Sentinel

Early Uptake of New Molecular Entities Approved in 2017 in a Multisite National US Healthcare Data Network

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Andrew L. Simon, ScM[1], Sruthi Adimadhyam, Ph.D[1], Catherine Corey, MSPH[2], Michael D. Nguyen, MD[2]

Author Affiliations: [1] Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, [2] U.S. Food and Drug Administration Center for Drug Evaluation and Research, Division of Epidemiology, Silver Spring MD

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Disclosures

- The views expressed in this presentation represent those of the presenters and do not necessarily represent the official views of the U.S. FDA.
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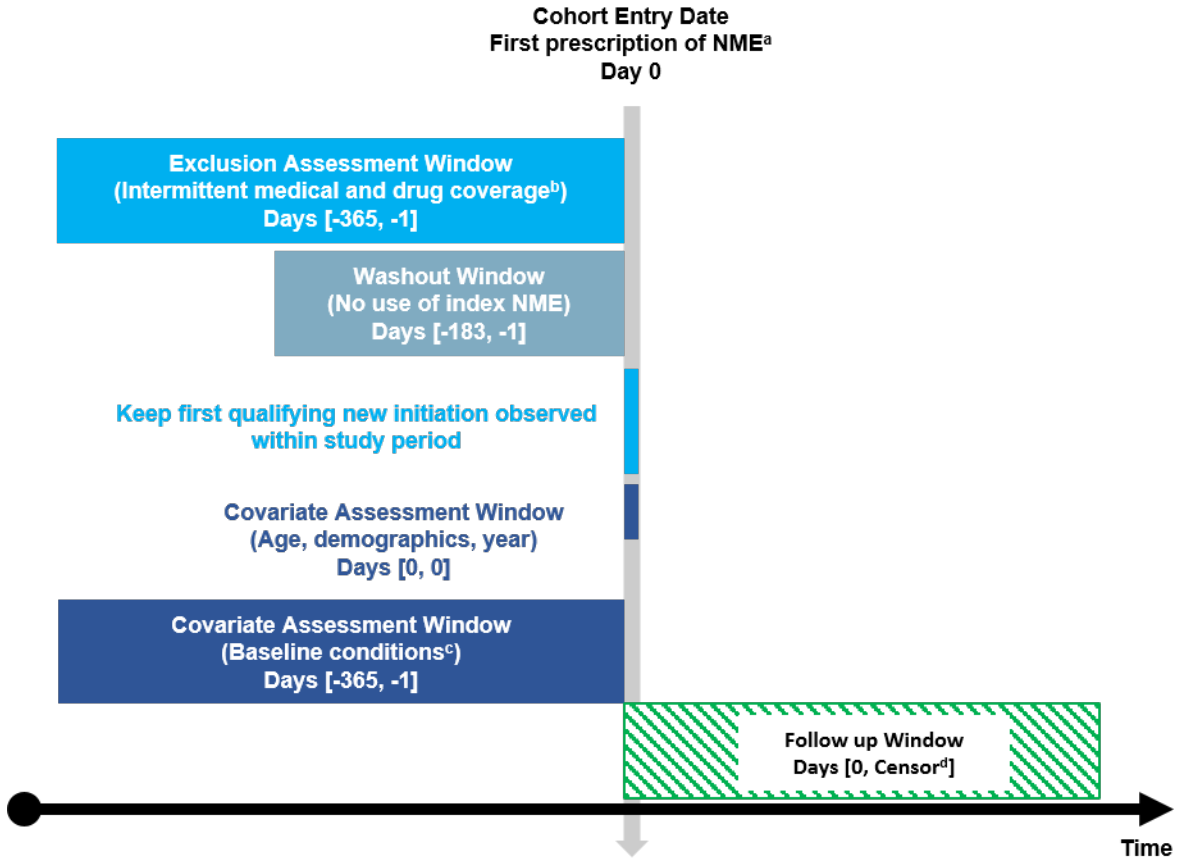
Planning for postmarket safety surveillance of newly approved drug products

- Over the past 6 years (2015-2020), the United States Food and Drug Administration (FDA) approved 46 new molecular entities (NMEs) every year on average[1]
- Postmarket surveillance of NMEs is a public health priority, but can be challenging due to variable uptake in the early post-approval period (first 2 years of approval)
- We examined uptake and duration of observation time available for the 46 NMEs approved in 2017 using the Sentinel Distributed Database (SDD) with 70 million+ members actively enrolled with drug and medical coverage at time of study among 16 Data Partners



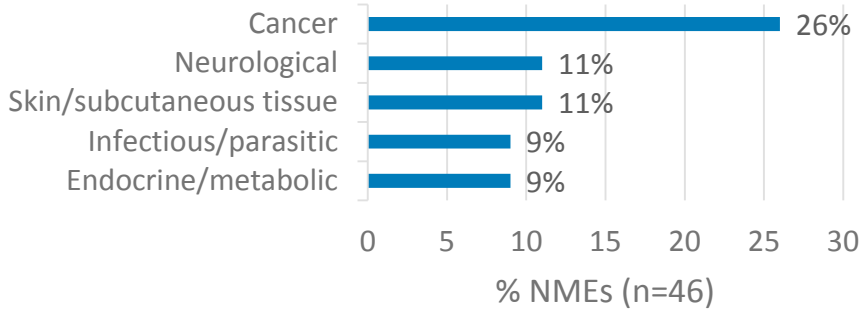
a. Treatment initiation defined by date of dispensing
b. Up to 45 day gaps in medical or pharmacy enrollment allowed
c. Baseline conditions included: history of chronic conditions, lifestyle-related factors
d. Earliest of: death, disenrollment, DP max date (Date of maximum data availability at participating Data Partner site. The month with the maximum date must have at least 80% of the number of records in the previous month.)

This analysis was designed on Sentinel Query Request Package (QRP) v. 9.0.0.

[1]Mullard A. 2020 FDA drug approvals. *Nature Reviews Drug Discovery*. 2021;20(2):85-90. doi:10.1038/d41573-021-00002-0

Characteristics of 2017 NMEs and accrual of new users during early post-approval period in SDD

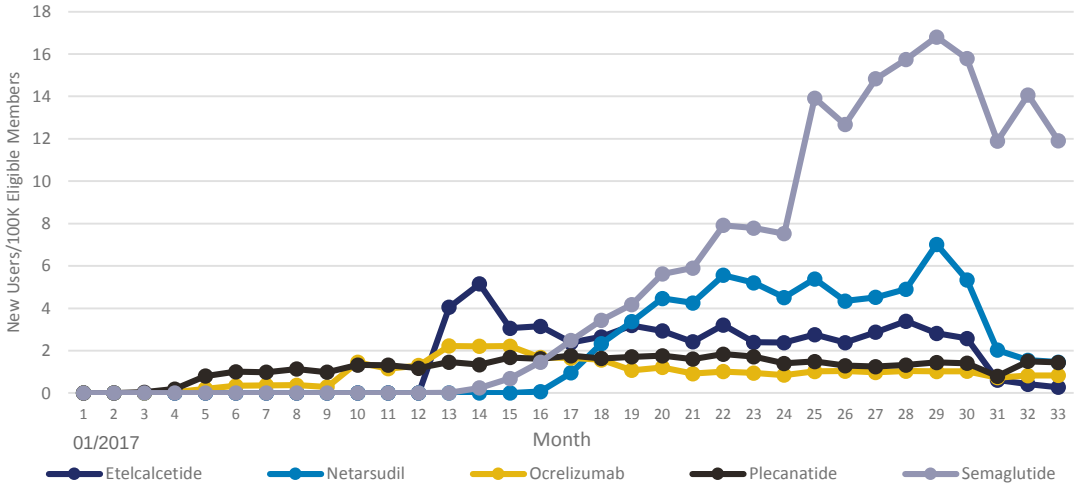
Most common indications on approval



Uptake of NMEs approved 2015-2017

	2017 NMEs (n = 46)	2016 NMEs (n = 45)	2015 NMEs (n = 22)
Low uptake (<1 new users/100K eligible members)	39%	40%	41%
Medium uptake (<10 new users/100K eligible members)	41%	36%	36%
High uptake (≥ 10 new users/100K eligible members)	20%	24%	23%

Monthly uptake of NMEs with most accrual of new users



Follow-up time available for NMEs with most new users

NME	Median [IQR] follow-up, days
Semaglutide	126 [59-230]
Netarsudil	179 [88-273]
Etelcalcetide	266 [126-420]
Plecanatide	315 [158-495]
Ocrelizumab	363 [167-503]

- Consistent with previous studies of early post-approval uptake, large variability exists in uptake across NMEs
- Given their higher uptake rates, newly approved drugs that treat common chronic conditions or are never-before-approved products are potential candidates for early postmarket safety monitoring