Assessment of Utilization Patterns of New Molecular Entities Approved in 2022 using the Sentinel Distributed Database

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BACKGROUND

- Understanding the uptake and utilization of new molecular entities (NMEs) in real-world clinical practice is essential for continued monitoring of their safety, especially considering the variability of post-approval users compared to the trial population.
- The US Food and Drug Administration's (FDA) Sentinel System routinely assesses utilization of products containing NMEs – new active moieties that FDA had not previously approved, either as a single ingredient drug or as part of a combination product.[1]
- These data provide FDA with information about patterns of use and availability of sufficient users for potential future safety assessments using the Active Risk Identification and Analysis (ARIA) System.

OBJECTIVES

- To describe the user characteristics and utilization patterns of 37 NMEs approved by US FDA in 2022 in the Sentinel Distributed Database (SDD).

METHODS

Data Source: Five SDD Data Partners (four national commercial insurers and Medicare) – those with at least of one year of available data after December 31, 2022

Exposures of Interest: 37 NMEs approved between January 1, 2022, to December 31, 2022, identified using
- National Drug Codes (NDCs) in pharmacy dispensing claims or
- International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) or Healthcare Common Procedure Coding System (HCPCS) procedure codes in any healthcare setting.

METHODS

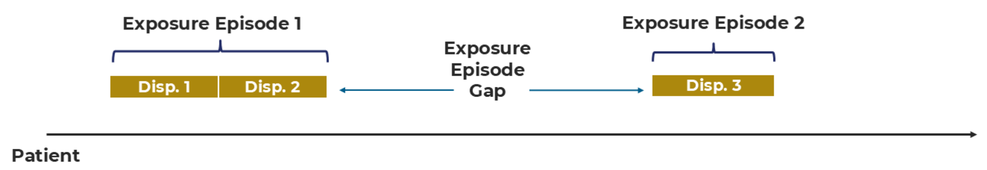
Study Cohorts:
✓Identified using first observed dispensing or administration code for each NME (index date) among individuals with six months of prior continuous medical and pharmacy coverage, with allowed gaps in coverage of up to 45 days.

Query Period:
✓January 1, 2022, to date of most recent available data i.e., last day of the most recent month for which all Data Partners have at least 80% of the record count (May 31, 2024). The date of the most recent available data differs across Data Partners.

Characteristics and Utilization Measures:
✓Characteristics - demographic; healthcare utilization; certain clinical[2] and lifestyle characteristics (smoking, obesity, alcohol abuse/dependence, etc.) assessed over six months before index date.

✓Utilization measures - distribution of days supplied per dispensing/administration; cumulative exposure duration; all, first, second and subsequent episode duration; and all and first episodes' gaps duration (Figure 1)

Figure 1. Measures of utilization assessed



Each patient can contribute multiple exposure episodes until they are censored (i.e., earliest of disenrollment, death, end of data availability, query end date)

Cumulative duration of episode = ∑ for each dispensing/administration, days' supply of dispensing, keeping in mind the censoring criteria.

RESULTS

- Of the 37 NMEs approved by US FDA in 2022,
  - 20 (54%) were first-in-class drugs, 20 (54%) were indicated for rare or orphan diseases, 12 (32%) were granted Fast-Track status, and 13 (35%) were designated as Breakthrough Therapies.
- Of the 37 NMEs, five had >10,000 users, seven between 10,000 and >1,000 users, 13 between 1,000 and >100 users, and 12 had 100 or fewer users over the query period.
- User characteristics and utilization measures of the five most frequently used NMEs users are summarized below.
- Tirzepatide – approved as subcutaneous injection in 2022 for type 2 diabetes mellitus and adults with obesity or overweight with weight related comorbidities – mean age 58 years, 62% female
- Faricimab-svoa – approved as intravitreal injection in 2022 for neovascular age-related macular degeneration and diabetic macular edema – mean age 79 years, 59% female
- Gadopiclenol – approved as intravenous injection in 2022 as radiologic contrast agent – mean age 63 years, 58% female
- Tapinarof – approved as topical cream in 2022 for plaque psoriasis – mean age 52 years, 52% female
- Daridorexant – approved as oral tablets in 2022 for insomnia – mean age 60 years, 62% female

Table 1. Measures of utilization for the top 5 most frequently used NME

	Number of Users	Number of Dispensings/ Administrations	Median Days' Supply per Dispensing, days (IQR)	Median Cumulative Exposure Duration, days (IQR)	Median First Treatment Episode Duration, days (IQR)
Tirzepatide	438,820	2,176,027	28 (1-28)	112 (46-224)	44 (28-96)
Faricimab-svoa	114,321	569,956	1 (1-1)	4 (2-7)	1 (1-1)
Gadopiclenol	22,748	24,310	1 (1-1)	1 (1-1)	1 (1-1)
Tapinarof	14,042	27,773	30 (30-30)	30 (30-60)	30 (30-30)
Daridorexant	10,520	31,814	30 (30-30)	42 (30-117)	30 (30-30)

IQR: Interquartile range

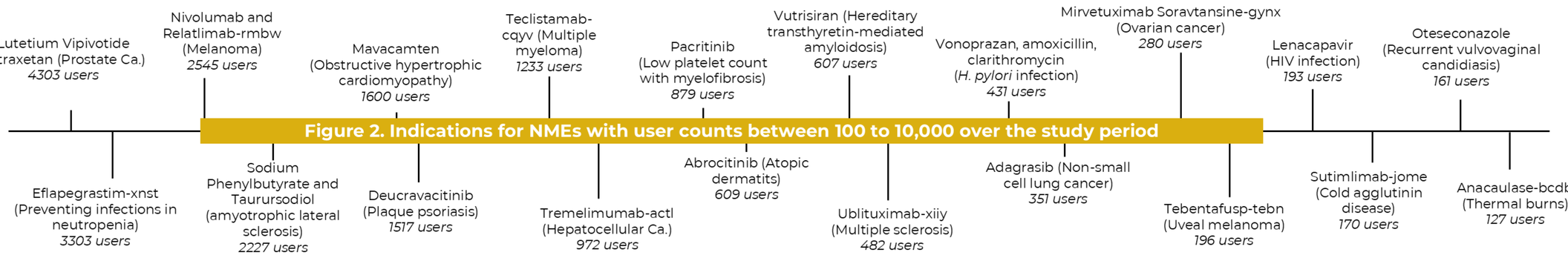


Figure 2. Indications for NMEs with user counts between 100 to 10,000 over the study period

CONCLUSION

- Of the NMEs approved in 2022, tirzepatide and faricimab-svoa were the two that were most utilized, both with indications for diabetes mellitus and its complications.
- Having insight into the way NMEs are used in clinical practice can inform feasibility for potential evaluations of medical product safety.

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Link to FDA Sentinel Report

Department of Population Medicine

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