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Pharmacy Briefing | January 2024

THE LATEST ON PHARMACY NEWS, TRENDS, AND INSIGHTS

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Highlights

- CVS Caremark announces removal of Humira (adalimumab) from national formularies
- FiercePharma publishes annual "Top 10 most anticipated drug launches of 2024" report
- Clarivate publishes annual "Drugs to Watch" report
- Peterson-KFF publishes annual "Health Cost and Affordability Policy Issues and Trends to Watch in 2024" report

FDA Approvals and Launches

- Prolia (denosumab) receives Boxed Warning from FDA addressing increased risk of hypocalcemia in patients with chronic kidney disease.
- Zelsuvmi (berdazimer topical gel) is approved for the treatment of molluscum contagiosum, a viral skin infection.
- Nilotinib capsules are approved as a generic alternative to chronic myeloid leukemia treatment Tasigna

News

CVS Caremark announces removal of Humira (adalimumab) from national formularies

- The change will go into effect on April 1, 2024 and will apply to plans that have adopted its national commercial template formularies.
- These formularies will instead cover Humira biosimilars and a co-branded version of *Humira*. The latter is manufactured through a partnership between AbbVie and CVS Health and will be available in Q2 2024.

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FiercePharma publishes annual "Top 10 most anticipated drug launches of 2024" report

- Investigational schizophrenia drug KarXT (xanomeline-trospium) is designated as the most anticipated drug with estimated sales of \$2.8 billion by 2028.
 - o The drug has a Prescription Drug User Fee Act (PDUFA) date in September 2024.
- The report also showcases Alzheimer's drug donanemab, which was rejected by the FDA in 2023 but was re-filed and is awaiting an additional approval decision in Q1 2024.

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Clarivate publishes annual "Drugs to Watch" report

• The report identifies 13 new-to-market drugs expected to launch in 2024, covering a wide range of indications including hemophilia A, sickle cell disease, Crohn's disease, and respiratory syncytial virus (RSV).

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Peterson-KFF publishes annual "Health Cost and Affordability Policy Issues and Trends to Watch in 2024" report

• Examples of policies and trends that are discussed include price transparency, the Inflation Reduction Act (IRA), and the drug development pipeline.

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Lilly launches LillyDirect, a direct-to-consumer, telehealth-based program for patients living with obesity, migraines, and/or diabetes

- The program will include a pathway for patients to receive GLP-1 treatment and other drugs manufactured by Lilly.
- In addition to a digital pharmacy, LillyDirect also offers educational information, telehealth services, and a search tool for inperson care.

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Evernorth launches EncircleRx to help plans manage chronic diseases

- The EncircleRx program is being positioned as a program that helps plans address members with cardiovascular disease, diabetes, and/or obesity.
- The program offers a GLP-1 financial guarantee to plan sponsors.

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Department of Health and Human Services (HHS) reaffirms plans' responsibility to cover contraceptive options with no member cost-sharing

- The HHS Secretary issued a letter to health plans and issuers and published a frequently asked questions (FAQ)
 document providing guidance on the topic.
- The Medicare Part D formulary clinical review process was updated for play year 2024 to include additional birth control types such as intramuscular and intrauterine contraceptives.

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Drug manufacturer Alvotech updates status on biosimilar approvals

Alvotech believes that, in February and April 2024, it will receive FDA approval for its biosimilars to reference products
 Humira (adalimumab) and Stelara (ustekinumab), respectively.

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SURMOUNT-4 trial finds that patients receiving weight loss treatment with *Zepbound* (tirzepatide) regained a substantial amount of lost weight after treatment discontinuation

- The phase 3 study examined patients who received treatment for 36 weeks, followed by continued treatment vs. discontinued treatment for 52 weeks.
- Patients in the study experienced a mean weight reduction of 20.9% through week 36; patients discontinuing treatment then experienced a mean weight increase of 14.0%. Patients remaining on treatment experienced an additional 5.5% reduction.

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PIFR-2 trial fails to reach superiority endpoint when comparing *Yupelri* (revefenacin) to *Spiriva* (tiotropium) for the treatment of chronic obstructive pulmonary disease

The phase 4 trial compared the improvement in forced expiratory volume over 12 weeks of treatment using each of the two
drugs.

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