1 Introduction

2 Background

Biologics, commonly referred to as biological products or biological drugs, are grown from organic tissue. Unlike tranditional "small-molecule" drugs such as Lipitor (atorvastatin) which are chemically synthesized and can be reproduced exactly, due to their organic nature biologics can't be replicated.

Generic copies of small-molecule drugs can enter a market after the expiration of patents by the brand drug. Regulations like the Hatch-Waxman Act of 1984, which provides pharmaceutical firms with a guaranteed exclusivity period for innovative products in exchange for the ability of generic drug manufacturers to enter markets through an expedited regulatory process, support the development of generics. In addition, many states have laws that encourage or mandate generic substitution of a small-molecule drug when available. Song and Barthold [2019] found that presumed consent laws encourage generic drug consumption. However, biologic generics could not take advantage of the same pathway set forth by the Hatch-Waxman due to the inability to create exact copies of the drug. As a result, close biosimilar copies needed to be approved using the regular NDA process. The Biologics Price Competition and Innovation Act (BPCIA) of 2009 attempted to bridge the gap between small-molecule generics and biosimilars by creating an abbreviated pathway for biosimilars. As defined by the Food and Drug Administration, a biosimilar is a biologic that is highly similar to and has no clinically meaningful differences from an existing reference or innovator biologic that is already in production. The phrase "meaningful differences" refers to the efficacy and safety of the biosimilars in comparison to the brand reference biologic. While having a similar intent to Hatch-Waxman, BPCIA guarantees a longer period of exclusivity for the reference drug and the interchangeability provisions in BPCIA are much stricter Timmis [2015].

In addition to regulatory and structural differences between small-molecule generics and biosimilars, the difficulties in developing biosimilars is exacerbated by much higher costs relative to small-molecule drug development. According to a 2018 speech by former Commissioner of Food and Drugs for the FDA, Scott Gottlieb, the typical cost of developing a biosimilar ranges from \$100 million to \$250 million while the development of a generic small molecule drug costs about \$10 million. The high development cost coupled with the aggressive strategies available to companies producing the reference biologics increase the risk for competitors looking to develop biosimilar products. Probably in part due to the high risk associated with bringing a biosimilar to market, the number of biosimilars developed for a reference biologic is highly correlated with the biologic's sales as shown in Figure 1.

Table 1 lists all 31 biosimilars approved for use in the United States as of Q3 2020. Of the 31 approved, 20 of those biosimilars have launched to market. Some of the drugs, like Amjevita which is a adalimumab biosimilar for Humira, haven't launched due to agreements with the producer of the reference biologic. Others have been approved and are in the process of launching. Granix, Basaglar, and Extavia all went through the traditional approval process put in place before BPCIA. The first biosimilar to be launched through the pathway created by BPCIA was the filgrastim biosimilar Zarxio in 2015, and in 2019 six new biosimilars were launched to market. The five year gap between BPCIA and the first biosimilar launch utilizing the pathway is a reflection of the inherent difficulties in bringing a biosimilar to market. Figure 2 shows the number of biosimilars approved in each year since 2015, and we observe an increase each year. Even in the presence of increased approval there is skepticism as to whether or not biosimilars are effective at competing with biologics Atteberry et al. [2019]. Regardless, it remains an empirical question as to whether the entry of biosimilars has any effect on biologics.

3 Data and Methods

3.1 Data

To get information on commercial drug prices and volume, we use a dataset maintained by a company called SSR Health. Our data spans Q1 2007 through Q3 2019 and includes data on list prices, net prices, wholesale acquisition costs (WAC), and discounts to Medicaid and

other payers for branded products reported by publicly traded companies. The list price of a drug is the price a consumer would have to pay if she didn't have insurance or were fulfilling a deductible, and the WAC is the price paid by the pharmacy to a distributor or manufacturer. The net price of a drug is the list price minus any rebates and discounts paid to pharmacy benefit managers (PBMs) and any other fees or coupons that exist. The list price and net price of a drug can vary over time in different ways. Hernandez et al. [2020] found that from 2007 to 2018 list prices of branded pharmaceutical drugs in the US increased by 159% while net prices increased by 60%. One limitation of our data is we do not have consistent information on any biosimilar products for commercial prices and volume. Our average sales price (ASP) data is publically available on the Centers for Medicare and Medicaid Services website and runs from Q1 2005 through Q2 2020 (**how does the lag fit in here? Does this mean it shows through Q4 2019?). Every quarter, manufacturers submit information on prices, rebates, and discounts to CMS and the ASP is calculated similary to the net price but doesn't take into account rebates or discounts to Part D, VA, or Medicaid. Medicare uses a volume-weighted ASP to determine reimbusement. For single-source drugs and biologics, the reimbursement rate is ASP plus 6%. In the case of small-molecule drugs that have a brand and generics, the reimbursement rate is the same regardless of which version is used. However, biosimilars are reimbursed in a slightly different way. Prior to 2018, all biosimilars of a given reference biologic were reimbursed equally, at ASP plus 6%of the reference drug's ASP. Starting in 2018 this was changed so that each biosimilar is now given a separate ASP calculation and each biosimilar is reimbursed at it's own ASP plus 6% of the reference biologic's ASP.

Our formulary data comes from MMIT analytics, a pharmacy advisory company with data covering a large majority of commercially insured lives. A formulary is a health plan's list of covered drugs, and each plan breaks drugs out into several categories or tiers of coverage. Most formulary designs capture some aspect of generic, preferred, or brand assignment as well as restricted or specialty assignment. Drugs that get put in the generic listing will have lower co-pays than those that get placed into a preferred tier, and preferred tier drugs will have lower co-pays than nonpreferred drugs. Similarly, unrestricted drugs will have a lower

co-pay or cost-sharing for the patient than restricted tier drugs. The assignment of tiers is not homogenous across insurers and plans. For a discussion on the differences between health plans' formularies see Appendix A. In our analysis, we follow Geruso et al. [2019] in categorizing formulary tiers. For each drug, we have a measure of lives that are at least covered on a formulary, lives that are under a preferred tier on a formulary, and lives on an unrestricted tier of a formulary. Covered simply means the biologic shows up on a plan's formulary. For preferred, we include any drug's universal status to a tier that references preferred brands or generics, value drugs, or zero co-pay. Anytime a drug is assigned to a status that includes prior authorization or a step therapy the lives under that plan are considered restricted. We make these distinctions to capture dimensions of coverage versus preferred and restricted versus unrestricted. One limitation of the data is that each plan tends to only list the "best covered" drug, so in some cases we may not have information about certain drugs.

For information on biosimilar approval dates we utilize publically available information on the FDA website, and we get launch dates for biosimilars through a variety of publically available sources (**how do I academically say we googled it?). We observe 100 drug-quarters of data for biologics after a biosimilar has launched.

3.2 Empirical Methods

We use the Difference-in-Differences modeling technique to assess the impact of biosimilar entry in US markets. Our main DiD specification is as follows:

$$y_{it} = \beta_1 Biosimilar Market_{it} + \beta_2 Drug_i + \beta_3 Quarter_t + \epsilon_{it}$$

where y_{it} is the outcome of interest for drug i in quarter t. Our outcomes are net price, WAC, units sold, the percentage of lives on a health plan with coverage for a drug, the percentage of lives on a health plan with preferred status for a drug, and the percentage of lives on a health plan with unrestricted access for a drug. $BiosimilarMarket_{it}$ is a binary indicator for whether or not a biosimilar has launched for drug i in or before quarter t, and

we include drug and quarter fixed effects. Our model design does not follow the standard DiD approach because biologics experience the entrance of a biosimilar in different quarters, so we follow the generalized DiD approach laid out in Imbens and Wooldridge [2009]. For a further discussion on identification of the average treatment on the treated see Appendix B.

As a placebo test, we also estimate a model with the following specification:

$$y_{it} = \beta_1 Biosimilar Market_{it} + \beta_2 Drug_i + \beta_3 Quarter_t + \beta_4 Biosimilar Approved_{it} + \epsilon_{it}$$

where $Biosimilar Approved_{it}$ is a binary indicator for whether or not a biosimilar has been approved for drug i in or before quarter t and serves as a placebo treatment effect. If behavior prior to launch but after a biosimilar has been approved is correlated with any underlying trends in prices, volume, or formulary status then the approval indicator should pick up such trends. As a final test, we examine whether multiple biosimilars launching has a differential effect on the market for a biologic we estimate a model that breaks out $Biosimilar Market_{it}$ into the number of biosimilars launched.

Our main estimation sample includes 8 "treated" biologics that experience the entrance of a biosimilar into the market and 24 "control" drugs (**I want to say something about the estimation sample, but not really sure where it fits.)

4 Results

Our main price and volume results are described in Table 2. In all models, each observation is at the drug-quarter level and we limit the sample to all drugs in a class that see the entry of a biosimilar. Our results are robust to different samples, and we present the estimation results for those samples in Appendix C. We examine this sample because it may help mitigate concerns about possible biosimilar selection to compete with existing biologics based on the potential outcome where a biosimilar didn't enter the market, but we report results with different samples in Appendix C. Our findings on formulary status are presented

4.1 Price and Volume Results

We use the percentage of lives that have covered, preferred, and unrestricted status on a formulary to measure the effect of a biosimilar launching on formulary status. Figure 3 displays quarterly Difference-in-Difference coefficient plots for net price, ASP, WAC, and units sold. The base quarter is the quarter prior to launch. Prior to biosimilar launch, WAC displays a small downward trend prior to biosimilar launch for the treated group and ASP shows a small upward trend. Net price and units sold show no discernible pre-launch trends. After a biosimilar is launched we see a pronounced downward trend for net price, ASP, and units sold. However, WAC seems to be unaffected by the introduction of a biosimilar.

The patterns from Figure 3 are reflected in Table 2 which shows regressions of the log of each price and volume measure accounting for within drug and within quarter period variation through fixed effects. Column 1 for each dependent variable includes only the fixed effects and an indicator for whether or not a biosimilar has launched in a way similar to the results shown in Figure 1. We see the launch of a biosimilar is associated with a 19.7% decrease in the net price of the reference biologic, a 5.6% decrease in the ASP, no statistically significant change in WAC, and a 46% decrease in units sold. Column 2 for each variable includes a flag for whether or not a biosimilar has been approved. We test whether or not a simple approval matters as a placebo test. The impact of a biosimilar launching in a market is unchanged with the addition of an approval indicator, and we see no detectable effect of biosimilar approval on price or volume. Column 3 for each variable looks at the difference in effect for molecules where one, two, or three biosimilars have launched. The magnitude of the effect of biosimilars launching increases with the number of biosimilar entrants. It is worth noting the number of product-quarters where three or more biosimilars have been launched is small and this is reflected in the relatively large standard errors for those estimates. In the case of net price and units sold we see a statistically significant negative effect for any number of biosimilars launched in the market, while for ASP the negative effect seems to be driven mainly by products that have experienced more than one biosimilar enter.

4.2 Formulary Results

In Figure 3 we see no trend in formulary status prior to a biosimilar's launch. After a biosimilar launches, the percentage of lives covered, preferred, and unrestricted all falls for the reference biologic. Table 3 follows a similar structure to Table 2, and the results for each formulary status are similar to those for net price. In all three regressions the launch of a biosimilar is associated with a decrease in percentage of lives covered at that tier of status. Additionally, an approval has no effect on the percentage of lives covered or unrestricted, but we do see a negative effect for the percentage of lives covered. It is worth noting that only about 8% of lives are on a plan that has preferred status for biologics before the entry of a biosimilar. A biosimilar launch is associated with a 5.3 percentage point decrease in lives on a plan that has covered formulary status, a 7.0 percentage point decrease in lives on a plan that has preferred status, and a 3.5 percentage point decrease in lives on a plan that has unrestricted status. At all three levels examined, the formulary status of a reference biologic is negatively affected by a biosimilar launch.

It is possible, although unlikely, that the reduced status of reference biologics is not accompanied by inclusion of biosimilars on the formulary. Referring back to Figure 3, we do not find evidence of pre-trends in formulary status. To alleviate this concern further, we show graphs of formulary coverage over time for each molecule in Figure 6-12. As can be seen by the pink trend line, the coverage of any drug for a molecule does not fall after the introduction of a biosimilar. It is also worth noting that in some cases the biosimilar coverage increases rapidly after launch with the main exception being Betaseron.

In this section we show evidence of biosimilars having a large impact on the market for a reference biologic in prices, volume, and formulary status. Strikingly, we see biosimilars having a large negative effect on the net price of a biologic, a modest effect on ASP, and little to no evidence of an effect on WAC. We also see a steep drop in volume after a biosimilar enters a market, and as Figure 4 shows, the effect seems to grow with the number of quarters since the biosimilar entered.

5 Discussion (or Conclusion)

To better understand if biosimilars have been effective at creating competition for biologics it's important to consider the results from Section 4 in the context of how effective small-molecule generics have been at creating competition for brand drugs. (**Outline in progress)



ENBREL

10

Figure 1: Market Size and Biosimilar Entry

AVASTIN

EPOGEN

2

BETASERON

6

5

Number of approved biosimilars

0

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Net sales in year before approval of first biosimilar (billion USD)

LANTUS

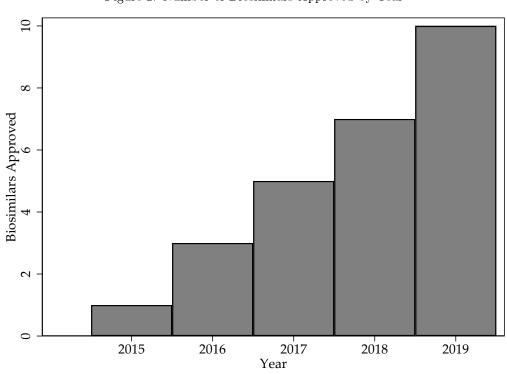


Figure 2: Number of Biosimilars Approved by Year

Table 1: Approval and launch dates of biosimilar products

	1 1		1
Drug	Molecule	Approval Date	Launch Date
Abrilada	Adalimumab	11/1/2019	unknown
Amjevita	Adalimumab	9/23/2016	1/31/2023
Cyltezo	Adalimumab	8/25/2017	7/1/2023
Hadlima	Adalimumab	7/1/2019	6/30/2023
Hyrimoz	Adalimumab	10/1/2018	9/1/2023
Hulio	Adalimumab	7/1/2020	7/1/2023
Mvasi	Bevacizumab	9/14/2017	7/18/2019
Zirabev	Bevacizumab	6/1/2019	12/31/2019
Retacrit	Epoetin Alfa	5/1/2018	11/12/2018
Erelzi	Etanercept	8/30/2016	unknown
Eticovo	Etanercept	4/26/2019	unknown
Granix ^a	Filgrastim	8/29/2012	11/11/2013
Nivestym	Filgrastim	7/1/2018	10/1/2018
Zarxio	Filgrastim	3/6/2015	09/03/2015
Avsola	Infliximab	12/1/2019	unknown
Inflectra	Infliximab	4/5/2016	11/30/2016
Ixifi	Infliximab	12/13/2017	unknown
Renflexis	Infliximab	4/21/2017	7/24/2017
Extavia	Interferon Beta-1B	8/14/2009	8/14/2009
Fulphila	Pegfilgrastim	6/1/2018	07/30/2018
Udenyca	Pegfilgrastim	11/1/2018	01/3/2019
Nyvepria	Pegfilgrastim	6/11/2020	unknown
Ziextenzo	Pegfilgrastim	11/1/2019	11/15/2019
Truxima	Rituximab	11/1/2018	11/11/2019
Ruxience	Rituximab	7/1/2019	1/23/2020
Herzuma	Trastuzumab	12/1/2018	3/1/2020
Kanjinti	Trastuzumab	6/1/2019	7/18/2019
Ogivri	Trastuzumab	12/1/2017	12/2/2019
Ontruzant	Trastuzumab	1/1/2019	4/1/2020
Trazimera	Trastuzumab	3/1/2019	2/15/2020
Basaglar ^a	Insulin Glargine	8/1/2014	12/15/2016
2 (77)		1 DIA 1 C	

^a This product was approved through a regular BLA before the accelerated procedure became available.

Table 2: Regression results (all class with biosimilar)

		1		0000000	the state of the s	101111111111111111111111111111111111111		(
]	Log net price	ć		${\rm Log~ASP}$			Log WAC		T	Log units sold	
	(1)	(2)	(3)	(1)	(2)	(3)	(1)	(2)	(3)	(1)	(2)	(3)
Biosimilar has launched	-0.219***	-0.252***		-0.079**	-0.085**		-0.016	-0.020		-0.631***	-0.568***	
Biosimilar has been approved		0.047			0.008			0.007			0.087	
1 Biosimilar launched		(000:0)	-0.171**		(070.0)	-0.039		(0.0.0)	090.0		0	-0.524***
			(0.072)			(0.0266)			(0.055)			(0.132)
2 Biosimilars launched			-0.279***			-0.127***			-0.134^{*}			-0.718***
			(0.093)			(0.027)			(0.071)			(0.171)
3 Biosimilars launched			-0.535**			-0.190***			-0.255			-1.770***
			(0.211)			(0.057)			(0.162)			(0.390)
Product FE	Ā	Ā	Ā	Y	Y	Y	Y	Ā	Y	Ā	Ā	I V
Quarter FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
N	1,264	1,264	1,264	629	629	629	1,295	1,295	1,295	1,295	1,295	1,295
R^2	0.954	0.954	0.954	0.999	0.999	0.999	0.970	0.970	0.971	0.890	0.890	0.891

Table 3: Formulary Regression Results (all class with biosimilar)

			_		`			/		
		% Covered			% Preferred	I	%	Unrestrict	ed	_
	(1)	(2)	(3)	(1)	(2)	(3)	(1)	(2)	(3)	_
Biosimilar has launched	-5.363***	-6.028*** (1.018)		-6.995*** (0.799)	-5.203*** (0.884)		-3.494*** (1.152)	-2.640** (1.291)		=
Biosimilar has been approved	(0.000)	1.180		(01100)	-3.179*** (0.710)		(11132)	-1.515 (1.036)		
1 Biosimilar launched		, ,	-7.611***		, ,	-7.264***		, ,	-2.708**	
2 Biosimilars launched			(1.047) -1.453 (1.232)			(0.929) -6.132*** (1.093)			(1.347) -4.348*** (1.586)	Note:
3 Biosimilars launched			-11.60*** (2.667)			-14.81*** (2.367)			-10.49*** (3.434)	
Constant	91.36*** (0.879)	91.31*** (0.879)	91.38*** (0.863)	8.216*** (0.772)	8.353*** (0.763)	8.254*** (0.766)	16.41*** (1.114)	16.48*** (1.114)	16.45*** (1.111)	
Product FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	_
Quarter FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	
N	792	792	792	792	792	792	792	792	792	_
R^2	0.757	0.757	0.766	0.965	0.966	0.966	0.932	0.932	0.932	

Describe what covered, preferred, and unrestricted mean, specifically how we use preferred to refer to preferred AND unrestricted in coverage which is why the intercept is so low.

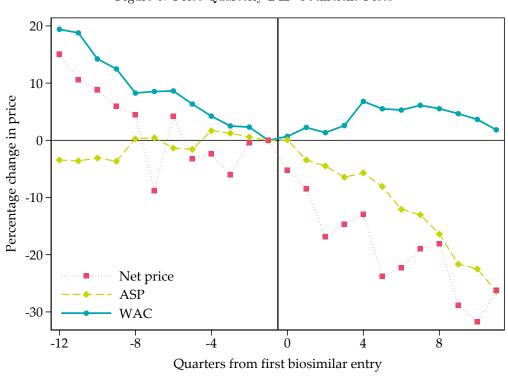


Figure 3: Price Quarterly DID Coefficient Plots

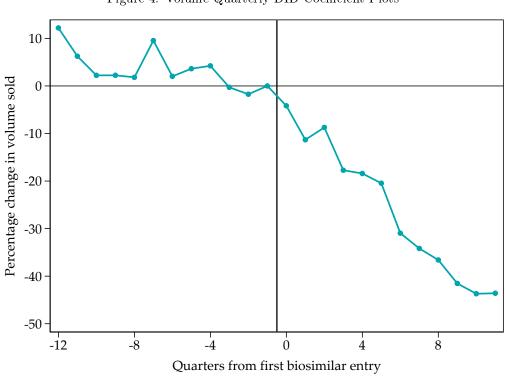


Figure 4: Volume Quarterly DID Coefficient Plots

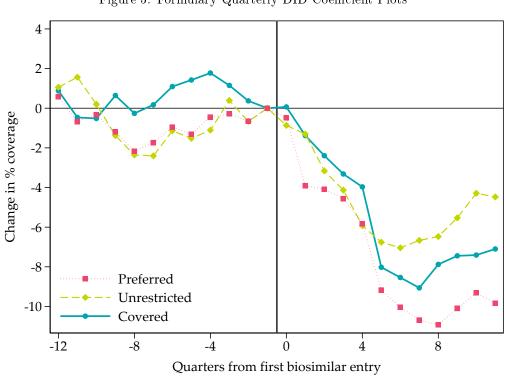


Figure 5: Formulary Quarterly DID Coefficient Plots

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6 Appendix A

• Example of Formulary

For example, one insurer might design a five tiered formulary where Tier 1 includes generic drugs, Tier 2 includes preferred brand-name drugs, Tier 3 includes nonpreferred brand-name drugs, Tier 4 includes preferred specialty drugs, and Tier 5 includes nonpreferred specialty drugs. The same insurer may have a second plan that has a two tiered system where Tier 1 includes preferred generics and Tier 2 includes everything else that's covered. It is hard to pin down how status on a formulary is explicitly related to drug prices, but some studies have alluded to the use of rebates as a tool to get favorable status on a formulary Dusetzina et al. [2017], Dusetzina and Bach [2019]. For this reason, it may be important to examine how both prices and formulary status change when determining the effect of a biosimilar's launch on a market.

7 Appendix B

Interpreting β_1 as an average treatment effect on the treated relies on a parallel trends assumption between the treated and untreated groups. In our context, where biologics that have a biosimilar launch are considered treated and other drugs in the sample are consider untreated, the outcome for treated drugs would have followed the same path as the untreated drugs. There may be concern that biosimilars select into development based on the potential price of a reference biologic had the biosimilar not entered the market.

8 Appendix C

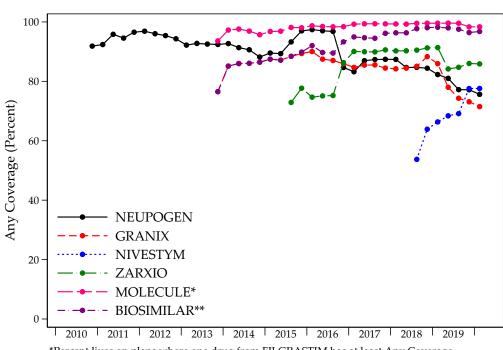


Figure 6: Covered Lives for Molecule Filgrastim

*Percent lives on plans where one drug from FILGRASTIM has at least Any Coverage. **Percent lives on plans where one biosimilar from FILGRASTIM has at least Any Coverage.

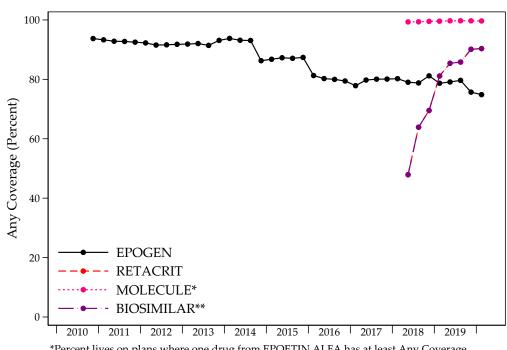


Figure 7: Covered Lives for Molecule Epoetin Alfa

*Percent lives on plans where one drug from EPOETIN ALFA has at least Any Coverage. **Percent lives on plans where one biosimilar from EPOETIN ALFA has at least Any Coverage.

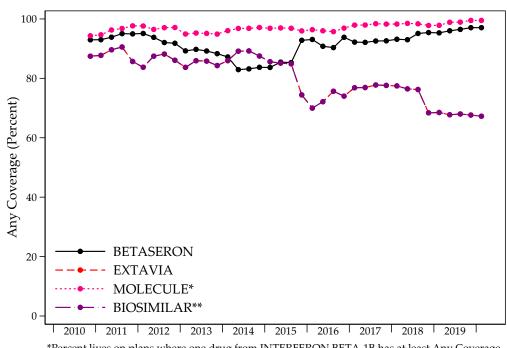


Figure 8: Covered Lives for Molecule Interferon Beta-1B

*Percent lives on plans where one drug from INTERFERON BETA-1B has at least Any Coverage. **Percent lives on plans where one biosimilar from INTERFERON BETA-1B has at least Any Coverage.

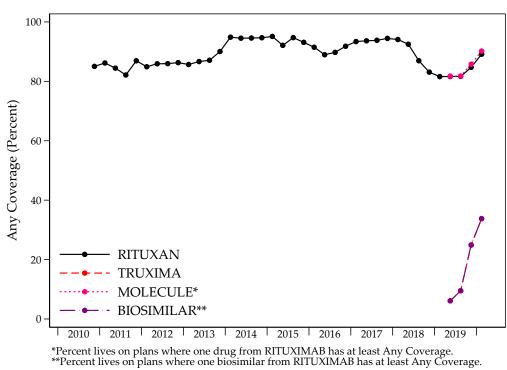


Figure 9: Covered Lives for Molecule Rituximab

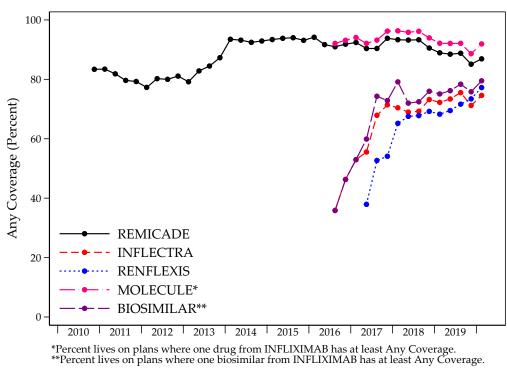


Figure 10: Covered Lives for Molecule Infliximab

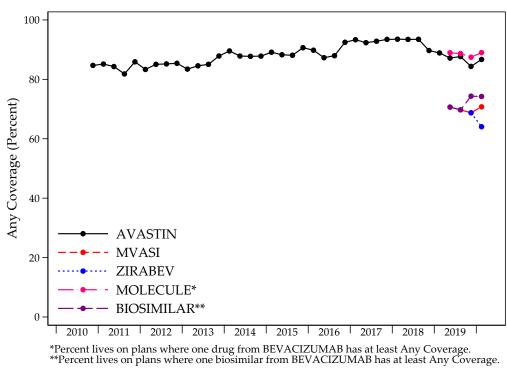


Figure 11: Covered Lives for Molecule Bevacizumab

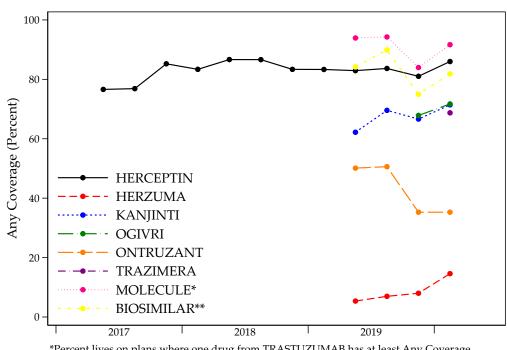


Figure 12: Covered Lives for Molecule Trastuzumab

*Percent lives on plans where one drug from TRASTUZUMAB has at least Any Coverage. **Percent lives on plans where one biosimilar from TRASTUZUMAB has at least Any Coverage.

-0.519*** (0.139) -0.632*** (0.156) -1.702*** (0.353) 1,036 0.871(3) Log Units sold -0.605*** (0.139) 0.013 (0.110) 1,036 0.869(5) -0.615*** (0.112) 1,036 0.869(1) 0.052 (0.070) -0.090 (0.078) -0.208 (0.177) $1,036 \\ 0.958$ Table 4: Regression results (biologics in a class with biosimilar) Log WAC $\begin{array}{c} -0.018 \\ (0.069) \\ 0.002 \\ (0.055) \end{array}$ $1,036 \\ 0.958$ (5) -0.017 (0.056) $1,036 \\ 0.958$ (1) 0.0270 (0.033) -0.109*** (0.0290) -0.158** (0.0636) $\frac{596}{0.998}$ -0.072*** (0.0320) -0.0200 (0.0241) ${\rm Log~ASP}$ $\begin{array}{c} 596 \\ 0.998 \end{array}$ (5)-0.057** (0.027) $\begin{array}{c} 596 \\ 0.998 \end{array}$ (1) 0.004 (0.077) -0.241*** (0.086) -0.489** (0.195) 1,007 0.9443 Log net price -0.188** (0.076) 0.096 (0.061) 1,007 0.944(5)-0.117* (0.062) 1,007 0.944(1) Biosimilar has been approved Biosimilar has launched 2 Biosimilars launched 3 Biosimilars launched 1 Biosimilar launched Product FE Quarter FE R_2

Table 5: Regression results (all biologics)

	T	Log net price	e e		Log ASP			Log WAC		Т	Log Units sold	
	(1)	(2)	(3)	(1)	(2)	(3)	(1)	(2)	(3)	(1)	(2)	(3)
Biosimilar has launched	-0.086	-0.191		-0.0587	-0.074		0.061	0.033		-0.619***	-0.552***	
Biosimilar has been approved	(0.094)	(0.122) 0.123		(0.0407)	(0.0508) 0.0179		(0.057)	(0.075) 0.0661		(0.154)	(0.200) -0.076	
Competitor has Biosimilar		(0.003)			(oco.o)			(0.0343)			(0.140)	
1 Biosimilar launched			0.024			0.035			0.140*			-0.467**
2 Biosimilars launched			(0.120) -0.185			(0.035) $-0.108**$			(0.079) -0.018			(0.131) -0.669***
3 Biosimilars launched			(0.154) -0.442 (0.307)			(0.043) -0.184* (0.099)			(0.082) (0.133) (0.188)			(0.220) $-1.823***$ (0.506)
Product FE Charter FE	7 >	> >	>	\ \ \	>	\ \ \	>	7 >	> >	X X	\ \ \	\ \ \ \
$\frac{N}{R^2}$	3,928	3,928	3,928	2,268	2,268	2,268	4,606	4,606	4,606	4,606	4,606	4,606 0.922