology creates controlled microchannels tens to hundreds of micrometers deep in the skin’s surface layer, effectively overcoming the stratum corneum barrier. This not only enables rapid onset of action for small-molecule drugs but also extends to efficient delivery of macromolecules, peptides, vaccines, and nucleic acid-based therapeutics. Furthermore, combined with dissolving materials and targeted drug loading designs, microneedles can precisely control drug release rates and locations, opening new pathways for therapeutic applications in endocrinology, tumor immunotherapy, and vaccination.
2. **Maintain the convenience of transdermal formulations:** Like traditional transdermal patches, microneedles retain the advantages of simple application and no reliance on professional administration, making them suitable for chronic disease management and home treatment settings. Building on this foundation, microneedles — being self-administered and delivering rapid onset of action — further enhance the patient experience, offering clinicians a more patient-centered treatment option.

Preoperative Sedation Market

Preoperative sedation is the application of sedative medications prior to a surgical or diagnostic procedure to reduce patient anxiety and facilitate induction of anesthesia, improving patient perioperative experience. It is often used in combination with analgesics or anesthetics and is tailored to the patient’s physical and psychological status.

Preoperative Sedation Market

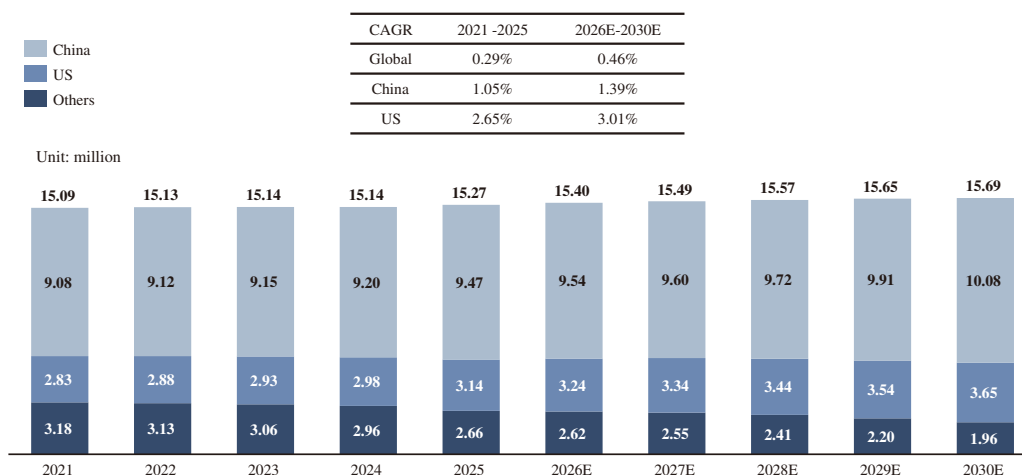


The scale of pediatric sedation patients in the U.S. is expected to increase slightly from 2.83 million in 2021 to 3.65 million in 2030E, reflecting stable demand. The market shows steady growth, with a CAGR of 2.65% from 2021 to 2025 and 3.01% from 2026 to 2030E. Globally, the total number

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of pediatric sedation patients is projected to rise modestly from 15.09 million to 15.69 million, with a CAGR of 0.29% and 0.46% across the two periods. Overall, future market growth is expected to be driven mainly by the U.S. and China, while other regions show a declining trend.

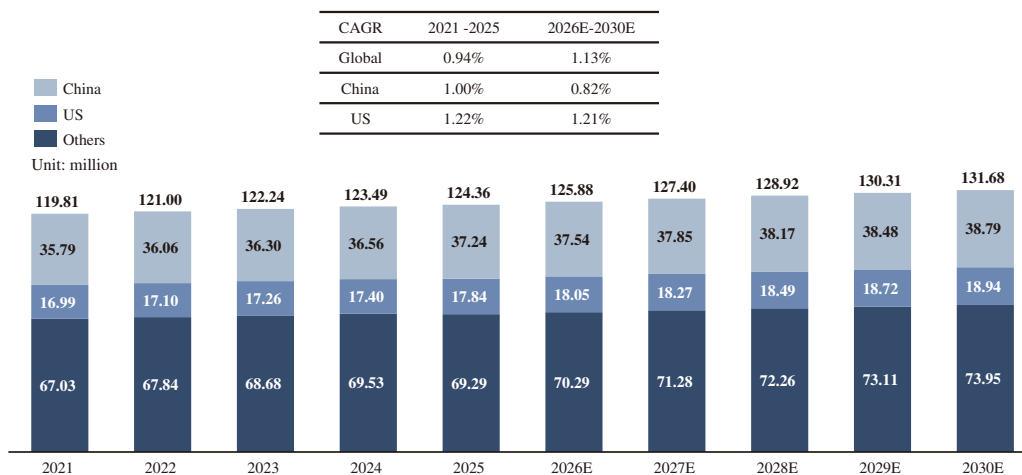
The Scale of Pediatric Sedation Patients, 2021–2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The scale of adult sedation patients in the U.S. is expected to maintain steady growth, increasing from 16.99 million in 2021 to 18.94 million in 2030E. The market demonstrates stable expansion momentum, with a CAGR of 1.22% from 2021 to 2025 and 1.21% from 2026 to 2030E. Globally, the total number of adult sedation patients is projected to rise from 119.81 million to 131.68 million, with a CAGR of 0.94% in 2021–2025 and 1.13% in 2026–2030E. Overall, the adult sedation market reflects a stable upward trend across the forecast period.

The Scale of Adult Sedation Patients, 2021–2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

China Market

The Scale of Pediatric and Adult Sedation Patients in China

The scale of pediatric sedation patients in China is expected to increase from 9.08 million in 2021 to 10.08 million by 2030. The CAGR increase from 1.05% (2021-2025) to 1.39% (2026E–2030E). The primary growth drivers stem from the continuous strengthening of policies such as “pain-free medical care” and “child-friendly hospitals,” which have spurred medical institutions to expand their sedation service capabilities, thereby enhancing patient compliance and clinical efficiency. The “Measures for Accelerating the Improvement of the Fertility Support Policy System and Promoting the Construction of a Fertility-Friendly Society” includes painless delivery in the scope of medical insurance reimbursement, clarifying that analgesic delivery is a choice for mothers. The promotion of painless

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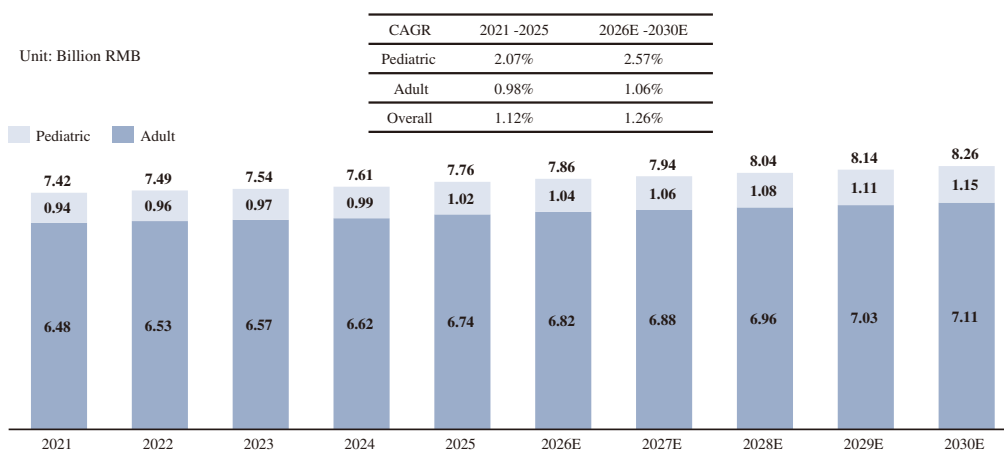
delivery in the policy stimulates the research and development demand for obstetric microneedle patches (used for prolactin secretion and hormone delivery), thereby promoting the application of microneedles in the field of reproductive health. The usage rate of sedative medication among children in China is 76% in outpatient settings, and 84% in inpatient settings. The proportion of children aged 2–6 who cannot tolerate intravenous sedation exceeds 60%.

From 2021–2030, the number of adult sedation patients in China is projected to grow from 35.79 million to 38.79 million, reflecting a modest yet steady increase. The CAGR is expected to slightly rise over time — from 1.00% during 2021–2025 to 0.82% in 2026–2030 — indicating a gradually saturating market. This stable trend highlights consistent clinical demand but also suggests limited room for rapid expansion, urging stakeholders to focus on value-added services, quality improvement, and innovation in sedation practices. The proportion of dexmedetomidine hydrochloride usage for sedation in Chinese adults is 50.8%, while the proportion of fentanyl-dexmedetomidine hydrochloride sedatives is 49.2%. The proportion of adult patients in China who use sedative medications is 75% in outpatient settings and 78% after hospitalization. The proportion of adults who cannot tolerate intravenous sedation is approximately 30%.

China Sedation Market Size

China’s preoperative sedation market is undergoing steady expansion. In 2021, the overall market size reached approximately RMB7.42 billion, with adult sedation drugs accounting for RMB6.48 billion and pediatric sedation drugs amounting to approximately RMB0.94 billion. Benefiting from rising surgical volumes, increased demand for comfort-oriented medical care, and expanded indications for sedation, the market is projected to exceed RMB7.76 billion by 2025, reach RMB7.85 billion by 2026, and grow to approximately RMB8.26 billion by 2030, with a CAGR of about 1.26% from 2026 to 2030. The pediatric sedation segment is growing significantly faster than the adult segment, with a projected CAGR of 2.57% from 2026 to 2030E, becoming the core driver of overall market expansion.

China Sedation Market Size, 2021–2030E

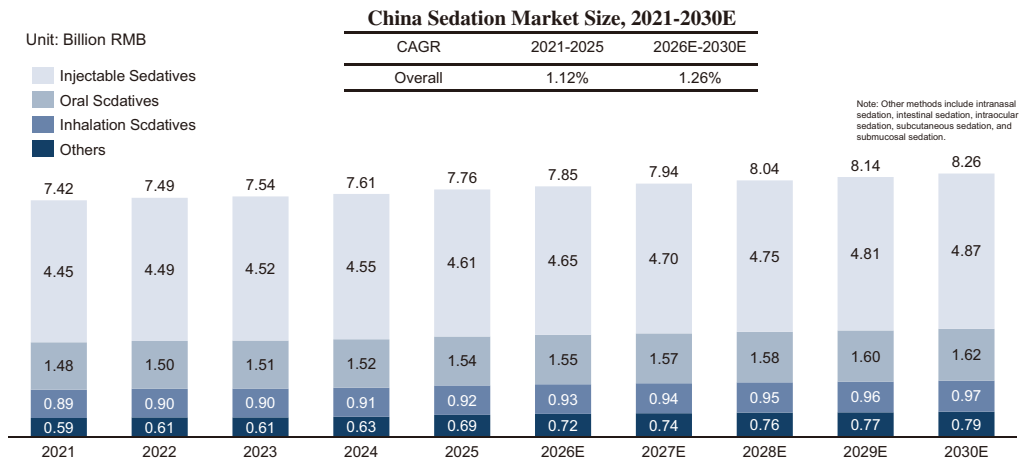


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Notes: The estimated market size for preoperative sedation in China is based on the following assumptions: (i) Market value = Average sedative drug price × Number of patients receiving treatment × Patient compliance. By 2026, the number of pediatric and adult patients undergoing preoperative sedation in China is projected to reach 9.37 million and 37.24 million, respectively, increasing to 10.33 million and 39.43 million by 2030; For details, refer to the subsection “Number of Pediatric and Adult Patients in China” above. (ii) Price assumptions are based on the catalog prices of marketed drugs. (iii) The average price of pediatric sedation drugs in China is approximately RMB300 (including single-use inhalers and intravenous drugs), while the average price for adult sedation drugs is approximately RMB500. Future price erosion will follow industry trends. (iv) Academic promotion and patient education activities will continue to intensify. (v) The patient population requiring treatment continues to expand rapidly. (vi) Significant unmet clinical needs exist; the preoperative sedation drug market will expand substantially as treatment volumes increase. Consequently, China’s preoperative sedation drug market is projected to reach RMB7.68 billion by 2026 and RMB8.24 billion by 2030.

China’s sedation market is undergoing steady expansion. In 2021, the overall market size reached approximately RMB7.42 billion. Growth has been supported by gradually increasing procedure volumes and the broader clinical adoption of sedation. By 2025, the market size rose to around RMB7.76 billion. It is expected to continue trending upward, reaching RMB7.85 billion by 2026E and approximately RMB8.26 billion by 2030E. In terms of growth pace, the CAGR is about 1.26% for 2026E–2030E, compared with 1.12% for 2021–2025. Overall, the market is expanding at a stable, incremental rate, reflecting modest upside momentum on top of a mature demand base.

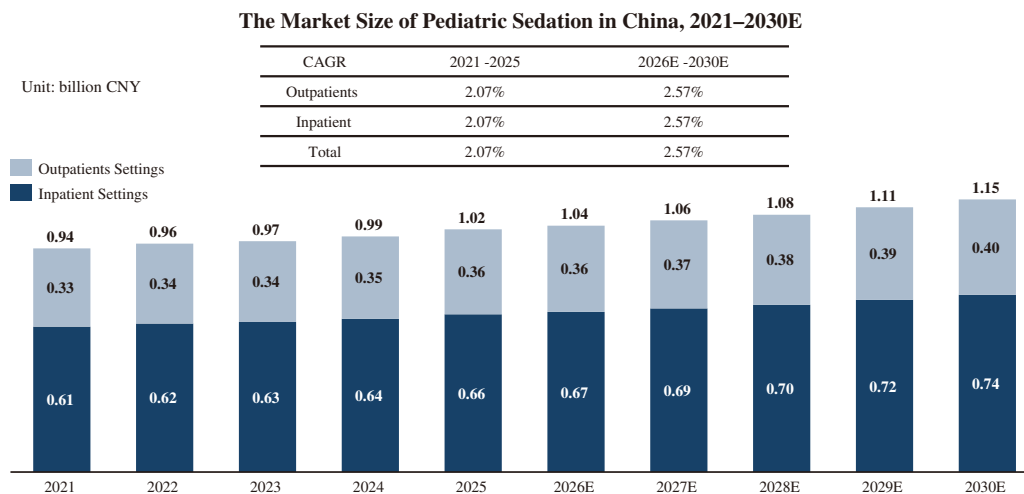
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Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The pediatric sedation market size in China increased steadily from 0.94 billion CNY in 2021 to 1.02 billion CNY in 2025, and is projected to further grow to 1.15 billion CNY by 2030. The market is expected to expand at a CAGR of 2.07% from 2021 to 2025, accelerating slightly to 2.57% during 2026 to 2030.

By segment, in 2025, outpatient settings reached 0.36 billion CNY, while inpatient settings accounted for 0.66 billion CNY, with inpatient continuing to dominate the market.



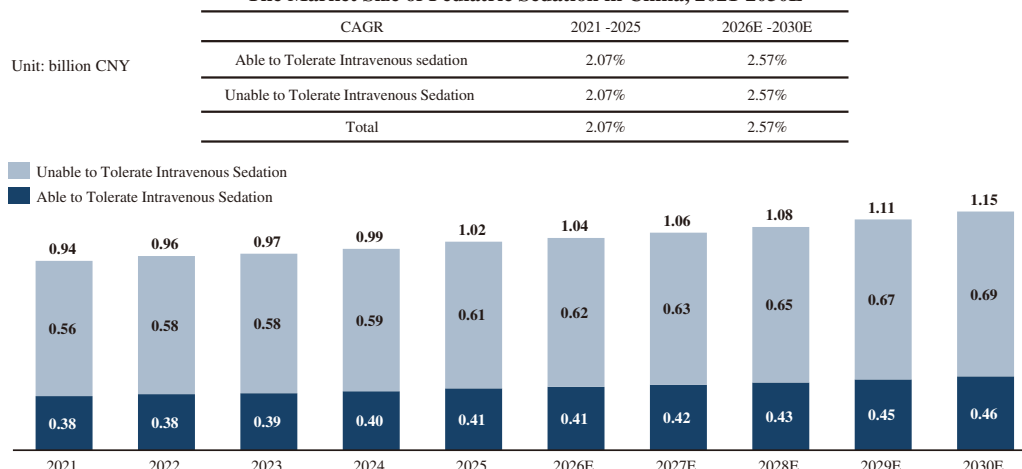
Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The pediatric sedation market size in China increased steadily from 0.94 billion CNY in 2021 to 1.02 billion CNY in 2025, and is projected to reach 1.15 billion CNY by 2030. The market is expected to grow at a CAGR of 2.07% from 2021 to 2025, accelerating to 2.57% during 2026 to 2030.

By segment, in 2025, patients unable to tolerate intravenous sedation accounted for 0.61 billion CNY, while those able to tolerate intravenous sedation reached 0.41 billion CNY, with the former continuing to dominate.

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The Market Size of Pediatric Sedation in China, 2021-2030E

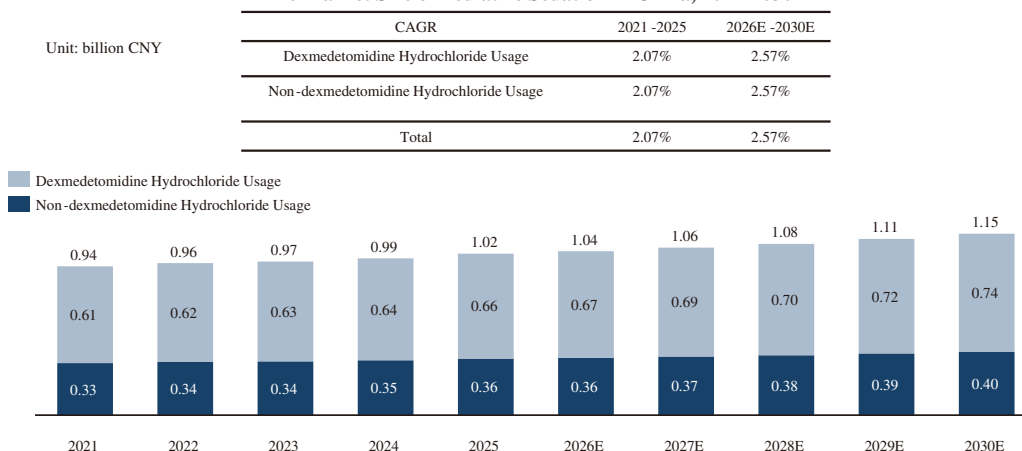


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The pediatric sedation market size in China increased steadily from 0.94 billion CNY in 2021 to 1.02 billion CNY in 2025, and is projected to reach 1.15 billion CNY by 2030. The market is expected to grow at a CAGR of 2.07% from 2021 to 2025, accelerating to 2.57% during 2026 to 2030.

By segment, in 2025, dexmedetomidine hydrochloride usage accounted for 0.66 billion CNY, while non-dexmedetomidine hydrochloride usage reached 0.36 billion CNY, with dexmedetomidine continuing to dominate.

The Market Size of Pediatric Sedation in China, 2021-2030E



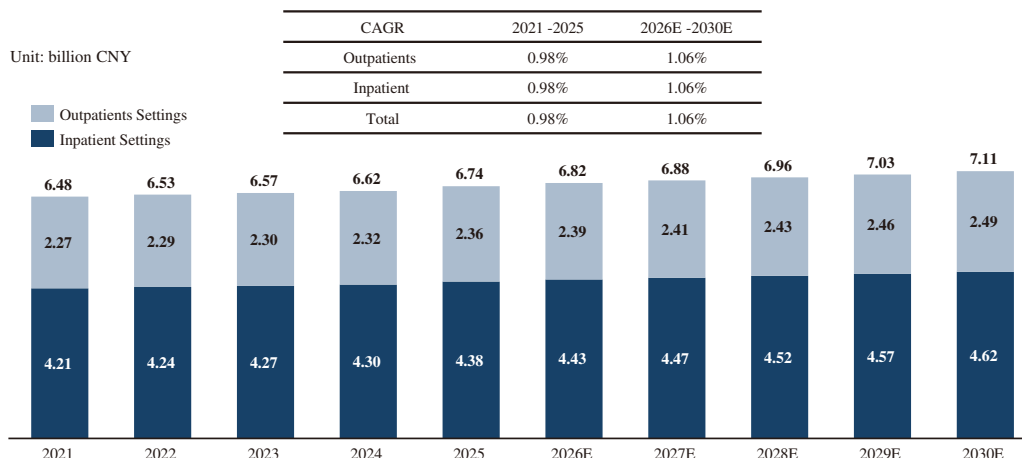
Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The adult sedation patient scale in China increased steadily from 6.48 billion CNY in 2021 to 6.74 billion CNY in 2025, and is projected to reach 7.11 billion CNY by 2030. The market is expected to grow at a CAGR of 0.98% from 2021 to 2025, with a slight acceleration to 1.06% during 2026 to 2030.

By segment, in 2025, inpatient settings sedation accounted for 4.38 billion CNY, while those outpatients settings sedation reached 2.36 billion CNY, with the former continuing to dominate.

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The Market Size of Adult Sedation in China, 2021-2030E

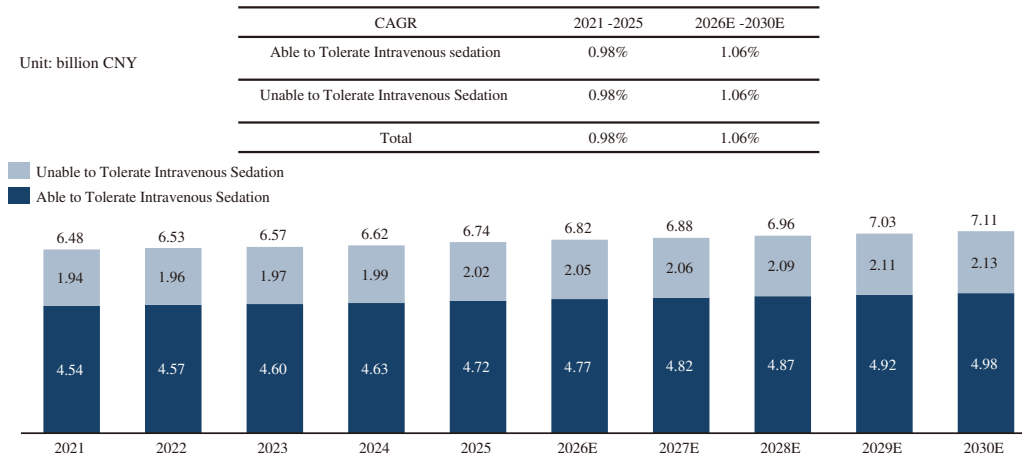


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The adult sedation patient scale in China increased from 6.48 billion CNY in 2021 to 6.74 billion CNY in 2025, and is projected to reach 7.11 billion CNY by 2030. The market is expected to grow at a CAGR of 0.98% from 2021 to 2025, slightly accelerating to 1.06% during 2026 to 2030.

By segment, in 2025, patients able to tolerate intravenous sedation accounted for 4.72 billion CNY, while those unable to tolerate intravenous sedation reached 2.02 billion CNY, with the former remaining dominant.

The Market Size of Adult Sedation in China, 2021-2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The adult sedation patient scale in China increased from 6.48 billion CNY in 2021 to 6.74 billion CNY in 2025, and is projected to reach 7.11 billion CNY by 2030. The market is expected to grow at a CAGR of 0.98% from 2021 to 2025, slightly accelerating to 1.06% during 2026 to 2030.

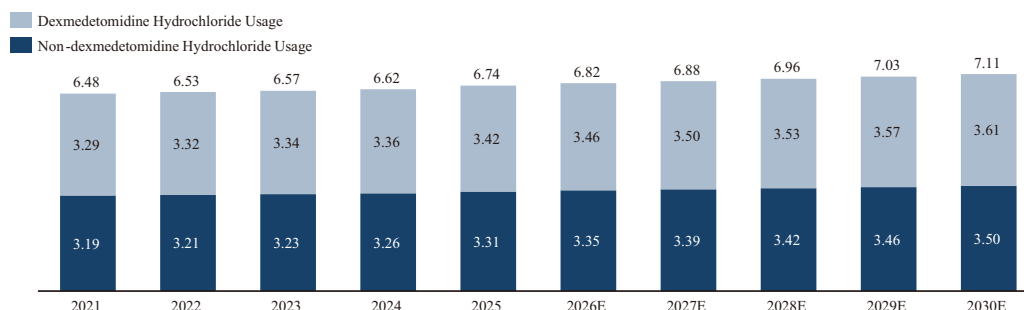
By segment, in 2025, spending by patients who used dexmedetomidine hydrochloride reached 3.42 billion CNY, while that of patients who did not use it reached 3.31 billion CNY, with the former remaining dominant.

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The Market Size of Adult Sedation in China, 2021-2030E

	CAGR	2021 -2025	2026E -2030E
Dexmedetomidine Hydrochloride Usage		0.98%	1.06%
Non-dexmedetomidine Hydrochloride Usage		0.98%	1.06%
Total		0.98%	1.06%

Unit: billion CNY

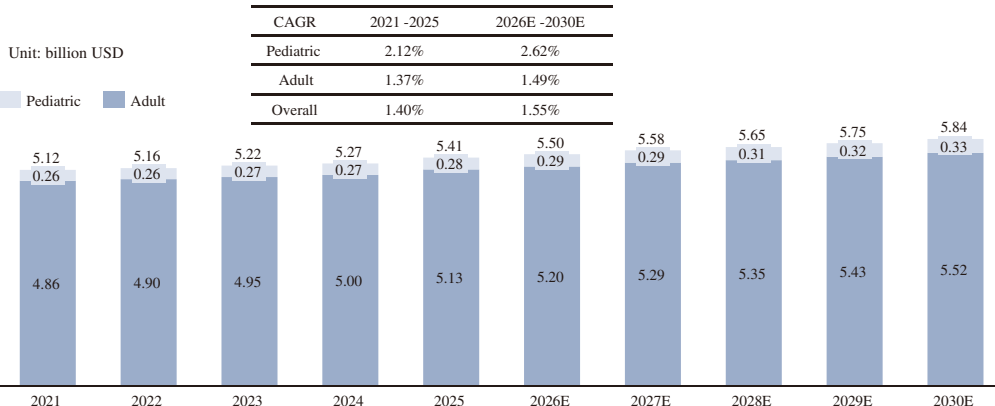


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

U.S. Sedation Market Size

The U.S. sedation market is projected to grow from USD5.12 billion in 2021 to USD5.84 billion in 2030, with an CAGR from 1.40% during 2021–2025 to nearly 1.55% between 2026–2030. This growth is predominantly driven by the pediatric segment. The steady expansion reflects broader clinical application of sedation in outpatient procedures, imaging diagnostics, and infant care, alongside rising awareness and accessibility of sedation services.

U.S. Sedation Market Size, 2021–2030E

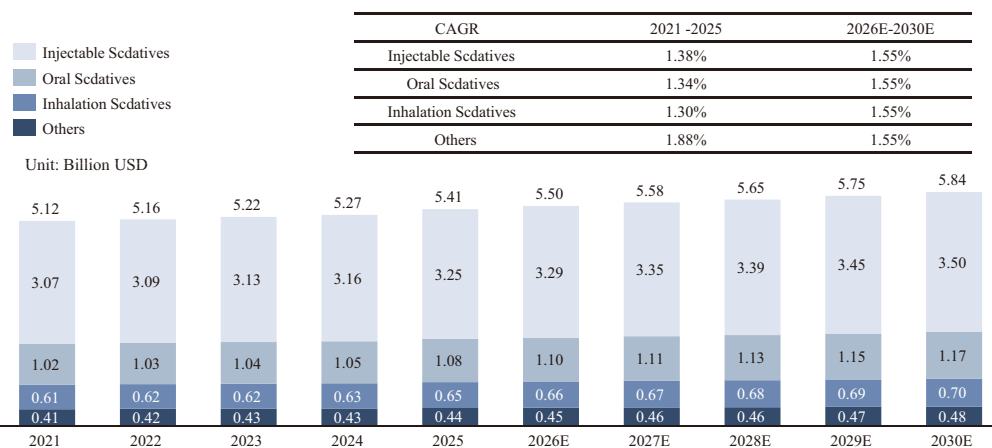


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The US sedation market is projected to grow steadily from 2021 to 2030E. The total market size increases from USD 5.12 billion in 2021 to USD 5.84 billion in 2030E. Injectable sedatives remain the largest segment throughout the period, rising from USD 3.07 billion in 2021 to USD 3.50 billion in 2030E. Oral sedatives also show stable growth, increasing from USD 1.02 billion to USD 1.17 billion, while inhalation sedatives rise from USD 0.61 billion to USD 0.70 billion. The “others” category remains the smallest segment, growing slightly from USD 0.41 billion in 2021 to USD 0.48 billion in 2030E. In terms of growth rate, injectable sedatives record a CAGR of 1.38% in 2021–2025 and 1.55% in 2026–2030E, while oral sedatives increase from 1.34% to 1.55%, inhalation sedatives from 1.30% to 1.55%, and others from 1.88% to 1.55%. Overall, the chart indicates moderate and continuous expansion in the US sedation market over the forecast period.

INDUSTRY OVERVIEW

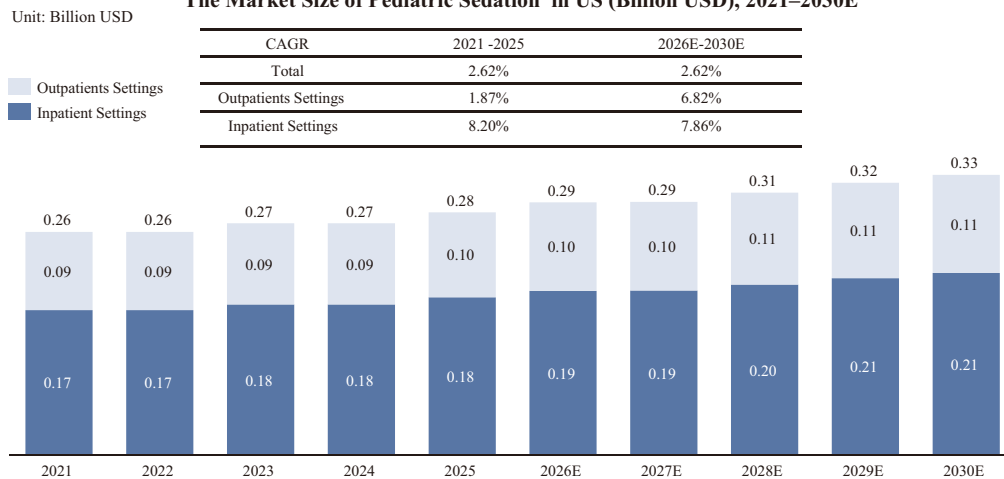
US Sedation Market Size, 2021–2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The US pediatric sedation patient market is expected to grow steadily from 0.26 billion USD in 2021 to 0.33 billion USD by 2030. Overall growth remains moderate and stable, with a consistent CAGR of 2.62% across both 2021–2025 and 2026–2030. Segment-wise, inpatient settings continue to dominate the market, supported by relatively strong and sustained growth, while outpatient settings exhibit a notable acceleration in the later period, with CAGR rising to 6.82%. Despite this improvement, outpatient demand remains smaller in scale. Overall, the market reflects gradual expansion with a stable structure and limited volatility.

The Market Size of Pediatric Sedation in US (Billion USD), 2021–2030E

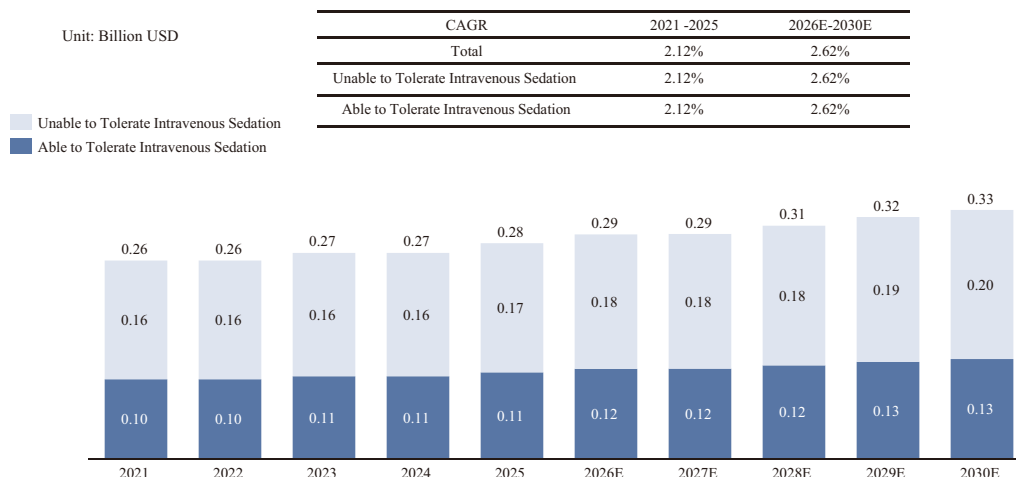


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The US pediatric sedation patient market is projected to increase steadily from 0.26 billion USD in 2021 to 0.33 billion USD by 2030. Overall growth remains moderate, with CAGR rising slightly from 2.12% in 2021–2025 to 2.62% in 2026–2030. Segment-wise, patients unable to tolerate intravenous sedation account for a larger share throughout the period, while those able to tolerate intravenous sedation represent a smaller but steadily growing segment. Both categories follow a similar growth trajectory, indicating a stable structural distribution. Overall, the market shows gradual expansion with balanced segment contributions and limited volatility over time.

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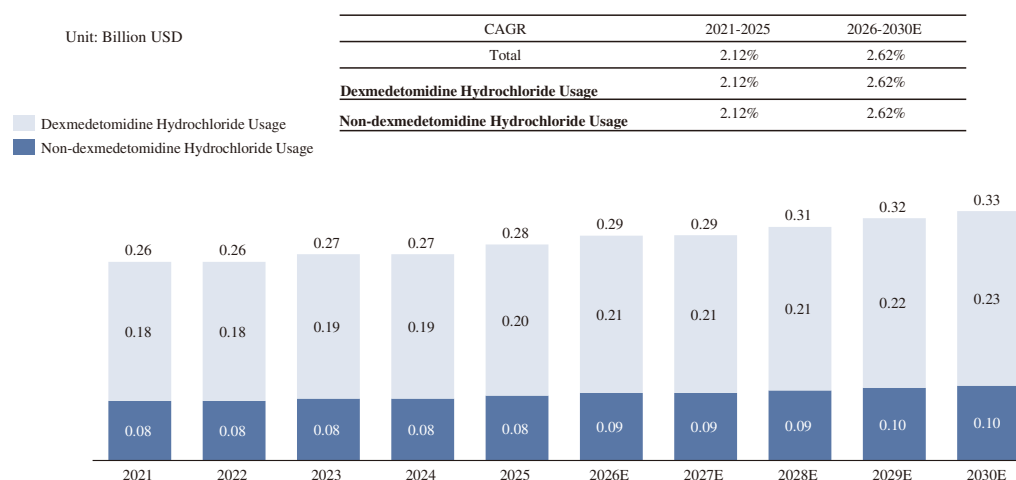
The Market Size of Pediatric Sedation in US (Billion USD), 2021–2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The US pediatric sedation patient market is projected to increase steadily from 0.26 billion USD in 2021 to 0.33 billion USD by 2030. Overall growth remains moderate, with CAGR rising slightly from 2.12% in 2021–2025 to 2.62% in 2026–2030. Segment-wise, patients Dexmedetomidine Hydrochloride sedation account for a larger share throughout the period, while those non-dexmedetomidine hydrochloride sedation represent a smaller but steadily growing segment. Both categories follow a similar growth trajectory, indicating a stable structural distribution. Overall, the market shows gradual expansion with balanced segment contributions and limited volatility over time.

The Market Size of Pediatric Sedation in US (Billion USD), 2021–2030E



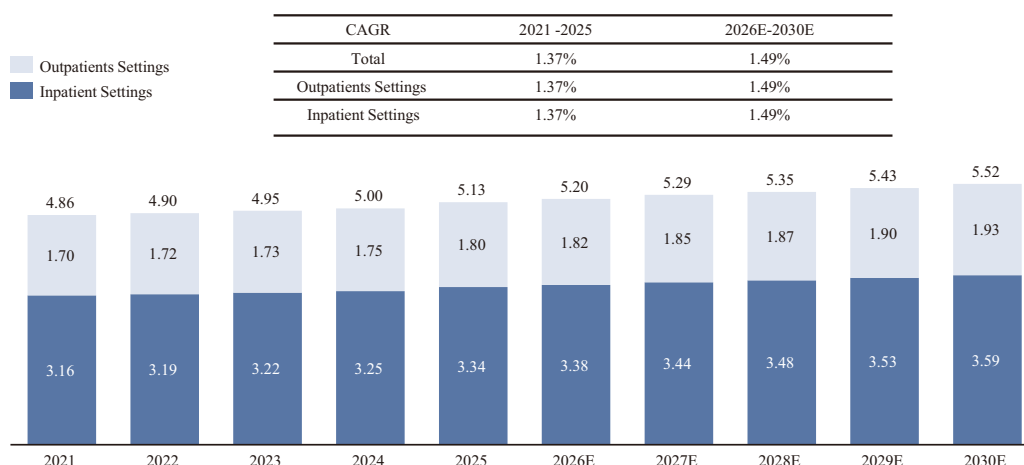
Source: Literature Review, Frost & Sullivan

The US adult sedation market is expected to grow modestly from 4.86 billion USD in 2021 to 5.52 billion USD by 2030. Overall expansion remains slow, with CAGR increasing slightly from 1.37% in 2021–2025 to 1.49% in 2026–2030, indicating a stable but mature market. Segment-wise, inpatient settings consistently account for the majority of demand, while outpatient settings represent a smaller yet steadily growing share. Both segments follow similar growth patterns, suggesting limited structural change over time. Overall, the market reflects gradual expansion with low volatility and a stable distribution across care settings.

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The Market Size of Adults Sedation in US (Billion USD), 2021–2030E

Unit: Billion USD

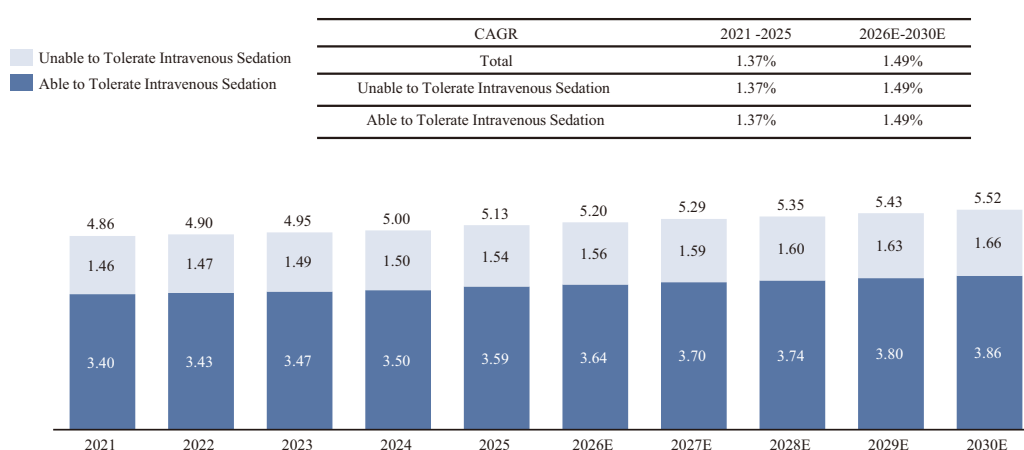


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The US adult sedation market is projected to grow gradually from 4.86 billion USD in 2021 to 5.52 billion USD by 2030. Overall growth remains modest, with CAGR rising slightly from 1.37% in 2021–2025 to 1.49% in 2026–2030, indicating a stable and mature market environment. Segment-wise, patients able to tolerate intravenous sedation consistently represent the larger share, while those unable to tolerate intravenous sedation account for a smaller portion. Both segments exhibit similar growth trends over time, suggesting limited structural change. Overall, the market reflects steady expansion with balanced segment dynamics and low volatility.

The Market Size of Adult Sedation in US (Billion USD), 2021–2030E

Unit: Billion USD

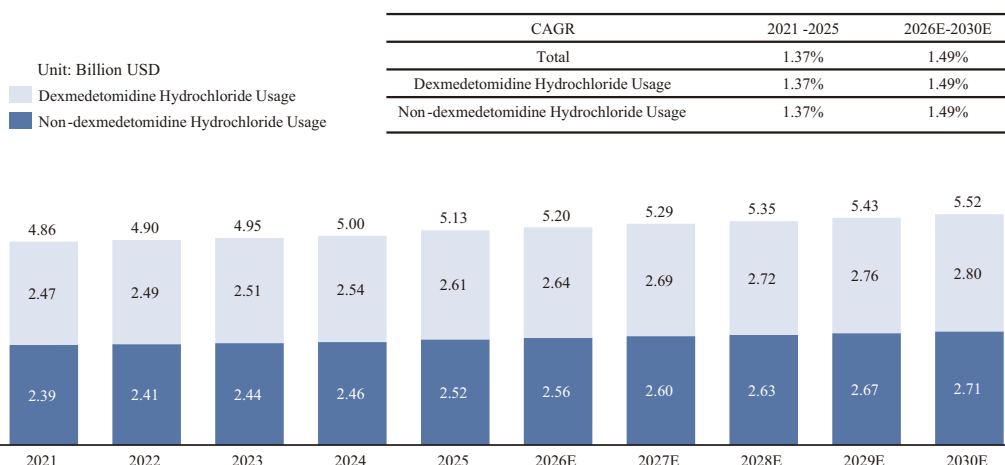


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The US adult sedation market is projected to grow gradually from 4.86 billion USD in 2021 to 5.52 billion USD by 2030. Overall growth remains modest, with CAGR increasing slightly from 1.37% in 2021–2025 to 1.49% in 2026–2030, reflecting a stable and mature market. Segment-wise, dexmedetomidine hydrochloride usage consistently accounts for a slightly larger share compared to non-dexmedetomidine usage, though both segments remain closely balanced in size. Growth trends are similar across both categories, indicating limited structural change over time. Overall, the market shows steady expansion with balanced segment contributions and low volatility.

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The Market Size of Adult Sedation in US (Billion USD), 2021–2030E

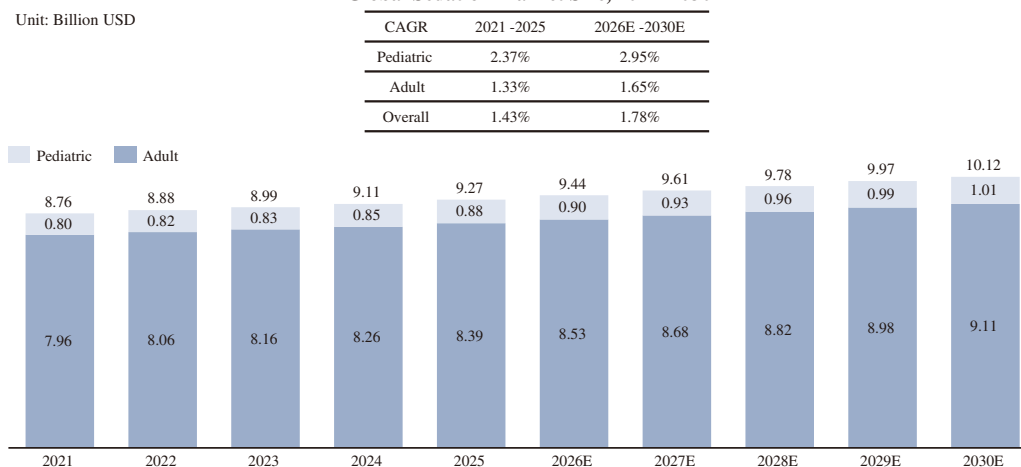


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Global Market

The global Sedation market is in a steady expansion phase. From 2021–2025, the overall market size grew from USD8.76 billion to USD9.27 billion, with a CAGR of 1.43%; it is expected to accelerate to 1.78% from 2026 to 2030, with the overall market expected to reach USD10.12 billion by 2030. Among these, adult sedation remains the dominant segment, with a market size of approximately USD8.39 billion in 2025, while the pediatric sedation market reaches USD0.88 billion during the same period. However, the growth rate of pediatric sedation exceeds that of adult sedation, reflecting a smaller baseline but accelerating demand release.

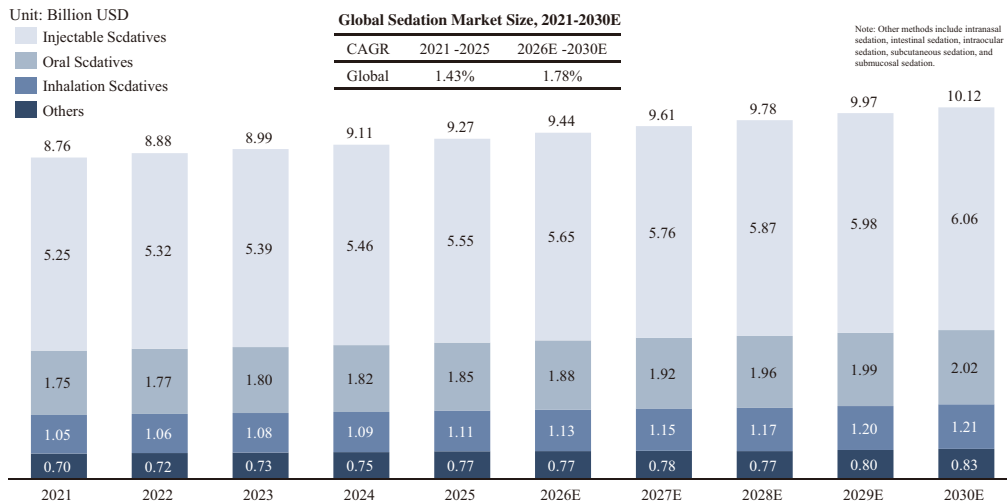
Global Sedation Market Size, 2021–2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

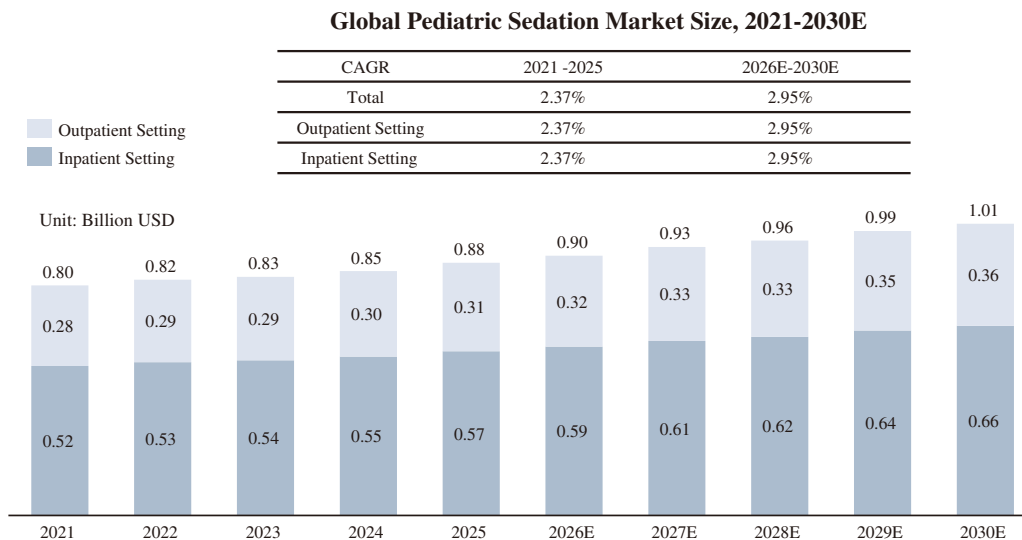
The global sedation market grew steadily from approximately USD8.76 billion in 2021 to USD9.27 billion in 2025, and is projected to reach USD10.12 billion by 2030, representing a CAGR of approximately 1.78% over the forecast period. In terms of market segments, injectable sedatives hold the largest market share, with approximately USD5.55 billion in 2025, and are expected to maintain their dominant position throughout the forecast period. Oral sedatives and inhalation sedatives represent relatively smaller market segments, with approximately USD1.85 billion and USD1.11 billion in 2025, respectively, and exhibit relatively flat growth trends. Overall, the global sedation market demonstrates a steady but moderate growth trajectory, with oral formulations being the primary driver of market growth.

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Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

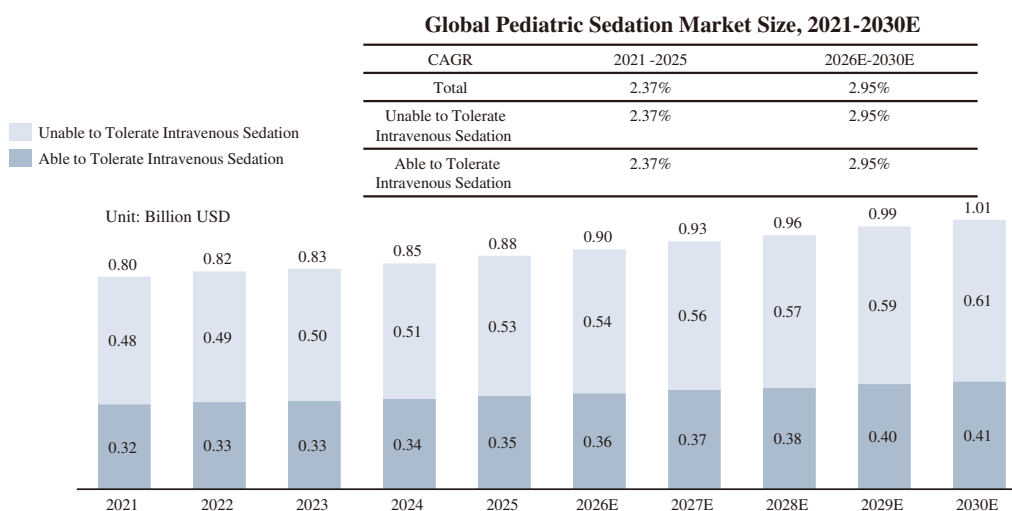
The global pediatric sedation market shows a steady upward trend from 2021 to 2030E. The total market size increases from USD 0.80 billion in 2021 to USD 1.01 billion in 2030E. Among the two segments, inpatient setting account for the larger share throughout the period, rising from USD 0.52 billion in 2021 to USD 0.66 billion in 2030E. Outpatient setting also grow gradually, from USD 0.28 billion to USD 0.36 billion. In terms of growth rate, the market records a CAGR of 2.37% during 2021–2025, which is expected to accelerate slightly to 2.95% in 2026E–2030E. Overall, the chart indicates stable and moderate growth in the global pediatric sedation market, with inpatient setting remaining the dominant product category.



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

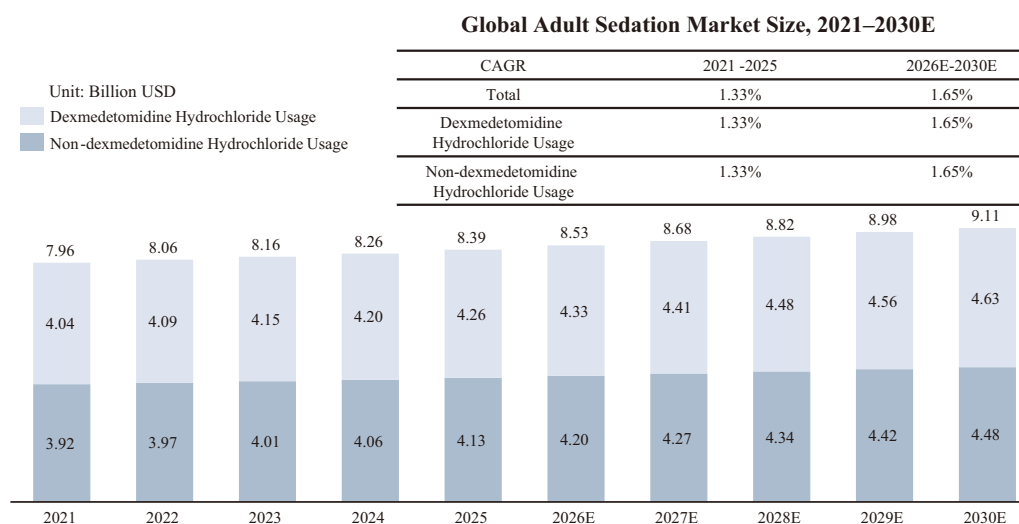
The global pediatric sedation market shows a stable upward trend from 2021 to 2030E, with total market size increasing from USD 0.80 billion to USD 1.01 billion. Patients unable to tolerate intravenous sedation remain the dominant segment, while both segments grow steadily over time. The market CAGR is expected to rise from 2.37% in 2021–2025 to 2.95% in 2026E–2030E, indicating moderate but continuous market expansion.

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Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The global adult sedation market is projected to grow gradually from 7.96 billion USD in 2021 to 9.11 billion USD by 2030. Overall growth remains modest, with CAGR increasing slightly from 1.33% in 2021–2025 to 1.65% in 2026–2030, reflecting a stable and mature market. Segment-wise, dexmedetomidine hydrochloride usage consistently accounts for a slightly larger share compared to non-dexmedetomidine usage, though both segments remain closely balanced in size. Growth trends are similar across both categories, indicating limited structural change over time. Overall, the market shows steady expansion with balanced segment contributions and low volatility.



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Preoperative Sedation Major Treatment

Preoperative medications is a crucial component of surgical preparation, designed to ensure the smooth progression of anesthesia. These drugs serve to calm patients, enhance cooperation, mitigate adverse reactions to certain anesthetics, and suppress unfavorable neural reflexes, thereby regulating autonomic nervous function (particularly vagal reflexes), and alleviate preoperative pain. Currently, commonly used pediatric sedatives include midazolam, dexmedetomidine, and chloral hydrate. Midazolam, a benzodiazepine, offers excellent anxiolytic and amnesic effects and is clinically convenient to administer. However, it may cause respiratory depression and may potentially have an adverse effect on pediatric neurodevelopment, leading to increasingly cautious use. Chloral hydrate, a traditional oral sedative, is simple to administer but is associated with poor safety profiles due to slow onset, prolonged duration, and susceptibility to respiratory depression and gastrointestinal irritation. Its use has declined in recent years.

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In contrast, dexmedetomidine is an α_2 adrenergic receptor that induces a sedation state resembling natural sleep. It is well-tolerated by pediatric patients, rarely causes respiratory depression, and offers exceptional safety. Its effects on the circulatory system are minimal, while it provides analgesia, anxiolysis, and reduces delirium incidence. However, intravenous administration of dexmedetomidine injection is challenging to perform and may cause patient anxiety. Additionally, it is used off-label, posing safety risks. DHMP holds promise for meeting clinical needs such as comfortable and convenient administration, low safety risks, and on-label application.

Preoperative Sedation Approved Medication

Currently, all innovative drugs approved for preoperative sedation are injectable formulations. The first two are imported drugs, while the rest are domestically produced. In the Chinese Mainland, the U.S. and other major global markets, current clinical practice for preoperative sedation still primarily relies on injectable sedative agents, which remain the prevailing route of administration in this field. The Company’s core product, dexmedetomidine hydrochloride microneedle patch (DHMP), is being developed as a dissolving microneedle patch for preoperative sedation. It enables painless, needle-free transdermal drug delivery and is distinct from oral, injectable, or inhalation routes. DHMP offers rapid onset like injection and the convenience of oral administration, while avoiding first-pass metabolism. Compared with conventional injectable formulations currently used in clinical practice, the microneedle patch is intended to provide a non-injectable administration option, which may be particularly relevant in pediatric settings where fear of needles and injection-related distress can adversely affect patient cooperation and perioperative experience. As such, if approved, DHMP may complement existing clinical practice in the Chinese Mainland by offering an alternative route of administration. It targets the pediatric and adult preoperative sedation market in mainland China, and is especially suitable for patients with needle phobia or poor venous access. The company has initiated preparations for its U.S. clinical trials and plans to expand into the U.S. and global preoperative sedation markets in the future. The company’s DHMP is suitable for both outpatient and inpatient settings.

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Preoperative Sedation Approved Medication

Drug	Company	Approval date	Route of Administration	Average End-Use Price	Registration Authority	Limitation
Nimbex / Cisatracurium Besylate Injection	Aspen Pharmacare	2021-06-11	Injection	90-120RMB / dose	NMPA	Contraindicated in patients with known hypersensitivity to the product or any of its components, and caution is advised for the risk of hypotension or shock; it is also contraindicated in pregnant and lactating women.
Propofol Fresenius / Propofol Injection	Fresenius Kabi	2021-11-04	Injection	40RMB / dose	NMPA	Contraindicated in patients allergic to the product or its emulsifier; it should be used with caution in patients with hypotension or shock, and is contraindicated for anesthesia in children under 3 years old, as well as in pregnant and lactating women.
Ciprofol Injection	Haisco Pharmaceutical	2022-07-12	Injection	100RMB / dose	NMPA	Contraindicated in patients with known hypersensitivity to the product or its excipients (such as soy); it should be used with caution in patients with severe heart failure, and pregnant or lactating women should use it cautiously after weighing the benefits and risks.
Ruibeiing / Remimazolam Tosylate Injection	Hengrui Pharmaceuticals	2024-10-24	Injection	100RMB / dose	NMPA	Due to the lack of established safety and efficacy data, it is not recommended for use in children; elderly patients are more sensitive to its effects, and strict monitoring of respiratory and circulatory status is required during use.
Ruima / Remimazolam Besylate Injection	Humanwell Pharmaceutical	2025-07-14	Injection	120RMB / dose	NMPA	Contraindicated in children; elderly patients should be aware of increased drug sensitivity, and the use of this medication requires the availability of monitoring and resuscitation equipment to manage potential respiratory depression or hypotension.
BYFAVO	Acacia Pharma	2020-07-02	Injection	45USD / dose (20mg)	FDA	It is only indicated for short procedures lasting 30 minutes or less, and is limited to adult use only, not for pediatric patients or longer surgical procedures.
PRECEDEX	Hospira	1999-12-17	Injection	11.2USD / dose (200mcg/2ml)	FDA	When used in the intensive care unit (ICU) setting, continuous infusion should not exceed 24 hours; the pediatric indication is limited to non-invasive procedures only, excluding invasive surgeries.
ATIVAN	Hikma Pharmaceuticals	1980-07-25	Injection	2.28USD / dose (2mg)	FDA	It is only approved for adult patients as preanesthetic medication, lacking evidence for pediatric preoperative sedation; additionally, as a benzodiazepine, it carries risks of respiratory depression and excessive sedation.

Source: [Clinicaltrials.gov](https://clinicaltrials.gov), Frost & Sullivan

Preoperative Sedation Clinical Pipeline

Current clinical research in the field of preoperative sedation primarily focuses on modifying existing first-line drug formulations. The core objective is to accelerate onset, improve patient compliance, and enhance safety through novel delivery routes such as microneedle patches and nasal spray formulations. Outside of China and the United States, there are currently 101 ongoing clinical trials worldwide.

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Drug	Applicant	Locations	Indication	Phase	Status	Initial date	Clinical No.	Registration Authority	Route of Administration	Limitation
Dexmedetomidine Hydrochloride (Microneedle Patch)	Guangzhou Novaken Pharm Co., Ltd.	China	Preoperative Sedation for Children Aged 2-6 Years	PHASE 2	In progress	Aug 2025	CTR20253327	NMPA	Dissolving Microneedles	Although microneedle technology can enhance transdermal drug delivery efficiency, it faces dual limitations of skin irritation reactions and limited drug loading capacity
SH081012	Shandong Bestcomm Pharmaceutical Co., Ltd/Shandong Langnuo Pharmaceutical Co., Ltd.,	China	Sedation for Pediatric Examinations and Procedures	PHASE 1	In progress	Aug 2025	CTR20253105	NMPA	Oral Solution	The formulation faces dual challenges of strong taste irritation and poor stability; the former affects patient compliance, while the latter requires reliance on key excipient control to ensure product quality.
Midazolam + fentanyl (IV sedation)	Brigham and Women's Hospital	United States	Personalized pre-procedural sedation vs. reassurance for adult patients undergoing regional anesthesia (nerve block)	PHASE 1	Completed	Oct 2022	NCT05579509	FDA	Intravenous Infusion	Co-administration may induce respiratory depression and hypotension risks, requiring close monitoring of vital signs and precise dose titration based on patient pain response to avoid excessive sedation
Midazolam + Dexmedetomidine	University of Mississippi Medical Center	United States	Premedication for Older Children Undergoing General Anesthesia for Dental Rehabilitation	PHASE 3	Completed	Jul 2017	NCT02250703	FDA	Dexmedetomidine Nasal Spray Combined with Midazolam Oral Solution	Dexmedetomidine may cause hypertension or hypotension as well as bradycardia, necessitating careful hemodynamic monitoring during co-administration
Dexmedetomidine + Midazolam	Cairo University	Egypt	Preoperative Anxiety Experienced by the Pediatric Patient	PHASE 2	In progress	May 2025	NCT06979791	FDA	Intravenous Infusion	Dexmedetomidine commonly causes hypotension and bradycardia requiring monitoring during co-administration, and its hepatic metabolism to active metabolites may increase drug interaction risks
SHR0302 Alkali Gel	Jiangsu HengRui Medicine Co., Ltd.	China	Preoperative Sedation of Adults	PHASE1	Completed	Aug 2025	NCT07098117	FDA	Topical Gel	may cause skin irritation or allergic reactions, and its stability is susceptible to temperature and light exposure, requiring special storage conditions
Dexmedetomidine Hydrochloride nasal spray	Yichang Humanwell Pharmaceutical Co., Ltd	China	Preoperative Sedation for Adults and Children	PHASE1	Terminated	July 2022	CTR20221669	NMPA	Nasal Spray	As a highly selective α_2 -adrenergic receptor agonist, this drug carries safety risks including respiratory depression, hypotension, and bradycardia, requires precise dose titration, and faces intense market competition as well as technical barriers of nasal spray formulations, limiting its extensive clinical application.

Challenges and Threats in the Global and China Preoperative Sedation Market

The global preoperative sedation market faces a triple challenge of safety risks (respiratory depression, hemodynamic instability, and postoperative delirium), cost pressures, and increasing industry consolidation

- **Safety and Adverse Reaction Risks:** Respiratory depression caused by oversedation, hemodynamic instability, and postoperative delirium represent major clinical challenges.
- **Evolving Competitive Landscape:** Large pharmaceutical companies are strengthening market dominance through mergers, acquisitions, and internal R&D, while small and medium-sized enterprises face risks of being acquired or squeezed out of the market.

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The China market, meanwhile, is constrained by clinical implementation barriers, intensifying competition from domestic brands, and tightening regulations, putting international brands under significant pressure regarding market share and compliance costs.

- **Clinical Practice Barriers:** Chinese academia indicates that preoperative sedation implementation is primarily influenced by surgical decisions and patient conditions; however, clinicians’ concerns about complications (such as respiratory depression), lack of standardized protocols, and insufficient staffing constitute major obstacles.
- **Strengthened Safety Regulations:** In response to adverse incidents caused by preoperative sedation (such as injuries from oversedation), regulatory authorities may tighten review standards, increasing compliance costs.

Drivers and Entry Barriers in the Global Preoperative Sedation Market

Stable Demand from Specific Patient Groups for Non-Invasive Alternatives: While the broader market shows steady growth, localized demand remains resilient due to prevalent needle phobia among children and anxious adults. Non-invasive alternatives, such as needle-free sedation platforms, primarily sustain their market footprint by addressing anxiety during routine pediatric procedures, dental numbing, and phlebotomy.

Incremental Market Expansion via Cross-Specialty Utilization: Market momentum relies on a gradual shift from centralized operating rooms to diverse clinical settings, including venous access and outpatient dental anesthesia. This gentle cross-specialty adoption expands the total addressable market and helps justify long-term investments despite lower overall growth rates.

New entrants to the global preoperative sedation market primarily face the following barriers:

Drug-loading ceiling: Current dissolving microneedles hold only tens of milligrams — fine for topical anaesthetics, not yet enough for systemic sedatives.

Manufacturing complexity & cost: Precision moulding, sterility assurance, and cold-chain stability keep costs above standard topical formulations.

Regulatory learning curve: Few precedents at FDA/EMA for combination “drug-device” microneedle sedatives; patch yields and dose uniformity are key hurdles.

Unproven systemic pipeline: No late-stage programs delivering midazolam, propofol or dexmedetomidine via microneedles — commercial upside remains speculative.

Drivers and Entry Barriers in the China Preoperative Sedation Market

Gradual Infiltration into the Primary Care Landscape: China’s ongoing healthcare system reforms continue to moderately elevate the service capacities of primary medical institutions. The expansion of community hospitals and primary care clinics yields steady incremental demand for safe preoperative screening and outpatient sedation solutions.

Technology-Driven Upgrades in Local Pharmaceutical Manufacturing: Gradual advancements by domestic pharmaceutical enterprises in drug delivery technologies provide solid foundational support for novel sedatives. This ongoing development satisfies routine domestic clinical requirements and drives a cost-effective product substitution across the existing healthcare infrastructure.

New entrants to the China preoperative sedation market primarily face the following barriers:

Stringent Regulatory Environment: China’s drug approval process is strict, particularly regarding safety assessments for sedative drugs, increasing the difficulty of market entry.

R&D Costs and Return Cycle: Although R&D costs in China are relatively low, substantial resources are still required from clinical trials to market launch, with extended return cycles.

High Clinical Trial and Quality Control Costs: New drugs must undergo rigorous clinical trial validation, requiring massive investment in R&D and testing expenses. Meanwhile, pharmaceutical production must comply with GMP standards, with quality control costs remaining high — creating a significant economic burden for small enterprises or new entrants.

Future Trend

The preoperative sedation market is evolving from traditional adjunctive medications to sophisticated perioperative management tools, exhibiting trends toward “expanded scenarios, refined patient targeting, and convenient clinical use.” Against a backdrop of strong demand, high usage, and diverse applications, market acceptance of next-generation sedation drugs and delivery methods continues to rise. Future industry development will focus on: more precise efficacy regulation

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mechanisms, safer short-acting drug structures, and innovative high-compliance formulations. This will provide solutions that balance standardization and personalization for different patient groups and scenarios, establishing a new ecosystem for preoperative sedation.

1. **Rigid demand for enhanced comfort in preoperative sedation settings continues to grow.** Preoperative sedation is gradually expanding beyond traditional surgical procedures to encompass a broader range of clinical procedures, including dental treatments, orthopedic day surgeries, imaging examinations (such as MRI/CT), endoscopic procedures, and interventional diagnostics — covering multiple high-frequency departments and medical scenarios. Particularly among pediatric patients, who are more prone to preoperative anxiety and tension, preoperative sedation not only alleviates anxiety and improves compliance but also serves as a critical means to enhance perioperative comfort and ensure smooth clinical procedures. With the ongoing rise in outpatient minimally invasive procedures and day surgery rates, patient demand for comfort-focused care continues to grow. As a cross-departmental, cross-age auxiliary measure, the application scope of sedation is continually expanding. It demonstrates stable clinical demand and exhibits greater therapeutic value in pediatric drug usage.
2. **Child-friendly policies drive the development of preoperative sedation products.** Children constitute a key demographic for preoperative sedation, exhibiting high rates of preoperative anxiety and significant resistance to injection routes and complex procedures, which can impede smooth clinical care. Addressing these challenges, novel pain-free, rapid-acting, and user-friendly administration methods are recognized as enhancing compliance, improving perioperative experiences, and advancing child-friendly healthcare environments such as “no-cry operating rooms.” At the policy level, the “Opinions on Promoting the Development of Child-Friendly Hospitals” issued by six departments including the National Health Commission explicitly advocate a “child-centered” service philosophy and encourages enhancing the safety and comfort of pediatric medical services. Concurrently, the nation continues to advance the research, development, and supply of pediatric-specific medications. Driven by these combined factors, innovative preoperative sedation products suitable for children are poised to gain increased attention in the future.

Diabetes Market

Diabetes mellitus is a chronic metabolic disease of high blood glucose, leading over time to damage in the heart, blood vessels, eyes, kidneys, and nerves. It is classified mainly into Type 1 diabetes, an autoimmune disease where the immune system destroys the pancreas’s insulin-producing beta cells, and Type 2 diabetes is a disorder of insulin resistance with a relative insulin deficiency.

Diabetes Mellitus		
Type 1 Diabetes	Type 2 Diabetes	Gestational Diabetes
Type 1 diabetes is caused by an autoimmune reaction that destroys insulin-producing beta cells in the pancreas. This can occur months or years before symptoms appear. Genetic factors increase risk, but not everyone with the genes develops the disease. Environmental triggers, like viruses, may contribute. It is not caused by diet or lifestyle.	In type 2 diabetes, the response to insulin is diminished — this is called insulin resistance. The body initially compensates by producing more insulin, but over time, insulin production decreases, leading to T2DM. It is most common in people over 45 but is increasingly seen in younger individuals due to rising obesity and physical inactivity.	Gestational diabetes is caused by hormones from the placenta that make insulin less effective, leading to insulin resistance. As a result, glucose builds up in the blood instead of entering cells. Unlike type 1 diabetes, it’s not due to a lack of insulin. Symptoms usually disappear after delivery.

Source: John Hopkins Medicine, CDC, NIH

Global Market

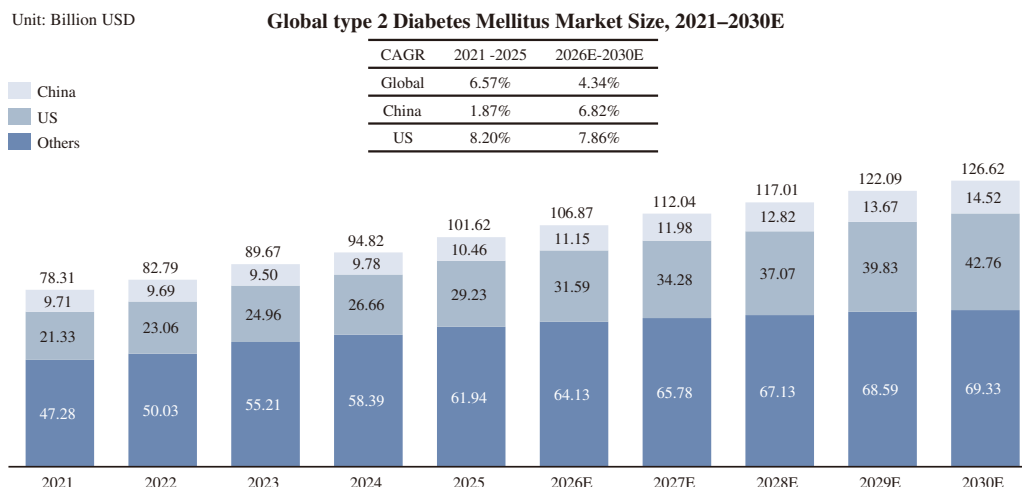
The Scale of Diabetes Mellitus Patients Global

From 2021 to 2030, the number of diabetes patients is projected to rise from 136.81 million to 168.5 million in China (with CAGRs of 2.73% from 2021–2025 and 1.83% from 2026–2030), and from 38.66 million to 56.02 million in the U.S. (with CAGRs of 4.52% and 3.96%, respectively). Globally, the diabetic population is expected to grow from 547.35 million in 2021 to 603.67 million by 2025 and 661.3 million by 2030, with a gradually slowing pace of expansion.

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Global type 2 Diabetes Mellitus Market Size

From 2021 to 2030, the type 2 diabetes market is projected to grow from \$9.71 billion to \$14.52 billion in China (with CAGRs of 1.87% from 2021–2025 and 6.82% from 2026–2030), and from \$21.33 billion to \$42.76 billion in the U.S. (with CAGRs of 8.20% and 7.86%, respectively). Globally, the market is expected to expand from \$78.31 billion in 2021 to \$126.62 billion by 2030, maintaining high single-digit growth but at a notably slower pace.



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Notes: The estimation of China's Type 2 diabetes market size is based on the following assumptions: (i) Market value = Average annual treatment cost for diabetes × Number of patients receiving treatment. In 2026, the number of Type 2 diabetes patients in China is expected to reach 156.73 million, projected to increase to 168.50 million by 2030. (ii) Price assumptions are based on the list prices of drugs already marketed for this indication. (iii) Type 2 diabetes treatment drugs expected to be launched during the forecast period are not included in China's national or provincial volume-based procurement plans. (iv) By 2029, the consultation rate for Type 2 diabetes patients in China is approximately 50%, the treatment ratio is approximately 34%-51%, and patient adherence is approximately 56%; the corresponding average annual treatment cost range is approximately RMB 5,000, with future price erosion following industry trends. (v) Academic promotion and patient education activities continue to be strengthened. (vi) The scale of treatable patient populations continues to expand rapidly. (vii) There is currently enormous unmet clinical demand; as treatment volume grows in parallel, the Type 2 diabetes therapy market within this indication will expand significantly. Therefore, China's Type 2 diabetes drug market is expected to reach USD 11.15 billion in 2026 and USD 14.52 billion by 2030.

Major Treatment Method

The primary treatment goals for modern diabetes management focus on three key areas: first, restoring or enhancing insulin action; second, achieving safe and stable blood glucose control; and third, preventing and delaying long-term vascular and organ complications. Treatment strategies vary significantly depending on the type of diabetes. For type 1 diabetes, where patients experience near-total loss of pancreatic beta cell function, treatment centers on exogenous insulin replacement to mimic physiological secretion rhythms. This is often supplemented with insulin analogues, glucagon-like peptide-1 (GLP-1) receptor agonists, and other adjunct medications to reduce postprandial blood glucose fluctuations. In contrast, type 2 diabetes management follows a stepwise approach: early treatment centers on improving insulin sensitivity (e.g., metformin) or suppressing hepatic glucose output; as the disease progresses, medications that enhance endogenous insulin secretion (such as sulfonylureas or DPP-4 inhibitors) or increase urinary glucose excretion (SGLT-2 inhibitors) may be added. When pancreatic beta-cell function reserves are gradually depleted, exogenous insulin therapy becomes necessary.

In recent years, GLP-1 receptor agonists have emerged as a significant breakthrough in the treatment of type 2 diabetes due to their unique mechanism and favorable clinical outcomes. GLP-1, an incretin hormone, stimulates insulin secretion and inhibits glucagon release after meals while delaying gastric emptying and increasing satiety, thereby achieving multifaceted glucose regulation. Compared to traditional hypoglycemic agents, GLP-1 receptor agonists not only effectively lower blood glucose but also offer advantages such as promoting weight loss, improving pancreatic beta-cell function, and reducing hypoglycemia risk. More importantly, extensive clinical research has confirmed the potential cardiovascular protective benefits of GLP-1 receptor agonists, positioning them as an “upgraded therapy” that simultaneously controls blood glucose and prevents complications. Consequently, within

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modern type 2 diabetes treatment systems, GLP-1 receptor agonists are progressively transitioning from second-line to first-line core status, particularly for overweight or obese patients with cardiovascular disease risk or weight management needs.

Basal & Bolus Insulins	<ul style="list-style-type: none"> Long-acting “basal” analogues (e.g., insulin glargine, degludec) provide 24-h background coverage, while rapid-acting analogues (e.g., insulin lispro, aspart) match meal-time glucose rises.
Metformin	<ul style="list-style-type: none"> Lowers hepatic gluconeogenesis and improves peripheral insulin sensitivity without weight gain or hypoglycaemia.
GLP-1 Receptor Agonists	<ul style="list-style-type: none"> Injectable (and now oral) incretin mimetics boost glucose-dependent insulin release, suppress glucagon, slow gastric emptying and promote satiety, driving weight loss.
SGLT2 Inhibitors	<ul style="list-style-type: none"> Block renal glucose re-uptake, causing glycosuria that lowers glucose and modestly reduces weight and blood pressure.
DPP-4 Inhibitors	<ul style="list-style-type: none"> Prevent breakdown of endogenous GLP-1/GIP, enhancing glucose-dependent insulin secretion with a neutral weight profile and low hypoglycaemia risk
Sulfonylureas	<ul style="list-style-type: none"> Stimulate pancreatic β-cells to release insulin irrespective of ambient glucose; effective and inexpensive but carry hypoglycaemia and weight-gain liabilities

Diabetes Microneedle Clinical Pipeline

The clinical development of diabetes microneedle technology primarily focuses on delivering drugs such as insulin and GLP-1 receptor agonists via microneedle patches as an alternative to traditional subcutaneous injections. This technology creates microchannels in the superficial layer of the skin, enabling transdermal drug absorption. It offers pain-free application, convenience, and precise dose control, with the potential to improve patient compliance and optimize drug absorption efficiency.

Drug	Applicant	Locations	Indication	Phase	Status	Initial date	Clinical No.	Registration Authority
Proinsulin peptide (gold-nanoparticle conjugate via microneedle patch)	Cardiff University	UK/Sweden	Diabetes Mellitus	Phase 1	Completed	Aug 2016	NCT02837094	FDA
Semaglutide Microneedle Patch in Type 2 Diabetes	Daewoong Pharmaceutical	Korea	Diabetes Mellitus	Phase 1	Not yet recruiting	April 2026	NCT07539415	FDA
Insulin (basal/bolus infusion via microneedle vs subcutaneous infusion)	Becton, Dickinson and Co.	U.S./Germany	Diabetes Mellitus	Phase 1/2	Completed	July 2012	NCT01557907	FDA
Insulin via MicronJet	Massachusetts General Hospital	U.S.	Diabetes Mellitus	Phase 2	Recruitment completed	September 2012	NCT01684956	FDA
Insulin Delivery Using Microneedles in Type 1 Diabetes	Emory University	U.S.	Diabetes Mellitus	Phase 2/3	Completed	January 2014	NCT00837512	FDA

Challenges and Threats in the Global and China Diabetes Microneedle Market

The global diabetes microneedle market faces challenges in dosing accuracy, safety concerns, competition from multiple technological routes, and cost pressures

- Dosing Accuracy and Safety Concerns:** Despite being minimally invasive, whether microneedles can accurately deliver large insulin doses (especially for high-dose patients) remains a technical challenge. Safety issues (such as post-needlestick infections and residual needle fragments) may also trigger patient concerns.
- Cost and Reimbursement Pressure:** The manufacturing cost of microneedle devices currently remains generally higher than traditional needles. If cost reductions through scale cannot be achieved, the market may face restricted insurance reimbursement and insufficient patient willingness to pay.

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The China market, meanwhile, is constrained by patient habit conversion, intense competition from domestic enterprises, and technical reliability challenges, with market penetration and brand building remaining a long-term endeavor.

- **Market Penetration and Patient Education:** Although patient demand is substantial, transitioning from traditional pen needles to microneedle devices requires changes in usage habits. The costs of training healthcare professionals and educating patients are high; without effective science communication, market penetration may remain slow.
- **Intense Domestic Competition:** As market potential becomes widely recognized, an increasing number of companies are entering the market, intensifying competition. Companies must continuously focus on product differentiation to avoid elimination by homogenized competition.

Drivers and Entry Barriers in the Global Diabetes Microneedle Market

Needle-free patient preference: The continuous expansion of the global diabetes patient base has directly amplified the urgent demand for comfortable drug delivery technology. The global diabetic population continues to grow, while traditional injections present “needle phobia” and pain issues. Microneedle technology (such as dissolving microneedle patches) offers a minimally invasive drug delivery method, significantly improving patient compliance and quality of life.

Diversified Demand for Vaccine and Drug Delivery: With the increasing prevalence of chronic diseases caused by global population aging and lifestyle changes, the demand for precise and effective drug delivery has become increasingly urgent, and microneedle technology is considered one of the solutions in this context. Beyond diabetes, the advantages of microneedles in vaccine delivery (such as influenza vaccines) and biologics (such as monoclonal antibodies) delivery have also driven R&D investment, indirectly advancing diabetes microneedle technology.

New entrants to the global diabetes microneedle market primarily face the following barriers:

High R&D and Clinical Validation Costs: Microneedle devices require rigorous clinical validation to demonstrate bioequivalence (particularly for narrow therapeutic index drugs like insulin). The R&D process demands interdisciplinary collaboration (materials science, microfabrication, pharmacology), with prohibitively expensive clinical trials.

Regulatory Approval and Quality Standards: Regulatory standards for microneedle devices remain incompletely harmonized across different countries, requiring manufacturers to meet high-level safety and sterile production requirements. Especially for drug-delivering microneedles, dual drug-device review compliance creates substantial costs.

Drivers and Entry Barriers in the China Diabetes Microneedle Market

Massive Potential User Base: China has one of the largest diabetic populations globally. With intensifying aging and widespread “needle phobia,” patients demonstrate strong demand for safe, minimally invasive, and comfortable insulin pen needles and microneedle devices.

Policy Support and Healthcare Insurance Orientation: The Chinese government supports innovative medical device development and incorporates diabetes management into the “Healthy China 2030” strategy. As medical insurance coverage expands (particularly reimbursement for diabetes-related products), the market access environment for novel delivery devices such as microneedles continues to improve.

New entrants to the China diabetes microneedle market primarily face the following barriers:

Stringent Regulatory Approval and Patent Landscape: Although China’s approval speed is relatively fast, drug-delivering microneedles (especially novel material microneedles) still require rigorous safety and efficacy assessments. Additionally, existing international microneedle patent portfolios (from U.S. and European companies) present certain technical barriers for domestic enterprises.

Technology R&D and Talent Bottlenecks: High-performance microneedles (such as dissolving microneedles and drug-loaded microneedles) involve advanced materials science and micro-nano manufacturing technologies. Domestic companies must invest substantial resources in R&D, while senior R&D talent remains relatively scarce.

Future Trend

Microneedle technology is advancing diabetes care toward a minimally invasive “apply-and-go” approach, integrating the delivery of insulin and GLP-1 receptor agonists with continuous monitoring. By encapsulating macromolecular drugs into room-temperature-stable ultra-thin patches, patients can

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apply them as easily as bandages. This innovation eliminates injection anxiety, reduces training time, and bypasses cold-chain logistics challenges, making it suitable for both technologically advanced markets and resource-limited settings.

Weight Management Market

Weight management primarily targets overweight and obese individuals, aiming to reduce the risk of various chronic diseases associated with abnormal weight by regulating energy intake and metabolic processes. Obesity is defined by the World Health Organization as a chronic, recurrent, and progressive disease, and has become one of the global public health challenges. This condition not only affects an individual’s weight but is also closely associated with various metabolic and endocrine disorders such as type 2 diabetes, cardiovascular disease, and polycystic ovary syndrome.

Currently, the proportion of overweight and obese individuals worldwide continues to rise, with a trend toward younger age groups. Especially under the influence of factors such as accelerated urbanization, changes in lifestyle, and unreasonable dietary structures, the prevalence of weight management-related diseases continues to climb, leading to a significant disease burden and clinical intervention needs.

Global Market

The Scale of Weight Management Patients Global

Global weight management patients grew from 3,203.71 million in 2021 to 3,726.9 million in 2025 (CAGR 3.85%), reaching 4,188.87 million by 2030 (CAGR 2.35%). China saw mild growth from 590.58 million to 627.94 million (CAGR 1.55%), targeting 659.86 million by 2030. The U.S. patient population increased from 188.1 million to 224.78 million over the same period.

Global Weight Management Market Size

The global weight management market is undergoing explosive expansion, surging from USD 1.96 billion in 2021 to USD20.96 billion in 2025 (CAGR 80.72%), and is projected to reach USD46.32 billion by 2030 (CAGR 17.12% from 2025 to 2030), driven primarily by the ramp-up of innovative GLP-1 drugs. The U.S. market mirrors this momentum, growing from USD 1.06 billion in 2021 to an estimated USD29.83 billion by 2030, with average annual growth of 81.25% from 2021 to 2025, moderating to 18.13% from 2026 to 2030. Meanwhile, China’s market is experiencing rapid expansion as well, transitioning from modest growth of 13.17% during 2021–2025 to an accelerated phase with a projected CAGR of 31.85% from 2026 to 2030, fueled by rising demand, increased awareness, and broader adoption of pharmaceutical weight control solutions.



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

The estimation of China’s weight management treatment market size is based on the following assumptions: (i) Market value = Average treatment cost × Number of patients receiving treatment. In 2026, the number of weight management patients in China is expected to reach 635.56 million, projected to increase to 659.86 million by 2030. (ii) Price assumptions are based on the list prices of drugs already marketed in this market. (iii) The consultation rate for overweight patients is approximately 1%–5%, with drug utilization ratio of approximately 5%–28%; the consultation rate for obese patients is approximately 2%–7%, with drug utilization ratio of approximately 21%–50%. (iv) The drug adherence rate for overweight patients is approximately 24%–33%; the drug adherence rate for obese patients is approximately 36%–44%. The average treatment cost range for overweight patients is approximately 280–840 USD; the

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average treatment cost range for obese patients is approximately 700–1260 USD, with future price erosion following industry trends. (v) Academic promotion and patient education activities continue to be strengthened. (vi) The scale of treatable patient populations continues to expand rapidly. (vii) There is enormous unmet clinical demand; as treatment volume grows in parallel, the weight management market will expand significantly. Therefore, China’s weight management treatment market is expected to reach USD1.02 billion in 2026 and USD3.09 billion by 2030.

Major Treatment Method

Pharmacological approaches to weight management primarily function by reducing energy intake, increasing energy expenditure, or decreasing nutrient absorption. Traditional central nervous system-acting medications, such as phentermine or bupropion/naltrexone combinations, primarily suppress appetite to reduce food consumption but are often accompanied by side effects like insomnia, anxiety, or elevated blood pressure. Another class of drugs, like orlistat, works by inhibiting intestinal lipase activity to reduce dietary fat absorption. While effective for weight loss to some extent, it frequently causes gastrointestinal adverse reactions such as diarrhea and oily stools, leading to poor compliance. In contrast, GLP-1 receptor agonists demonstrate certain advantages in weight management. By mimicking endogenous GLP-1, these drugs not only enhance insulin secretion and inhibit glucagon release to improve glucose metabolism but also delay gastric emptying and increase satiety, thereby effectively reducing food intake. Furthermore, their low risk of hypoglycemia and long-term metabolic benefits have made them a hot topic in weight management and diabetes treatment in recent years. They are increasingly being incorporated into preferred treatment regimens for patients with obesity and diabetes-related overweight.

Challenges and Threats in the Global and China Weight Management Market

The global weight management supplement market faces a triple challenge of prescription drug competition, safety and compliance risks, and slowing growth in mature markets

- **Competition and Differentiation Challenges:** Beyond traditional health supplements, significant pressure comes from prescription drugs (such as GLP-1 medications). Given these drugs’ substantial clinical weight-loss efficacy, consumers may prefer medical interventions over standalone health supplements, resulting in intense market competition.
- **Market Saturation and Slowing Growth:** Despite overall growth potential, growth rates may decelerate in mature markets (such as the U.S.). Certain regions experienced post-pandemic growth fluctuations, with consumer confidence and willingness to pay affected.

The China market, meanwhile, confronts multiple pressures from pharmaceutical competition, consumption upgrading, and tightening regulations, making industry trust rebuilding and differentiated competition the key to breaking through.

- **Drug Competition and Trust Crisis:** In recent years, prescription weight-loss drugs represented by semaglutide have exerted powerful pressure on traditional health supplements with their significant weight-loss effects. Meanwhile, some companies continue to illegally add prohibited pharmaceutical ingredients, leading to declining consumer trust in the entire weight management supplement category.
- **Regulatory Risks and Compliance Pressure:** Although current market concentration remains low with relatively low entry barriers, regulatory scrutiny over functional ingredient safety and promotional compliance is tightening as weight-loss supplement markets gain attention. Companies must remain vigilant against policy changes that could trigger compliance risks, preventing market exit due to promotional violations or prohibited ingredient additions.

Drivers and Entry Barriers in the Global Weight Management Market

Obesity Prevalence and Health Crisis: Global obesity rates continue to climb, becoming a major disease affecting human lifespan. According to the latest data, the global obesity rate is rising at an alarming rate. In 2025, the global obese population will account for about 18% of adult males and about 21% of females. Obesity-related comorbidities — including cardiovascular, respiratory, digestive, and joint diseases — are numerous. As health awareness awakens, consumers’ emphasis on weight management has significantly increased, directly driving explosive market demand growth.

Technological Innovation and Precision Nutrition: Companies are moving beyond traditional calorie concepts to focus on multi-dimensional precision interventions targeting gut, immune, cellular, and neural systems. Novel drugs such as GLP-1 receptor agonists (e.g., semaglutide) have become powerful competitors with their significant weight-loss effects. Meanwhile, weight management is shifting from mere weight loss to healthy weight maintenance, emphasizing metabolic flexibility and

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overall health. With the increasing demand from consumers for scientific, safe, and efficient weight loss solutions, maintaining a healthy weight (metabolic flexibility) is becoming a new core focus, and technological innovation and precision nutrition are jointly driving this track towards higher value.

New entrants to the global weight management market primarily face the following barriers:

High R&D and Regulatory Costs: Weight management products (especially those involving pharmaceutical ingredients) require rigorous clinical validation and regulatory approval. R&D cycles are long and costly, with different regulatory requirements across regions (such as the EU and Japan) to navigate.

Technology and Patent Barriers: Underlying mechanism R&D involves deep integration of biotechnology, precision nutrition, and intelligent hardware. Entrants must overcome technical challenges in ingredient safety, formulation stability, and metabolic intervention, while also navigating existing patent landscapes.

Drivers and Entry Barriers in the China Weight Management Market

Population Base and Policy Support: China has one of the largest obese populations globally. With the advancement of Healthy China policy, residents’ demand for weight loss and control has become increasingly strong.

Technological Innovation and Product Differentiation: As market competition intensifies, companies are accelerating transformation from homogenized competition toward “functional segmentation” and “personalized customization.” Beyond traditional fat-reduction formulations, the market is witnessing the emergence of precision nutrition products based on “scientific nutritional ratios” (such as functional coffee and meal replacement shakes), emphasizing metabolic intervention rather than simple “eat less, move more” approaches to achieve weight management.

New entrants to the China weight management market primarily face the following barriers:

Channel and Customer Acquisition Cost Barriers: As industry concentration increases, new entrants face customer acquisition costs significantly higher than industry averages. Large leading enterprises, leveraging long-term channel accumulation and brand effects, can compress new brands’ market survival space, making it difficult for new companies to gain market share in a short time.

Technology and Innovation Capability: Market competition is fierce, and simple weight-loss promotion is no longer viable. Entrants must possess R&D strength to provide products with scientific nutritional ratios and multi-target efficacy validation; otherwise, survival in competition is difficult.

Future Trend

The Weight management market is transitioning from traditional lifestyle interventions and basic drug therapies to a new phase characterized by diversified mechanisms, personalized treatment, and innovative delivery methods. Novel formulation technologies, such as microneedle patches, hold promise to overcome the limitations of poor compliance associated with existing injectable formulations, potentially becoming a key enabler for the broader adoption of weight loss therapies across a wider population. This shift is expected to further unlock the clinical and commercial potential of the weight management field.

- 1. New formulations promote convenience and accessibility in weight control treatment:** Currently, the mainstream weight-loss drugs on the market are primarily injectable formulations, which still have room for improvement in terms of compliance, ease of use, storage, and patient coverage. Particularly among individuals with mild to moderate obesity or those requiring long-term maintenance therapy, acceptance levels need to be enhanced. With advances in drug delivery technology, novel formulations such as microneedle patches and oral biologic macromolecule preparations are gradually becoming key areas of research and development. Among these, microneedle delivery systems offer advantages such as transdermal absorption, high bioavailability, minimally invasiveness, and ease of self-administration. They enable stable delivery of large-molecule drugs and hold promise as an ideal vehicle for GLP-1 agonists and subsequent multi-target activators. This innovativedelivery approach not only enhances the medication experience and lowers compliance barriers but also lays the technological foundation for expanding weight loss treatment to broader patient populations.
- 2. Extending the scope of indications to promote joint management of chronic diseases:** Obesity, as a fundamental risk factor for various metabolic diseases, is driving the expansion of related drugs into indications such as type 2 diabetes, non-alcoholic fatty liver disease,

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cardiovascular disease, and obstructive sleep apnea. This approach enables a comprehensive metabolic management strategy of “one drug, multiple indications,” thereby enhancing the product lifecycle and clinical value.

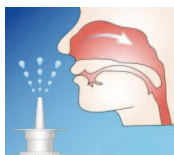
3. **Multi-target mechanism promotes efficacy leap:** Following GLP-1 drugs, multi-target metabolic drugs such as GIP/GLP-1 dual agonists and triple agonists are accelerating clinical development, significantly improving weight loss and metabolic indicator improvement. Future product development will focus more on long-term efficacy, cardiovascular benefits, and synergistic intervention capabilities for concomitant diseases.

NASAL SPRAY FORMULATION MARKET

Overview

Nasal sprays represent a non-invasive drug delivery method that utilizes the nasal mucosa for absorption. Due to their ease of use, rapid onset of action, and high patient compliance, they have progressively emerged as a significant therapeutic platform in recent years. Their unique physiological advantage lies in the nasal mucosa’s rich blood supply and high permeability, enabling rapid absorption while bypassing first-pass metabolism in the gastrointestinal tract and liver. This characteristic makes nasal sprays suitable not only for treating localized conditions but also systemic diseases. Additionally, the upper nasal passage connects to the olfactory nerve, offering the potential for direct access to the central nervous system via the olfactory pathway. This characteristic enables nasal sprays to bypass the blood-brain barrier, delivering drugs directly to the brain via the olfactory region. Certain products show promise in treating central nervous system disorders such as Alzheimer’s disease, Parkinson’s disease, migraine, and epilepsy. Compared to injection or oral administration, nasal spray delivery offers distinct advantages. Since drugs are absorbed directly through the nasal mucosa, the nasal spray route avoids degradation of biomolecules (such as certain vaccine-like drugs) by the gastrointestinal environment and loss of efficacy due to the hepatic first-pass effect. Additionally, nasal spray formulations offer more convenient dose control and generally better patient compliance. Compared to injections, nasal sprays are non-invasive, reducing pain and psychological burden during administration, thereby demonstrating application potential in managing certain conditions. The development of devices suitable for nose-to-brain drug delivery faces three core challenges: first, due to anatomical constraints and mucociliary clearance mechanisms, drugs struggle to effectively deposit in the olfactory region and remain there for extended periods, resulting in low and unstable delivery efficiency; second, existing nasal spray devices exhibit significant technical bottlenecks, with spray angle and particle size being difficult to precisely control, leading to substantial bioequivalence variability; third, local safety and tolerability constitute limiting factors, particularly as high-concentration drugs or novel delivery systems may trigger adverse reactions such as nasal irritation and mucosal damage. Clinical trials for nasal drug delivery targeting central nervous system indications, such as the intranasal insulin glulisine trial (NCT02503501) initiated by Health Partners Institute on September 28, 2015 was terminated due to insufficient efficacy. For XJN010, this means that even if the drug itself possesses therapeutic potential, the technical limitations of the nasal spray delivery route and patient tolerability issues may still lead to clinical failure. Successful delivery technology does not equate to clinical efficacy, and patient selection and mechanism validation are paramount. Therefore, clinical advancement must prioritize local safety and device technical precision, addressing the aforementioned delivery efficiency and tolerability issues; otherwise, it may face similar termination risks.

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Respiratory Treatments

As a localized drug delivery method, nasal sprays are highly effective in relieving symptoms of allergic rhinitis and nasal congestion. Commonly used medications include corticosteroid nasal sprays and antihistamine sprays, offering advantages such as rapid onset, minimal systemic side effects, and high patient compliance.



Neurological Disorders

With the ability to bypass the blood-brain barrier quickly, nasal spray delivery has emerged as a key therapeutic approach for central nervous system diseases such as Parkinson's disease, migraines, and Alzheimer's disease. Drugs administered via nasal routes can deliver fast relief, particularly valuable for acute symptom management.

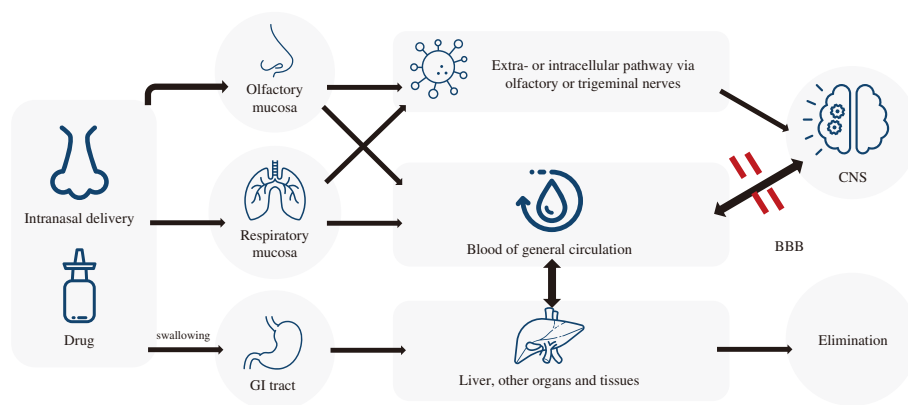


Beyond conventional use, nasal sprays are also widely applied in hormone therapy (e.g., estrogen replacement), local anesthesia (e.g., dental procedures), and anti-infective treatments (especially for respiratory tract infections), covering a wide range of non-injection systemic and topical use cases.

Broader Clinical Applications

It can be divided into three categories:

1. **Central Nervous System Delivery :** The nasal cavity possesses a unique anatomical structure, with high mucosal permeability and abundant blood flow enabling drugs to enter the central nervous system directly through the olfactory pathway. This advantage positions nasal sprays as a potential therapeutic route for central nervous system disorders such as Alzheimer's disease, Parkinson's disease, migraine, and epilepsy, bypassing the blood-brain barrier to enhance drug delivery efficiency within the brain.
2. **Topical Nasal Delivery :** Nasal sprays are widely used for treating localized conditions such as rhinitis, sinusitis, and nasal allergies. The medication acts directly on the nasal mucosa, achieving high concentrations at the site of inflammation to rapidly relieve symptoms while significantly reducing the risk of systemic adverse reactions. Utilizing adhesive formulation technology further prolongs drug retention on the mucosal surface, creating a drug reservoir that enhances local bioavailability.
3. **Systemic Disease Nasal Delivery:** Nasal sprays can also serve as a delivery route for systemic diseases such as osteoporosis. Through nasal absorption, drugs can enter systemic circulation, potentially bypassing gastrointestinal degradation and hepatic first-pass effects in certain cases, thereby enhancing bioavailability.



Challenges and Threats in the Global, U.S. and China Nasal Spray Formulation Market

The global nasal spray formulation market faces mounting pressures from intensifying competition, high technical barriers, compatibility challenges between formulations and devices, evolving regulatory policies, and supply chain volatility

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- **Market Competition and Entry Barriers:** Rising allergic disease prevalence drives nasal spray demand but intensifies competition; for generics, the manufacturing complexity — requiring precise delivery mechanisms and dosage control — serves as a major barrier, as minor formulation or device deviations can compromise performance.
- **Technological Innovation and Formulation Compatibility:** Nasal spray products need to address interaction issues between the formulation and the spray device, which presents technical challenges. Meanwhile, insufficient technological innovation may place companies at a disadvantage in intense international competition.

The U.S. market, under stringent FDA oversight, is caught in a dual dilemma of quality control and efficiency enhancement due to manual testing variability, insufficient diagnostic tools, and large-scale production demands.

- **Regulatory Compliance and Product Testing:** The U.S. market imposes very strict regulations on nasal sprays. Companies must meet the high demands of agencies such as the FDA for product quality consistency and reproducibility. Operational differences between analysts when manually actuating pumps for testing, which also affect data reproducibility; and insufficient diagnostic tools to assess the mechanical performance of spray devices.
- **Demand for Efficient Quality Control Processes:** As market scale expands (for example, over 150 million fluticasone spray units sold annually in the U.S.), the testing process has become labor-intensive and time-consuming. Companies urgently need to shift toward more efficient workflows to maximize output and minimize analyst time requirements.

The Chinese nasal spray formulation market is heavily constrained by extreme import dependence, vulnerable supply chains, high technical barriers for generics, and stringent regulatory and pricing pressures.

- **External Dependence & Market Squeeze:** The domestic nasal spray market remains heavily import-dependent, with foreign giants dominating through technological, brand, and patent advantages — severely limiting local players’ market share. Meanwhile, reliance on external suppliers for spray mechanisms, filter components, and raw materials exposes manufacturers to supply chain disruptions and rising costs driven by geopolitical factors such as tariffs.
- **Internal Barriers & Policy Pressures:** Generic nasal spray development faces long R&D cycles, complex manufacturing, and strict patent constraints, making it difficult to replicate imported best-sellers. Additionally, stringent bioequivalence (BE) requirements raise approval hurdles and rejection risks, while volume-based procurement (VBP) policies compress profit margins. The market also faces competition from alternative nasal care solutions and price-sensitive consumers.

Drivers and Entry barriers

The growth of nasal spray market is expected to continue being driven by the following factors:

- **Advantages in onset speed and dosing efficiency:** Compared with the traditional oral or injection routes, nasal sprays enter the systemic circulation directly through the rich vascular network in the nasal cavity, and the drugs are absorbed quickly, avoiding the gastrointestinal decomposition and the first pass metabolism of the liver. This “direct to the blood” feature has greatly improved the bioavailability of drugs. The efficient drug delivery mode greatly reduces the therapeutic dose, reduces the patient’s drug burden, and reduces potential gastrointestinal irritation. With its advantages of non-invasive, convenient and efficient, nasal spray has become a “new blue ocean” for enterprises to compete for layout, directly promoting the rapid expansion of market scale. Nasal spray enables rapid absorption through the nasal mucosa and, in some cases, reduces the first pass effect, meeting therapeutic demands with stringent requirements for onset time.
- **Expansion of central nervous system delivery and systemic disease nasal delivery applications:** With the deepening of research into the nose-to-brain pathway and systemic absorption mechanisms, the potential applications of nasal spray administration in the central nervous system and other therapeutic areas continue to expand.

New entrants to the nasal spray market primarily face the following barriers:

- **Technological Barriers:** The development of nasal spray drugs involves complex drug delivery technologies, particularly the need to overcome traditional methods of drug absorption and release. Additionally, maintaining drug stability and preventing degradation during the delivery process is a major technical challenge.

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- **High Capital Requirement Barriers:** The development and production of nasal spray drugs require substantial financial investment, particularly in the early stages. Whether it’s for drug research and development, clinical trials, or establishing compliant production lines, significant capital support is needed. The high costs and risks associated with R&D make it financially challenging for many companies to enter the market.

Future Trend

In the future, nasal sprays are expected to continue expanding their applications in treating localized diseases, systemic disorders, and central nervous system conditions. Leveraging their non-invasive nature, patient-friendly characteristics, and the unique physiological structure of the nasal cavity, nasal sprays offer an efficient route for novel drug delivery. They demonstrate particular potential in central nervous system-targeted applications for neurodegenerative diseases such as Parkinson’s and Alzheimer’s, as well as for biological agents like exosome and gene therapies.



Precision and Personalized Delivery

- With the advancement of precision medicine, nasal spray systems are evolving toward customizable dosing and controlled-release profiles. In the future, drug delivery regimens may be tailored to individual patient conditions and metabolism, particularly benefiting indications like migraines and Parkinson’s disease where rapid relief is essential.

- As a non-invasive method, nasal spray delivery significantly enhances patient adherence. Future developments are expected to integrate smart hardware, enabling features such as automated dosing, medication reminders, and data synchronization via connected “smart nasal devices.”



Non-Invasive and Smart Integration



Cross-Sector Innovation and Expansion

- The application boundaries of nasal sprays are rapidly expanding beyond respiratory and neurological fields. Emerging opportunities lie in areas such as oncology and anti-aging treatments. For example, the combination of nasal delivery and nanocarriers could enable targeted therapies with reduced toxicity and enhanced efficacy.

Parkinson’s disease Market

Parkinson’s disease, also known as “paralysis agitans” is a chronic neurodegenerative disorder commonly seen in middle-aged and elderly individuals. It is primarily characterized by the gradual degeneration and reduced of dopaminergic neurons in the substantia nigra region of the brain, leading to motor dysfunction and various non-motor symptoms. Key clinical manifestations include bradykinesia (slowness of movement), tremors in the hands, feet, or other parts of the body, and loss of physical flexibility resulting in stiffness.

The core clinical features of Parkinson’s disease include the following motor symptoms: Resting tremor: Rhythmic shaking of the limbs during a state of rest, which is one of the most representative early signs of Parkinson’s disease; Muscular rigidity: Manifested as stiffness in muscles, particularly in the limbs and trunk, with increased resistance to movement; Bradykinesia: Slowness of movement and difficulty initiating actions, which is a necessary symptom for diagnosis; Postural instability: A late-stage symptom characterized by loss of balance and increased tendency to fall.

Overview of Parkinson’s Disease “Off” episodes

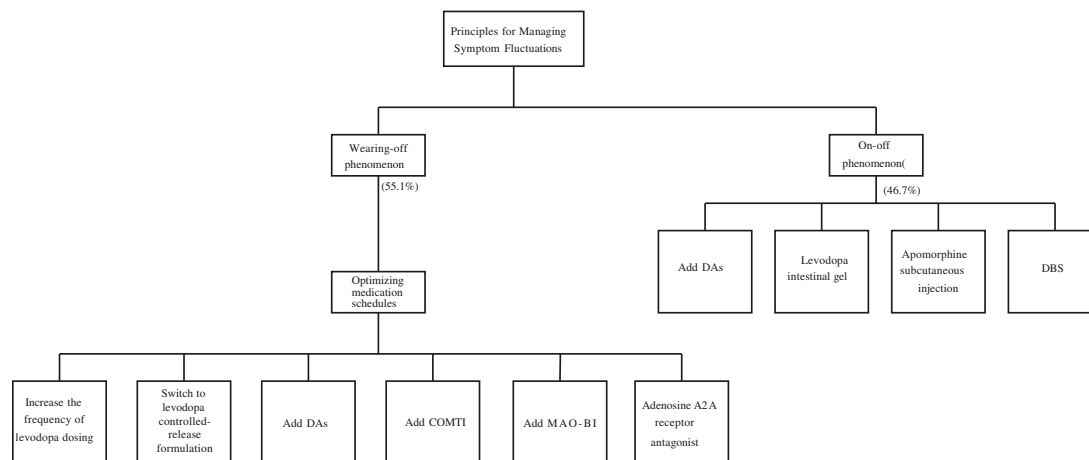
During long-term medication treatment, Parkinson’s patients often experience “Off” episodes, which refer to fluctuations in drug efficacy. An “Off” episodes refers to a period after taking medications like levodopa when the drug’s effects gradually diminish, causing motor symptoms such as rigidity, tremors, and bradykinesia to reappear or worsen. This state typically occurs when blood levels of the medication drop, manifesting as the “on-off phenomenon” or “end-of-dose fluctuations,” and represents one of the major challenges in Parkinson’s disease treatment. Approximately 50% of patients with a disease duration exceeding five years experience pronounced “Off” episodes, a proportion rising to 70%–80% among those with over ten years of disease progression. These episodes are often sudden and unpredictable in duration, causing rapid symptom exacerbation that severely impairs daily functioning. Related studies have found that 67% of patients experience 1 to 2 “off” episodes per day,

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90% have episodes lasting more than 15 minutes, and 55% report their “off” episode symptoms as mild. They may also be accompanied by non-motor symptoms like anxiety and depression, significantly diminishing quality of life. Furthermore, as the disease progresses and with long-term levodopa use, the sustained effect of medication gradually diminishes, making the “Off” episodes one of the most challenging aspects of Parkinson’s disease treatment management.

Major Treatment Methods

Currently, there are no medications specifically approved for treating Parkinson’s disease “Off” episodes as an independent indication. Clinical management primarily relies on off-label use of existing Parkinson’s disease medications. Management of Parkinson’s disease “Off” episodes primarily revolves around two treatment strategies: first, prolonging the patient’s “on period” to minimize entry into “Off” episodes; second, rapidly restoring the “on period” state when “Off” episodes occur to promptly alleviate motor and non-motor symptoms. Strategies to prolong the “on” period primarily involve optimizing levodopa administration regimens (such as increasing dosage frequency or using controlled-release formulations), or combining dopamine receptor agonists, COMT inhibitors, MAO-B inhibitors, and adenosine A₂A receptor antagonists to extend therapeutic duration and stabilize plasma drug concentrations. For rapid relief of off-period symptoms, short-acting dopamine agonists, subcutaneous apomorphine injections, or continuous enteral gel infusion of levodopa can restore the on-period state within a short timeframe. Additionally, for patients with suboptimal medication control, advanced interventions such as deep brain stimulation (DBS) may be considered to improve on-off fluctuations and enhance quality of life. Among Parkinson’s disease (PD) patients, 60% receive a dopa decarboxylase inhibitor and 75% are on a levodopa regimen. The global prevalence of Parkinson’s disease is 152 cases per 100,000 population, the prevalence in the United States ranges from 100.8 to 112.0 cases per 100,000 population, and the prevalence in China is 245.7 cases per 100,000 population. The global incidence is 16.92 cases per 100,000 population, the incidence in the United States ranges from 23.41 to 33.33 cases per 100,000 population, and the incidence in China is 24.3 cases per 100,000 population. The prevalence of “Off” episodes affect approximately 70% of PD patients, with a diagnostic rate of 64.0%. Within the first four to six years following diagnosis, up to 60% of patients experience “Off” episodes, regardless of disease severity. Over time, these episodes become longer, more severe, more disabling, and more frequent, as well as less predictable, potentially occupying more than half of the waking day. By slowing or preventing the completion of daily activities, “Off” episodes significantly alter patients’ functional ability, imposing a substantial burden and distress on both individuals with PD and their care partners. For patients with severe wearing-off periods that cannot be improved by oral medications, non-oral administration routes are adopted, similar to levodopa-carbidopa intestinal gel. Currently, the treatment regimen of XJN010 based on intranasal administration to supplement levodopa has not yet been included in clinical guidelines.



Source: Chinese Guidelines for the Management of Parkinson’s Disease (Fourth Edition), Frost & Sullivan Analysis

Notes: The main reasons why it is not possible to obtain the patient proportion rates for each specific treatment modality for “wearing-off phenomenon” and “on-off phenomenon” are as follows: The treatment of Parkinson’s disease is highly stepwise and individualized. Different treatment modalities (such as adjusting oral medications, adding adjunctive drugs, and advanced device-assisted or surgical treatments) are not mutually exclusive options but are often used in combination or sequentially, making it difficult to perform independent statistical analysis on any single method. Additionally, existing research has primarily focused on the overall epidemiology of symptoms or the efficacy of specific therapies, lacking large-scale, up-to-date real-world data focusing on treatment patterns in populations with symptom fluctuations.

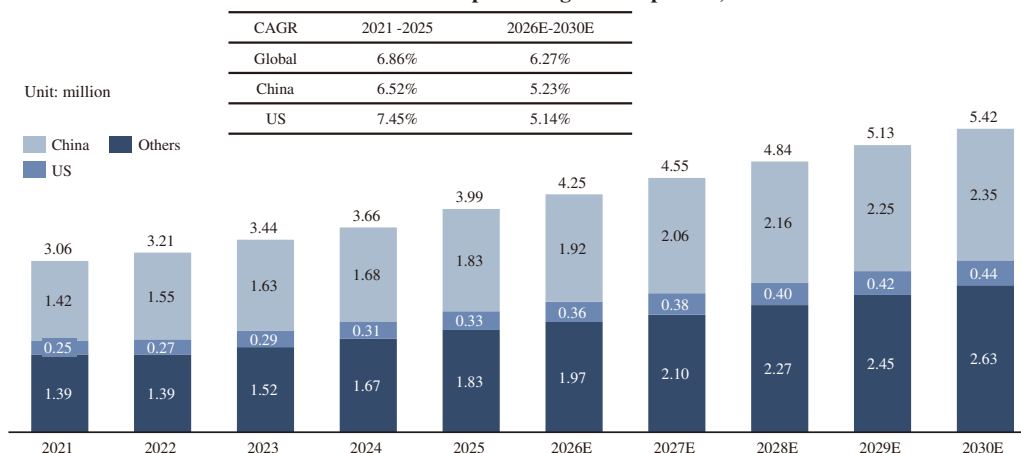
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Global Market

The Global Scale of Parkinson’s Disease Patients Experiencing “Off” Episodes

Globally, the number of Parkinson’s disease patients experiencing “Off” episodes is projected to rise from approximately 3.06 million in 2021 to 5.42 million by 2030, driven primarily by aging populations, increased early diagnosis, and disease progression. In China, this patient population is expected to nearly double from 1.42 million in 2021 to 2.35 million in 2030 (CAGR 6.52% in 2021–2025, decelerating to 5.23% in 2026–2030), while in the United States, it is projected to grow from 0.25 million to 0.44 million over the same period (CAGR 7.45% in 2021–2025, easing to 5.14% in 2026–2030). These trends underscore a mounting healthcare burden and an urgent need for innovative therapies, optimized long-term care models, and adaptive healthcare payment systems.

Global Scale of Parkinson’s Disease Patients Experiencing “Off” Episodes, 2021–2030E

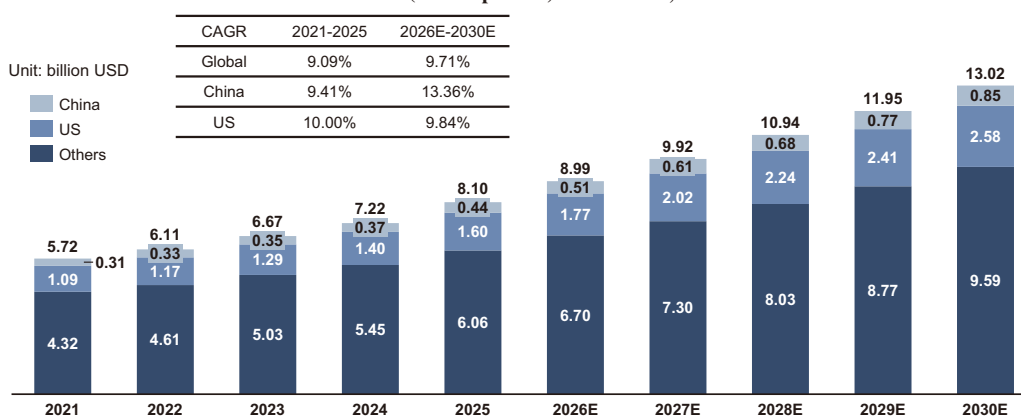


Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Global Parkinson’s Disease (“Off” episodes) Market Size

Globally, the Parkinson’s disease “Off” episodes market is expanding rapidly, projected to grow from USD5.72 billion in 2021 to over USD13.02 billion by 2030, with a CAGR accelerating from 9.09% (2021–2025) to 9.71% (2026–2030). The U.S. market is expected to nearly triple from USD1.09 billion to USD2.58 billion over the same period (CAGR of 10.00% in 2021–2025, peaking at 9.84% in 2026–2030), driven by increasing patient volume, advanced therapies, and expanded insurance coverage. Meanwhile, China’s market is forecasted to grow from USD0.31 billion in 2021 to USD0.85 billion by 2030, with a notable acceleration in CAGR from 9.41% (2021–2025) to 13.36% (2026–2030), fueled by a rising patient base, improved diagnosis and treatment penetration, and the introduction of advanced drug formulations positioning the “Off” episodes segment as a key driver of neurological pharmaceutical innovation.

Global Parkinson’s Disease (“Off” episodes) Market Size, 2021–2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

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Notes: The estimated market size of Parkinson’s therapy in China is based on the following assumption: (i) Market size of Parkinson’s off stage = Number of people receiving drug treatment for middle and late stage Parkinson’s disease x Average annual treatment cost. By 2026, the number of people receiving drug treatment for Parkinson’s disease in the middle and late stages in China is expected to be 1.92 million, and by 2030, it is expected to reach 2.35 million. (ii) The price assumption is based on the listed price of the drug for that indication. (iii) For China, the expected visit rates for Parkinson’s disease patients in the middle and late stages are 60%, drug treatment rates are 34%-53%, off phase symptoms are 40%, patient compliance rates are 54%-74%, and the average annual treatment cost in China is about 2,897 USD. The future price trends is consistent with industry trends.(iv) Academic promotion and patient-education initiatives are intensifying. (v) There is a significant unmet clinical need, with the synchronous growth of treatment volume, the market for Parkinson’s therapy will significantly expand. Therefore, by 2026, the estimated Parkinson’s off stage drug market in China is USD0.51 billion, and it is expected to reach USD0.85 billion by 2030.

XJN010, is the first and only investigational product addressing the “Off” episodes in Parkinson’s disease approved for clinical trials in China, filling a domestic market gap. In the field of central nervous system (CNS) therapeutics, the nasal spray products that have been launched in the market include Diazepam and Sumatriptan. The former is indicated for the treatment of epilepsy, while the latter is indicated for migraine. Currently, there is no nasal spray formulation available for the treatment of Parkinson’s disease. However, hUC-MSC-sEV-001 Nasal Drops is a nasal spray product. There are no innovative products for Parkinson’s disease “off” episodes on the market, and no terminal prices are available for any listed products. For Parkinson’s disease, current treatment practice in the Chinese Mainland, the U.S. and other major markets primarily relies on dopaminergic therapies, including levodopa-based regimens and adjunctive medications, for chronic symptom control and maintenance treatment. For patients experiencing “Off” episodes, management generally involves optimization of background therapy under existing clinical practice. Against this treatment landscape, XJN010 is being developed as a nasal spray for the intermittent treatment of “Off” episodes in adult patients with Parkinson’s disease receiving levodopa/decarboxylase inhibitor therapy. As such, if approved, XJN010 may complement existing treatment practice by providing a non-oral treatment option for this specific clinical setting.

Parkinson’s Disease Nasal Spray Clinical Pipeline

Drug/Active Pharmaceutical Ingredient	Applicant	Locations	Registration Authority	Indication	Phase	Status	Initial date	Clinical No.
XJN010 (Levodopa Nasal Spray)	Guangzhou Novaken Pharm Co., Ltd	China	NMPA, FDA	For intermittent treatment of adult patients with Parkinson's disease during “off” periods while receiving dopa decarboxylase inhibitor/levodopa therapy	Phase 2	Recruiting	August 2025	CTR20253290
INP103 (Levodopa Nasal Spray)	Impel Pharmaceuticals	Australia	FDA	Parkinson’s Disease	Phase 2	Completed	August 2020	NCT03541356
Intranasal Human FGF-1 (Human FGF-1 Nasal Spray)	Zhittya Genesis Medicine, Inc.	Bahamas	FDA	Parkinson’s Disease	Phase 1	Not yet recruiting	August 2022	NCT05493462
Regular Novolin R (Insulin Nasal Spray)	HealthPartners Institute	U.S.	FDA	Parkinson’s Disease	Phase 2	Completed	March 2025	NCT04251585
INS-GSH (Insulin and Glutathione Nasal Spray)	Gateway Institute for Brain Research	U.S.	FDA	Parkinson’s Disease	Phase 2	Recruiting	April 2025	NCT05266417
NeuroEPO (Non - hematopoietic recombinant EPO Nasal Spray)	International Center for Neurological Restoration	Cuba	FDA	Parkinson’s Disease	Phase 1/2	Completed	July 2020	NCT04110678
hUC-MSC-sEV-001 (Extracellular Vesicles Nasal Drops)	Xuanwu Hospital	China	FDA	Parkinson’s Disease	Phase 1	Not yet recruiting	July 2025	NCT06607900

Challenges and Threats in the Global and China Parkinson’s Disease (“Off” episodes) Market

The global Parkinson’s Disease (“Off” episodes) market confronts a triple challenge of high treatment costs, limited efficacy of existing therapies, and high R&D failure rates; the China market, meanwhile, faces significant barriers to market expansion under multiple pressures of intense competition, insufficient patient compliance, and lack of curative therapies.

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- **Treatment Costs and Burden:** High treatment costs represent a major challenge. The expensive pricing of innovative drugs may impose excessive patient burden and impact drug market penetration rates.
- **Efficacy and Safety Risks:** Existing drugs are primarily symptomatic treatments, with long-term use potentially causing motor fluctuations, nausea, vomiting, and other side effects. Patients hold high expectations for treatment outcomes, yet current therapeutic approaches struggle to meet demands for “cure” or “disease progression slowing.”

The China market, meanwhile, faces significant barriers to market expansion under multiple pressures of intense competition, insufficient patient compliance, and lack of curative therapies.

- **Intensifying Market Competition:** As an increasing number of pharmaceutical giants and innovative drug companies enter the market, competition in China has become exceptionally fierce. Intense market battles exist between established foreign pharmaceutical enterprises and emerging domestic innovative drug companies.
- **Limitations of Treatment Modalities:** lacking “curative” therapies that can significantly slow disease progression. Patients hold high expectations for treatment outcomes, yet the limited efficacy of existing therapies creates certain psychological Most current market drugs remain symptomatic treatments, barriers to market expansion for pharmaceutical companies.

Drivers and Entry Barriers in the Global Parkinson’s Disease (“Off” episodes) Market

Population Aging and Rising Prevalence: As global population aging accelerates, the incidence of Parkinson’s Disease (“Off” episodes) has significantly increased. By 2050, the global number of PD patients is expected to reach 25.2 million, an increase of 112% compared to 2021. The global patient population is projected to continue growing, directly driving demand for therapeutic drugs and medical services.

Innovative Therapies and R&D Breakthroughs: Beyond traditional symptom management drugs, gene therapies, cell therapies (such as stem cells), and disease-modifying therapies (DMTs) targeting pathological mechanisms are becoming R&D hotspots. Novel drug delivery systems (such as micropumps and transdermal patches) and digital neurology tools (for remote monitoring and precision dosing) are reshaping the market landscape.

New entrants to the global parkinson’s disease market primarily face the following barriers:

High R&D and Regulatory Costs: As a neurodegenerative disease, Parkinson’s Disease (“Off” episodes) drug clinical trials feature long cycles and high costs. Market entry requires massive R&D investment and navigation through stringent regulatory approvals (such as FDA and EMA).

Patent and Technology Barriers: Formulation patents for mainstream therapeutic drugs remain valid, and novel delivery technologies (such as microneedle patches) involve complex formulation processes, restricting generic drug entry.

Drivers and Entry Barriers in the China Parkinson’s Disease (“Off” episodes) Market

Massive Population Base and High Growth Potential: China has one of the largest Parkinson’s disease patient populations globally. With accelerating population aging, patient numbers will continue to climb, driving substantial drug demand.

Policy Support and Market Opening: The government attaches high importance to aging-related health issues, with gradual improvement of medical security and reimbursement policies reducing patient healthcare burdens. Accelerated approval of innovative drugs (such as first generics) has facilitated domestic companies’ market breakthroughs.

New entrants to the China parkinson’s disease market primarily face the following barriers:

Stringent Regulation and Approval: China’s evaluation standards for new drugs (especially innovative drugs) are increasingly strict, requiring sufficient clinical efficacy and safety data. Even first generics face rigorous generic drug consistency evaluation (medium-term) or post-marketing re-evaluation (long-term).

High R&D and Clinical Costs: Innovative drug R&D for Parkinson’s Disease (“Off” episodes) is extremely costly, with clinical trials (especially Phase III) requiring large-scale patient samples. For small and medium-sized pharmaceutical companies, R&D funding and clinical trial resource investment pose enormous challenges.

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Future Trend

As the global population ages at an accelerated pace, Parkinson’s disease — a classic neurodegenerative disorder — continues to rise in prevalence, with symptoms increasingly manifesting at younger ages. More patients now experience onset during middle adulthood. Beyond disease management, patients harbor heightened expectations for a high-quality later life, encompassing the maintenance of daily functional abilities, independence, and social engagement. The market demands increasingly urgent solutions that deliver “faster onset, simpler administration, and enhanced safety.” The future Parkinson’s disease treatment market will evolve around two core directions: rapid symptom relief and overall improvement in patient quality of life. Key trends include:

1. Emphasis on rapid-onset treatment solutions to meet clinical urgency. Many traditional drugs currently suffer from slow onset and fluctuating efficacy, making them inadequate for addressing sudden motor impairments or “on-off phenomena.” Future treatment trends will focus on drug formulations that offer “rapid onset and stable maintenance,” such as nasal sprays and sublingual fast-dissolving films. These innovative formulations bypass the gastrointestinal tract and first-pass metabolism, enhancing the initial speed of drug efficacy. This provides patients with more efficient immediate control, particularly benefiting elderly patients experiencing sudden “Off” episodes.
2. Long-acting and convenient treatment solutions to improve medication experiences for patients with multiple comorbidities. Most Parkinson’s disease patients are elderly and often suffer from multiple chronic conditions such as cardiovascular diseases, diabetes, and cognitive impairments, leading to complex medication regimens. The market is accelerating the development of long-acting and low-frequency administration methods, including sustained-release tablets, nasal sprays, and fixed-dose combinations. These approaches reduce daily dosing frequency, simplify administration processes, minimize the risk of missed doses and drug interactions, and enhance treatment adherence, thereby better aligning with the practical living scenarios of elderly patients.
3. Focus on comprehensive intervention for non-motor symptoms, expanding treatment boundaries. Non-motor symptoms (e.g., depression, anxiety, constipation, sleep disorders, and cognitive impairment) are highly prevalent in Parkinson’s disease and significantly impact the quality of life, especially among elderly patients. Several targeted drugs for non-motor symptoms are currently under development. Future efforts will further promote multi-target combined interventions and cross-disciplinary collaborative diagnosis and treatment, shifting from “motor-centric” management to “holistic symptom management” to address more complex clinical needs.

Migraine Market

Migraine is a recurrent neurovascular disorder characterized by unilateral or bilateral throbbing moderate-to-severe headache, with attack duration usually ranging from 4 to 72 hours, often accompanied by autonomic symptoms such as nausea, vomiting, photophobia and phonophobia. About 30% of patients experience aura manifestations, such as visual flashes, limb numbness, or speech disturbances, before the headache attack. The pathogenesis involves abnormal functioning of the trigeminal vascular system, accompanied by diffuse inhibition of the cerebral cortex and neuroinflammatory responses, and is often triggered by a variety of factors such as stress, sleep deprivation, and hormonal fluctuations. Clinical diagnosis is based on the patient’s medical history and symptoms, combined with the criteria set by the International Headache Society (ICHD-3), and the exclusion of organic brain lesions through imaging tests. Migraine headache is most common in young adult females, with significant genetic susceptibility and gender differences, and the frequency and severity of its attacks can change over time, and some patients may develop chronic migraine headache, which manifests itself as headache for more than 15 days per month. The disease has a significant impact on the quality of life and social functioning of patients and is one of the leading causes of disability worldwide.

Major Treatment Methods

Migraine treatment primarily focuses on rapid relief of acute attacks and preventive therapy for patients with frequent or severe episodes. Acute management typically involves NSAIDs and triptans, emphasizing early intervention and avoidance of medication overuse. Preventive strategies include traditional medications such as beta-blockers, antidepressants, and antiepileptics, as well as newer CGRP-targeted therapies aimed at reducing attack frequency and severity. Special populations, including pregnant women and children, require tailored treatment plans prioritizing safety. Overall, effective migraine management relies on individualized approaches to improve patient outcomes and quality of life. The prevalence rate of migraine is 9.4%, the diagnostic rate for migraine is 52.9%.

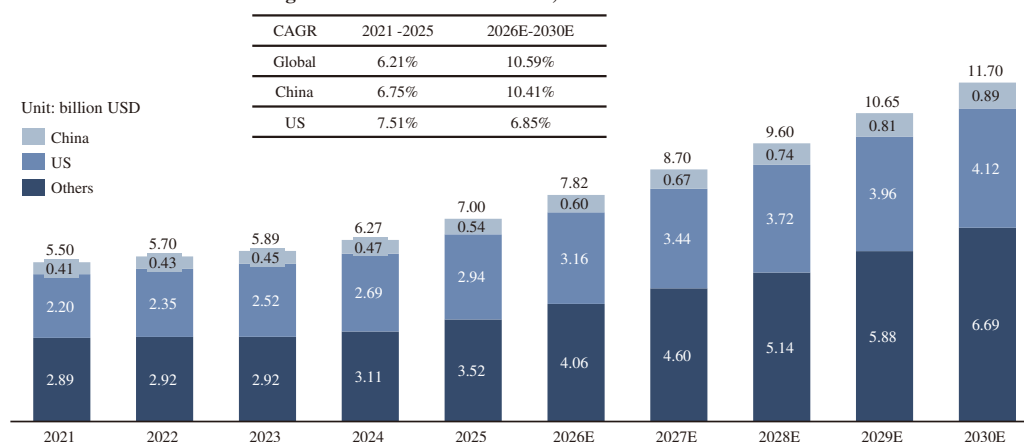
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Global Market

The number of migraine headache patients in China is projected to grow significantly from 118.66 million in 2021 to 146.43 million by 2030. The CAGR is estimated at 2.54% from 2021 to 2025 and 1.67% from 2026 to 2030. The number of migraine patients in the United States is projected to steadily increase from 43.41 million (2021) to approximately 56.26 million by 2030, reflecting persistent growth in disease prevalence. Globally, the number of migraine patients is projected to rise steadily from 1.16 billion in 2021 to approximately 1.43 billion by 2030.

China’s migraine medicine market is growing rapidly, expanding from USD 0.41 billion in 2021 to a projected USD 0.89 billion by 2032. This reflects a compound annual growth rate (CAGR) of 6.75% from 2021 to 2025 and an accelerated 10.41% from 2026 to 2030. The U.S. migraine treatment market is projected to expand significantly, rising from USD 2.20 billion in 2021 to over USD 4.12 billion by 2030. The global migraine treatment market is expected to expand strongly, growing from USD 5.50 billion in 2021 to over USD 11.70 billion by 2030.

Global Migraine Headache Market Size, 2021–2032E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Notes: The market size estimation of migraine therapy in China is based on the following assumptions: (i) migraine market size = non-specific drug treatment migraine market size + specific drug treatment migraine market size + other drug treatment migraine market size. By 2026, the number of migraine patients receiving medication treatment in China is expected to be 137.06 million, and by 2030, it is projected to reach 146.43 million. (ii) Price assumptions are anchored to the list prices of drugs already on the market for this indication. (iii) For China, the expected visit rate for migraine patients is 7%–12%, migraine prevalence is 8%–11%, patient compliance is 39%–48%, non-specific drug average treatment, specific drug average treatment, and other drug average treatment are roughly priced at 70 USD, 362 USD, 241 USD, the future price trend is consistent with the industry trend. (iv) Proportion of non-specific drug therapy, specific drug therapy, and other drug therapy are around 72%–62%, 23%–33% and 5% respectively. (v) Academic promotion and patient-education initiatives are intensifying. (vi) Academic promotion and patient-education initiatives are intensifying. (vi) There is a significant unmet clinical need, with the synchronous growth of treatment volume, the market for migraine therapy will significantly expand. Therefore, by 2026, the estimated migraine’s drug market in China is USD0.60 billion, and it is expected to reach USD0.89 billion by 2030.

Migraine Nasal Spray Clinical Pipeline

Currently, four nasal spray formulations for migraine treatment have been approved for market release: Pfizer’s Zavzpret, GSK’s Imitrex nasal spray, Bausch Health’s Migranal nasal spray, and Upsher-Smith’s Tosymra. However, there is still room for improvement in its overall clinical efficacy. The majority of clinical pipelines for migraine nasal sprays under development focus on CGRP receptor antagonist nasal sprays.

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Migraine nasal spray pipeline

Drug	Applicant	Locations	Indication	Phase	Status	Latest date	Clinical No.	Registration Authority
Zavzpret nasal spray	Pfizer	U.S.	Migraine Headache	Approved	/	/	/	FDA
Imitrex nasal spray	GSK	U.S.	Migraine Headache	Approved	/	/	/	FDA
Migranal nasal spray	Bausch Health Companies Inc.	U.S.	Migraine Headache	Approved	/	/	/	FDA
Tosymra	Upsher-Smith Laboratories, LLC	U.S.	Migraine Headache	Approved	/	/	/	FDA
STS101	Satsuma Pharmaceuticals, Inc.	U.S.	Migraine Headache	Approved	/	/	/	FDA
Zomig Nasal Spray	Impax Laboratories, LLC	U.S.	Migraine Headache (in adults and pediatric patients 12 years and older)	Approved	/	/	/	FDA
INP104	Impel NeuroPharma	Australia	Migraine Headache	Approved	/	/	/	FDA
Zomig Nasal Spray	Impax Laboratories, LLC	U.S.	Migraine Headache (pediatric patients 6–11 years)	Phase 3	Completed	January 2021	NCT03275922	FDA
Nasal Carbon Dioxide	Capnia, Inc.	U.S.	Migraine Headache	Phase 2	Completed	August 2012	NCT00690716	FDA
Xionglong Pain-Relief Nasal Spray	Yikangtai Technology	China	Migraine Headache	Phase 2	Not yet recruiting	October 2014	CTR20140667	CDE
B244	AOBiome Therapeutics	U.S.	Migraine Headache	Phase 2	Completed	April 2018	NCT03488563	FDA
TNX-1900	Tonix Pharmaceuticals, Inc.	U.S.	Migraine Headache	Phase 2	Completed	February 2025	NCT05679908	FDA
PRT-064040	Sichuan Purity Pharmaceutical	China	Migraine Headache	Phase 2	Recruiting	December 2025	CTR20254825	CDE
Sumatriptan Nasal Spray	Optinose US Inc.	U.S.	Migraine Headache	Phase 1	Completed	February 2012	NCT01507610	FDA
PRT-064040 Nasal Spray	Sichuan Purity Pharmaceutical Technology Co., Ltd.	China	Migraine Headache	Phase 1	Recruiting	September 2025	NCT07016516	FDA
ASY202	Aspeya	U.S.	Migraine Headache	Phase 2	Completed	June 2026	NCT07646613	FDA

Challenges and Threats in the Global and China Migraine Market

The global migraine market faces a triple pressure of high costs limiting popularization, unmet needs from existing therapies, and intensifying competition

- **Treatment Costs and Burden:** Despite excellent efficacy of new drugs, their high costs deter many patients, limiting global popularization. This premium pricing strategy may also trigger intense healthcare reimbursement negotiations, affecting corporate profit models.
- **Limitations of Existing Therapies and Unmet Needs:** Although multiple drugs are available on the market, many patients remain dissatisfied with existing therapy efficacy, and drug resistance or side effects may occur. Insufficient treatment options raise expectations from patients and medical institutions for new therapies, intensifying competition.

The China market, meanwhile, confronts significant resistance to new drug promotion under multiple challenges of heavy patient burden, insufficient professional awareness, and substitute product impact.

- **High Costs and Patient Burden:** The high cost of novel drugs remains a major obstacle in China. Despite healthcare insurance policies, exorbitant prices limit their application in broader patient populations.
- **Insufficient Efficacy and Safety Awareness:** Some medical professionals lack adequate knowledge and understanding of new therapies, potentially leading to insufficient prescription volumes. Additionally, patient concerns about side effects may also impact actual drug utilization.

Drivers and Entry Barriers in the Global Migraine Market

Rising Prevalence and Population Aging: In recent years, the global prevalence of migraine has continued to rise, becoming a major neurological disease that seriously affects quality of life and productivity. According to the latest global burden of disease research, the number of migraine sufferers worldwide has significantly increased compared to the past. The number of female patients is significantly higher than that of men, and the incidence rate and growth rate of women are far higher than that of men. The aging population further amplifies this burden. Although the growth rate in high-income regions is slower, the global migraine prevalence and disability adjusted life years are still on the rise, especially in middle and high-income regions where the burden is significantly increasing. It is expected that by 2050, the number of migraine sufferers worldwide will continue to rise significantly, becoming a major global public health challenge. This trend will not only cause serious functional impairments, but also result in significant productivity losses, directly driving the sustained growth in

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demand for treatment solutions. Migraine and other headache disorders affect significant portions of the global population. Its high prevalence, particularly among women, makes it a major global public health issue. The condition not only causes substantial disability but also inflicts enormous productivity losses, directly driving demand growth for treatment solutions.

R&D Breakthroughs in Novel Treatment Options: Traditional treatment approaches face limitations in efficacy and side effect concerns. In recent years, The introduction of some new formulations and therapies represents a major paradigm shift in treatment, offering superior efficacy and better safety profiles, becoming the core engine of market growth. With the commercialization of these new therapies, the migraine treatment market is transitioning from traditional low- priced drugs to high-value biologics and innovative drugs, driving rapid growth in the industry.

New entrants to the global migraine market primarily face the following barriers:

High R&D and Clinical Validation Costs: Migraine treatment drugs, especially innovative drugs targeting the nervous system, feature long R&D cycles and high costs. Demonstrating safety and efficacy requires large-scale, long-term clinical trials, representing massive capital and time investment for small and medium-sized enterprises.

Complex Regulatory Approval: Approval standards for nervous system drugs are increasingly stringent, particularly for innovative drugs targeting novel targets. The complexity and uncertainty of approval processes may delay new drug market entry, increasing commercialization risks.

Drivers and Entry Barriers in the China Migraine Market

Massive Population Base and Demand Growth: As one of the most populous countries in the world, China’s huge population base provides the most solid demand foundation for the migraine market. At the same time, it is worth noting that with the improvement of economic level and the change of lifestyle, especially the increase of work pressure and smoking rate, this incidence rate shows a continuous upward trend. This huge patient base directly translates into a rapid expansion of market demand. China has one of the largest migraine patient populations globally. With rising economic levels and lifestyle changes (such as increased stress and smoking rates), migraine incidence continues to climb, driving rapid market expansion.

Technological Innovation and Treatment Option Upgrades: With the entry of global innovative drugs and acceleration of domestic R&D, the China market is beginning to adopt novel therapies. Additionally, the penetration rate of digital treatment methods (such as mobile applications) is rising in China, providing patients with more convenient management approaches.

New entrants to the China migraine market primarily face the following barriers:

Policy Regulations and Approval Processes: Although China is accelerating drug approvals, approval for nervous system drugs (especially innovative drugs) remains challenging. Complex clinical trial requirements and stringent safety assessments constitute access barriers.

Competition and Market Concentration: The China market is exceptionally competitive, facing pressure from multiple domestic and international pharmaceutical giants. The market is undergoing transformation from “head-to-head confrontation” to “market fragmentation,” requiring companies to continuously innovate to maintain market share.

Future Trend

In the future, the migraine treatment market will exhibit multidimensional development trends: First, acute attack management will evolve toward rapid onset, non-invasive, and high-compliance approaches. Novel delivery methods such as nasal sprays and buccal absorption formulations are gaining attention for their ability to provide swift symptom relief and enhance patient adherence, while also catering to populations unable to take oral medications or experiencing sudden symptom onset. Second, long-term preventive treatment will emphasize personalized combination therapies and comprehensive intervention strategies to enhance treatment stability and quality of life.

INDUSTRY OVERVIEW

Novel Drug Delivery Technologies Drive Market Innovation	Increased trend towards combination of treatment options	Rapid Growth of Regional Migraine Treatment Market Differentiation
Acute medication for migraine requires high speed of onset of action, and traditional oral formulations carry the risk of slow onset of action and gastrointestinal side effects. New delivery methods such as nasal sprays, sublingual agents and microneedle patches are becoming the focus of market attention due to their rapid absorption and non-invasive advantages. In the future, these innovative delivery systems will significantly improve patients' medication experience and compliance, leading to growth in the acute care market.	In order to enhance therapeutic efficacy and minimize side effects, migraine management tends to favor multidrug combinations and cross-class combinations. The rational combination of acute and preventive drugs, as well as the combined application of auxiliary antiemetic and analgesic drugs, has become the clinical norm. This combination strategy not only optimizes efficacy, but also meets the diverse needs of patients at different stages of the disease and promotes the diversification of the therapeutic market.	In the future, emerging markets such as Asia Pacific and Latin America will see a rapid increase in demand for migraine treatment due to improved diagnostics and healthcare coverage, especially for cost-effective acute and preventive medications. Mature markets in Europe and the United States will focus more on innovative therapies and treatment optimization. Regional differences will drive companies to adjust their strategies to realize market diversification.

Antiemetic Market

Vomiting is a complex physiologic process in which gastric contents reflux through the esophagus into the oral cavity and are forcibly expelled, which is regulated by the central nervous system and is often triggered by a variety of internal and external factors. According to the different triggers and neural pathways, vomiting can be divided into reflex vomiting, central vomiting and vestibular vomiting of internal and external factors. There are significant differences in the clinical presentation and management of different types of vomiting, and a clear categorization will help in accurate diagnosis and treatment.

Major Treatment Methods

Drugs currently in clinical use to prevent vomiting include dopamine receptor antagonists, 5-hydroxytryptamine receptor antagonists (5-HT₃RA), and neurokinin-1 receptor antagonists (NK-1RA). Each of the marketed antiemetic prophylactic drugs primarily blocks a particular type of receptor, and no common pathway has been identified that triggers the emetic response; therefore, no single drug has been able to achieve complete blockade of the different types of nausea and vomiting.

5-HT ₃ receptor antagonist	<ul style="list-style-type: none"> Antiemetic effect by blocking the binding of 5-HT₃ receptors to 5-HT₃ in the vagus nerve and emetic chemoreceptor area
NK-1 receptor antagonists	<ul style="list-style-type: none"> NK-1 receptor antagonists exert antiemetic effects by competitively inhibiting the binding of NK-1 receptors to substance P. They are mainly used to prevent delayed nausea and vomiting.
Glucocorticosteroid	<ul style="list-style-type: none"> Prevention of nausea and vomiting by interaction with 5-HT₃, NK-1 and NK-2 receptor proteins, or direct action on the nucleus tractus solitarius in the medulla oblongata
Atypical antipsychotics	<ul style="list-style-type: none"> It mainly includes olanzapine and mirtazapine, which can antagonize a variety of receptors such as 5-HT₃, 5-HT₂, dopamine, histamine, acetylcholine, etc., and is effective in the prevention of acute and delayed nausea and vomiting
Others	<ul style="list-style-type: none"> These include dopamine receptor blockers, benzodiazepines, phenothiazines, and butyrophenazines. All of these drugs are of low antiemetic potency and are not recommended for prophylactic antiemetic use in moderate-to-high emetic risk regimens.

Antiemetic Nasal Spray Clinical Pipeline

Nasal spray formulations have gained increasing attention as a novel delivery method for antiemetic drugs in global clinical development in recent years. Their core advantages lie in their rapid onset of action and ability to avoid gastrointestinal burden, making them particularly suitable for patients experiencing acute vomiting due to chemotherapy, postoperative recovery, or other causes — especially when oral administration is difficult or intravenous access is limited. Early and mid-stage clinical trials of 5-HT₃ receptor antagonist nasal sprays have been completed, demonstrating favorable safety and efficacy profiles. These formulations are expected to complement traditional oral or injectable dosage forms, thereby enhancing the convenience and compliance of antiemetic therapy.

INDUSTRY OVERVIEW

Drug	Applicant	Locations	Indication	Phase	Status	Initial date	Clinical No.	Registration Authority
Metoclopramide Nasal Spray	Evoke Pharma	United States	vomiting	Approval	Completed	June 2020	NCT02025725	FDA
Granisetron Hydrochloride Nasal Spray	Maxinase Life Sciences Ltd.	Taiwan	vomiting	Phase 1	Completed	January 2016	NCT02563951	FDA

Challenges and Threats in the Global and China Antiemetic Market

The global antiemetic market faces a triple challenge of adverse effects risks from new drugs, price competition from generics, and low compliance rates with clinical guidelines.

- **Safety and Side Effect Concerns:** Although new drugs demonstrate better efficacy, potential side effects (such as headache and constipation) remain, particularly for elderly patients where drug safety and interactions are key concerns.
- **Competition and Pricing Pressure:** As novel therapies mature, market competition intensifies. Entry of generic drugs leads to price declines, creating revenue pressure for innovative pharmaceutical companies.
- **Poor Guideline Adherence:** In actual clinical practice, execution rates for guideline-recommended standardized antiemetic regimens (especially prophylactic use before chemotherapy) are not high, resulting in unrealized market demand potential.

Meanwhile, the Chinese market is experiencing significant constraints on corporate profit margins and market expansion due to multiple pressures including cost pressures, medical insurance cost control, insufficient guideline adherence, and intensifying homogenized competition.

- **Cost and Pricing Pressure:** Antiemetic production costs are relatively high, facing substantial price pressure from healthcare insurance negotiations, squeezing profit margins.
- **Low Guideline Execution Rates:** Despite guideline recommendations for antiemetic regimens, actual clinical practice — particularly among chemotherapy patients — shows suboptimal execution rates for standardized antiemetic preventive measures, potentially leading to actual drug utilization below expectations.

Intensifying Competition: As an increasing number of pharmaceutical companies enter this field, market competition is becoming increasingly fierce. Competition between new drugs and existing products regarding efficacy and safety, as well as price competition with generic drugs, are challenges facing enterprises.

Drivers and Entry Barriers in the Global Antiemetic Market

Aging Population and Increased Surgical/Chemotherapy Demand: The rising proportion of elderly population globally has increased demand for antiemetic drugs due to gastrointestinal diseases, surgery, and chemotherapy-induced nausea and vomiting (CINV). Antiemetic usage has significantly increased before and after surgery and during chemotherapy. It is worth noting that the application scenarios of antiemetic drugs are becoming increasingly diversified. In addition to traditional chemotherapy and postoperative needs, migraine and pregnancy related nausea and vomiting are also becoming important emerging areas driving market growth.

Technological Innovation and Delivery System Upgrades: The rise of digital therapeutics — including mobile application platforms, wearable devices, and cloud-based patient monitoring systems — provides personalized, remote solutions for migraine management. This not only enhances patient medication compliance but also offers big data support for healthcare systems, driving expansion of related technology markets.

New entrants to the global antiemetic market primarily face the following barriers:

High R&D and Compliance Costs: Antiemetics belong to CNS drug categories, featuring long R&D cycles and requiring rigorous safety and efficacy validation. Clinical trials targeting chemotherapy patients in particular require massive investment.

Regulatory Approval and Patent Landscape: Antiemetics belong to CNS drug categories, featuring long R&D cycles and requiring rigorous safety and efficacy validation. Clinical trials targeting chemotherapy patients in particular require massive investment.

INDUSTRY OVERVIEW

Drivers and Entry Barriers in the China Antiemetic Market

Popularization of Surgery and Chemotherapy: As surgical procedure volumes and chemotherapy populations increase, antiemetics are gradually being incorporated into guidelines and promoted in cancer hospitals in China, significantly expanding market space.

Technology and Formulation Innovation: Chinese companies are accelerating layout in innovative drugs and novel delivery technologies (such as oral formulation optimization), attempting to break through limitations of traditional single formulations.

New entrants to the China antiemetic market primarily face the following barriers:

Regulatory and Approval Difficulty: Domestic drug approval processes are strict, with new drugs (especially innovative drugs) requiring lengthy clinical validation and registration procedures. Furthermore, regulatory authorities’ requirements for safety and efficacy are increasingly stringent.

Pricing and Reimbursement Pressure: China’s healthcare insurance negotiation pricing pressure strategies impose significant price pressure on antiemetics, particularly for high-cost novel drugs where new entrants struggle to compete with generic drugs on price.

Future Trend

1. **Formulation Innovation** — In the future, antiemetic therapy will focus on multi-target interventions, innovations in non-oral formulations (such as nasal spray formulations), and the integration of personalized and digital management to enhance treatment efficiency, adapt to various clinical scenarios, and facilitate a shift from symptom relief to precise prevention.
2. **Mechanistic Precision and Target Diversification** — As understanding of vomiting neural pathways and neurotransmitter networks deepens, the industry is gradually shifting from traditional single-target interventions to new strategies involving multi-target combined actions. Future drug development will place greater emphasis on emerging targets while integrating central and peripheral mechanisms to improve efficacy through synergistic blockade of multiple pathways. This trend not only enhances the ability to manage complex or refractory vomiting but also enables personalized medication for different etiologies, driving antiemetic therapy toward greater precision and efficiency.
3. **Delivery Innovations Expanding Clinical Applicability** — Traditional oral formulations face limitations such as slow onset and unstable absorption in scenarios like postoperative recovery, chemotherapy, or acute severe vomiting. Consequently, the industry is accelerating innovation in non-oral dosage forms, particularly the development of nasal spray formulations. Due to their rapid onset, convenience, and avoidance of gastrointestinal interference, nasal sprays are expected to improve patient compliance and provide immediate symptom relief, making them especially suitable for clinical situations where oral administration is impractical or rapid intervention is required.

CHINA CRO SERVICES MARKET

Overview

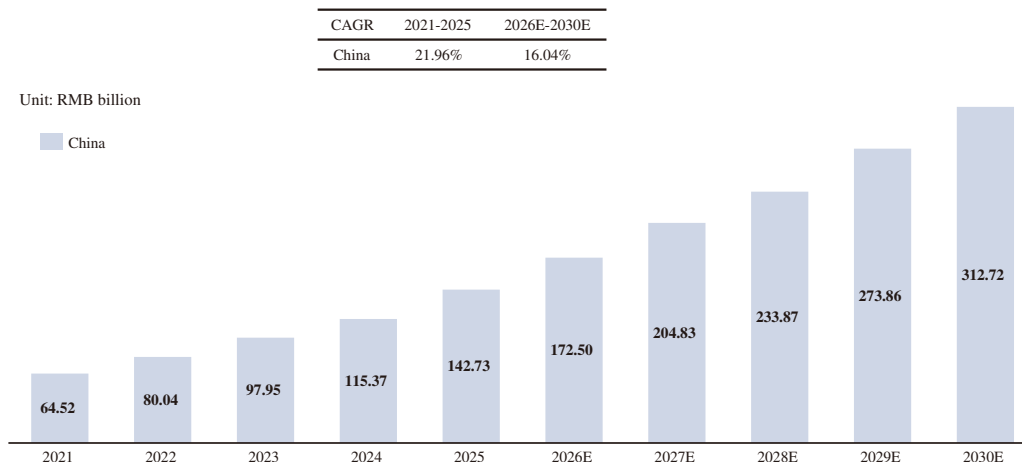
A CRO (Contract Research Organization) is a specialized institution that provides comprehensive outsourcing services for the entire drug R&D process to pharmaceutical companies, biotechnology firms, and medical device companies. Its core value lies in helping clients reduce R&D costs, shorten cycles, improve success rates, and enhance R&D efficiency through specialized division of labor.

China Market

From 2021 to 2030, China’s CRO market is expected to grow significantly from RMB64.52 billion to RMB312.72 billion. Growth will remain strong, with a CAGR of 21.96% during 2021–2025, moderating to 16.04% in 2026E–2030E. This expansion reflects increasing outsourcing demand across drug discovery, preclinical, and clinical development, underscoring CROs’ critical role in supporting pharmaceutical innovation.

INDUSTRY OVERVIEW

The Scale of China CRO Market, 2021-2030E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Notes: The estimation of the size of the Chinese CRO market is based on the following assumptions: (i) the size of the Chinese CRO market = the size of the drug discovery market+the size of the preclinical market+the size of the clinical stage market. By 2025, the estimated market size for drug discovery, preclinical market, and clinical stage market in China is RMB37.1 billion, RMB32.9 billion, and RMB68.6 billion, respectively. In 2032, the estimated market size for drug discovery, preclinical market size, and clinical stage market size in China are RMB106.8 billion, RMB74.8 billion, and RMB169.1 billion, respectively.(ii) With the synchronous growth of treatment, the CRO market will significantly expand. Therefore, by 2025, the estimated size of China's CRO market is RMB142.73 billion, and it is expected to reach RMB312.72 billion by 2030.

Challenges and Threats in China CRO Market

The China market, meanwhile, faces multiple pressures from price wars, service homogenization, and international trade policy uncertainty, making differentiated positioning and sustainable profitability the key to breaking through.

- **Market Saturation and Homogenized Competition:** As massive capital flows in, the number of CROs in the market has surged, resulting in prominent service homogenization issues. Companies need to seek differentiated services (such as rare diseases and specific therapeutic areas) to avoid being squeezed by price wars.
- **International Trade and Policy Uncertainty:** Geopolitical risks (such as trade friction) may affect multinational pharmaceutical companies' outsourcing decisions. Additionally, domestic drug pricing reforms and healthcare insurance negotiation pressures may also impact CRO project sources.

Drivers and Entry Barriers in the China CRO Market

Cost Advantages and Capital Operations: The Asian region (especially China) offers significant cost advantages, making global pharmaceutical companies inclined to outsource R&D to China to reduce overall R&D costs. Meanwhile, with capital market support, Chinese CROs continue increasing investment in infrastructure and technology platforms °

Rise of Precision Medicine and Innovative Drugs: The Chinese government strongly supports precision medicine and biopharmaceutical innovation, creating urgent demand for high-quality R&D services. As more innovative drugs enter clinical trial stages, demand for Chinese CROs in early drug discovery and preclinical research has grown significantly.

New entrants to the China CRO market primarily face the following barriers:

Regulatory and Approval Difficulty: Although China's regulatory environment is optimizing, approval requirements for new drug R&D — especially biologics and gene therapies — remain strict. CROs need to establish sound quality management systems (QMS) to comply with GMP, GLP, and GCP standards.

Market Access and Channel Control: To stand out in competitive markets, advanced technology platforms (such as high-throughput screening and pharmacokinetic/pharmacodynamic models) are essential. This requires massive capital investment and long-term R&D accumulation.

INDUSTRY OVERVIEW

Future Trend

- **Penetration rates continue to rise, and service depth keeps expanding.** As pharmaceutical R&D activities grow increasingly complex and specialized, pharmaceutical companies are becoming more reliant on external professional services for cost control, R&D efficiency, and compliance management. CRO services have evolved from traditional single-function support to encompassing the entire process — from drug discovery and clinical research to regulatory submissions and post-marketing studies.
- **Service capabilities are evolving toward specialization, integration, and platformization.** Driven by R&D demands in biotechnology and complex formulations, the CRO industry is exhibiting pronounced trends toward specialized division of labor and capability upgrades. On one hand, specialized service capabilities — such as expertise in specific therapeutic areas, technological platforms, or methodologies — have become core competitive factors. On the other hand, CROs offering cross-phase, integrated service capabilities enhance project coordination efficiency and client retention. The industry as a whole is evolving toward becoming “platform-based, comprehensive service providers.”

GLOBAL AND CHINA MAH MARKET

Overview

The Marketing Authorization Holder (MAH) system is a revolutionary innovation in pharmaceutical regulation. Its core lies in the separation of “marketing authorization” and “production authorization.” The fundamental features of this system include:

- **Diversification of Eligible Entities:** Drug R&D institutions, research institutes, innovative enterprises, and even individuals can become Marketing Authorization Holders.
- **Restructured Rights and Responsibilities System:** Holders bear primary responsibility for drug quality throughout the entire lifecycle, covering R&D, production, distribution, and post-market studies.
- **Optimized Resource Allocation:** Specialized collaboration enables efficient integration of R&D, production, and sales.

Challenges and Threats in the Global and China MAH Market

The global MAH market is facing frequent regulatory policy changes, data security and compliance risks, as well as supply chain fluctuations caused by geopolitical factors.

- **Data Security and Compliance Risks:** MAHs need to manage massive volumes of clinical trial data, production records, and adverse reaction reports. Data breaches or non-compliant use will result in hefty fines and reputational damage, constituting significant business risks.
- **Geopolitics and Supply Chain Volatility:** Global trade friction (such as U.S.-China relations) may lead to instability in critical raw material supply, affecting MAH production schedules. Additionally, international sanction risks may prevent MAHs from conducting cross-border business.

At the same time, the Chinese MAH market is dealing with uncertainties in the implementation details of the system, impacts on international trade due to geopolitical influences, and profit compression caused by intensified industry competition.

- **Policy Detail and Implementation Uncertainty:** Although the MAH system has been implemented for years, details at the execution level still await further interpretation. For example, variations in regulatory enforcement intensity across different provinces create difficulties for enterprises when applying for production licenses.
- **International Trade and Geopolitical Risks:** As geopolitical factors such as U.S.-China relations fluctuate, Chinese MAH enterprises face potential market access barriers and trade policy risks in international business. Furthermore, trust in the safety and regulatory system of Chinese pharmaceuticals in international markets still needs strengthening.
- **Intensifying Industry Competition and Profit Compression:** As an increasing number of enterprises enter the MAH market, industry competition intensifies. Large multinational pharmaceutical companies may directly establish internal MAH departments to capture market share, potentially leading to declining market concentration and squeezed profit margins.

INDUSTRY OVERVIEW

Drivers and Entry Barriers in the Global MAH Market

Unified Global Regulatory Compliance Requirements: As international pharmaceutical regulation gradually converges, many countries (such as the EU, U.S., and Japan) require designation of an MAH for local market authorization. This system ensures full lifecycle safety management of drugs, driving demand growth for MAH services, particularly for multinational pharmaceutical companies.

Strengthened Post-Marketing Surveillance: Globally, post-marketing drug safety monitoring (Pharmacovigilance) and manufacturing process oversight are becoming increasingly stringent. Regulatory agencies in various countries are promoting the establishment of a “full lifecycle safety database”, requiring MAHs to have real-time collection, rapid response, and accurate evaluation of drug vigilance capabilities, and compressing adverse reaction reporting time limits to shorter windows. As the legally responsible party, MAHs must possess robust pharmacovigilance capabilities and traceability systems, promoting professionalization of MAH services and market demand.

New entrants to the global MAH market primarily face the following barriers:

High Compliance and Qualification Costs: Becoming an MAH requires strict GMP/GLP/GCP certifications, pharmacovigilance (PV) systems, and comprehensive quality management systems. Establishing these systems requires massive capital investment and long-term operational costs.

Complex Global Regulatory Barriers: Drug regulations vary significantly across countries (such as EU Directive 2001/83/EC and U.S. FDCA). New entrants often lack experience and resources to navigate multi-country complex regulations, making it difficult to establish global compliance networks in the short term.

Drivers and Entry Barriers in the China MAH Market

Full Policy Implementation and Maturation: With full implementation of the MAH system, the policy environment is becoming increasingly mature. Coupled with institutionalization of “drug registration holder changes,” enterprise awareness and acceptance of the MAH system have significantly improved, rapidly unleashing market demand.

Innovative and Patented Drug Promotion: As the number of innovative drugs launched in China increases, demand for professional MAH services grows among enterprises to ensure compliance in drug registration and post-marketing supervision.

New entrants to the China MAH market primarily face the following barriers:

High Regulatory Compliance Costs: Domestic drug regulation is becoming increasingly strict; MAH enterprises must invest substantial funds to build facilities compliant with GMP, GSP, and GDP standards and establish efficient pharmacovigilance systems. Compliance costs are the main obstacle facing new entrants.

Technology Barriers and Professional Talent Scarcity: MAH business involves high technical thresholds such as biologics and cell therapy. Particularly for high-risk products like antibody-drug conjugates, compliance pathways for segmented and multi-site production are not yet fully clarified domestically, making it difficult for enterprises to rapidly follow up.

Future Trend

- **Market expansion driven by policies.** The deepening of the MAH system has streamlined drug registration and approval processes, lowered barriers to entry for R&D and production, and incentivized enterprises and research institutions to develop novel drugs and technologies. These reforms are fostering a more open innovation ecosystem, driving domestic pharmaceutical companies to actively build innovative pipelines.
- **International Standards Promote Global Competitiveness.** The MAH system is progressively aligning with international drug registration standards, enabling Chinese innovative drugs to meet global regulations while facilitating easier export. This regulatory optimization not only enhances corporate compliance capabilities but also strengthens the competitiveness of domestic innovative drugs in the global market.
- **A Diverse Innovation Ecosystem Takes Shape.** The MAH system encourages research institutions, startups, and individual developers to participate in drug innovation, promoting a diverse range of innovation entities. In the future, policy support, capital investment, and technological accumulation will collectively drive the rapid development of China’s innovative drug market, fostering sustained innovation momentum and creating opportunities for industrial upgrading.

INDUSTRY OVERVIEW

SOURCE OF INFORMATION

We engaged Frost & Sullivan to conduct an analysis and prepare a report on the major markets relevant to our pipeline products. We agreed to pay Frost & Sullivan a total fee of approximately RMB0.49 million. All data and projections presented in this section are derived from the Frost & Sullivan Report. Frost & Sullivan, established in 1961 and based in the United States, is an independent global market research and consulting firm. Their services include market assessments, competitive benchmarking, and strategic market planning across various industries.

The Frost & Sullivan Report was based on the following assumptions: (i) the overall social, economic, and political environment, both globally and in China, is expected to remain stable throughout the forecast period; (ii) the economic and industrial growth globally and in China is anticipated to continue its steady upward trajectory over the next decade; (iii) key industry drivers will likely sustain market growth during the forecast period; and (iv) there will be no extreme force majeure events or regulatory changes that could significantly disrupt the market.

In preparing the Frost & Sullivan Report, the firm employed a range of methodologies to gather and validate data: (i) secondary research, which involved reviewing published sources such as national statistics, annual reports of listed companies, industry reports, and data from Frost & Sullivan’s proprietary research database; and (ii) primary research, which included detailed interviews with industry participants.

Frost & Sullivan’s projections are based on various market determinants and the weight assigned to each, indicating their relative importance. These determinants combine both subjective assumptions and objective factors, which means that the projected data may differ from actual outcomes.