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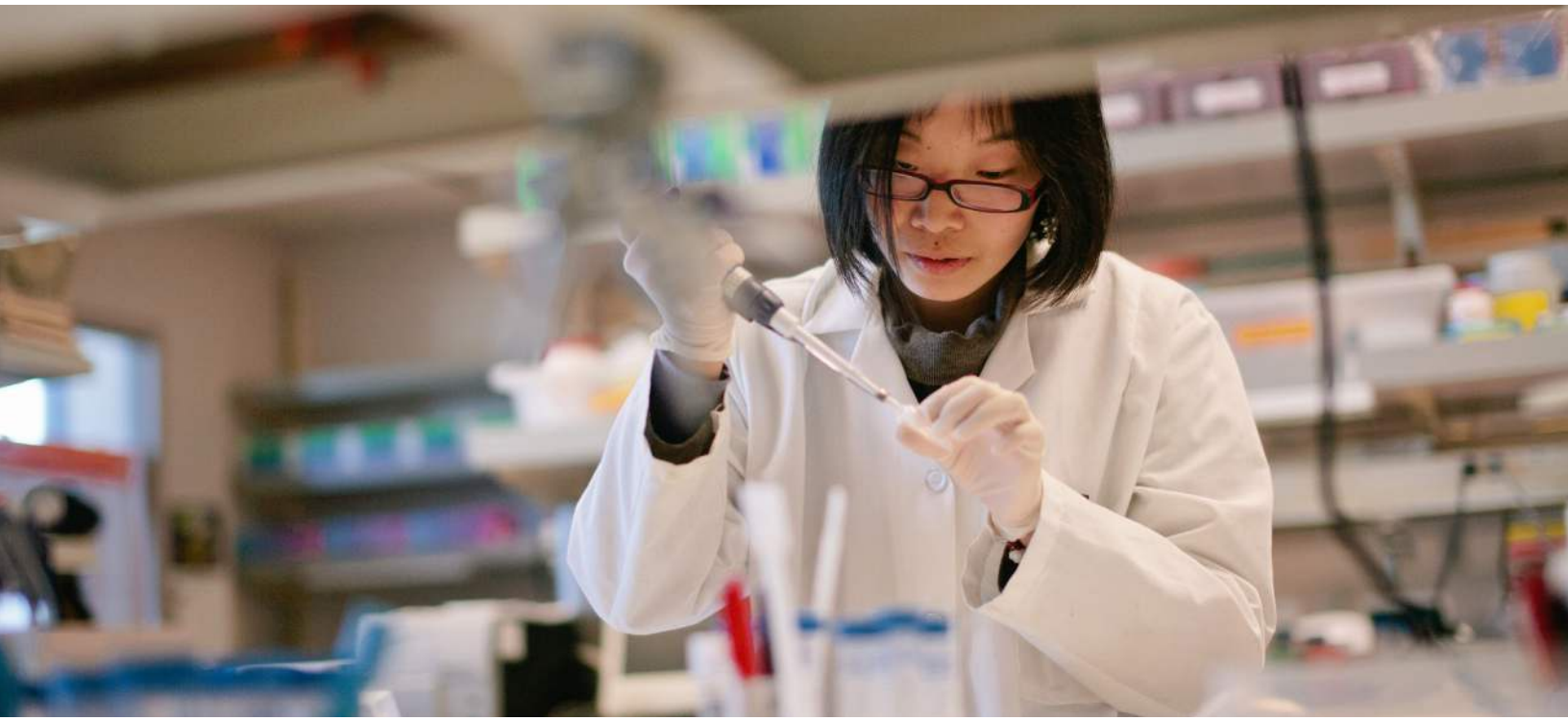

# Rx newsletter

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# Market Trends

## The future of AI in health care

The future of artificial intelligence (AI) in health care holds immense promise and potential. AI has already made significant strides in transforming various aspects of the health care industry, and its impact is expected to grow exponentially in the coming years.

### Medical diagnostics

One of the key areas where AI is revolutionizing health care is in medical diagnostics. AI algorithms can analyze vast amounts of patient data, including medical records, lab results, and imaging scans, to identify patterns and make accurate diagnoses. Studies have demonstrated AI's ability to meet or exceed the performance of human experts in image-based diagnoses across various medical specialties.[1] This can help health care professionals detect diseases at an early stage, leading to more effective treatments and improved patient outcomes.

### Personalized medicine

AI is also playing a crucial role in personalized medicine. By analyzing an individual's genetic information, lifestyle factors, and medical history, AI algorithms can provide tailored treatment plans and medication recommendations.[2] This can lead to more precise and targeted therapies, minimizing side effects and optimizing patient care.

### Patient engagement and support

Furthermore, AI-powered virtual assistants and chatbots are enhancing patient engagement and support. These intelligent systems can provide patients with personalized health information, answer their queries, and even offer mental health support. Virtual patient assistants can guide a patient to appropriate and accurate medical information and address common queries.[3] This not only improves patient satisfaction but also reduces the burden on health care providers.

### Health care operations and administration

In addition to diagnostics and patient care, AI is transforming health care operations and administration. AI algorithms can streamline administrative tasks, such as appointment scheduling, billing, and insurance claims processing, thereby reducing administrative costs and improving efficiency. For instance, AI's predictive analytics capabilities can assist hospitals to forecasting patient admission rates and allocating resources and staffing levels to reduce wait times for patients.[4]

### Ethics and regulations

However, the widespread adoption of AI in health care also raises important ethical and regulatory considerations. Ensuring patient privacy, data security, and transparency in AI algorithms are critical challenges that need to be addressed.[2] Additionally, there is a need for robust regulations and guidelines to govern the development and deployment of AI technologies in health care.

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# Pharmacy 101

## Maximum Allowable Cost (MAC) schedules and generic effective rate guarantees (GER)

Pharmacy maximum allowable cost (MAC) schedules and generic effective rate (GER) guarantees are two important concepts in the field of pharmacy benefit management (PBM). These mechanisms play a crucial role in controlling costs and ensuring the availability of affordable medications for patients.

A pharmacy MAC schedule is a list of maximum prices that a PBM is willing to reimburse pharmacies for generic drugs. Once a generic is available from multiple manufacturers setting their own price, there often will be a wide range of prices based on Average Wholesale Price (AWP). The MAC schedule helps PBMs manage costs by setting a limit on the amount they will pay for a particular generic medication. Unfortunately, there is currently no industry standard on which drugs are to be included, what methodology is used to determine the maximum price, nor guidelines on how the list is changed or updated.[1] This encourages pharmacies to source generic drugs at lower prices, which in turn helps to reduce overall healthcare expenses.

On the other hand, a GER guarantee is a commitment made by a PBM to ensure that the average cost of generic drugs dispensed by pharmacies remains below a certain threshold. This guarantee is typically expressed as a percentage discount off the average wholesale price (AWP) of the medication. The GER guarantee provides pharmacies with assurance that they will be reimbursed at a rate that allows them to cover their costs and maintain profitability.

### Similarities

Both MAC schedules and GER guarantees are designed to promote cost-effective prescribing practices and encourage the use of generic medications. Generic drugs are typically less expensive than their brand-name counterparts, and they offer the same therapeutic benefits. By incentivizing the use of generics, PBMs can help reduce health care costs for patients, employers, and insurers.

It is important to note that MAC schedules and GER guarantees are subject to regular review and adjustment. PBMs continuously monitor market conditions, drug pricing trends, and changes in the availability of generic alternatives. This allows them to update MAC schedules and GER guarantees to reflect current market dynamics and ensure appropriate reimbursement for pharmacies.

In conclusion, pharmacy MAC schedules and GER guarantees are essential tools in managing medication costs and promoting the use of cost-effective generic drugs. By striking a balance between cost containment and quality care, MAC schedules and GER guarantees contribute to the overall sustainability of the health care system.

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# Disease Spotlight

## Latent Autoimmune Diabetes of Adults (LADA)

Latent Autoimmune Diabetes of Adults (LADA) is a form of diabetes that shares characteristics of both type 1 and type 2 diabetes. It is often misdiagnosed as type 2 diabetes due to its onset in adulthood and its slow progression. LADA is characterized by the presence of autoimmune markers, such as autoantibodies, which are typically associated with type 1 diabetes.[1]

The history of LADA dates back to the late 1970s when researchers first identified a group of individuals who were initially diagnosed with type 2 diabetes but later exhibited autoimmune markers.[2] This discovery led to the recognition of LADA as a distinct form of diabetes. Since then, numerous studies have been conducted to better understand the incidence and characteristics of LADA.

The incidence of LADA varies across different populations, but it is estimated to account for approximately 4-14% of all cases of diabetes in adults.[3] LADA typically affects individuals over the age of 30, although it can occur at any age. It is more common in individuals who are lean or have a normal body mass index (BMI) compared to those with type 2 diabetes.[4]

### Treatment

Pharmaceutical treatment for LADA is similar to that of type 1 diabetes. Since LADA is characterized by autoimmune destruction of pancreatic beta cells, individuals with LADA eventually require insulin therapy to manage their blood glucose levels. However, the progression to insulin dependence is usually slower in LADA compared to type 1 diabetes.[2]

In the early stages of LADA, oral antidiabetic medications, such as metformin or sulfonylureas, may be prescribed to help control blood sugar levels. However, as the disease progresses and beta cell function declines, insulin therapy becomes necessary. The specific insulin regimen and dosage vary depending on individual needs.[4]

It is important to accurately diagnose LADA to ensure appropriate treatment and management. This requires testing for autoimmune markers, such as islet cell antibodies (ICA), insulin autoantibodies (IAA), glutamic acid decarboxylase antibodies (GADA), and insulinoma-associated-2 autoantibodies (IA-2A).[5] These tests, along with clinical evaluation, can help differentiate LADA from other forms of diabetes.

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# Clinical Spotlight

## Rezdiffra – A new treatment for noncirrhotic non-alcoholic steatohepatitis (NASH)

Rezdiffra (resmetirom) is a newly approved (March 14, 2024) medication for the treatment of noncirrhotic non-alcoholic steatohepatitis (NASH), a form of fatty liver disease. It is manufactured by Madrigal Pharmaceuticals and has been granted accelerated approval by the U.S. Food and Drug Administration (FDA).[1] Rezdiffra is an oral pill that acts as a thyroid hormone receptor (THR)-beta agonist, reducing liver fat accumulation and improving liver health.

Prior to the availability of this new drug therapy, nonalcoholic steatohepatitis (NASH) was treated primarily through lifestyle modifications and managing underlying risk factors. These included maintaining a healthy diet, exercising regularly, managing blood pressure, cholesterol and diabetes, as well as avoiding alcohol and medications that may be harmful to the liver.

The mechanism of action of Rezdiffra involves activating the THR-beta receptor, which helps to regulate lipid metabolism, reduce triglyceride levels, and reduce liver fat.[2] By targeting this receptor, Rezdiffra aims to resolve NASH without worsening fibrosis, a common complication of the disease.

### Clinical trials and side effects

Clinical trials have shown promising results for Rezdiffra. In an ongoing Phase III trial, the medication was tested at two dose strengths. At the lower dose, Rezdiffra resolved NASH without worsening fibrosis in 26% of patients, while at the higher dose, this rate increased to 30%.[2] Additionally, in the Phase 3 MAESTRO-NASH biopsy trial, 80% of patients treated with a dosage of Rezdiffra 100 mg experienced improvement or stabilization of fibrosis.[3]

The most common side effects associated with Rezdiffra, affecting at least 5% of patients, include diarrhea, itching, constipation, nausea, vomiting, and stomach pain. The medication can also be toxic to the liver and requires monitoring for liver injury.[1]

Rezdiffra should be used in conjunction with a healthy diet and exercise regimen. It is indicated for adults with moderate to advanced liver scarring (fibrosis) due to NASH, but not for those with cirrhosis of the liver.

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# Pipeline

## Pending drug approvals

| Drug name | Manufacturer | Indication/use | Expected FDA decision date |
|---|---|---|---|
| mavorixafor | X4 | Warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome | 9/05/2024 |
| Tovorafenib | Day One Bio | Glioma (relapsed/ progressive, low-grade, monotherapy) | 9/11/2024 |
| "Ocrevus SC (ocrelizumab/ hyaluronidase)" | Genentech | Multiple sclerosis | 9/13/2024 |
| Tradipitant | "Vanda Pharmaceuticals" | Gastroparesis | 9/18/2024 |
| pembrolizumab (Keytruda®) | Merck | Mesothelioma | 9/24/2024 |
| Xanomeline/ trospium | Bristol Myers Squibb | Schizophrenia | 9/26/2024 |
| Nivolumab | Bristol Myers Squibb | NSCLC | 10/08/2024 |
| Octreotide | Camurus | Acromegaly | 10/21/2024 |
| Ribociclib (Kisqali®) | Novartis | Breast cancer | 10/31/2024 |
| Benralizumab (Fasenra®) | AstraZeneca | "Anti-neutrophil cytoplasmic antibodies-associated vasculitis" | July – December 2024 |
| Durvalumab (Imfinzi®) | AstraZeneca | Endometrial cancer | July – December 2024 |
| Olaparib (Lynparza®) | AstraZeneca | Endometrial cancer | July – December 2024 |

## Brands Losing Patent

| Drug name | Manufacturer | Indication/use | Date Generic Available |
|---|---|---|---|
| Abilify | Aripiprazole | Schizophrenia | July 2024 |
| Xarelto | rivaroxaban | Prevent blood clots | August 2024 |
| Vandazole | Metronidazole | Bacterial vaginosis | September 2024 |
| Somatuline Depot | lanreotide acetate | Neuroendocrine tumors | September 2024 |
| Sustol | granisetron | Nausea and vomiting | September 2024 |
| Prialt | ziconotide acetate | Severe chronic pain | October 2024 |
| Xopenex HFA | levalbuterol tartrate | Prevention of bronchospasm | October 2024 |
| Nourianz | istradefylline | "wearing-off" episodes in adults with Parkinson's disease | November 2024 |
| Macrilen | macimorelin acetate | Adult growth hormone deficiency | December 2024 |

*Actual launch dates depend on FDA approvals and may change at any time

For more information about Rx and other solutions from MMA, visit www.mmaeast.com, or contact your local representative.

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