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Association of Formulary Coverage and Outcomes in Medicare Patients with Multiple Sclerosis

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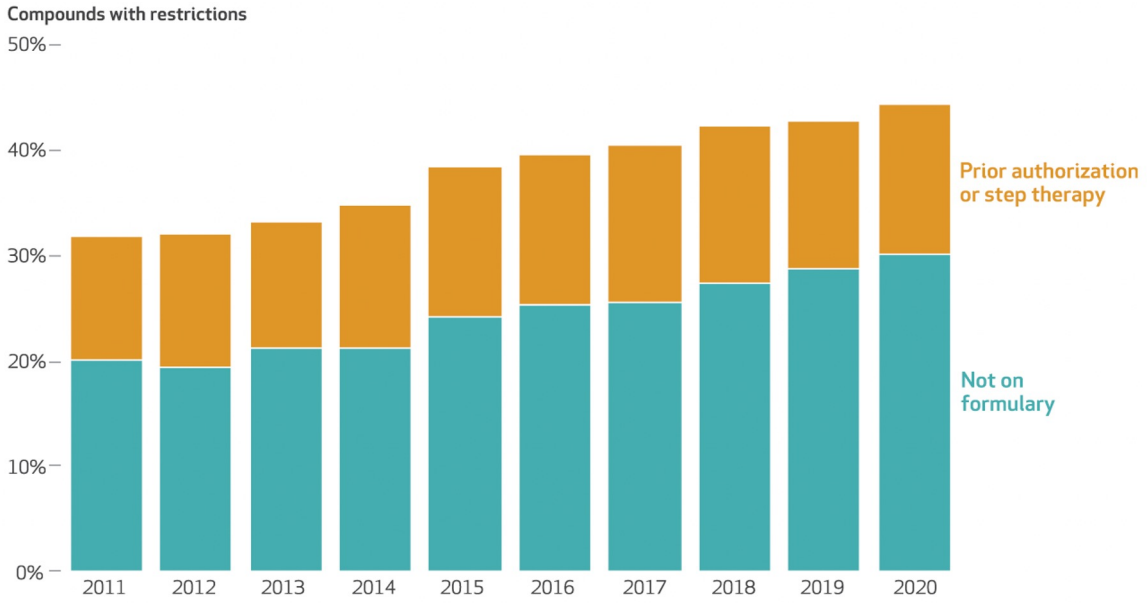
Growth in formulary restrictions in Medicare Part D

EXHIBIT 1

Proportion of compounds with restrictions (not on formulary, or prior authorization or step therapy) on Medicare Part D formularies, 2011–20



SOURCE Authors' analysis of data from the 100 percent sample of Medicare administrative data, including Part D formularies files, 2011–20. **NOTES** The universe of compounds was defined as those covered by any formulary, including excluded drugs if a plan covered excluded drugs and excluding over-the-counter products and protected classes. Averages are weighted by plan enrollment.

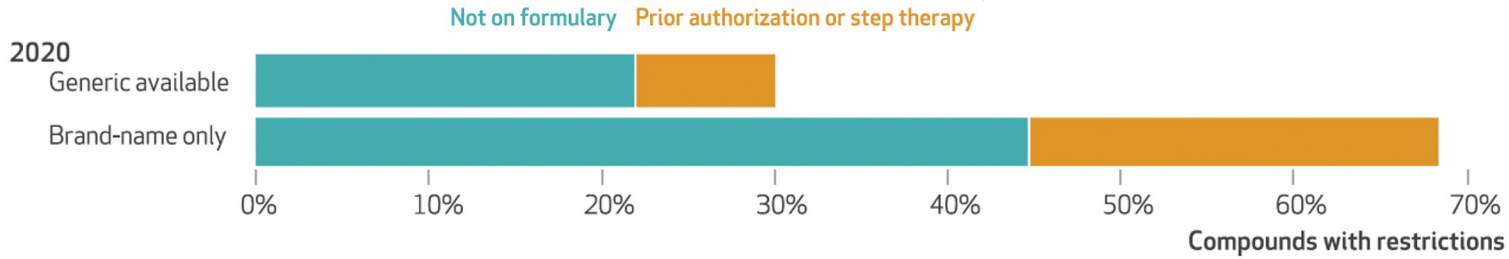
- Medicare Part D:
  - A voluntary outpatient prescription drug benefit
- Formulary restrictions:
  - Prior authorization/ step therapy/ quantity limits (PA/ ST/ QL)
  - Formulary exclusions (FE)
- Access restrictions of non-protected drug classes became more common over years, especially **FE**

Joyce, G., Blaylock, B., Chen, J., & Van Nuys, K. (2024). Medicare part D plans greatly increased utilization restrictions on prescription drugs, 2011–20. Health Affairs, 43(3), 391–397. https://doi.org/10.1377/hlthaff.2023.00999

Restrictions on brand-name only compounds

EXHIBIT 2

Proportion of compounds with restrictions (not on formulary, or prior authorization or step therapy) on Medicare Part D formularies, by generic availability, 2011–20



- In addition, restrictions were found **higher** among:
  - More costly compounds
  - Stand-alone Part D plans (PDP) than Medicare Advantage plans (MAPD)

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Stakeholder implications on coverage restrictions

Pharmacy benefit managers (PBMs) & payers:

- Improve safety and control costs
- More cost-effective prescriptions
- Cost savings in drugs > administrative burdens (Brot-Goldberg et al., 2023)

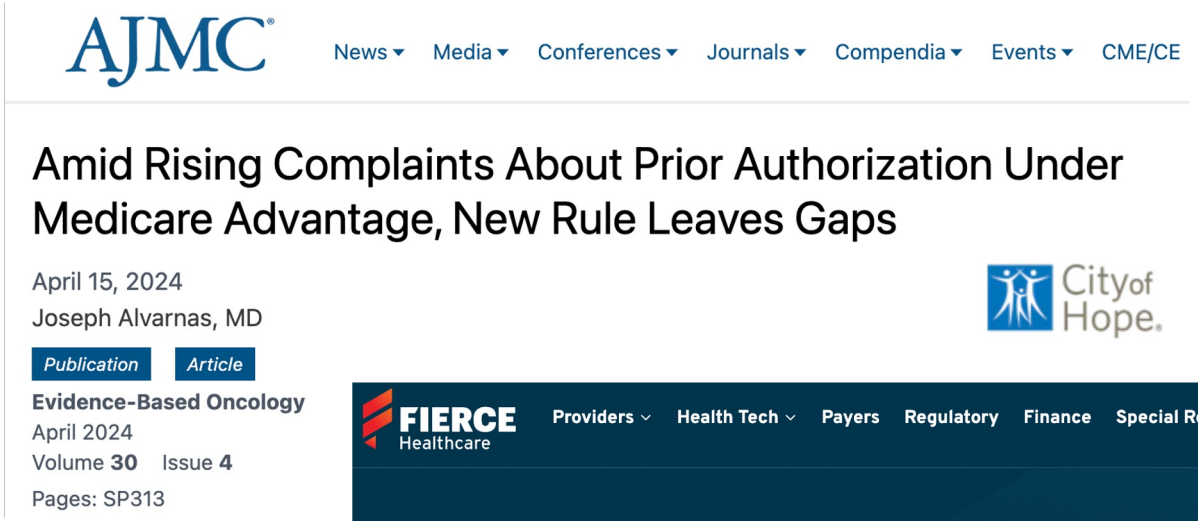
Physicians:

- Prior authorizations are overused, costly, inefficient, opaque, and can delay access to care (American Medical Association, 2024)

Patients:

- PA/ST can delay access to therapies
- Exclusions can foreclose access to needed care
- Restrictions can harm treatment outcomes, e.g.:
  - Formulary restrictions of oral anticoagulants and stroke risk (Zhou et al., 2022)
  - Systematic review of restrictions on patient and payer outcomes (Park et al., 2017)

Attention to prior authorizations is growing…



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Amid Rising Complaints About Prior Authorization Under Medicare Advantage, New Rule Leaves Gaps

April 15, 2024

Joseph Alvarnas, MD

Publication *Article*

Evidence-Based Oncology

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CMS finalizes rule setting prior authorization deadlines for payers

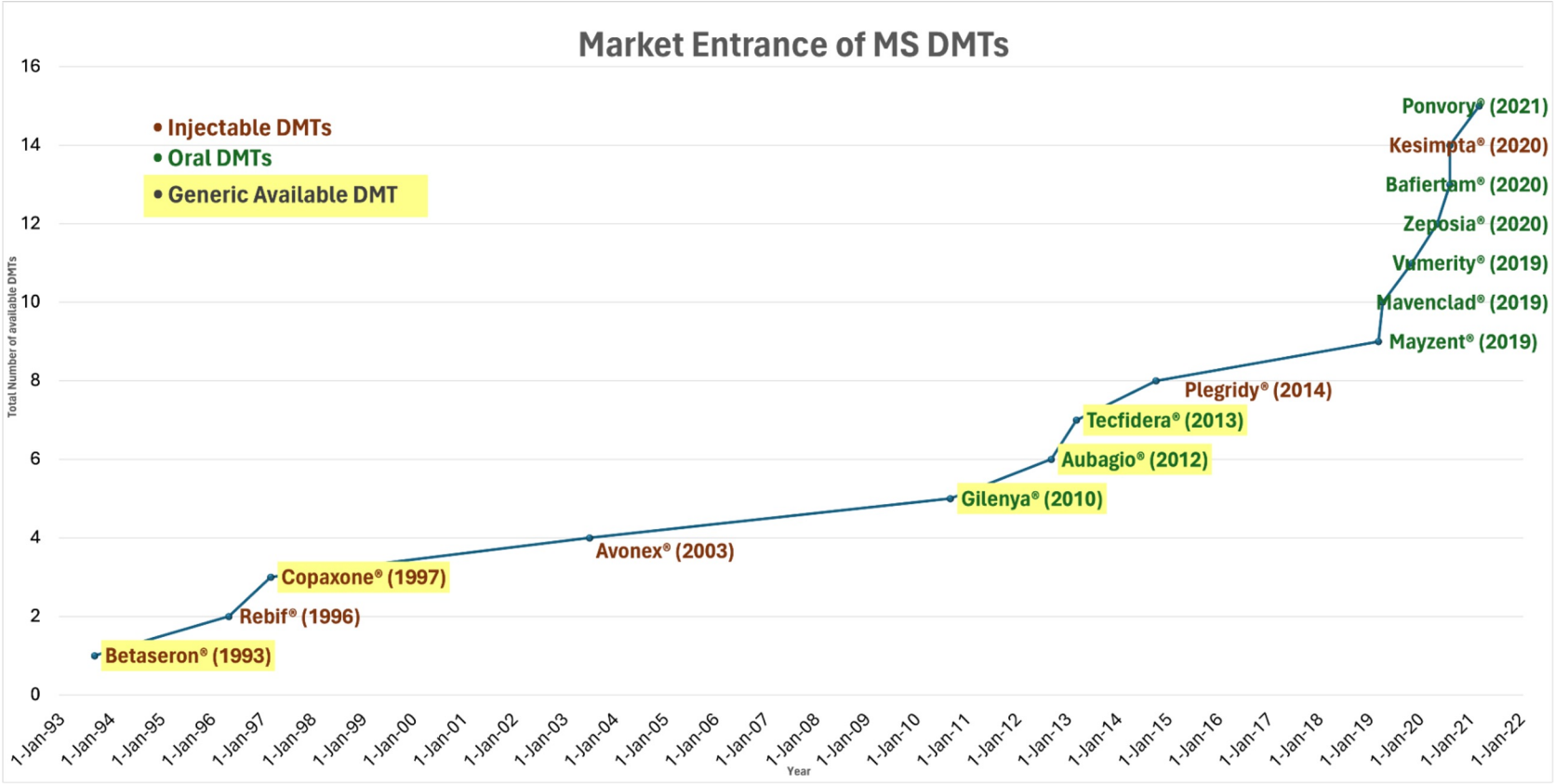
By **Noah Tong** · Jan 17, 2024 11:49am

- However, **formulary exclusions are still rising** with more difficult appeal process

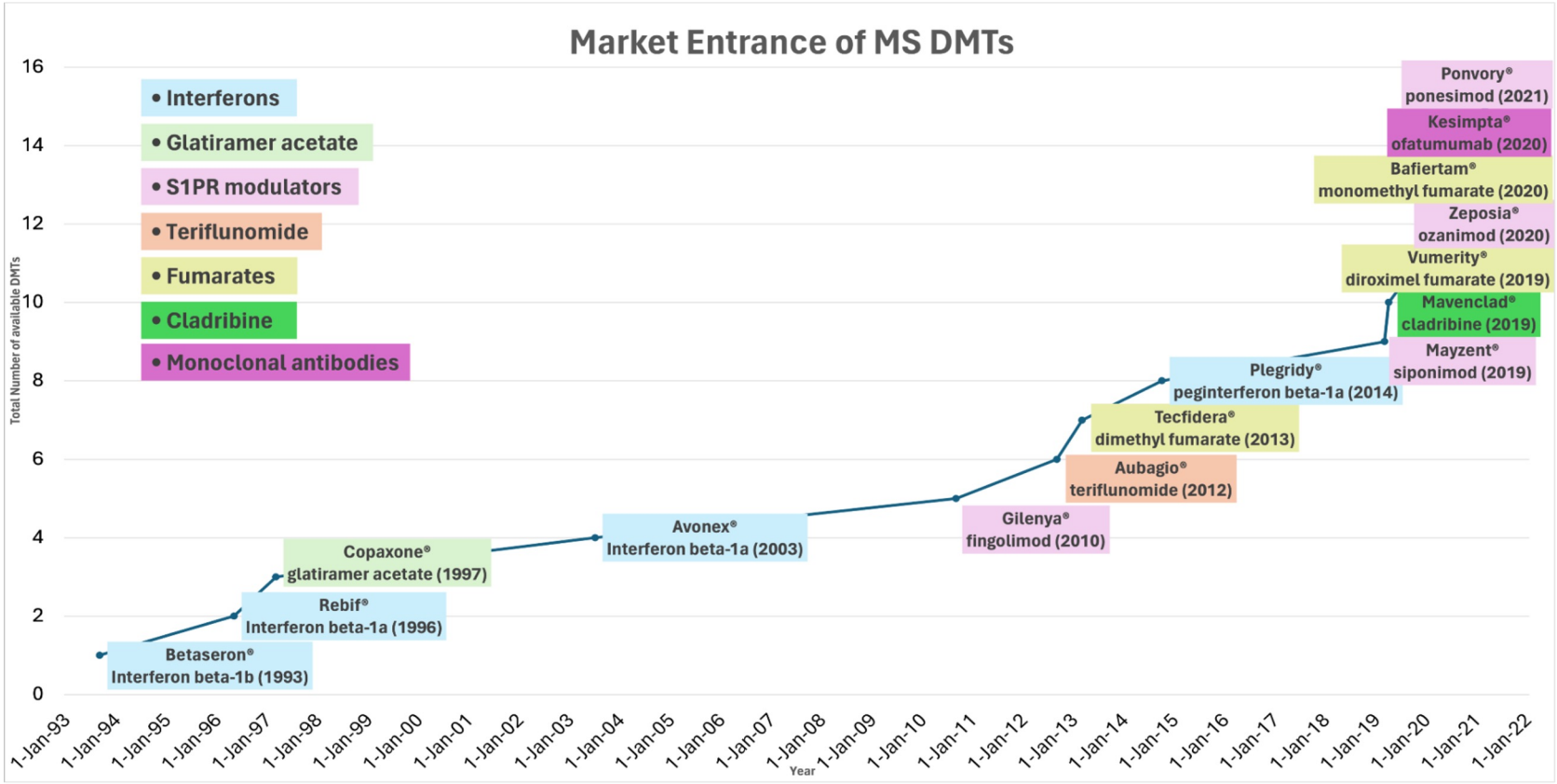
Do formulary restrictions adversely affect patient outcomes? Case study: Multiple sclerosis (MS)

- Historically, exclusions applied to drugs with generic equivalents or treatments of similar effects
- Today, increasingly applied to drugs for complex therapeutic areas (TAs):
  - e.g. Autoimmune disorders, endocrine disorders, cancers (AmerisourceBergen & Xcenda, 2022)
  - Marked by heterogeneous treatment effects across products and patients
- **MS is a good test case**:
  - An autoimmune disease that affects patients differently
  - Expanding number of costly disease-modifying therapies (DMTs) in recent years
  - Heterogeneity in treatment responses and no standard line of therapy (LoT) guideline
  - Tradeoff between efficacy and safety among DMT classes
  - DMTs are available by different routes of administration (RoA), i.e., oral, injectable, and infusion
  - “Breakthroughs” or “relapses” are common: need switch options

MS treatment landscape in Part D plans by RoA



MS treatment landscape in Part D plans by drug class



Study objectives

- To describe the formulary coverage of MS DMTs in Medicare Part D
- To examine how restrictions on MS DMTs are associated with patient outcomes

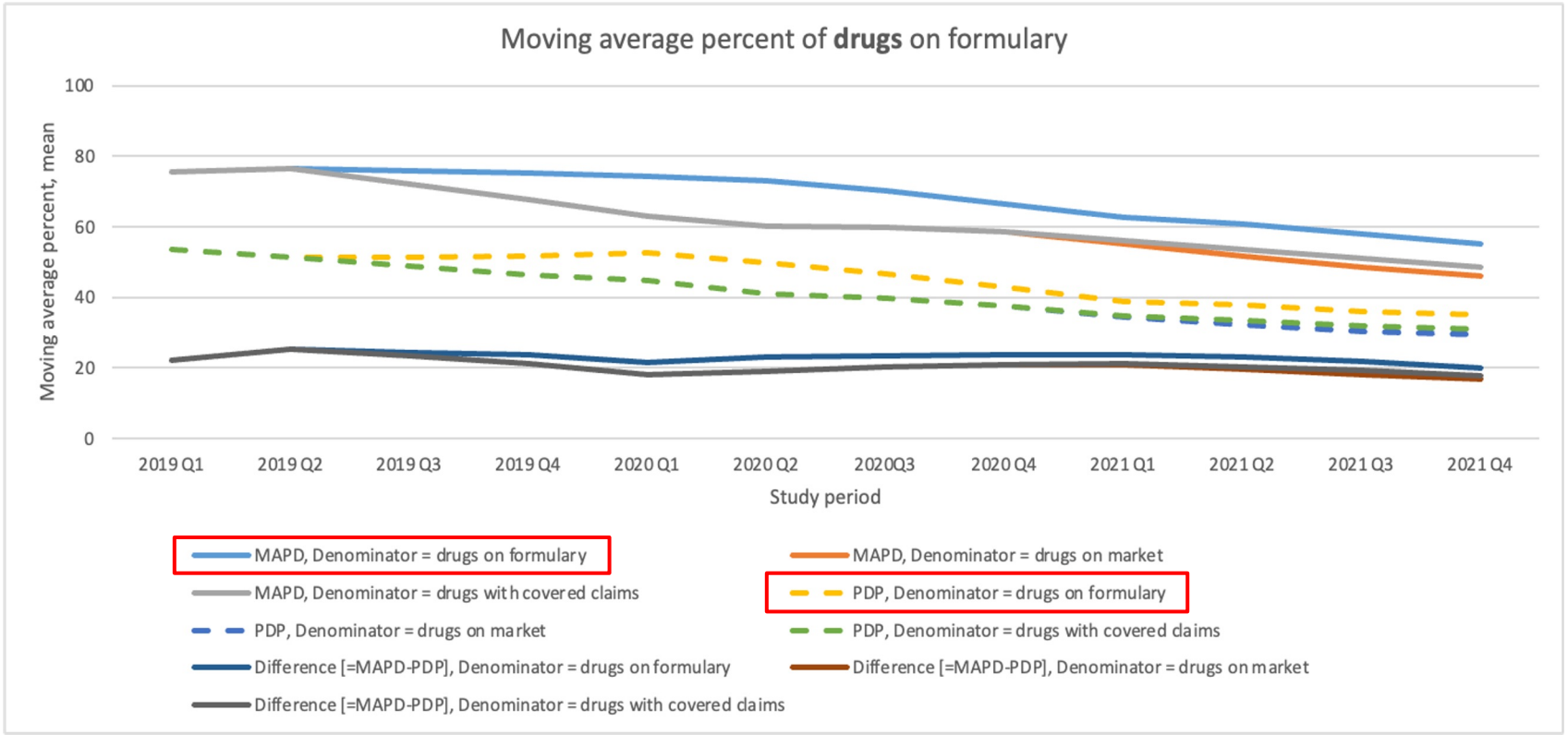
Study methods

- **Data:** Medicare administrative data 100% sample for 2018-2021
- **Study Design:** Retrospective, observational study of administrative healthcare claims at a beneficiary-quarter level for each quarter in 2019-2021
- **Study population:** Beneficiaries with confirmed MS diagnosis in fee-for-service (FFS) Medicare or Medicare Advantage (MA) plans
- **Study model:** Logistic regression
- **Study outcome:** Any relapse/ refractory (R/R) MS episode
- **Key explanatory variable:** Moving average of the % of drugs/ % drug classes covered in each plan over the 4 quarters prior to the quarter observed
- **Other explanatory variables:** Patient demographics, comorbidities, MS disease severities, MS DMT use, and plan characteristics, all measured in baseline

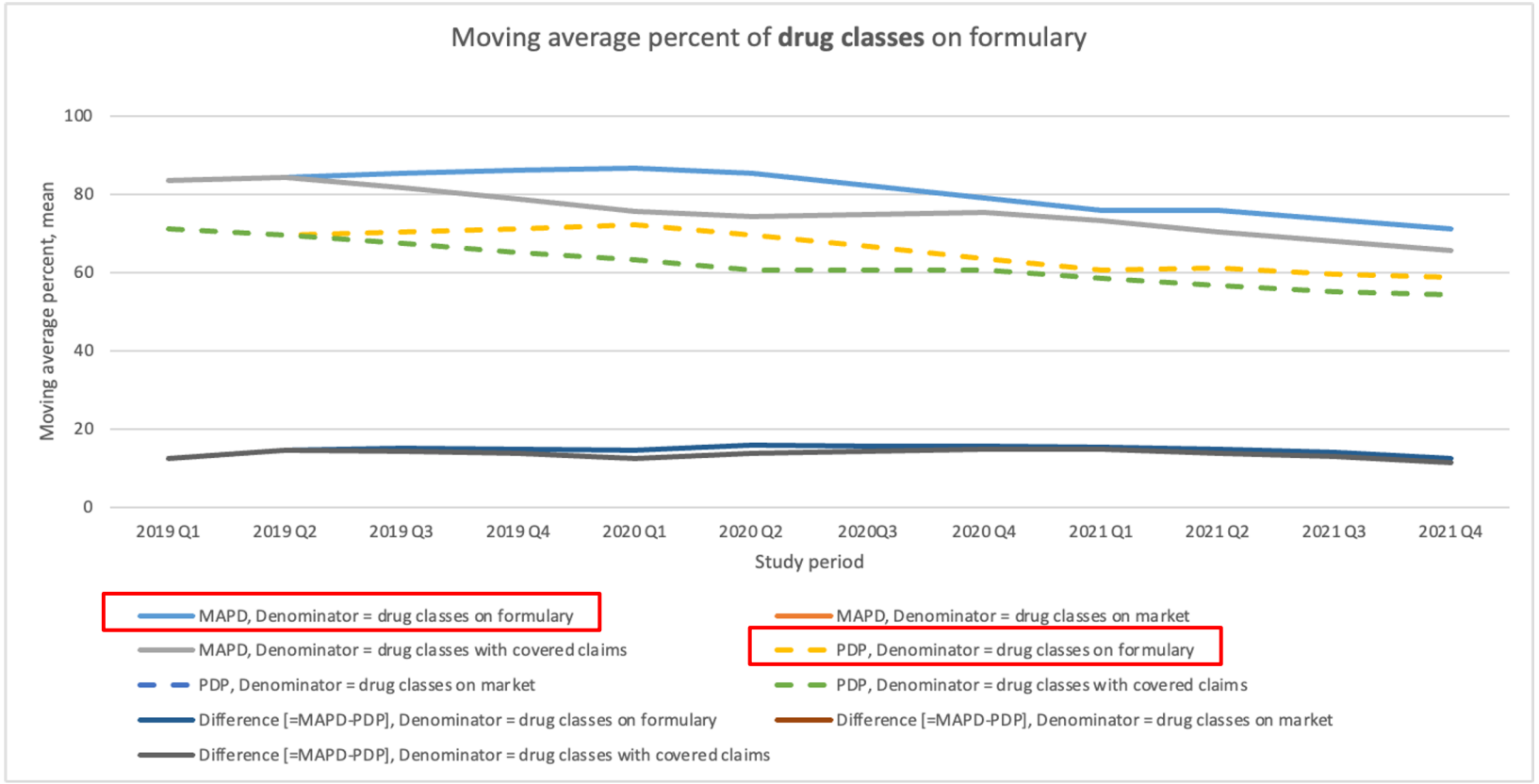
Sample selection

Description	Count of unique beneficiaries
Count of beneficiaries in a Part D plan with any MS diagnosis code on claims/ encounters	265,000
With continuous enrollment A/B/D	247,438
With continuous enrollment same plan	225,830
With eligible plan (FFS or MA with high data completeness)	221,886
With enrollment in FFS-PDP or MA-MAPD combination	217,772
With MS diagnosis	54,673
Not missing baseline CCI	54,640
Not missing baseline EDSS-DDI	54,640
Not missing formulary info	**52,763**

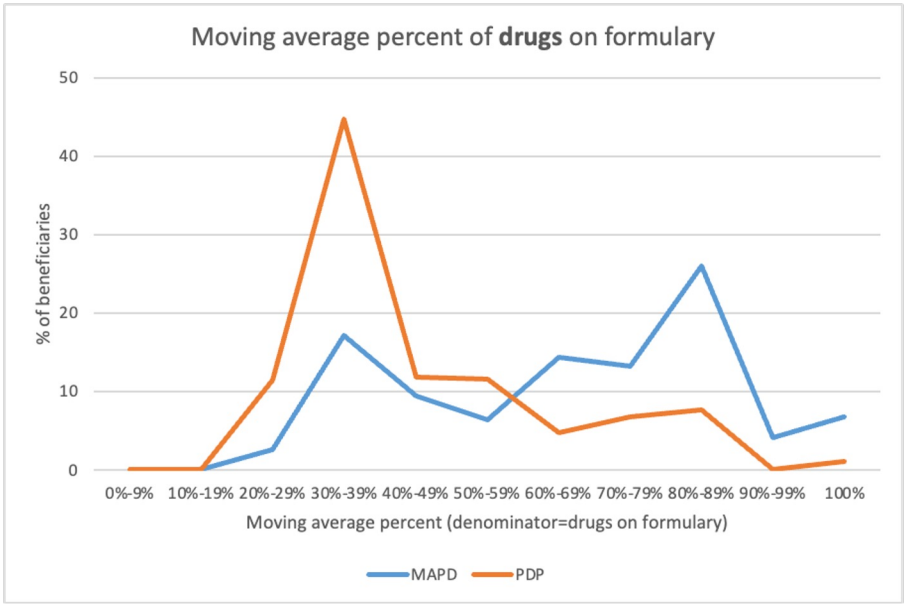
Preliminary results - Part D DMT coverage by drug

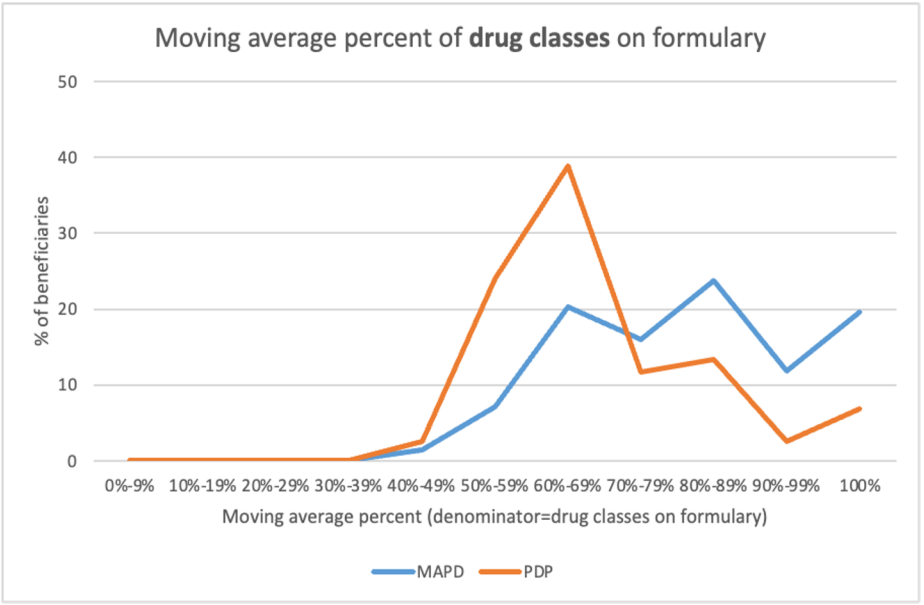


Preliminary results - Part D DMT coverage by drug class



Preliminary results - Part D DMT coverage distribution





Preliminary results - Logistic regression:

% drugs/ % drug classes covered on R/R MS episode

Outcome	Key explanatory variable	Estimate	P-value	Odds Ratio (OR)	95% Confidence Interval (CI)
Any R/R	% **drugs** on formulary	-0.1154	0.0127	0.8910	(0.8136, 0.9755)
Any R/R	% **drug classes** on formulary	-0.1867	0.0028	0.8297	(0.7340, 0.9378)
Outpatient R/R	% **drugs** on formulary	-0.1828	0.0002	0.8329	(0.7565, 0.9169)
Outpatient R/R	% **drug classes** on formulary	-0.2697	<0.0001	0.7636	(0.6706, 0.8693)

Conclusions

- Our past and working papers show:
  - Growing trend of PA/ST & FE
  - Downward trend and insufficient coverage of MS DMTs in Medicare Part D plans
  - The lack of representation of MS treatment choices matters:
    - Potential harm to patient outcomes
    - The implication might apply to other TAs
- Next steps:
  - More outcomes: MS-related inpatient stays, emergency department (ED) visits, and office visits; disability status, mortality
  - Sensitivity analysis by age group
  - To examine the broader impact of formulary restrictions on other TAs
- Takeaways:
  - Tradeoff between cost control and patient access
  - Overuse of restriction policy could induce adverse consequences
  - Timely coverage of quality innovations may improve patient outcomes

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