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## INDUSTRY OVERVIEW

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### GLOBAL AND CHINA NEW DRUGS WITH ADVANCED FORMULATIONS MARKET

#### Overview

New drugs with advanced formulations 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).

New drugs with advanced formulations 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:

1. **Treatment of Neurological Diseases:** Nasal 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.
2. **Chronic Disease Management:** Microneedle patches offer a painless and user-friendly option for daily chronic care, making them especially suitable for elderly and pediatric populations.
3. **Large-molecule Drug Delivery:** New drugs with advanced formulations are enabling broader clinical applications beyond traditional injections. Innovations such as transdermal or intranasal systems are being developed to overcome challenges of poor

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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.



Treatment of neurological disorders

- 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.



Chronic disease management

- 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.



Large-molecular drug delivery

- New drugs with advanced formulations 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.

### Category

New drugs with advanced formulations generally refer to drugs that feature complex formulations, complex delivery routes, or complex dosage forms, as well as drug-device combination products. The following categories can be defined as advanced formulations:

- (1) Transdermal drug formulations: They are characterized by complex delivery routes.
- (2) Dissolving microneedle patches: They feature complex delivery routes, complex dosage forms, and uncertainties in the regulatory review pathways.
- (3) Nasal inhalation formulations: They possess complex delivery routes, complex dosage forms, and potential drug-device combinations.
- (4) Nanomedicines (e.g., liposomes, nanoparticles): They exhibit complex formulations, complex delivery routes, and complex dosage forms.

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### R&D Hotspots

The core value of new drugs with advanced formulations 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. Current R&D focuses include transdermal delivery systems, nasal spray/inhalation formulations, sustained-/controlled-release formulations, and nano-formulations. Among these, transdermal formulations (e.g., patches, microneedles, iontophoresis) enable painless and efficient drug delivery through the skin, significantly improving patient compliance; nasal spray/inhalation formulations leverage the nasal cavity’s rich vasculature and neural pathways to achieve rapid absorption and “nose-to-brain” targeted delivery, effectively bypassing the blood-brain barrier; sustained-/controlled-release or long-acting formulations use advanced materials and encapsulation technologies to precisely control drug release, maintain stable plasma concentrations, reduce dosing frequency, and enhance safety; and nano-formulations utilize nanoscale carriers (such as liposomes, nanoparticles, and micelles) to improve solubility and stability of poorly soluble drugs, enable targeted delivery, reduce systemic toxicity, and enhance therapeutic efficacy — positioning them as a key platform technology for precision medicine.

### Industrial Chain Analysis of New Drugs with Advanced Formulations Market

China’s new drugs with advanced formulations industry feature a comprehensive value chain, with pharmaceutical companies and research institutions at its core, focusing on formulation innovation and clinical translation across key technologies such as transdermal drug formulations (e.g., microneedle formulations), nasal inhalation formulations, sustained-/controlled-release formulations, and nanomedicines.

Upstream participants include suppliers of high-purity APIs, functional excipients, specialized equipment, and CROs providing critical raw materials and technical support.

Midstream players are pharmaceutical enterprises with strong R&D and patent capabilities driving large-scale production and commercialization.

The downstream segment spans hospitals, pharmacies, distributors, healthcare insurance systems, and end patients, together forming a complete ecosystem that supports both the clinical value realization and commercial growth of new drugs with advanced formulations.

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### **Advantages of New Drugs with Advanced Formulations**

With the rise of precision medicine and patient-centric care, innovative drug products with advanced formulations are transforming drug development. Advanced 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 advanced formulations are reshaping the pharmaceutical value chain.

### **Drivers and Entry Barrier in New Drugs with Advanced Formulations Market**

The development of new drugs with advanced formulations 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 painless 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.

Overall, new drugs with advanced formulations 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.

New drugs with advanced formulations 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.

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### Future Trend in New Drugs with Advanced Formulations 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 new drugs with advanced formulations 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 new drugs with advanced formulations is evolving from macroscopic controlled release to microscopic precision delivery, with microneedles and nasal sprays being prime examples. Microneedle formulations create a painless 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.

#### 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 painless delivery solutions (e.g.,

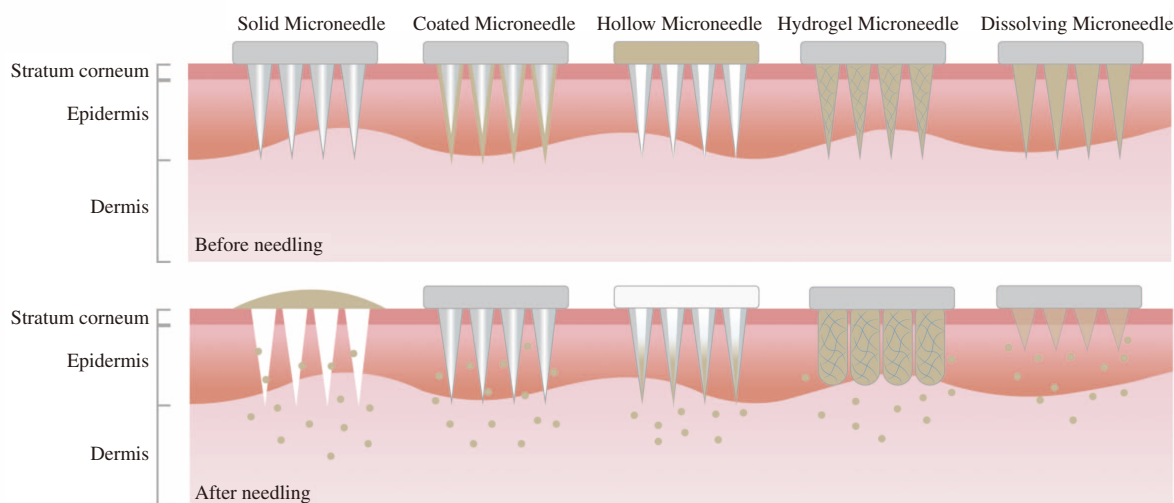
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microneedles) for biologics (e.g., proteins, nucleic acid drugs) to enhance patient compliance; 3) Enabling personalized dosing through flexible dosage form design. Ultimately, new drugs with advanced formulations will transcend their role as mere “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 new drugs with advanced formulations.



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### Drivers and entry barriers

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:** 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.
- **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.

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.
- **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.

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### 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.

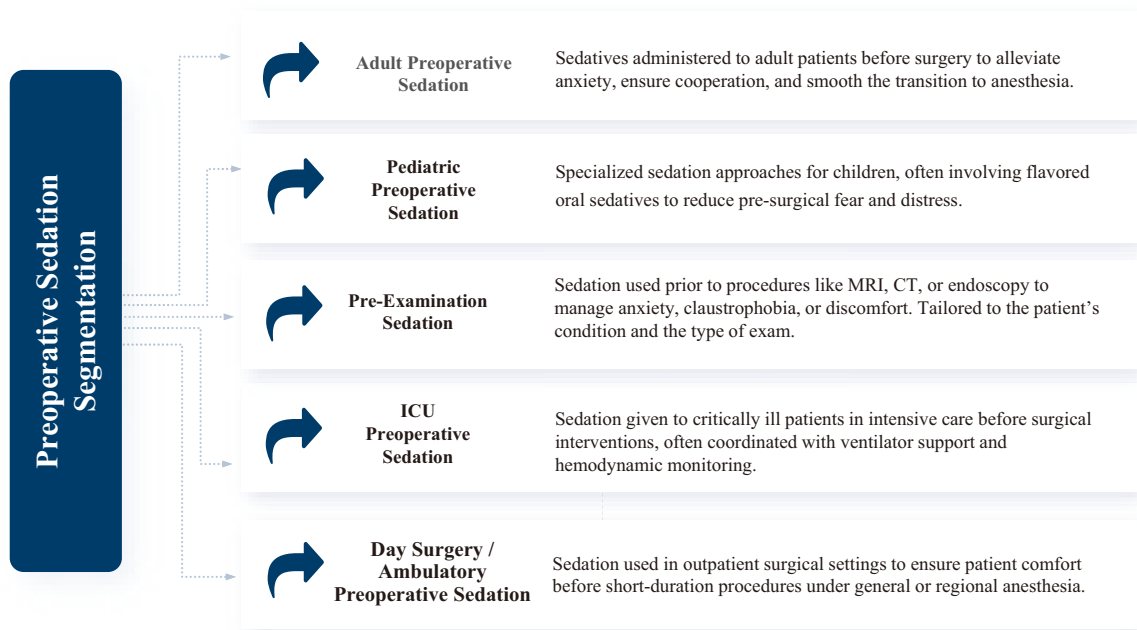
1. **Achieving iterative development in the treatment approach for traditional transdermal formulations:** Traditional transdermal formulations (such as patches and gels) are constrained by the barrier function of the skin’s stratum corneum, limiting their delivery to small-molecule drugs. They exhibit 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.

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### Preoperative Sedation Market

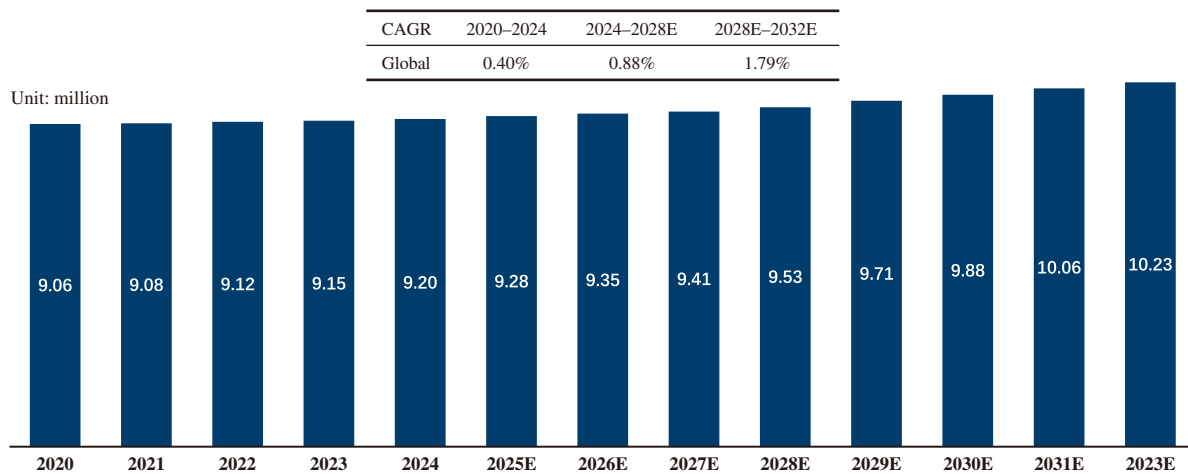


#### China Market

The scale of pediatric sedation patients in China is expected to increase from 9.06 million in 2020 to 10.23 million by 2032. The compound annual growth rate (CAGR) increase from 0.40% (2020–2024) to 1.79% (2028–2032). 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.

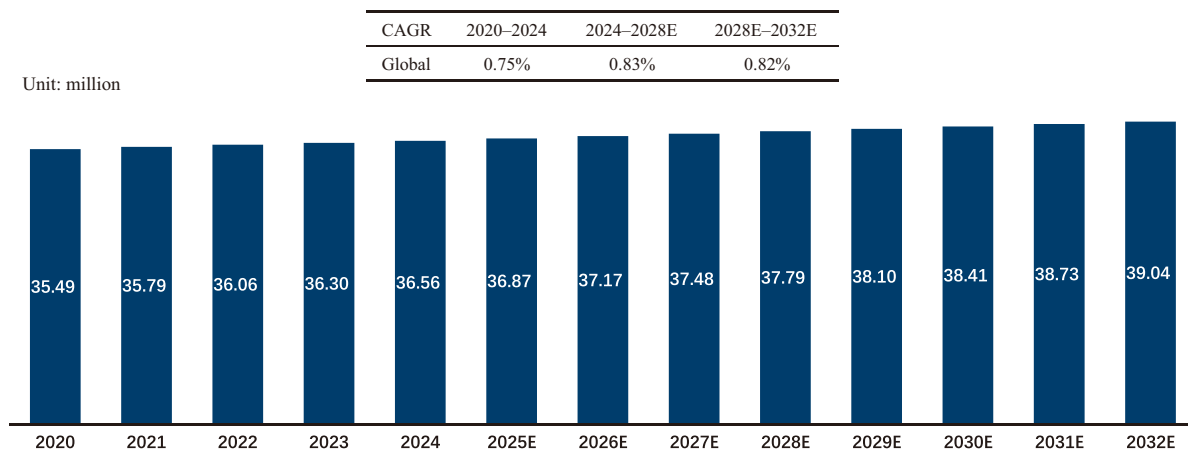
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**The Scale of Pediatric Sedation Patients in China, 2020–2032E**



From 2020 to 2032, the number of adult sedation patients in China is projected to grow from 35.49 million to 39.04 million, reflecting a modest yet steady increase. The compound annual growth rate (CAGR) is expected to slightly rise over time — from 0.75% during 2020–2024 to 0.82% in 2028–2032 — 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.

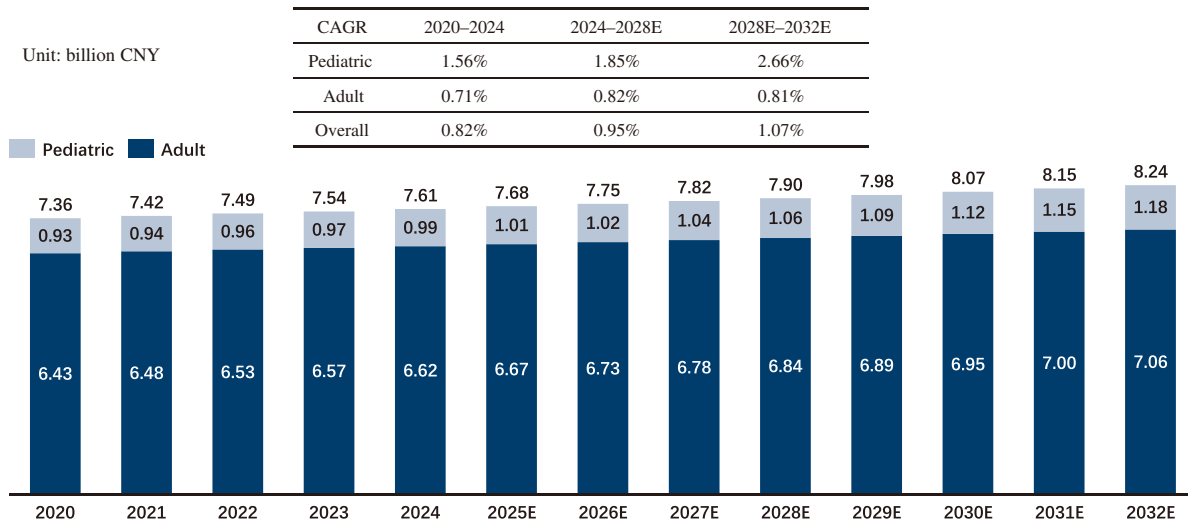
**The Scale of Adult Sedation Patients in China, 2020–2032E**



China’s preoperative sedation market is undergoing steady expansion. In 2020, the overall market size reached approximately RMB7.36 billion, with adult sedation drugs accounting for RMB6.43 billion and pediatric sedation drugs amounting to approximately RMB0.93 billion. Benefiting from rising surgical volumes, increased demand for comfort-oriented medical care, and expanded indications for sedation, the market is projected to exceed RMB7.6 billion by 2024,

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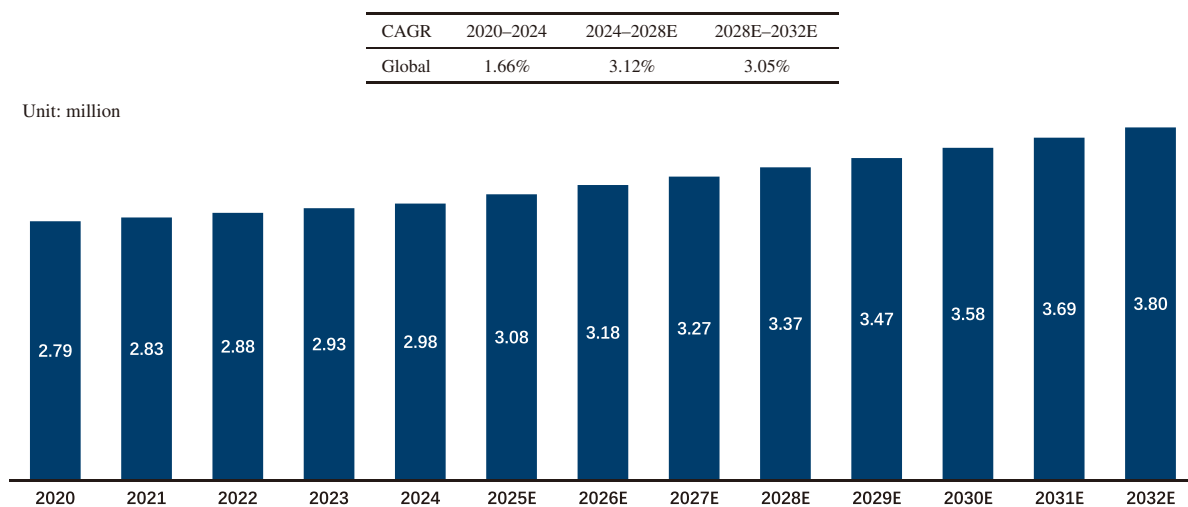
reach RMB7.90 billion by 2028, and grow to approximately RMB8.24 billion by 2032, with a compound annual growth rate (CAGR) of about 1.07% from 2028 to 2032. The pediatric sedation segment is growing significantly faster than the adult segment, with a projected CAGR of 2.66% from 2028 to 2032E, becoming the core driver of overall market expansion.



### U.S. Market

The scale of pediatric sedation patients in the U.S. is projected to increase slightly from 2.79 million in 2020 to 3.80 million by 2032. With a CAGR of 1.66% to 3.12%, then to 3.05% across all periods, the market demonstrates a steady trend.

#### The Scale of Pediatric Sedation Patients in U.S., 2020–2032E



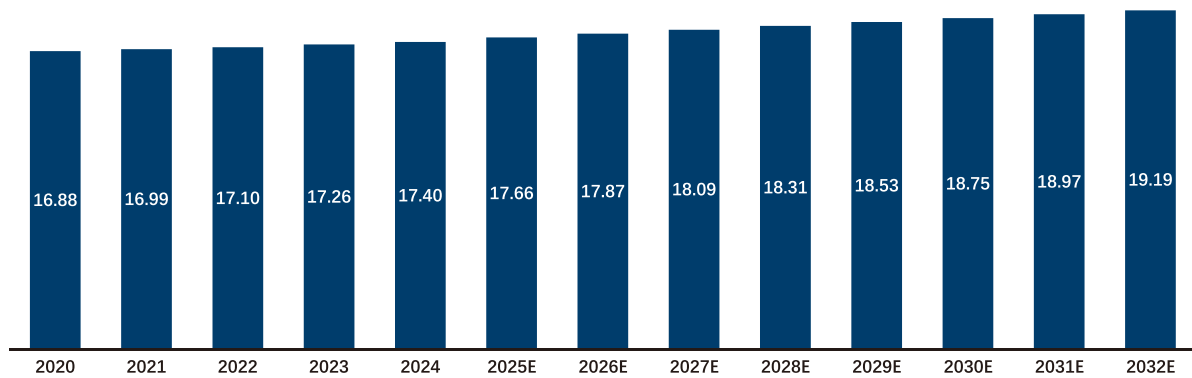
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The adult sedation patient population in the U.S. is projected to grow steadily from 16.88 million in 2020 to 19.19 million by 2032. Notably, the CAGR rises from 0.76% (2020–2024) to 1.28% (2024–2028E), before slightly easing to 1.18% (2028–2032E). This upward trajectory reflects the increasing demand for sedation in outpatient settings, aging population trends, and the growing adoption of sedation in diagnostic and therapeutic procedures.

**The Scale of Adult Sedation Patients in U.S., 2020–2032E**

CAGR	2020–2024	2024–2028E	2028E–2032E
Global	0.76%	1.28%	1.18%

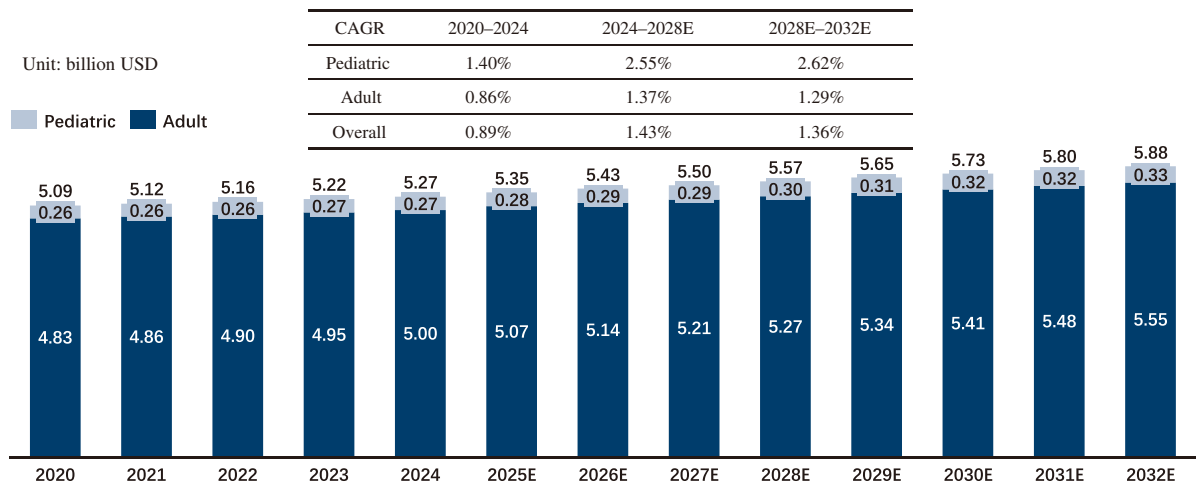
Unit: million



The U.S. sedation market is projected to grow from USD5.09 billion in 2020 to USD5.88 billion in 2032, with an accelerating compound annual growth rate (CAGR) from 0.89% during 2020–2024 to nearly 1.35% between 2024–2032. 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.

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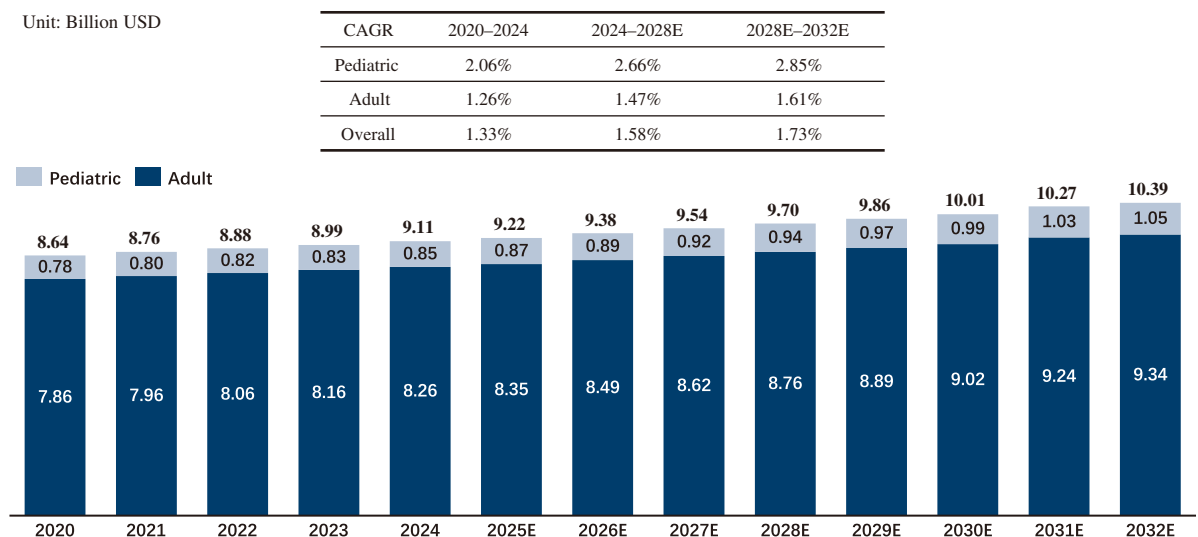
### U.S. Sedation Market Size, 2020–2032E



### Global Market

The global sedative drug market is in a steady expansion phase. From 2020 to 2024, the overall market size grew from USD8.64 billion to USD9.11 billion, with a CAGR of 1.33%; it is expected to accelerate to 1.58% from 2024 to 2028, further rising to 1.73% from 2028 to 2032, with the overall market expected to reach USD10.39 billion by 2032. Among these, adult sedation remains the dominant segment, with a market size of approximately USD8.26 billion in 2024, while the pediatric sedation market reaches USD0.85 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, 2020–2032E



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## INDUSTRY OVERVIEW

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### *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.

In contrast, dexmedetomidine is an  $\alpha_2$  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. The dexmedetomidine hydrochloride microneedle patch holds promise for meeting clinical needs such as comfortable and convenient administration, low safety risks, and on-label application.

### *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.

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Drug	Applicant	Locations	Indication	Phase	Status	Initial date	Clinical No.
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
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
Midazolam + fentanyl (titrated 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
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
Dexmedetomidine + Midazolam	Cairo University	Egypt	Preoperative Anxiety Experienced by the Pediatric Patient	PHASE 2	In progress	May 2025	NCT06979791
SHR0302 Alkali Gel	Jiangsu HengRui Medicine Co., Ltd.	China	Preoperative Sedation of Adults	PHASE1	Completed	Aug 2025	NCT07098117
Dexmedetomidine Hydrochloride nasal spray	Yichang Humanwell Pharmaceutical Co., Ltd	China	Preoperative Sedation for Adults and Children	PHASE1	Terminated	July 2022	CTR20221669

### 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 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.

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- 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.

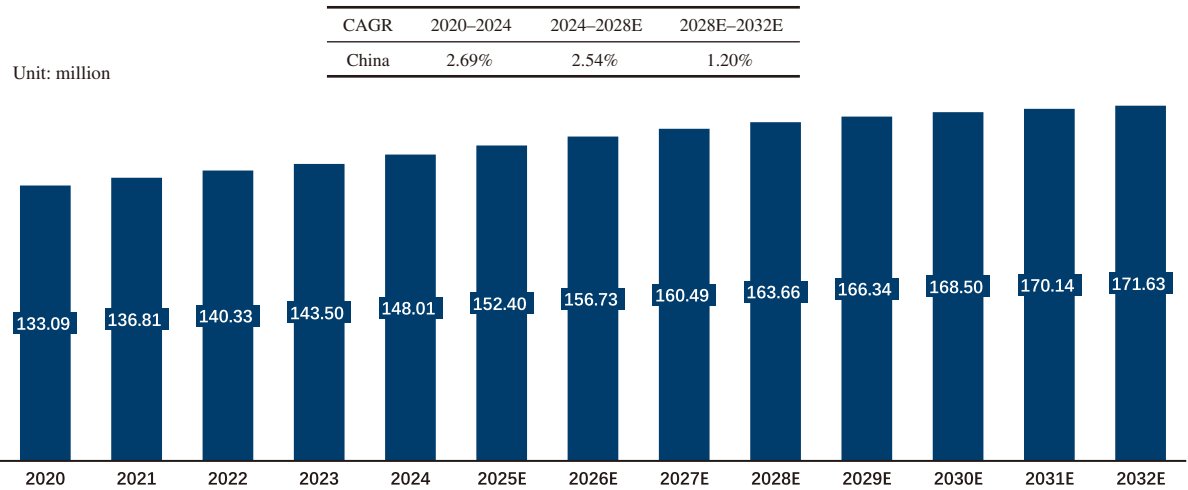
Diabetes Mellitus		
Type 1 Diabetes	Type 2 Diabetes	Gestational Diabetes
Type 1 diabetes is caused by an autoimmune reaction that destroys insulin-producing beta cells in the pancreas. This can occur months or years before symptoms appear. Genetic factors increase risk, but not everyone with the genes 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.

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### China Market

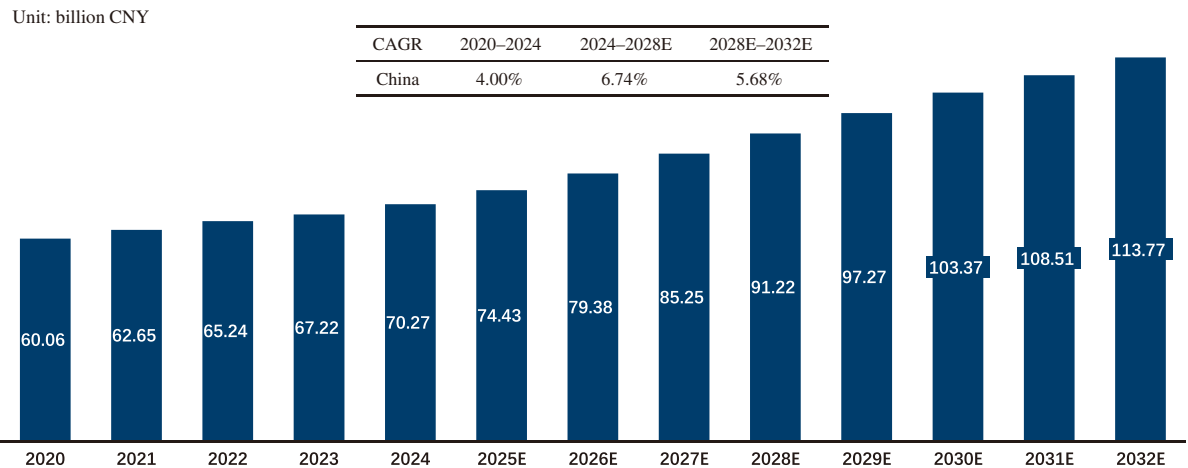
The number of diabetes mellitus patients in China is projected to grow steadily from 133.09 million in 2020 to 171.63 million by 2032. The compound annual growth rate (CAGR) stands at 2.69% from 2020 to 2024, and slightly increase to 2.54% between 2024 and 2028.

**The Scale of Diabetes Mellitus Patients in China, 2020–2032E**



China’s type 2 diabetes market is experiencing robust expansion, with total market size expected to grow from RMB60.06 billion in 2020 to RMB113.77 billion by 2032. This represents a CAGR of 4.00% from 2020 to 2024, accelerating to 6.74% from 2024 to 2028.

**China type 2 Diabetes Mellitus market Size, 2020–2032E**

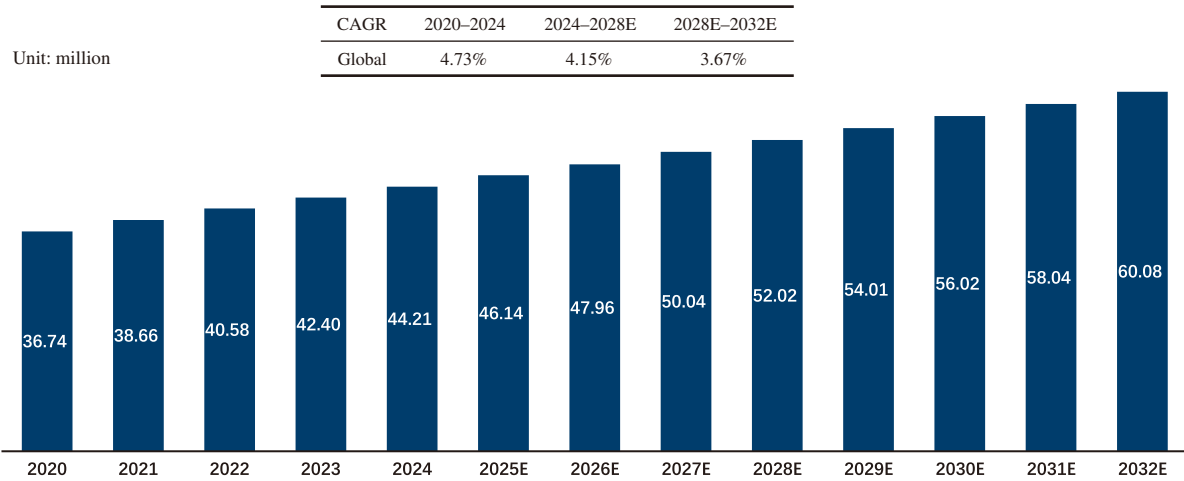


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### U.S. Market

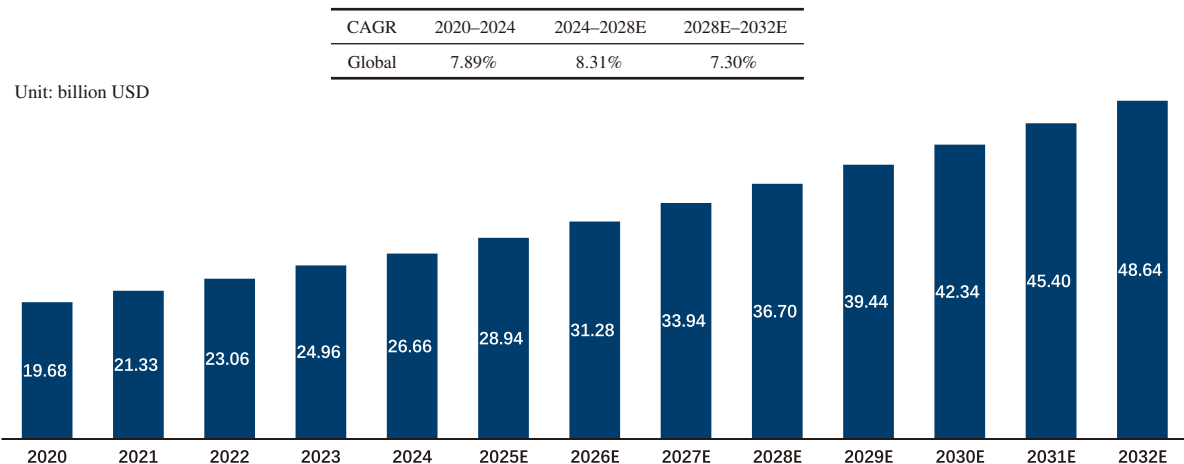
The number of diabetes mellitus patients in the United States is expected to rise steadily from 36.74 million in 2020 to 60.08 million by 2032. The compound annual growth rate (CAGR) is forecasted at 4.73% between 2020 and 2024, and 4.15% between 2024 and 2028.

**The Scale of Diabetes Mellitus Patients in U.S., 2020–2032E**



The diabetes market in the United States has experienced strong and sustained growth, expanding from USD19.68 billion in 2020 to a projected USD48.64 billion by 2032. The compound annual growth rate (CAGR) is estimated at 7.89% between 2020 and 2024, and 8.31% from 2024 to 2028.

**U.S. type 2 Diabetes Mellitus Market Size, 2020–2032E**

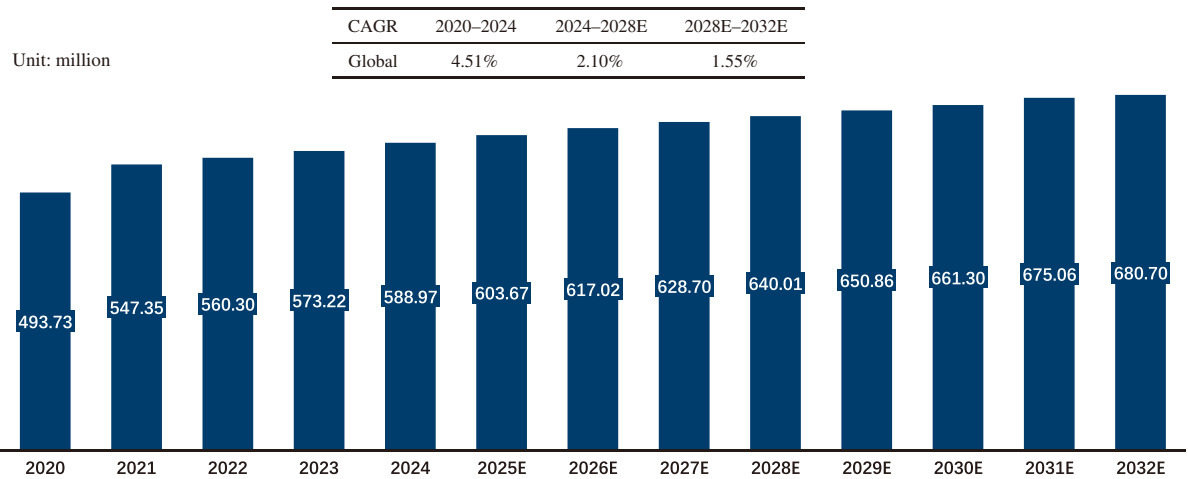


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### Global Market

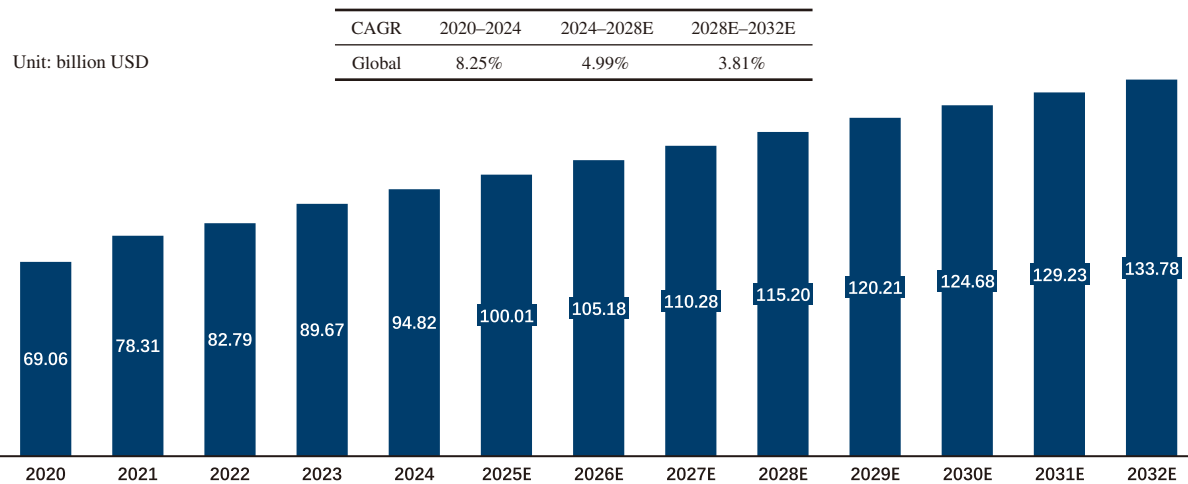
The global diabetes patient population continues to expand, though at a gradually slowing pace. The number of people living with diabetes reached approximately 493.73 million in 2020, rising to 588.97 million by 2024 and projected to reach 680.70 million by 2032.

**The Scale of Diabetes Mellitus Patients Global, 2020–2032E**



The global type 2 diabetes mellitus market expanded from 69.06 billion in 2020 to an estimated 133.78 billion by 2032, maintaining overall high single-digit growth but at a noticeably slower pace.

**Global type 2 Diabetes Mellitus Market Size, 2020–2032E**



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### 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 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.

## INDUSTRY OVERVIEW

<b>Basal &amp; Bolus Insulins</b>	<ul style="list-style-type: none"> <li>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.</li> </ul>
<b>Metformin</b>	<ul style="list-style-type: none"> <li>Lowers hepatic gluconeogenesis and improves peripheral insulin sensitivity without weight gain or hypoglycaemia.</li> </ul>
<b>GLP-1 Receptor Agonists</b>	<ul style="list-style-type: none"> <li>Injectable (and now oral) incretin mimetics boost glucose-dependent insulin release, suppress glucagon, slow gastric emptying and promote satiety, driving weight loss.</li> </ul>
<b>SGLT2 Inhibitors</b>	<ul style="list-style-type: none"> <li>Block renal glucose re-uptake, causing glycosuria that lowers glucose and modestly reduces weight and blood pressure.</li> </ul>
<b>DPP-4 Inhibitors</b>	<ul style="list-style-type: none"> <li>Prevent breakdown of endogenous GLP-1/GIP, enhancing glucose-dependent insulin secretion with a neutral weight profile and low hypoglycaemia risk</li> </ul>
<b>Sulfonylureas</b>	<ul style="list-style-type: none"> <li>Stimulate pancreatic <math>\beta</math>-cells to release insulin irrespective of ambient glucose; effective and inexpensive but carry hypoglycaemia and weight-gain liabilities</li> </ul>

### 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.
Proinsulin peptide (gold-nanoparticle conjugate via microneedle patch)	Cardiff University	UK/Sweden	Diabetes Mellitus	Phase 1	Completed	Aug 2016	NCT02837094
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
Insulin Delivery Using Microneedles in Type 1 Diabetes	Emory University	U.S.	Diabetes Mellitus	Phase 2/3	Completed	January 2014	NCT00837512
Insulin via MicronJet	Massachusetts General Hospital	U.S.	Diabetes Mellitus	Phase 2	Active, not recruiting	September 2016	NCT01684956

## INDUSTRY OVERVIEW

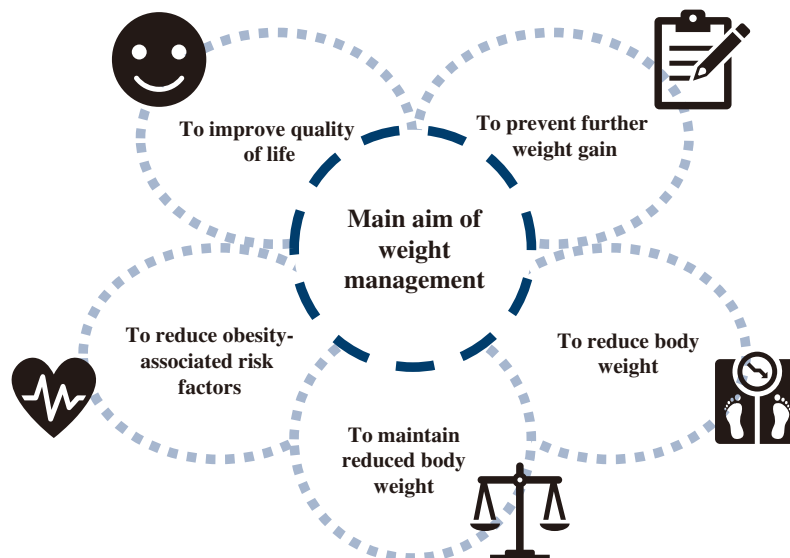
### Future Trend

Microneedle technology is advancing diabetes care toward a painless “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 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, Metabolic Dysfunction-Associated Steatohepatitis (MASH), 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.

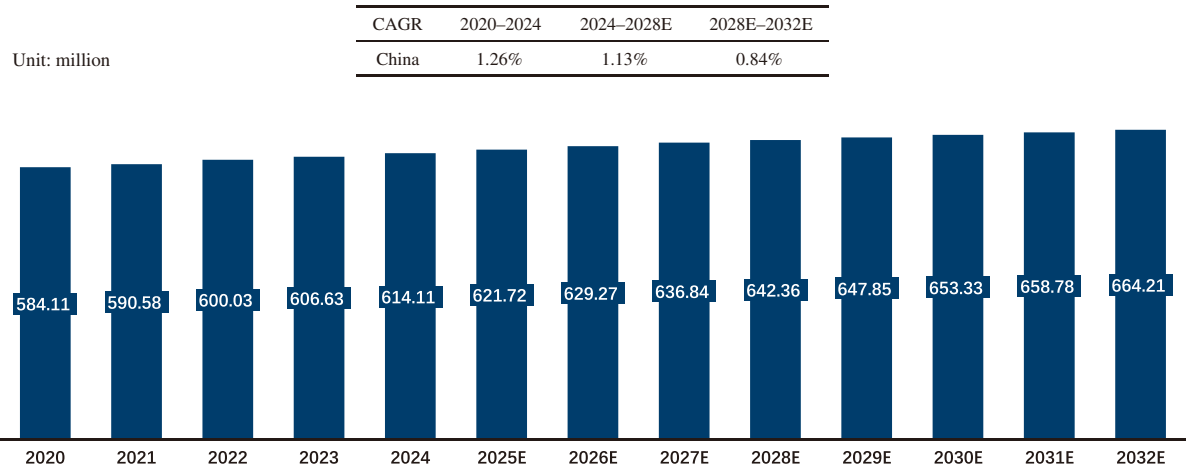


## INDUSTRY OVERVIEW

### China Market

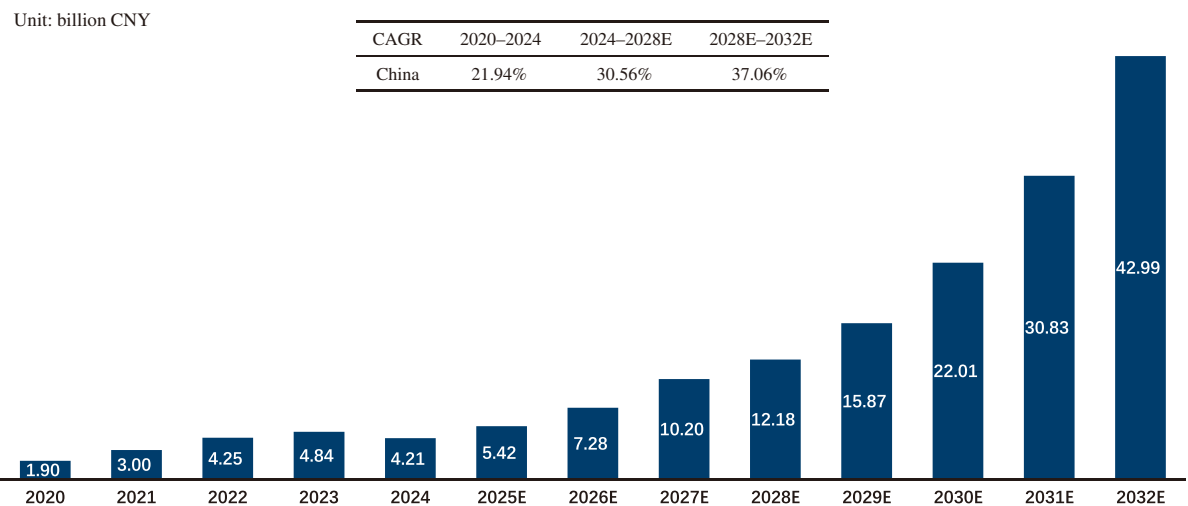
The number of weight management patients in China showed a mild fluctuation over the years, increasing from 584.11 million in 2020 to 614.11 million in 2024 with a CAGR of 1.26%, and is expected to rebound steadily to reach 664.21 million by 2032.

**The Scale of Weight Management Patients in China, 2020–2032E**



China’s weight management medicines market is experiencing rapid expansion. After a modest growth of 21.94% during 2020–2024, the market entered an accelerated growth phase, with a projected CAGR of 30.56% from 2024 to 2028. The market is expected to more than triple, rising from RMB42.1 billion in 2024 to RMB429.9 billion by 2032, driven by rising demand, increased awareness, and broader adoption of pharmaceutical solutions for weight control.

**China Weight Management Market Size, 2020–2032E**

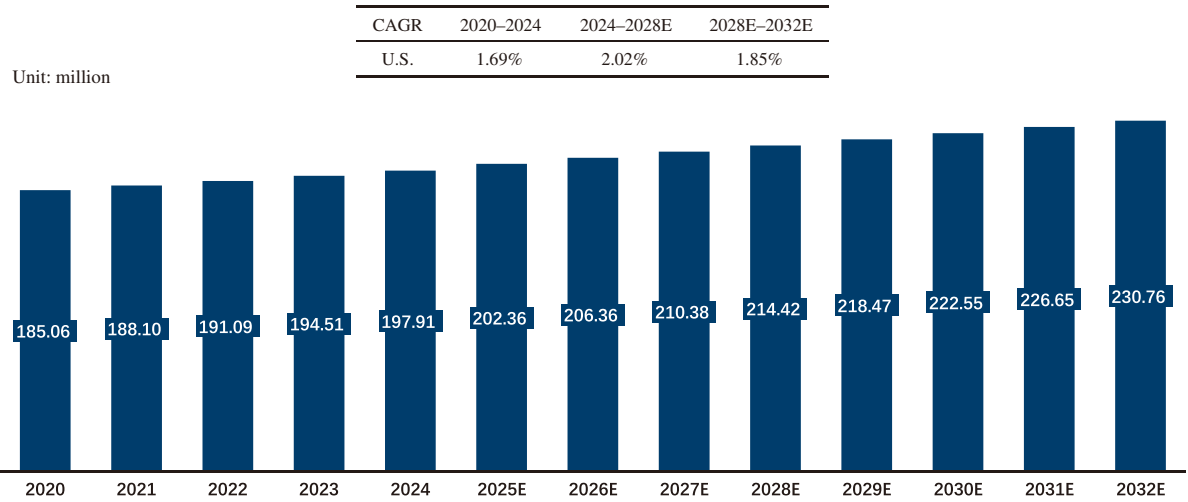


## INDUSTRY OVERVIEW

### U.S. Market

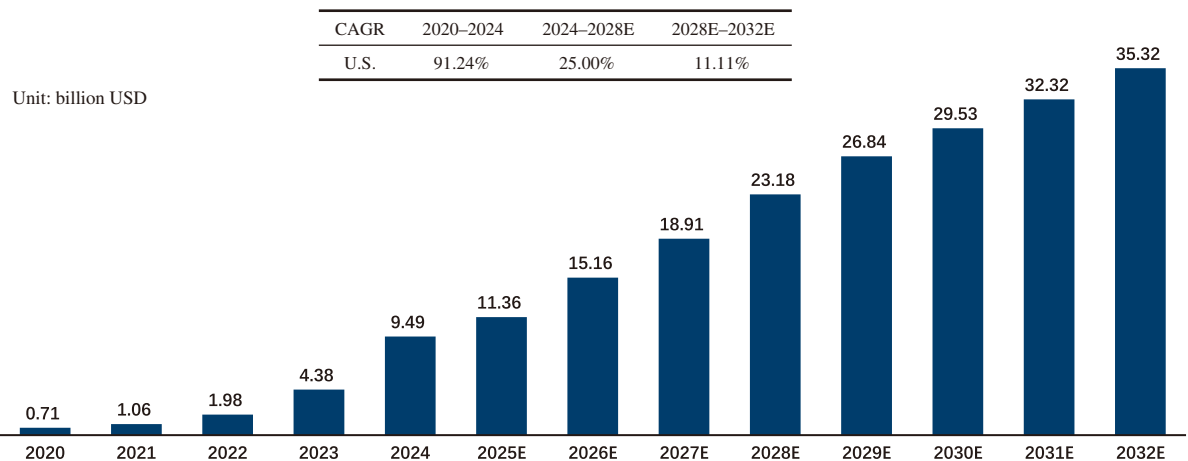
The weight management patient population in the U.S. has shown steady growth, increasing from 185.06 million in 2020 to an estimated 230.76 million by 2032.

**The Scale of Weight Management Patients in U.S., 2020–2032E**



The U.S. weight management market has experienced robust growth, rising from USD0.71 billion in 2020 to an estimated USD35.32 billion in 2032. The market saw an average annual growth rate of 91.24% between 2020 and 2024, with growth expected to further accelerate to 25.00% annually from 2024 to 2028.

**U.S. Weight Management Market Size, 2020–2032E**

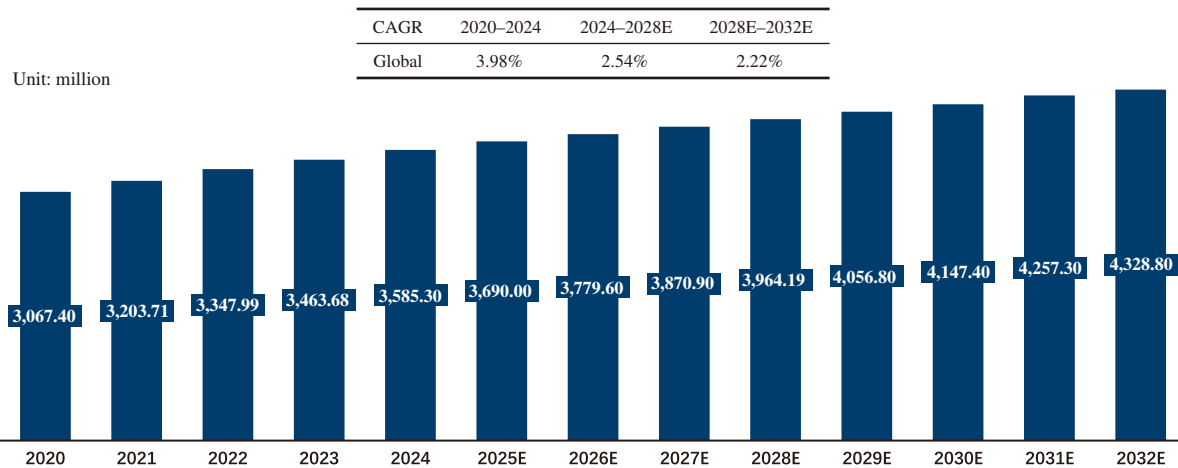


## INDUSTRY OVERVIEW

### Global Market

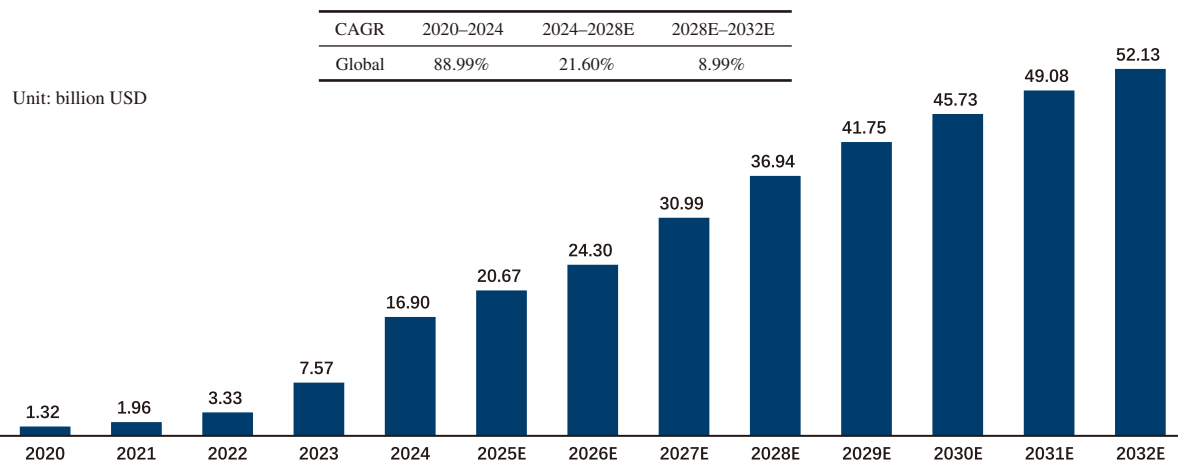
In 2020, the number of individuals requiring weight management reached 3,067.4 million worldwide, projected to rise to 3,585.30 million by 2024, representing a compound annual growth rate (CAGR) of 3.98%. Looking ahead, the patient population is projected to grow at a CAGR of 2.54% from 2024 to 2028, reaching 3,964.19 million.

**The Scale of Weight Management Patients Global., 2020–2032E**



The global weight management market is undergoing explosive expansion. Its size surged from USD1.32 billion in 2020 to USD16.90 billion in 2024, achieving a remarkable compound annual growth rate (CAGR) of 88.99% during this period. Driven by the ramp-up of innovative GLP-1 drugs, the market is projected to surge to USD36.94 billion from 2024 to 2028 at a compound growth rate of 21.60%. Although growth will moderate from 2028 to 2032, it will still maintain a robust 8.99% annual rate, pushing the market size beyond USD52.13 billion by 2032.

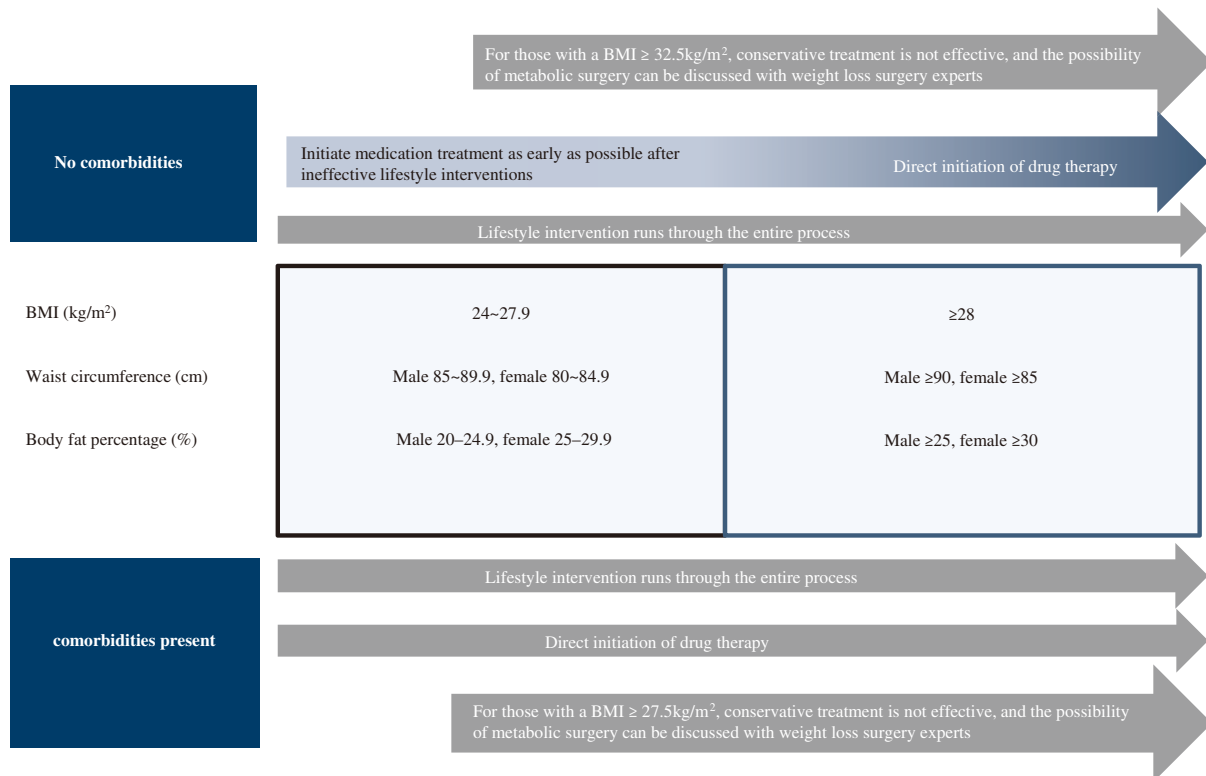
**Global Weight Management Market Size, 2020–2032E**



## INDUSTRY OVERVIEW

### 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.



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## INDUSTRY OVERVIEW

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### 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.

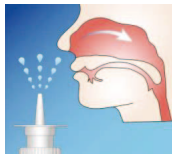
- 1. New formulations promote convenience and accessibility in weight control treatment:** Currently, the mainstream weight-loss drugs on the market are primarily injectable formulations, which still have room for improvement in terms of compliance, ease of use, storage, and patient coverage. Particularly 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 innovative delivery 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, 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.

## INDUSTRY OVERVIEW

### 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.



**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.



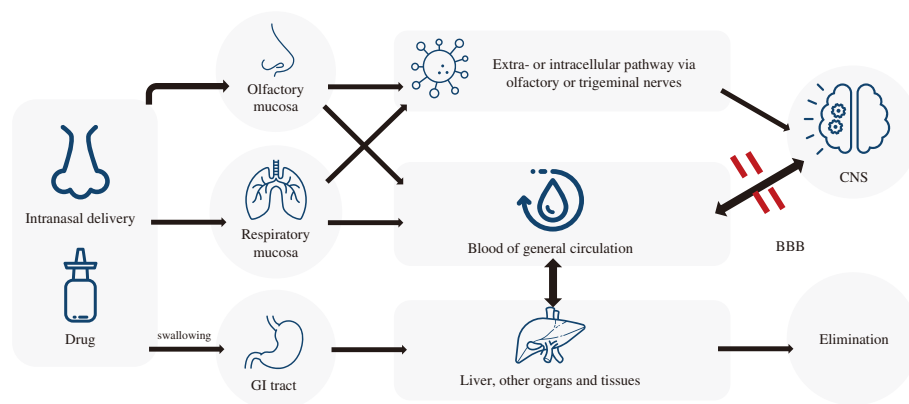
**Broader Clinical Applications**

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.

## INDUSTRY OVERVIEW

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.



### 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:** 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.

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## INDUSTRY OVERVIEW

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- **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.
- **Production and Quality Control Barriers:** The production of nasal spray drugs involves stringent quality control requirements. This demands that manufacturing enterprises possess strong production capabilities and quality assurance systems to ensure the product meets high standards of drug safety and efficacy.
- **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.

## INDUSTRY OVERVIEW



### 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.

### “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

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## INDUSTRY OVERVIEW

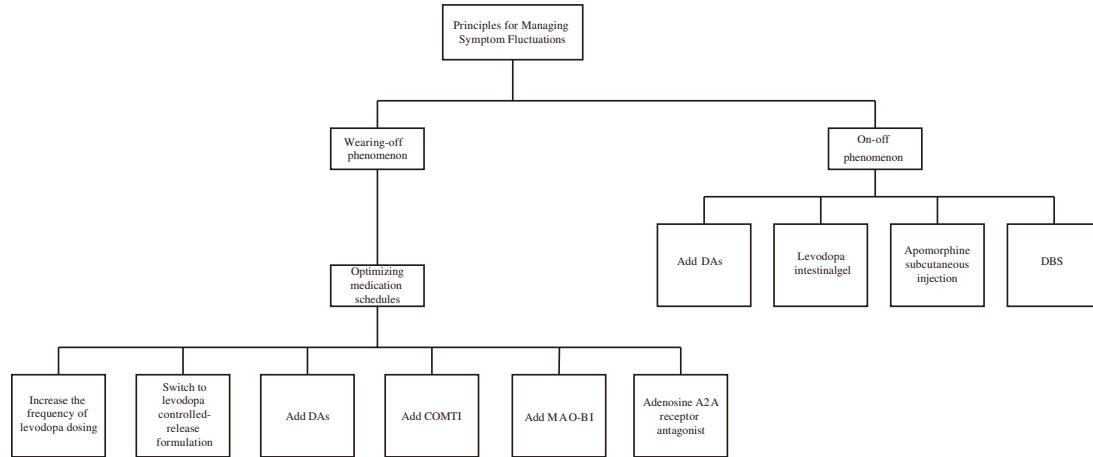
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fluctuations,” and represents one of the major challenges in Parkinson’s disease treatment. Approximately 50% of patients with a disease duration exceeding five years experience pronounced “Off” episodes, a proportion rising to 70%–80% among those 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. 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 A<sub>2</sub>A 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.

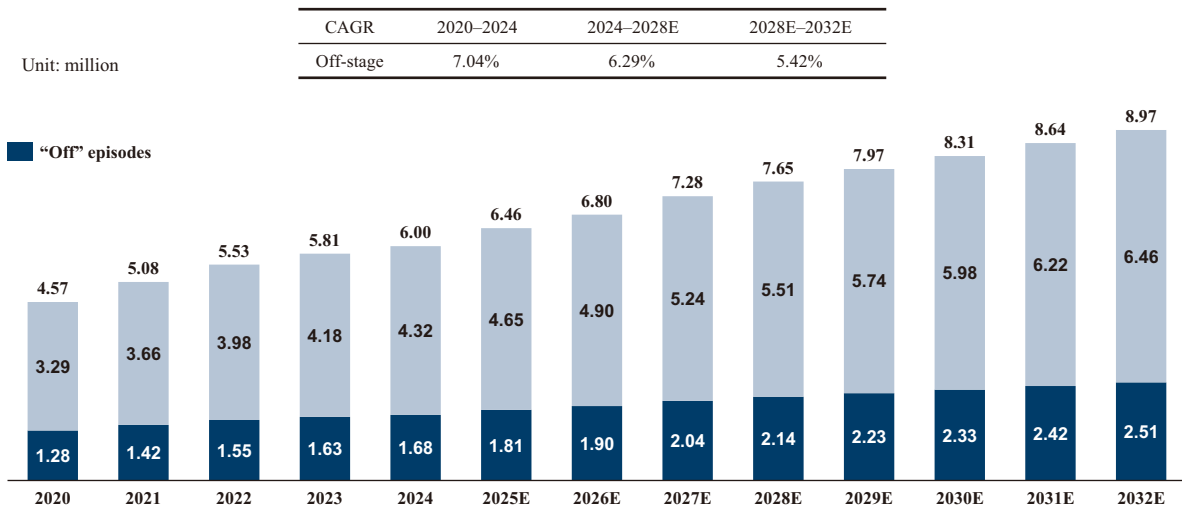
## INDUSTRY OVERVIEW



### China Market

In 2024, the number of Parkinson’s disease patients in China is estimated to be approximately 6 million, with those experiencing “Off” episodes accounting for about 28% of the total. The number of Parkinson’s disease patients in the “Off” episodes in China is expected to nearly double from 1.28 million in 2020 to 2.51 million in 2032. The compound annual growth rate (CAGR) stands at 7.04% during 2020–2024 during 2020–2024, gradually decelerating to 5.42% by 2028–2032. This strong upward trend is largely attributed to China’s rapidly aging population and the increasing rate of progression from early- to off-stage Parkinson’s among diagnosed patients. The data highlights a growing healthcare burden and signals an urgent need for optimized long-term care, enhanced therapeutic strategies, and support infrastructure for Parkinson’s disease management.

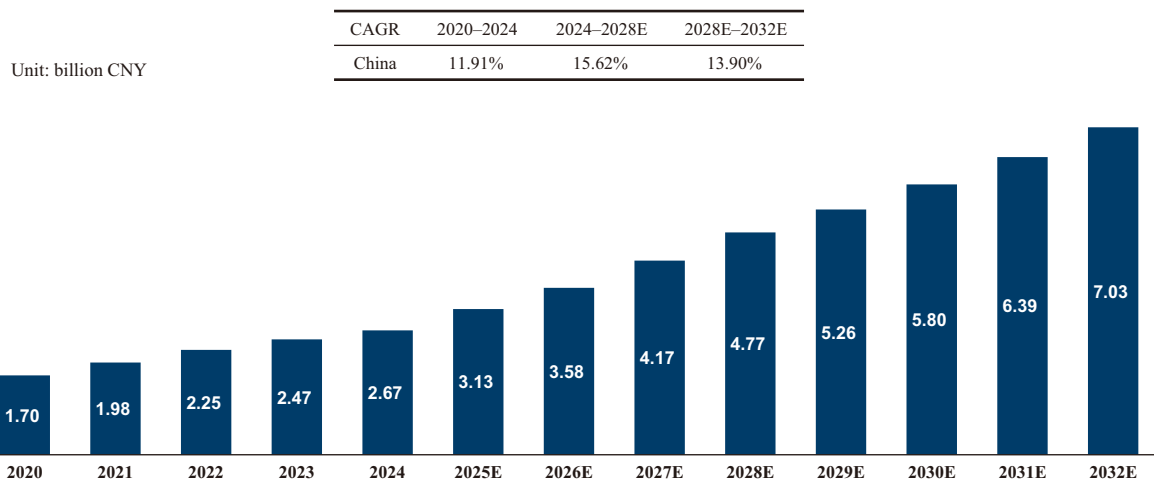
**The Scale of Parkinson’s Disease Patients in China, 2020–2032E**



## INDUSTRY OVERVIEW

China’s off-stage Parkinson’s disease market is forecasted to grow significantly from RMB1.70 billion in 2020 to RMB7.03 billion by 2032. This corresponds to a high compound annual growth rate (CAGR) of 11.91% from 2020–2024, accelerating to 15.62% between 2024–2028, before slightly easing to 13.90% during 2028–2032. The market boom is largely driven by the rising patient base, increased diagnosis and treatment penetration, and the introduction of advanced drug formulations. With a growing emphasis on motor complication management and patient quality of life, the off-stage Parkinson’s segment is emerging as a key driver of neurological pharmaceutical innovation in China.

**China Parkinson’s Disease (“Off” episodes) Medicines Market Size, 2020–2032E**

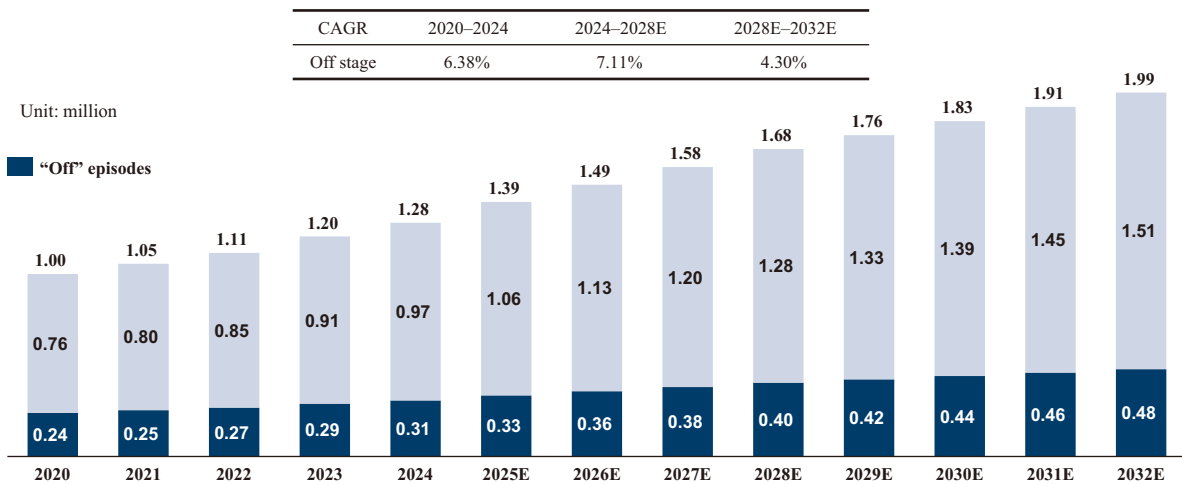


### *U.S. Market*

The number of patients experiencing Parkinson’s disease “Off” episodes in the United States is projected to double over the next decade, rising from 240,000 in 2020 to 480,000 by 2032. The compound annual growth rate (CAGR) stands at 6.38% from 2020 to 2024, accelerating to 7.11% during 2024–2028 before moderating slightly to 4.30% in the final forecast period (2028–2032). This sustained expansion is primarily driven by the aging of the baby boomer generation, increased early diagnosis rates, and disease progression among existing patients. This trend not only reflects a significant increase in the burden of Parkinson’s disease over the next decade but also signals heightened demand for innovative therapy development, optimized long-term disease management models, and enhanced adaptability within healthcare insurance and payment systems.

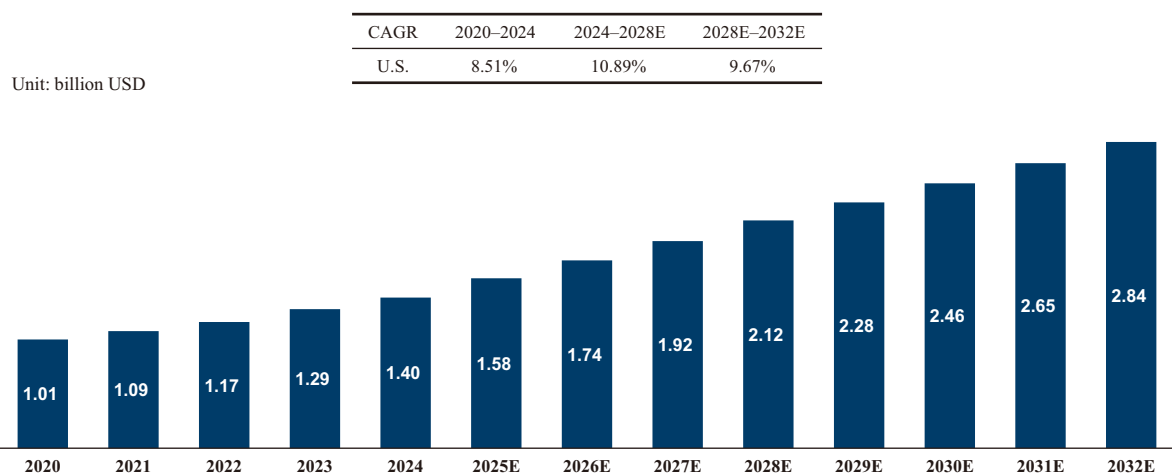
## INDUSTRY OVERVIEW

**The Scale of Parkinson’s Disease Patients in U.S., 2020–2032E**



The U.S. off-stage Parkinson’s disease market is projected to nearly triple in value, rising from USD1.01 billion in 2020 to USD2.84 billion in 2032. With a compound annual growth rate (CAGR) of 8.51% during 2020–2024 and peaking at 10.89% in 2024–2028, the market demonstrates robust momentum, driven by both increasing patient volume and evolving clinical treatment needs. The introduction of advanced therapies, expanded insurance coverage, and heightened focus on managing motor and non-motor complications further bolster demand. As the patient burden grows, pharmaceutical innovation and accessible long-term care will remain critical for sustaining market growth.

**U.S. Parkinson’s Disease (“Off” episodes) Medicines Market Size, 2020–2032E**

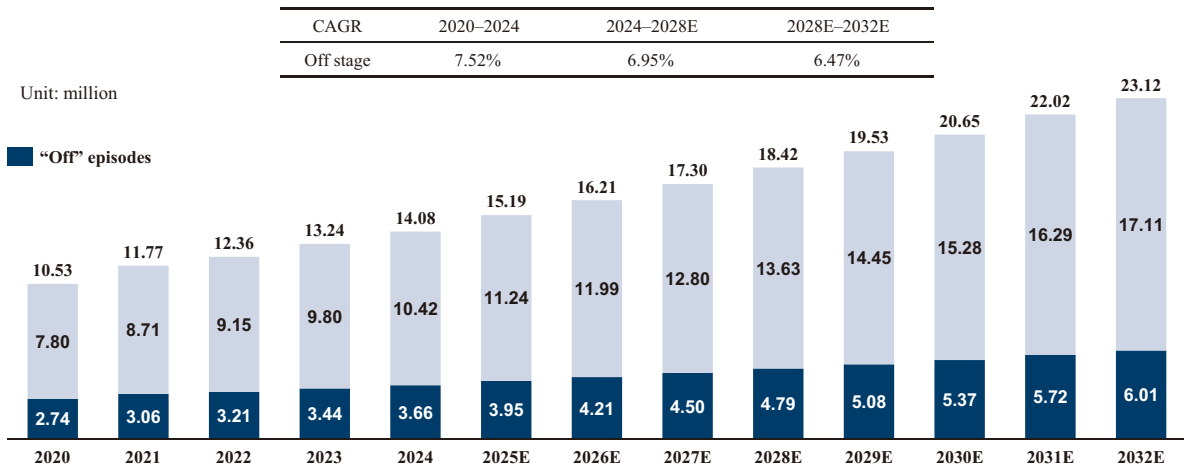


## INDUSTRY OVERVIEW

### Global Market

The global population of Parkinson’s disease patients experiencing “Off” episodes has steadily increased from approximately 2.74 million in 2020 to 3.66 million in 2024, representing a compound annual growth rate (CAGR) of 7.52% from 2020 to 2024. Driven by an aging population and increased diagnostic and treatment penetration, the patient base will continue to expand, reaching approximately 4.79 million by 2028 (CAGR 6.95% from 2024 to 2028) and potentially surpassing 6.01 million by 2032 (CAGR 6.47% from 2028 to 2032).

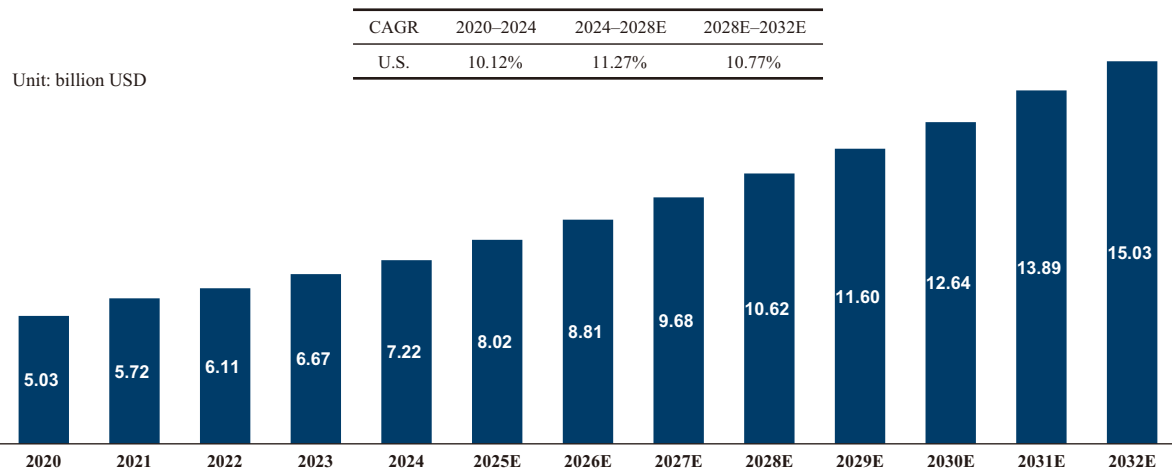
**The Scale of Parkinson’s Disease Patients Global, 2020–2032E**



The global Parkinson’s disease “Off” episodes market is undergoing rapid expansion. Its scale has surged from USD5.03 billion in 2020 to USD7.22 billion in 2024, achieving a compound annual growth rate (CAGR) of 10.12% from 2020 to 2024. Projections indicate it will surpass USD10.62 billion by 2028, with the CAGR accelerating to 11.27% from 2024 to 2028. The market is expected to reach USD15.03 billion by 2032 (CAGR 10.77% from 2028 to 2032). Overall, the global market is projected to maintain a CAGR exceeding 10% from 2020 to 2032, establishing a high-value growth corridor for innovative therapies.

## INDUSTRY OVERVIEW

Global Parkinson’s Disease (“Off” episodes) Market Size, 2020–2032E



### Parkinson’s Disease Nasal Spray Clinical Pipeline

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

### 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:

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## INDUSTRY OVERVIEW

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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

## INDUSTRY OVERVIEW

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*

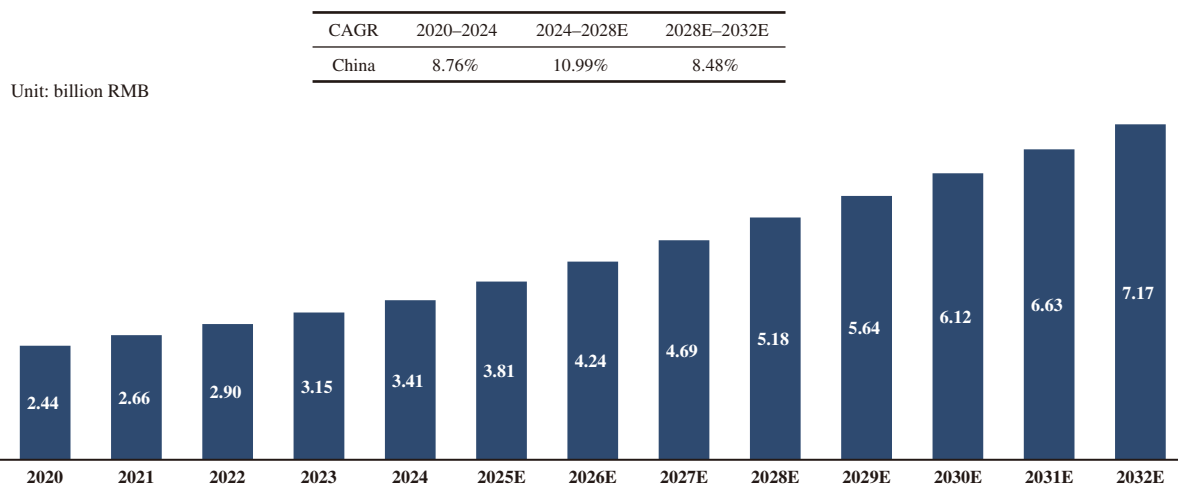
Migraine treatment primarily focuses on rapid relief of acute attacks and preventive therapy for patients with frequent or severe episodes. Acute management typically involves NSAIDs and triptans, emphasizing early intervention and avoidance of medication overuse. Preventive strategies include traditional 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.

### *China Market*

The number of migraine headache patients in China is projected to grow significantly from 114.38 million in 2020 to 130.97 million by 2032. The CAGR is estimated at 3.69% from 2020 to 2024 and 2.00% from 2024 to 2028.

China’s migraine medicine market is growing rapidly, expanding from RMB2.44 billion in 2020 to a projected RMB7.17 billion by 2032. This reflects a compound annual growth rate (CAGR) of 8.76% from 2020 to 2024 and an accelerated 10.99 % from 2024 to 2028.

**China Migraine Headache Medicine Market Size, 2020–2032E**



## INDUSTRY OVERVIEW

### *U.S. Market*

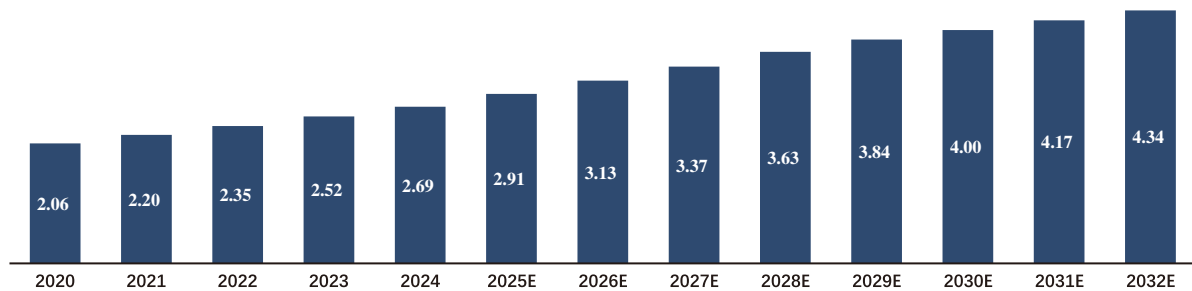
The number of migraine patients in the United States is projected to steadily increase from 41.92 million (2020) to approximately 57.09 million by 2032, reflecting persistent growth in disease prevalence.

The U.S. migraine treatment market is projected to expand significantly, rising from USD2.06 billion in 2020 to over USD4.34 billion by 2032.

**U.S. Migraine Headache Medicine Market Size, 2020–2032E**

CAGR	2020–2024	2024–2028E	2028E–2032E
U.S.	6.90%	7.80%	4.58%

Unit: billion USD



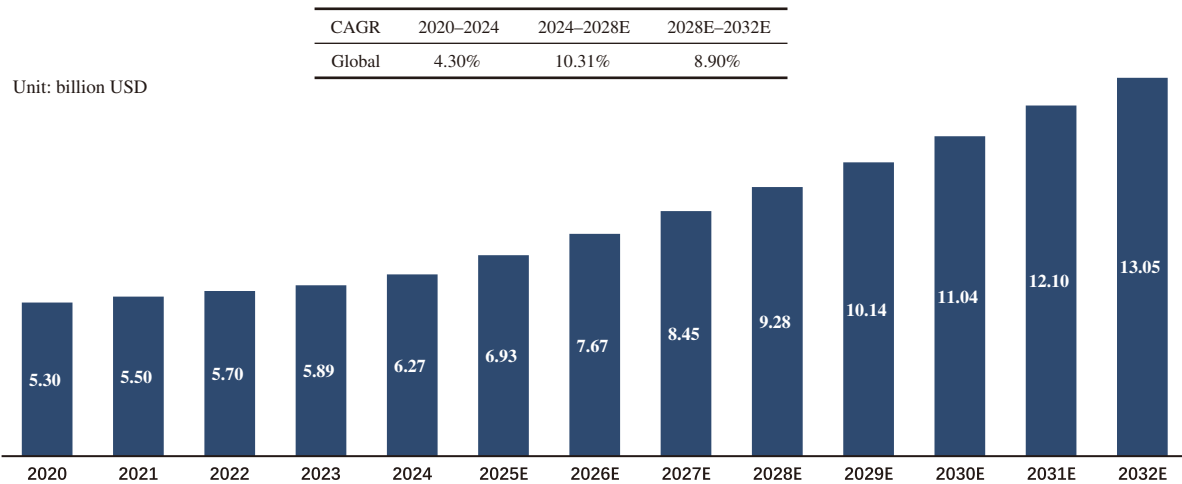
### *Global Market*

Globally, the number of migraine patients is projected to rise steadily from 1.13 billion in 2020 to approximately 1.48 billion by 2032.

The global migraine treatment market is expected to expand strongly, growing from USD5.3 billion in 2020 to over USD13.0 billion by 2032.

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### Global Migraine Headache Medicine Market Size, 2020–2032E



### 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.

### Migraine nasal spray pipeline

Drug	Applicant	Locations	Indication	Phase	Status	Latest date	Clinical No.
Zavzpret nasal spray	Pfizer	U.S.	Migraine Headache	Approved	/	/	/
Imitrex nasal spray	GSK	U.S.	Migraine Headache	Approved	/	/	/
Migranal nasal spray	Bausch Health Companies Inc.	U.S.	Migraine Headache	Approved	/	/	/
Tosymra	Upsher-Smith Laboratories, LLC	U.S.	Migraine Headache	Approved	/	/	/
Nasal Carbon Dioxide	Capnia, Inc.	U.S.	Migraine Headache	Phase 2	Completed	August 2012	NCT00690716
PRT-064040 Nasal Spray	Sichuan Purity Pharmaceutical Technology Co., Ltd.	China	Migraine Headache	Phase 1	Recruiting	June 2025	NCT07016516
TNX-1900	Tonix Pharmaceuticals, Inc.	U.S.	Migraine Headache	Phase 2	Completed	February 2025	NCT05679908
Zomig Nasal Spray	Impax Laboratories, LLC	U.S.	Migraine Headache	Phase 3	Completed	January 2021	NCT03275922
STS 101	Satsuma Pharmaceuticals, Inc.	U.S.	Migraine Headache	Phase 3	Completed	June 2023	NCT03901482
Sumatriptan Nasal Spray	Optinose US Inc.	U.S.	Migraine Headache	Phase 1	Completed	February 2012	NCT01507610

## INDUSTRY OVERVIEW

### 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.

Novel Drug Delivery Technologies Drive Market Innovation	Increased trend towards combination of treatment options	Rapid Growth of Regional Migraine Treatment Market Differentiation
<p>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.</p>	<p>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.</p>	<p>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.</p>

### 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-HT<sub>3</sub>RA), and neurokinin-1 receptor antagonists (NK-1RA). Each of the marketed antiemetic prophylactic drugs primarily blocks a particular type

## INDUSTRY OVERVIEW

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.

<b>5-HT<sub>3</sub> receptor antagonist</b>	<ul style="list-style-type: none"> <li>• Antiemetic effect by blocking the binding of 5-HT<sub>3</sub> receptors to 5-HT<sub>3</sub> in the vagus nerve and emetic chemoreceptor area</li> </ul>
<b>NK-1 receptor antagonists</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Glucocorticosteroid</b>	<ul style="list-style-type: none"> <li>• Prevention of nausea and vomiting by interaction with 5-HT<sub>3</sub>, NK-1 and NK-2 receptor proteins, or direct action on the nucleus tractus solitarius in the medulla oblongata</li> </ul>
<b>Atypical antipsychotics</b>	<ul style="list-style-type: none"> <li>• It mainly includes olanzapine and mirtazapine, which can antagonize a variety of receptors such as 5-HT<sub>3</sub>, 5-HT<sub>2</sub>, dopamine, histamine, acetylcholine, etc., and is effective in the prevention of acute and delayed nausea and vomiting</li> </ul>
<b>Others</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

### *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-HT<sub>3</sub> 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.

Drug	Applicant	Locations	Indication	Phase	Status	Initial date	Clinical No.
Metoclopramide Nasal Spray	Evoke Pharma	United States	vomiting	Phase 3	Completed	July 2020	NCT02025725
Granisetron Hydrochloride Nasal Spray	Maxinase Life Sciences Ltd.	Taiwan	vomiting	Phase 1	Completed	January 2016	NCT02563951

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## INDUSTRY OVERVIEW

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### Future Trend

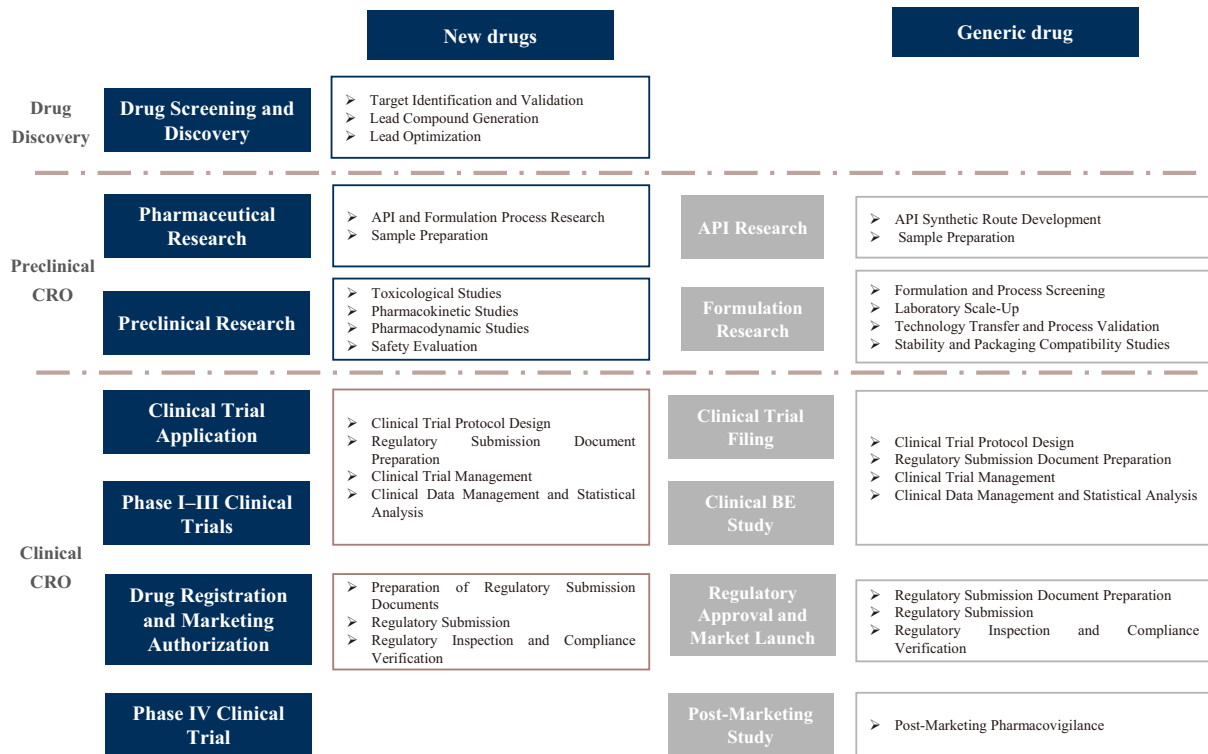
1. **Formulation Innovation** — In the future, antiemetic therapy will focus on multi-target interventions, innovations in non-oral formulations (such as nasal spray formulations), and the integration of personalized and digital management to enhance treatment efficiency, adapt to various clinical scenarios, 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.

## GLOBAL AND 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.

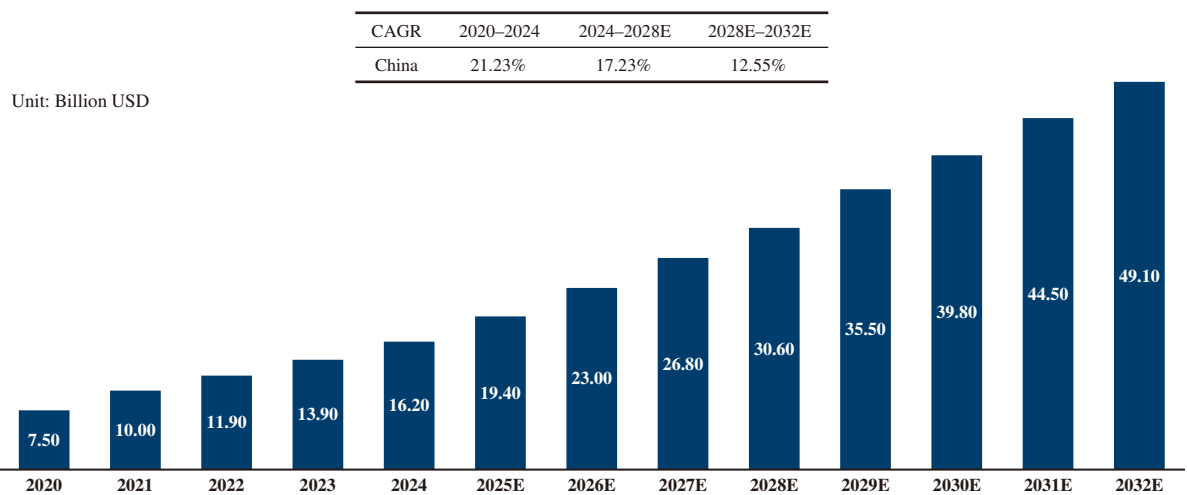
## INDUSTRY OVERVIEW



### China Market

From 2020 to 2032, China’s CRO market is expected to grow significantly from USD7.5 billion to USD49.1 billion. Growth will remain strong, with a CAGR of 21.23% during 2020–2024, moderating to 17.23% in 2024–2028E, and 12.55% in 2028–2032E. This expansion reflects increasing outsourcing demand across drug discovery, preclinical, and clinical development, underscoring CROs’ critical role in supporting pharmaceutical innovation.

**The Scale of China CRO Market, 2020–2032E**



## INDUSTRY OVERVIEW

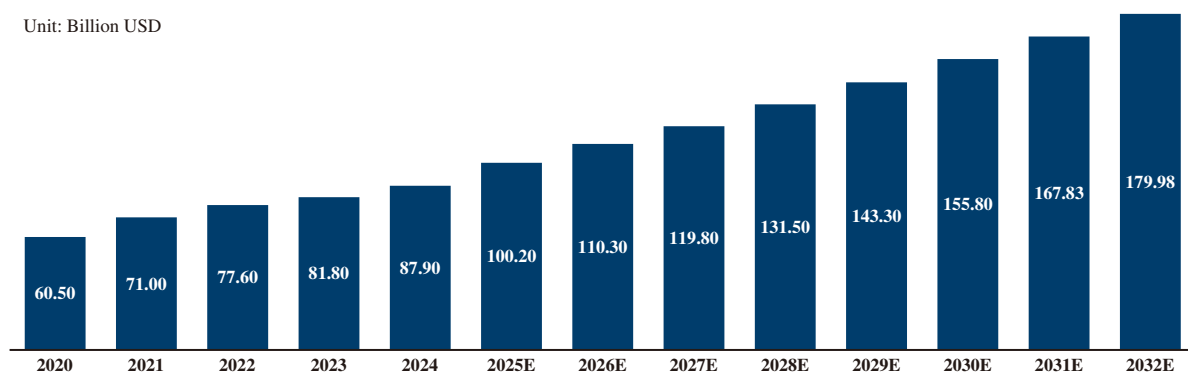
### Global Market

From 2020 to 2032, the global CRO market is projected to grow from USD60.5 billion to USD179.98 billion, nearly tripling in size. The CAGR is expected to reach 9.79% during 2020–2024, strengthen to 10.59% in 2024–2028E, and then stabilize at 8.16% in 2028–2032E. This expansion highlights increasing reliance on outsourcing across the pharmaceutical value chain, underscoring CROs’ central role in driving global R&D efficiency and innovation.

**The Scale of global CRO Market, 2020-2032E**

CAGR	2020-2024	2024-2028E	2028E-2032E
Global	9.79%	10.59%	8.16%

Unit: Billion USD



### Industrial Chain Analysis

The CRO industry chain has formed a closed loop of “pharmaceutical company demands → CRO professional execution → compliance supervision and assurance → data technology empowerment.”

### 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.

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## INDUSTRY OVERVIEW

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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.

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Classification	Definition
<div style="display: flex; align-items: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); padding-right: 5px;">Marketing Authorization Holder (MAH) System</div> <div style="background-color: #003366; color: white; padding: 5px; margin-right: 10px;">Applicant Entity</div> <div style="flex-grow: 1;"> <ul style="list-style-type: none"> <li><input type="checkbox"/> Applicant</li> <li><input type="checkbox"/> Holder</li> </ul> </div> </div>	<ul style="list-style-type: none"> <li>• Drug R&amp;D institutions and pharmaceutical manufacturing enterprises located within the pilot administrative regions, as well as Chinese national researchers working within these regions, may act as drug registration applicants (hereinafter referred to as the “applicant”).</li> <li>• An applicant who submits a drug clinical trial application and a marketing authorization application, and obtains the marketing authorization and the drug approval number, may become the Marketing Authorization Holder (hereinafter referred to as the “holder”).</li> </ul>
<div style="display: flex; align-items: center;"> <div style="background-color: #003366; color: white; padding: 5px; margin-right: 10px;">Specific Requirements</div> <div style="flex-grow: 1;"> <ul style="list-style-type: none"> <li><input type="checkbox"/> Scope of Drugs</li> <li><input type="checkbox"/> Requirements for Contract Manufacturing Enterprises</li> </ul> </div> </div>	<ol style="list-style-type: none"> <li>1. New drugs approved for marketing after the implementation of this policy</li> <li>• Chemical drugs under Categories 1–4 and Category 5 (limited to targeted, sustained-release, and controlled-release preparations) according to the current Drug Registration Regulation.</li> <li>• After the implementation of the chemical drug registration classification reform, chemical drugs declared under the new Categories 1 and 2 (hereinafter referred to as the “new classification”).</li> <li>2. Generic drugs approved under new standards for quality and efficacy equivalence with originator drugs</li> <li>• After the implementation of the new chemical drug classification system, chemical drugs declared under new Categories 3 and 4.</li> <li>3. Drugs approved for marketing prior to the implementation of this policy</li> <li>• Drugs that have passed the quality and efficacy consistency evaluation.</li> <li>• In pilot administrative regions, drugs with approval numbers held by pharmaceutical manufacturers that have relocated or been merged and relocated as a whole.</li> <li>• The contract manufacturing enterprise shall be a pharmaceutical manufacturer legally established within the pilot administrative region, holding a valid Drug Manufacturing License and a GMP certificate covering the relevant drug production scope.</li> </ol>

### 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.

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## INDUSTRY OVERVIEW

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### 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.