

The High Cost of Multiple Sclerosis Drugs: A Case Study in Pharmaceutical Market Dysfunction

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- AbbVie Pharmaceuticals (research contract)
- National Multiple Sclerosis Society (research contract)

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- NIH / NIDA
- CDC
- AHRQ

- Multiple Sclerosis is progressive, immune-mediated, neurologic condition associated with significant physical disability and functional impairment
- Prevalence in US ~ 1 million
- Economic burden is significant
 - ~\$70K/year – direct and indirect costs
 - 50% to 75% of total direct medical spending is for Rx Drugs
- MS Disease-modifying therapy (DMT) are not curative but can reduce relapses and delay progression
- DMT should be offered to all individuals with RRMS

Disease-Modifying Therapies for Relapsing-Remitting MS (RRMS)

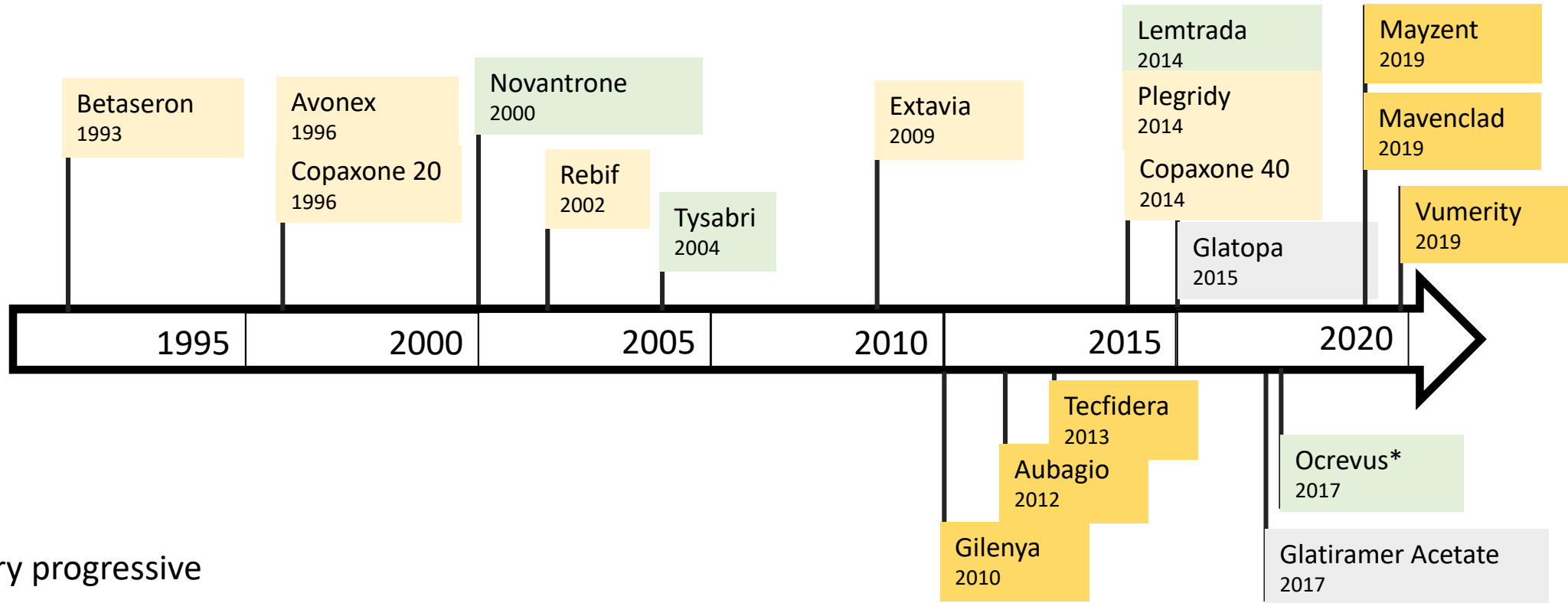
- FDA approved 1st MS drug in 1993
- 19 FDA approved drugs that differ by MOA, administration, efficacy and adverse effects

Self-administered injection = 7

Oral = 6

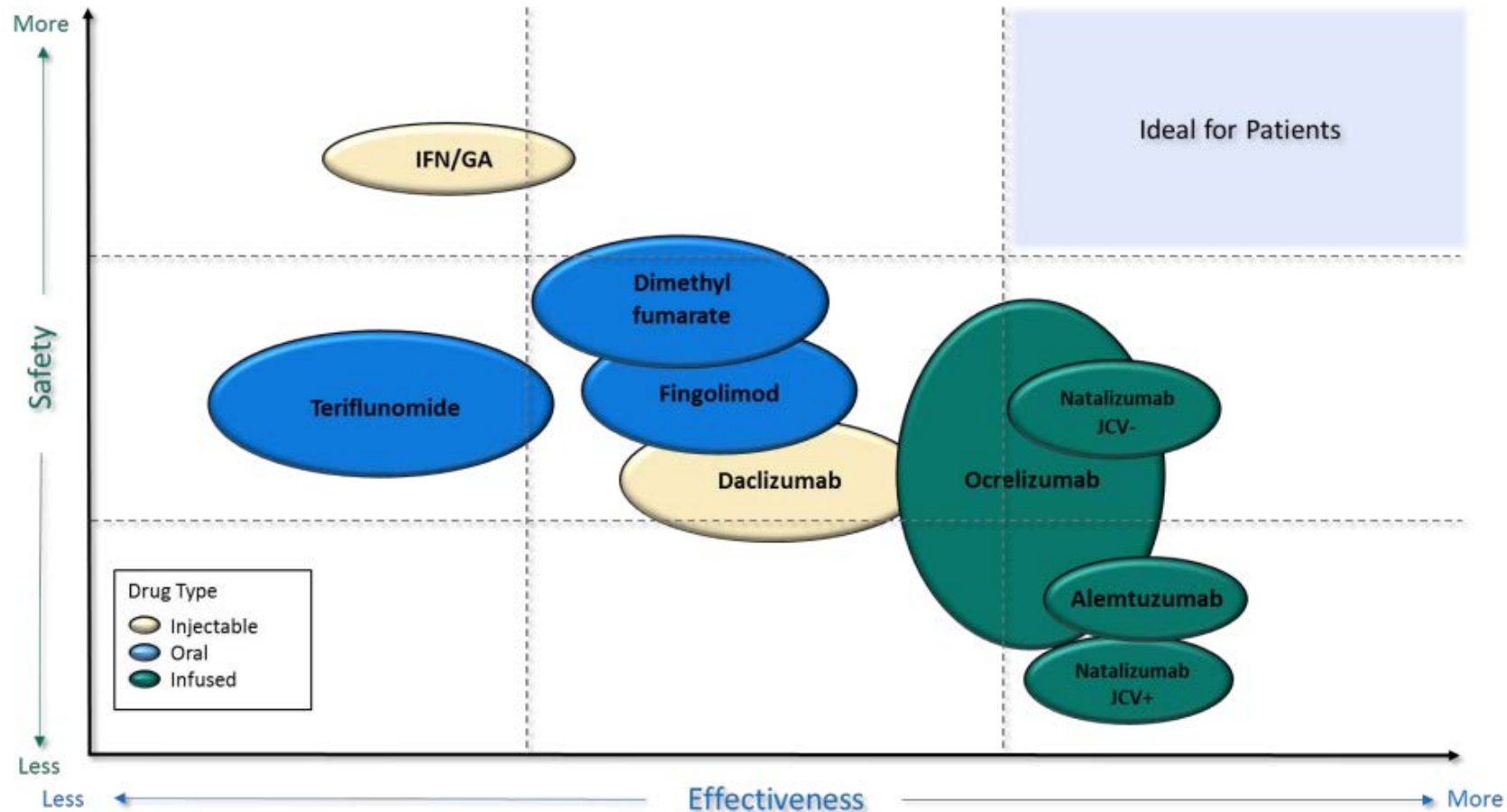
Infusions = 4

Generic = 2
(glatiramer acetate)



*Primary progressive

Qualitative summary of safety and effectiveness

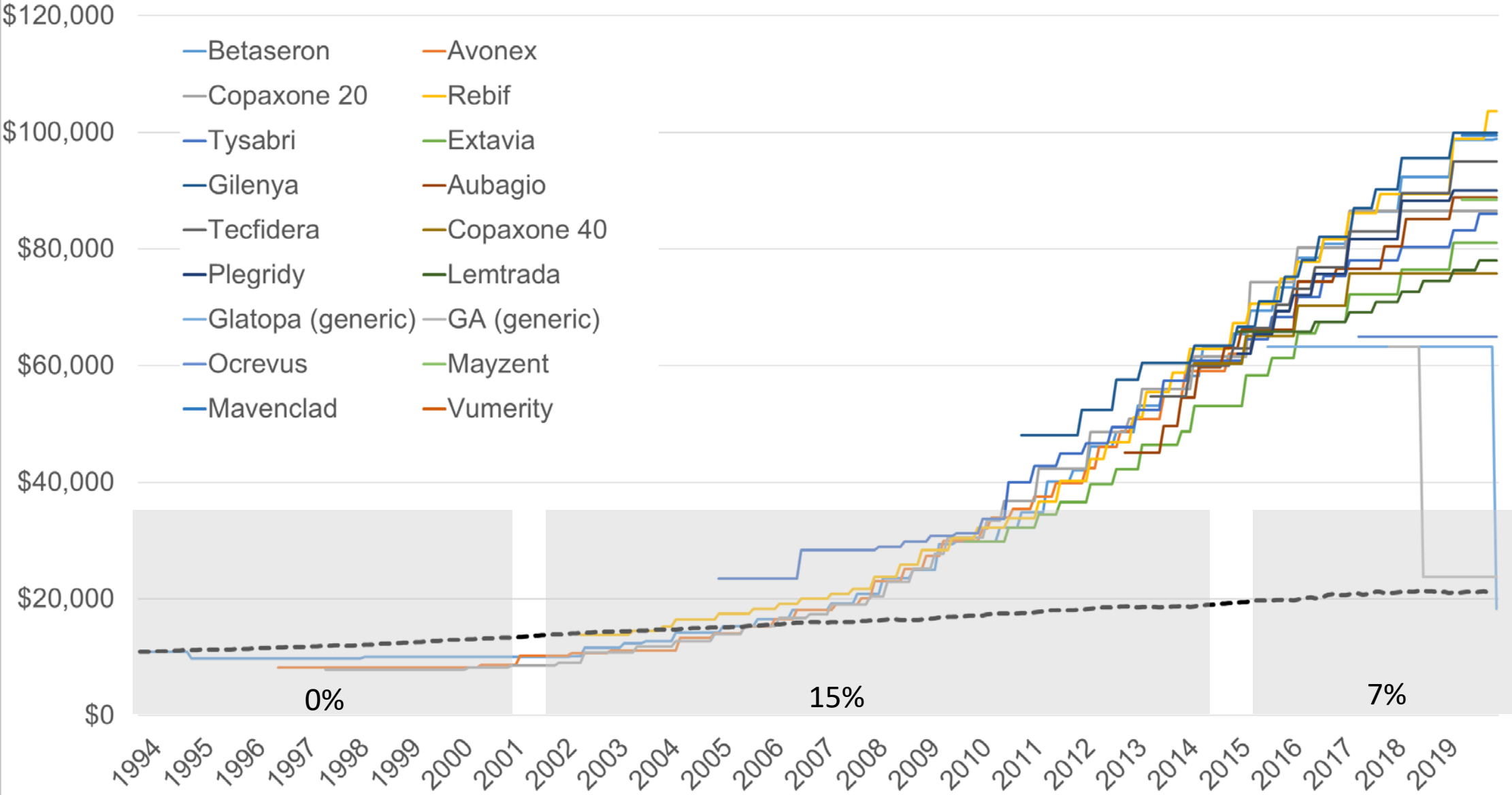


Wider and taller shapes indicate greater uncertainty. Not drawn to scale.

ICER Report: DMT for RRMS and PPMS: Effectiveness and Value

https://icer-review.org/wp-content/uploads/2016/08/CTAF_MS_Final_Report_030617.pdf

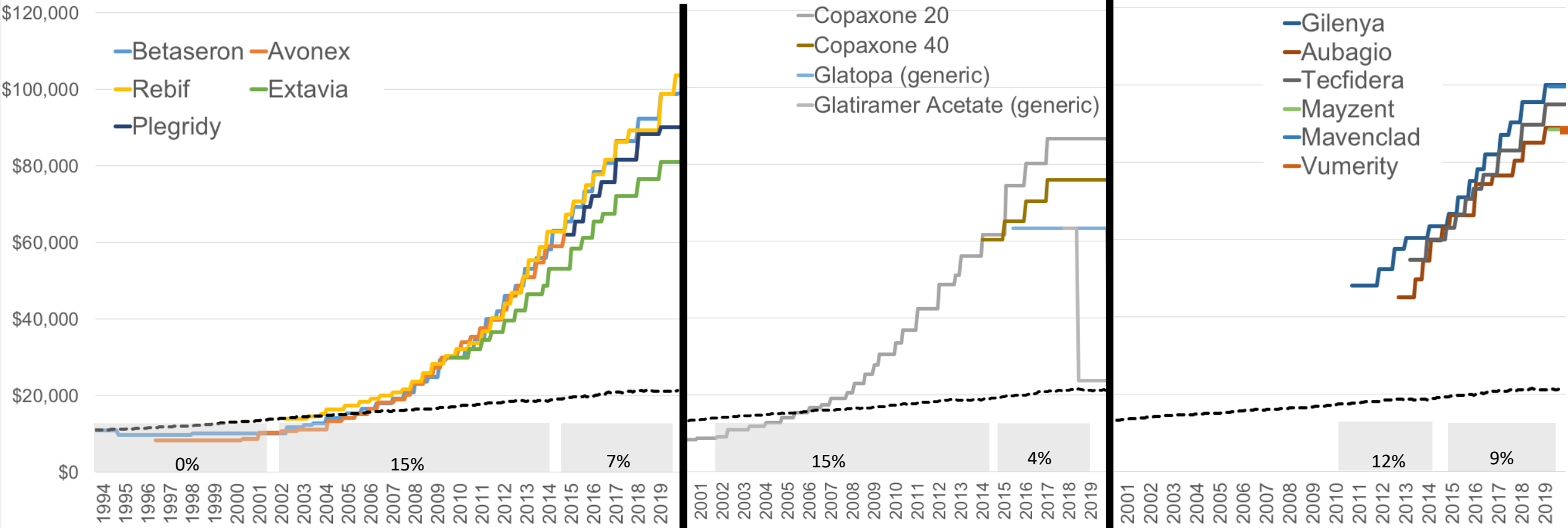
Annual DMT Pricing (WAC): 1993 to 2019



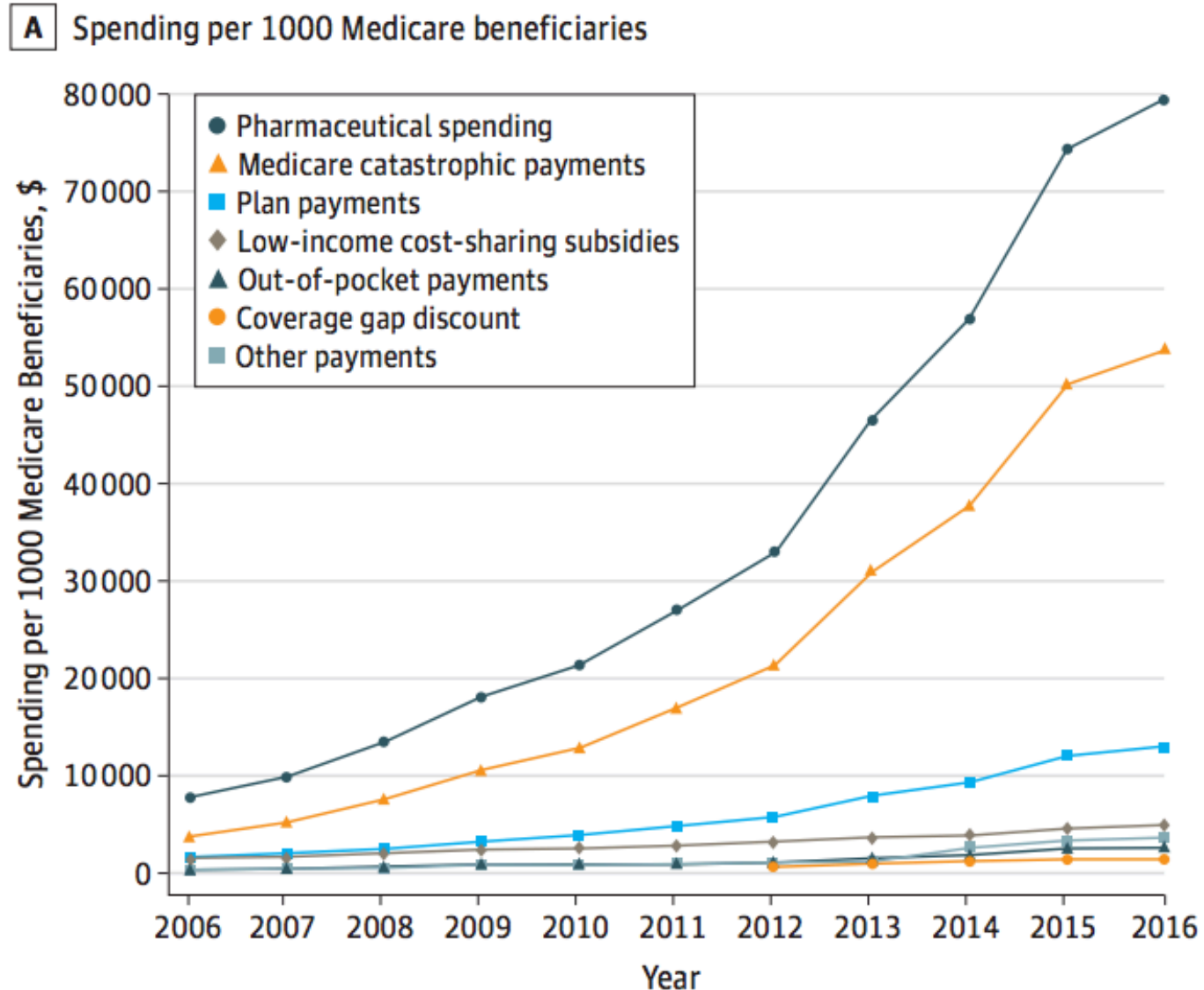
Interferons



Glatiramer Acetate

Orals



DMT Spending in Medicare Part D



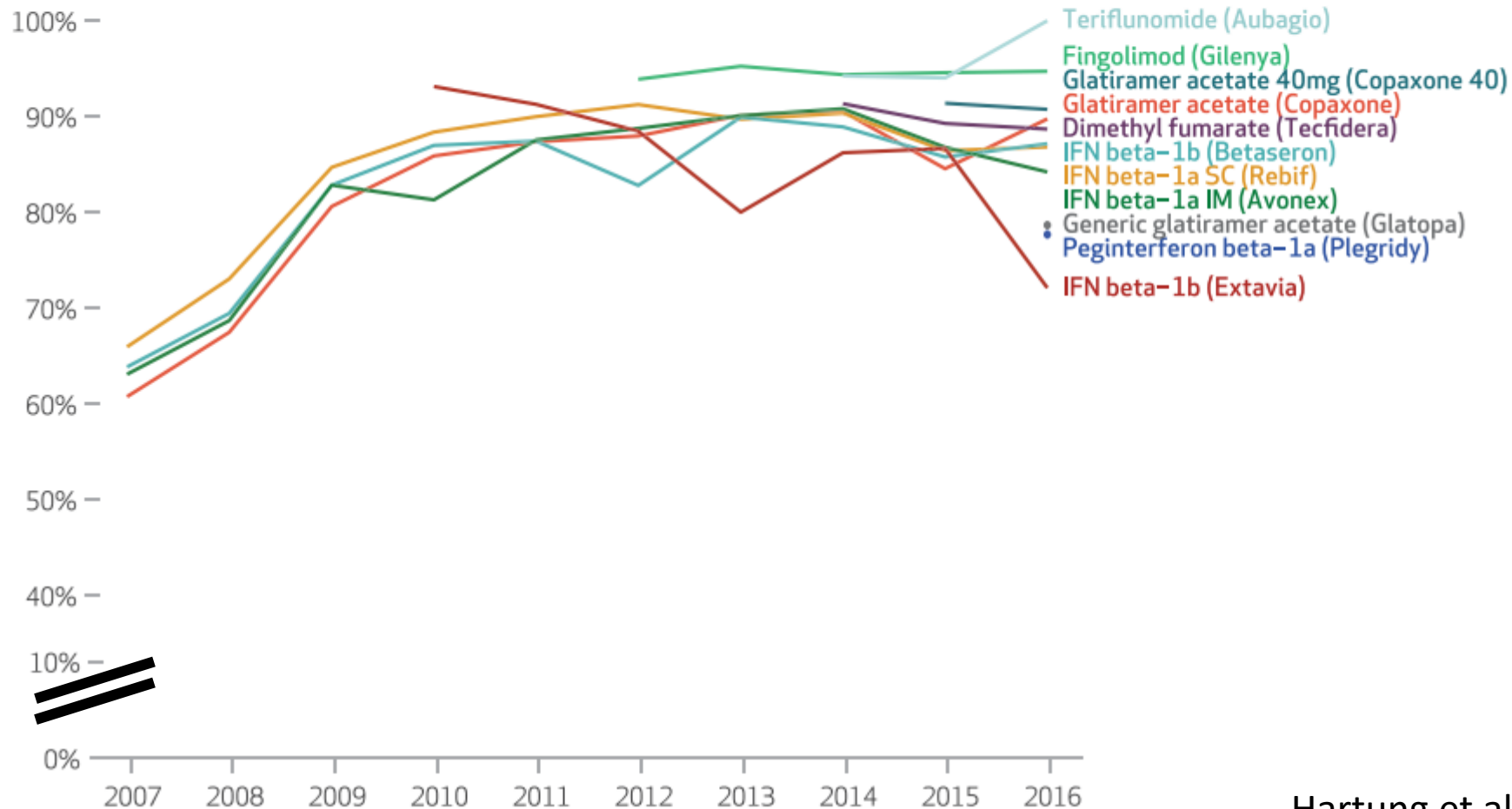
- 2017 Medicare
 - ~ \$5 B for DMTs
 - ~\$1.5 B for branded Copaxone
 - ~\$1.4 B for neurology services
- Between 2006 and 2016
 - DMT spending  10 fold
 - Patient OOP  7 fold

Hartung, Bourdette; 2019 JAMA Neurology
San-Juan Rodriguez; 2019 JAMA Neurology

Increasing Access Restrictions (Medicare Part D)

EXHIBIT 2

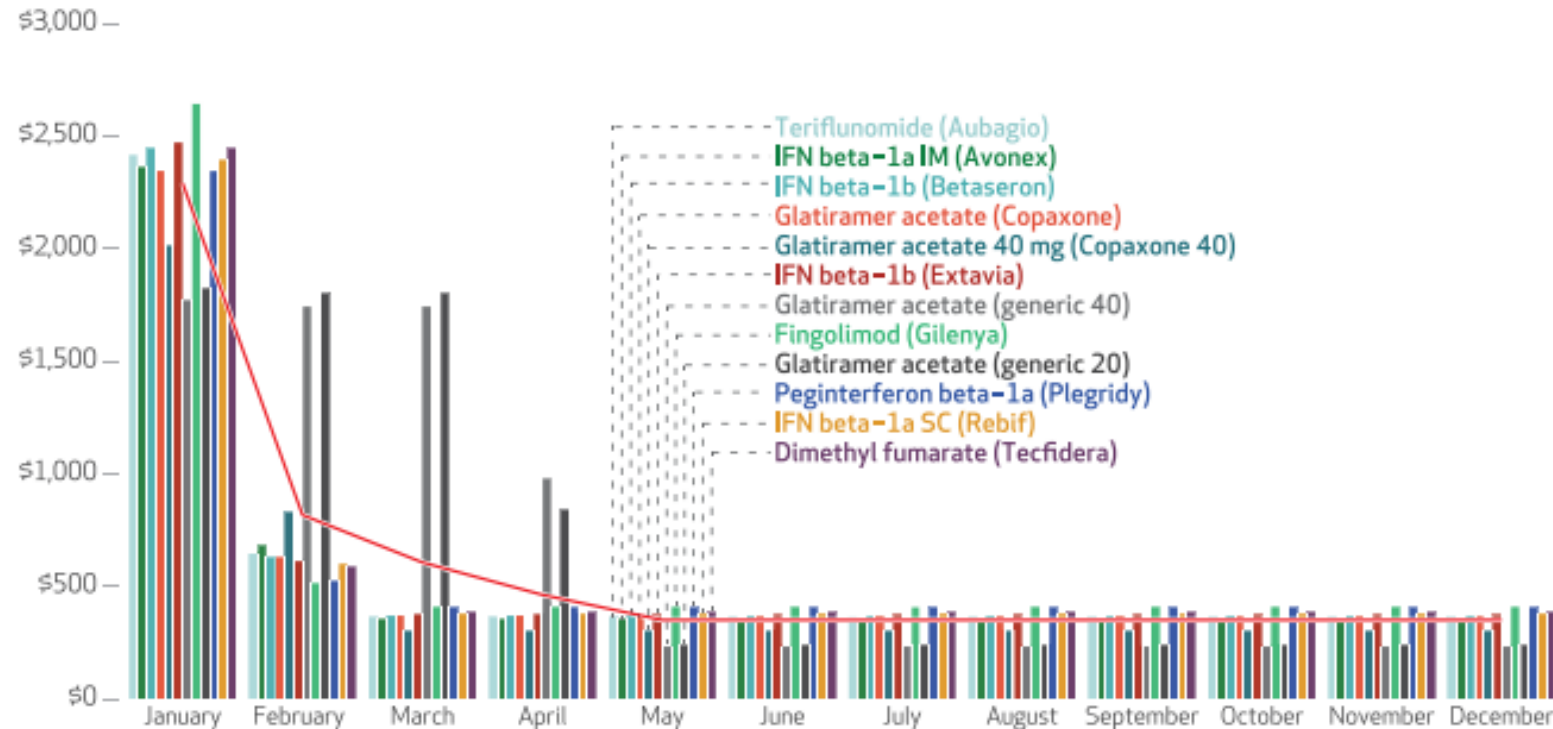
Weighted percentages of prescription drug plans that used prior authorization policies to manage multiple sclerosis disease-modifying therapies, 2007-16



Projected Out-of-pocket Costs(Medicare Part D)

EXHIBIT 4

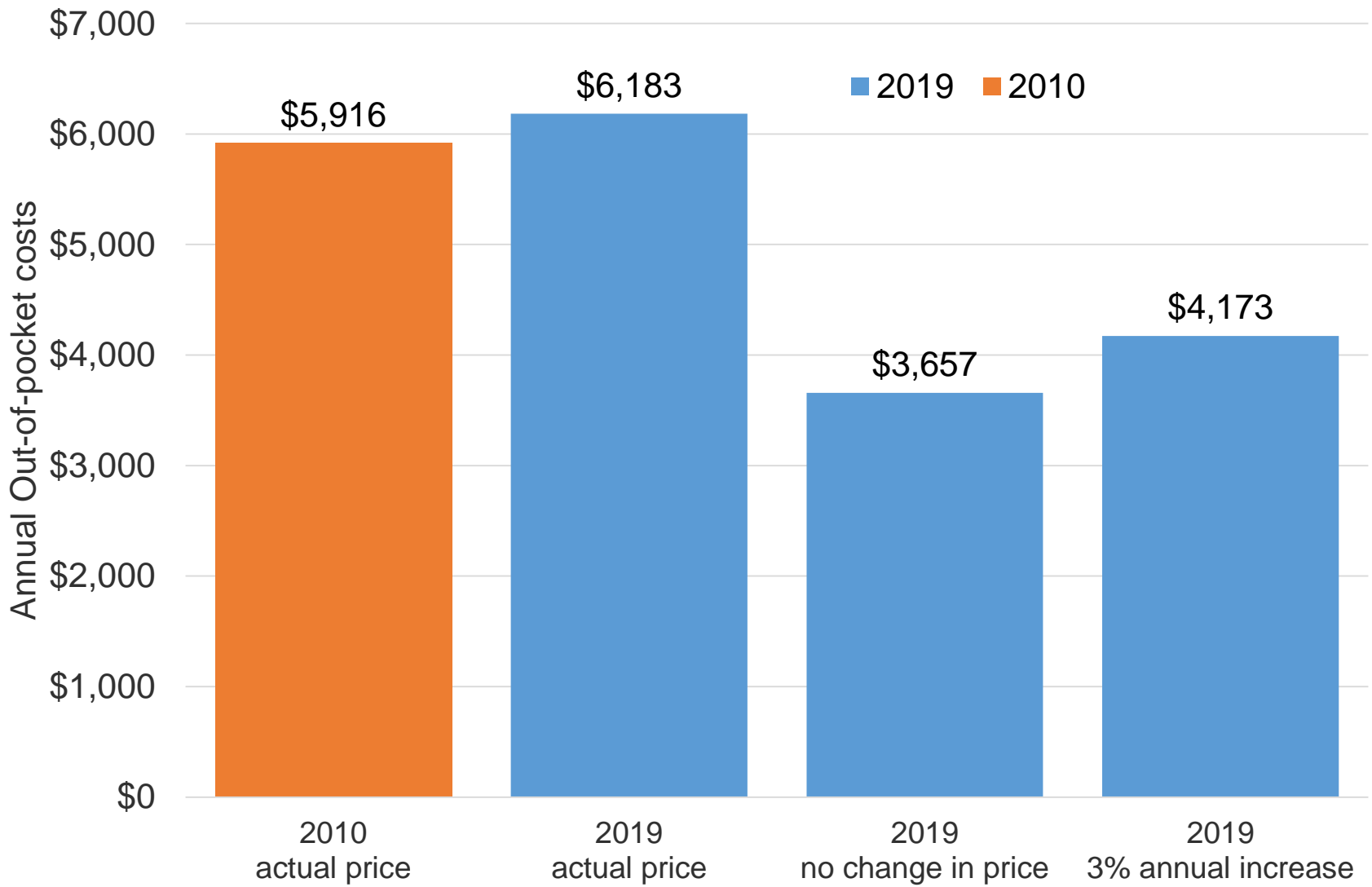
Projected out-of-pocket spending for beneficiaries without a low-income subsidy for multiple sclerosis disease-modifying therapies, by month, 2019



Rising Prices Have Undermined Policy Efforts to Reduce Medicare Beneficiary OOP

Disease-modifying therapy (Brand name), year approved	Monthly price (\$D)			Annual change ^b		Projected annual out-of-pocket ^c			Annual change ^b	
	2010	2016	2019	2010 to 2019	2016 to 2019	2010	2016	2019	2010 to 2019	2016 to 2019
Interferon beta-1b (Betaseron) 1993	\$5169 (104)	\$6109 (77)	\$7762 (245)	2.7%	9.1%	\$7,336	\$6,246	\$6,632	-2.5%	1.0%
Interferon beta-1a (Avonex) 1996	\$2716 (101)	\$5564 (80)	\$7076 (238)	12.2%	9.1%	\$5,864	\$5,909	\$6,228	0.1%	0.8%
Glatiramer acetate 20 mg (Copaxone) 1996	\$2891 (57)	\$6669 (86)	\$7273 (391)	14.3%	3.2%	\$5,968	\$6,578	\$6,347	1.6%	-0.6%
Interferon beta-1a SC (Rebif) 2002	\$2596 (54)	\$5987 (184)	\$7706 (285)	14.3%	9.6%	\$5,792	\$6,153	\$6,603	1.0%	1.1%
Fingolimod (Gilenya) 2010		\$6483 (94)	\$8426 (250)		10.0%		\$6,464	\$7,033		1.4%
Teriflunomide (Aubagio) 2012		\$6194 (233)	\$7482 (259)		7.1%		\$6,291	\$6,503		0.5%
Dimethyl fumarate (Tecfidera) 2013		\$6110 (140)	\$7988 (289)		10.2%		\$6,229	\$6,752		1.3%
Glatiramer acetate 20 mg (Glatopa - generic) 2015		\$5208 (253)	\$4123 (1209)		-8.1%		\$7,494	\$6,879		-1.4%
Median	\$2804	\$5987	\$7009	13.2%	7.9%	\$5916	\$6229	\$6618	0.5%	0.5%

Medicare Part D Annual OOP



Escalating DMT prices have undermined the effect of closing the Part D Coverage Gap

Effects of DMT Costs on Individuals with MS

- National MS Society Survey (n=8,778)
 - 55% report challenges with cost of treatment
 - 21% report challenges with insurance policies and coverage
- Policies that reduce coverage and increase cost-sharing can negatively affect DMT use
 - Reduced DMT initiation
 - Reduced DMT adherence
 - Increase DMT discontinuation
 - Increased DMT abandonment

Palmer L. Am J Pharm Benefits. 2012

Li. Health Serv Res. 2017. 2017

Starner Cl. Health Affairs. 2014

Hartung – ICPE 2018

<https://www.nationalmssociety.org/NationalMSSociety/media/MSNational/Advocacy/surveydetail.pdf>



“Companies have been able to raise prices because nobody has pushed back or told them that they’re not able to”
-X pharmaceutical executive
(paper forthcoming)

<https://khn.org/news/doughnut-hole-is-gone-but-medicares-uncapped-drug-costs-still-bite-into-budgets/>



Tod Gervich injects himself with the prescription drug Copaxone, three times a week. While he’s accustomed to managing his condition, he can’t get used to Medicare’s high coinsurance payments. (COURTESY OF TOD GERVICH)

“I feel like I’m being punished financially for having a chronic disease,”