Evolution of the Use of Restrictions in Commercial Formularies

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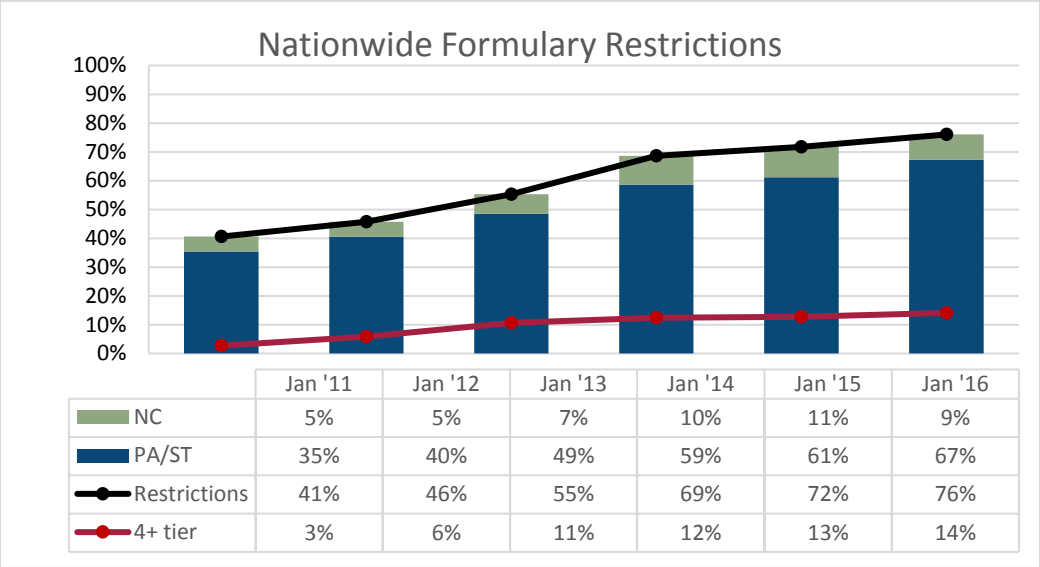
EXECUTIVE SUMMARY

Prescription drug formularies include a variety of utilization and cost-controlling mechanisms. Specific drugs may be assigned to formulary tiers that require increased cost sharing; may be subject to step therapy requirements, prior authorization, quantity limits; or may be excluded from the formulary altogether. Taken together, these formulary management techniques may encourage the use of lower cost therapies, ensure compliance with products' labeled indication, and seek to optimize utilization of efficacious therapies.[1, 2] If excessive or inappropriate, though, formulary management techniques may compromise a patient's access to necessary therapies. Patient access concerns have led to legislation limiting prescription drug restrictions.[3,4]

This report, commissioned by Pfizer, Inc. uses drug formulary data from Managed Markets Insight & Technology, LLC (MMIT)[5] covering over 150 million lives in the US to examine the trends in the use of prior authorization, step therapy and formulary exclusion in commercial formularies for the years 2011-2016. We examined sole-source brand drugs within four therapeutic classes: chronic myeloid leukemia (CML) antineoplastic agents, multiple sclerosis (MS) agents, immunological agents used to treat rheumatoid arthritis (RA) and other autoimmune diseases, and antidepressants. We reviewed the entire US commercial market and five large states (California, Florida, Illinois, New York, and Texas), accounting for over 50 million lives, or about one third of the total commercial lives in the US.

We measured formulary restrictions by the member-weighted percentage of pharmacy-dispensed, non-infused drugs subject to step therapy, prior authorization, and formulary exclusion (collectively "restrictions") for each therapeutic class. We also measured the increase in the percentage of drugs assigned to formulary tiers four and above (tiers 4+). Tiers 4+ are typically used for specialty and, sometimes, non-preferred brand drugs and have larger copayments and/or higher coinsurance than lower tiers.[6,7,8,9,10] We conclude that the use of restrictions on sole-source brand drugs and the use tiers 4+ has become significantly more common over the past five years. Figure 1 presents our findings.

Figure 1. Nationwide Formulary Restrictions from 2011-2016[a]
Select Therapeutic Classes [b]



	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	5%	5%	7%	10%	11%	9%
PA/ST	35%	40%	49%	59%	61%	67%
Restrictions	41%	46%	55%	69%	72%	76%
4+ tier	3%	6%	11%	12%	13%	14%

Source: Author's analysis of MMIT formulary data (Jan 2011- Jan 2016)

[a] ST = Step Therapy, PA = Prior Authorization, NC = Not Covered
[b] CML agents, MS agents, RA agents, and antidepressants

Nationwide over the 6 year period, total restrictions increased from 41% to 76% (a nearly 2-fold increase) and assignment to tiers 4+ increased from 3% to 14% (a more than 4-fold increase). The member-weighted percentage of sole-source products subject to prior authorization or step therapy increased from 35% to 67% and the member-weighted use of formulary exclusion (not covered status) increased from 5% to 9%. These findings were largely replicated at the state level for California, Florida, Illinois, New York, and Texas, with the exception of New York, where the use of specialty tiers is prohibited.

With some nuances, each of the four therapeutic classes, when analyzed separately, presented similar patterns. The use of formulary restrictions including step therapy, prior authorization, and formulary exclusion of sole-source products is now close to 70% for CML antineoplastic agents, MS agents and antidepressants, up from 26% to 58% in 2011, while restrictions in sole-source immunological agents used to treat RA has increased to over 90%. With the exception of antidepressants, the use of tiers 4+ more than quadrupled for the drugs analyzed: as of January of 2016, over 15% of sole-source CML antineoplastic, MS, and RA agents were placed on tiers 4+, up from 2% to 4% in 2011.

This report was commissioned by Pfizer, Inc. and reflects the authors' findings and opinions. It should not be interpreted as an endorsement of any particular legislation by Milliman. Because extracts of this report taken in isolation can be misleading, we ask that this report be distributed only in its entirety.

The authors are employees of Milliman and two of the authors, Gabriela Dieguez and Tia Goss Sawhney, are members of the American Academy of Actuaries and meet its qualification standards to issue this report.

BACKGROUND

Drug formulary restrictions are one mechanism commercial insurers use to manage health insurance and employer costs by encouraging the use of generic drugs and products that they have identified as likely to provide similar efficacy at lower cost over other drugs. The most onerous of these restrictions can impose logistic and financial barriers to the patient's access to drugs. While the processes and criteria for approval are diverse, obtaining approval for a drug that is subject to restrictions can be a time consuming process for prescribing physicians and payers.[11] In addition to submitting the required paperwork, the patient may need to first "try and fail" one or more drugs.

Tier assignments in formularies allow plans to impose varying cost sharing to drugs. In formularies with four or more tiers, the most expensive drugs are typically assigned to a "specialty" tier 4+[a] with the highest member cost sharing.[12] According to the Kaiser Family Foundation (KFF),[13] the percentage of insureds with drug formularies with 4 or more tiers increased from 14% in 2011 to 23% in 2015. KFF estimates that the average 2015 tier 4 copayment was $93 and that the average coinsurance was 32% -- on drugs that may cost several thousands of dollars a month.[14] We note that several states have taken actions to limit cost sharing for patients in commercial health plans by setting monthly or annual prescription drug cost sharing limits. Most notable for this report is that New York prohibits the use of a specialty tiers,[15] while California has implemented a cap on cost sharing for prescription drugs.

In order to better understand the evolution of these issues, we examined formulary restrictions and tier assignments for four classes of brand drugs over the six years, from January 2011 to January 2016, at a national level and for five large states. This report presents our findings.

[a] Tiers 4+ are typically used for specialty and, sometimes, non-preferred brand drugs.

FINDINGS

In order to measure formulary restrictions, we summarized the member-weighted percentage of single source brands subject to step therapy or prior authorization (which may have step therapy requirements integrated into the authorization process), and formulary exclusion (collectively "restrictions") for four therapeutic classes:

- CML antineoplastic agents,
- MS agents,
- Immunological agents indicated for RA , and
- Antidepressants.

We also measured the increase in the use of formularies with a higher number of tiers by the percentage of drugs assigned to formulary tiers four and above (tiers 4+).

Our results are presented in this section, separately for all formularies in the database (nationwide) and for five large states: California, Florida, Illinois, New York and Texas.

Nationwide Formulary Restrictions

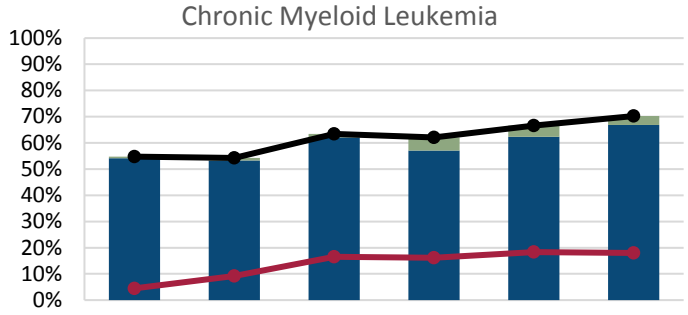
Figure 1 in the Executive Summary shows the member-weighted average percentage of drugs with formulary restrictions and tier 4+ assignments for the four therapeutic classes in our study. Over the 6 year period, the use of restrictions nearly doubled, and assignment to tiers 4+ more than quadrupled.

Figures 2A through 2D show the results for each class separately. Nationwide, 65% to 85% of sole-source brand drugs for the four classes analyzed have restrictions as of January 2016. Total restrictions increased from 2011 to 2016 across all four classes, and tier 4+ assignments increased across all classes except antidepressants. Antidepressant drugs are rarely assigned to Tier 4+; however, their exclusion from formularies increased from 2% to 11%, on average, from 2011 to 2016. For the other three classes, 15% to 18% of drugs are assigned to Tier 4+ as of January 2016.

With some year-to-year variation, the use of step therapy or prior authorization increased for all four classes. While RA agents have the highest percentage of drugs subject to step therapy or prior authorization (85% as of January of 2016), the fastest growth in the use of these restrictions was observed in the multiple sclerosis agents class, from 18% to 59%.

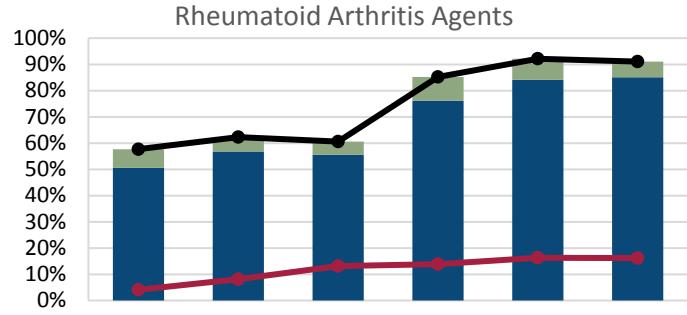
Nationwide Formulary Restrictions from 2011-2016[a]

Figure 2a. Chronic Myeloid Leukemia Agents



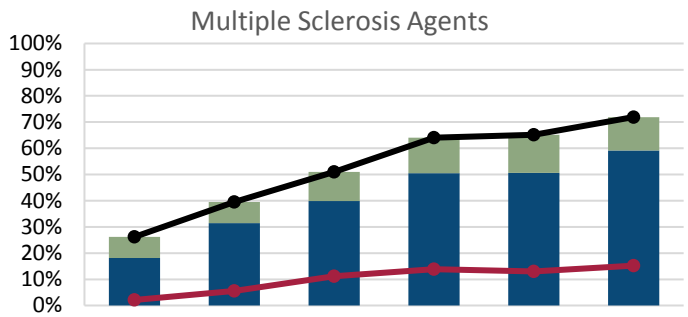
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	1%	1%	1%	5%	4%	3%
PA/ST	54%	53%	62%	57%	62%	67%
Restrictions	55%	54%	63%	62%	67%	70%
Tier 4+	4%	9%	17%	16%	18%	18%

Figure 2c. RA Immunological Agents



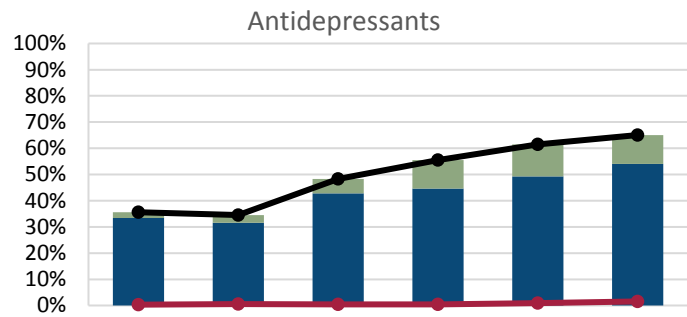
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	7%	6%	5%	9%	8%	6%
PA/ST	51%	57%	56%	76%	84%	85%
Restrictions	58%	62%	61%	85%	92%	91%
Tier 4+	4%	8%	13%	14%	16%	16%

Figure 2b. Multiple Sclerosis Agents



	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	8%	8%	11%	14%	15%	13%
PA/ST	18%	31%	40%	50%	51%	59%
Restrictions	26%	39%	51%	64%	65%	72%
Tier 4+	2%	6%	11%	14%	13%	15%

Figure 2d. Antidepressants



	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	2%	3%	6%	11%	12%	11%
PA/ST	33%	32%	43%	45%	49%	54%
Restrictions	36%	35%	48%	55%	61%	65%
Tier 4+	0%	1%	0%	0%	1%	2%

Source: Author's analysis of MMIT formulary data (Jan 2011- Jan 2016)
[a] ST = Step Therapy, PA = Prior Authorization, NC = Not Covered

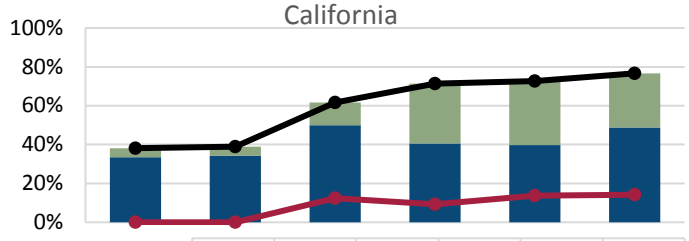
Formulary Restrictions in Select Large States

To examine regional differences, we analyzed five large states that collectively account for over one third of the total commercial lives in the US. Figures 3A through 3F show formulary restrictions and tier 4+ assignments for California, Florida, Illinois, New York, Texas and all other states combined. The trends by state are quite similar to each other, with the exception of New York, where the use of specialty tiers is not allowed.[b]

[b] Tiers 4+ are typically used for specialty and, sometimes, non-preferred brand drugs.

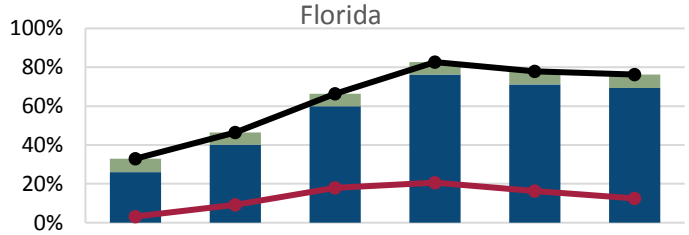
State Formulary Restrictions from 2011-2016[a]

Figure 3a. California



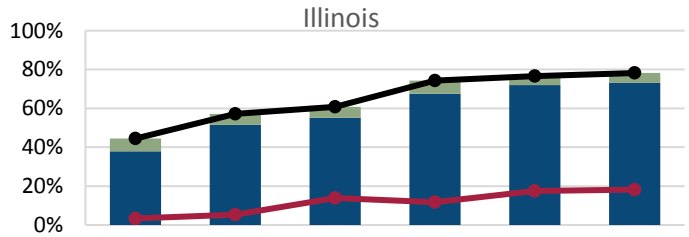
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	5%	5%	12%	31%	33%	28%
PA/ST	34%	34%	50%	41%	40%	49%
Restrictions	38%	39%	62%	71%	73%	77%
4+ tier	0%	0%	12%	9%	14%	14%

Figure 3b. Florida



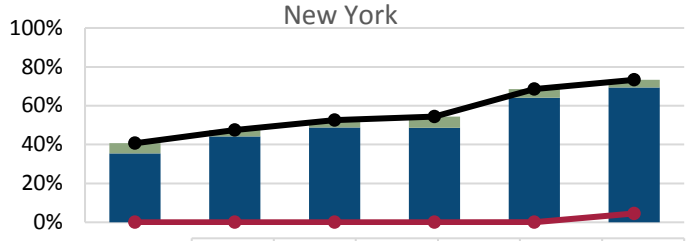
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	7%	6%	7%	6%	7%	7%
PA/ST	26%	40%	60%	76%	71%	69%
Restrictions	33%	46%	66%	83%	78%	76%
4+ tier	3%	9%	18%	21%	16%	12%

Figure 3c. Illinois



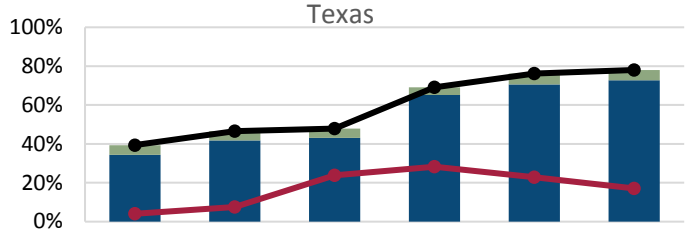
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	7%	6%	6%	7%	5%	5%
PA/ST	38%	52%	55%	68%	72%	73%
Restrictions	44%	57%	61%	74%	77%	78%
4+ tier	3%	5%	14%	12%	17%	18%

Figure 3d. New York



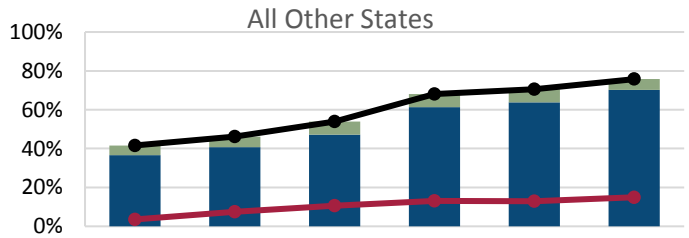
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	5%	3%	4%	6%	4%	4%
PA/ST	35%	44%	49%	49%	64%	69%
Restrictions	41%	47%	53%	54%	69%	73%
4+ tier	0%	0%	0%	0%	0%	5%

Figure 3e. Texas



	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	5%	5%	5%	4%	6%	5%
PA/ST	34%	42%	43%	65%	71%	73%
Restrictions	39%	47%	48%	69%	76%	78%
4+ tier	4%	7%	24%	28%	23%	17%

Figure 3f. All Other States



	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
NC	5%	5%	7%	7%	7%	5%
PA/ST	37%	41%	47%	61%	64%	70%
Restrictions	42%	46%	54%	68%	71%	76%
4+ tier	4%	8%	11%	13%	13%	15%

Source: Author's analysis of MMIT formulary data (Jan 2011- Jan 2016)
[a] ST = Step Therapy, PA = Prior Authorization, NC = Not Covered

METHODOLOGY AND DATA SOURCES

We examined formulary restrictions and tier assignments for four classes of sole-source brand drugs on January 1st of each year 2011 through 2016. These classes were chosen because they have competing oral drugs and represent a wide range of prices. A summary of the classes, defined as groups of drugs that treat distinct diseases and the number of sole-source brands included in the study are shown in Table 1.

Table 1. Number of Single Source Brands Examined by Class

Therapeutic Class	Brand Drugs
Chronic Myeloid Leukemia Agents	5
Multiple Sclerosis Agents	9
Rheumatoid Arthritis Agents	9
Antidepressants	6

Because new drug launches can take several months to impact the market, we excluded from the analysis some products for specific time periods, as noted below:

1. Brand drugs with a generic equivalent, once the generic has been approved for more than 6 months, and

2. New brand drugs, until they have been approved for at least one year

The drugs that we examined each year are shown in Table 2.

Table 2. Brand Drugs Examined for Select Classes, by Formulary Date

CML Agents						
DRUG	**Jan-11**	**Jan-12**	**Jan-13**	**Jan-14**	**Jan-15**	**Jan-16**
BOSULIF				X	X	X
GLEEVEC	X	X	X	X	X	X
ICLUSIG				X	X	X
SPRYCEL	X	X	X	X	X	X
TASIGNA	X	X	X	X	X	X
COUNT	**3**	**3**	**3**	**5**	**5**	**5**

MS Agents						
DRUG	**Jan-11**	**Jan-12**	**Jan-13**	**Jan-14**	**Jan-15**	**Jan-16**
AUBAGIO				X	X	X
BETASERON	X	X	X	X	X	X
COPAXONE	X	X	X	X	X	
EXTAVIA	X	X	X	X	X	X
GILENYA		X	X	X	X	X
REBIF	X	X	X	X	X	X
REBIF REBIDOSE					X	X
TECFIDERA					X	X
TYSABRI	X	X	X	X	X	X
COUNT	**5**	**6**	**6**	**7**	**9**	**8**

RA Agents						
DRUG	**Jan-11**	**Jan-12**	**Jan-13**	**Jan-14**	**Jan-15**	**Jan-16**
CIMZIA	X	X	X	X	X	X
ENBREL	X	X	X	X	X	X
HUMIRA	X	X	X	X	X	X
ORENCIA SC			X	X	X	X
SIMPONI SC			X	X	X	X
XELJANZ				X	X	X
COUNT	**3**	**3**	**5**	**6**	**6**	**6**

Antidepressants						
DRUG	**Jan-11**	**Jan-12**	**Jan-13**	**Jan-14**	**Jan-15**	**Jan-16**
BRINTELLIX					X	X
CYMBALTA	X	X	X	X		
FETZIMA					X	X
LEXAPRO	X	X				
PRISTIQ	X	X	X	X	X	
VIIBRYD			X	X	X	X
COUNT	**3**	**3**	**3**	**3**	**4**	**3**

We used MMIT's commercial formulary data from January 1, 2011 through January 1, 2016. The data indicates, for each drug, the formulary status and any applicable restrictions by "account" or entity that manages the formulary. An account may be a health plan, a large self-insured employer, or a prescription benefit manager (PBM). An account may simultaneously have several formularies (for example a health plan may have a separate formularies for small and large group employers). For the state analysis, we focused on the top ten accounts in each of the five states, which represented over half of all commercially insured lives in each state.

For the purposes of this analysis, commercial insurance includes insurance plans, health maintenance organizations, and large self-insured employers (including the Federal Employee Health Plan) but excludes Medicare, Medicaid, and ACA exchange plans.

We selected California, Florida, Illinois, New York, and Texas for state-level analysis based on their size and geographic dispersion. The five states combined have more than 1/3 of the total US commercial covered lives and the top ten accounts have the majority of the lives in each of the five states.

Table 3: Covered Lives by State and All Other States for Top 10 Accounts in Each State

	Covered Lives in Top 10 Accounts					
	Jan '11	Jan '12	Jan '13	Jan '14	Jan '15	Jan '16
California	16,074,719	15,708,767	11,417,687	15,133,441	16,214,909	15,594,183
Florida	5,933,068	6,336,588	6,215,115	5,997,518	6,166,695	6,035,047
Illinois	5,008,909	5,035,382	5,124,094	4,573,693	4,894,760	5,340,307
New York	4,770,279	4,866,455	5,957,127	6,679,164	7,135,867	7,067,795
Texas	8,046,848	8,435,621	8,554,210	8,496,603	8,449,095	9,428,916
All Other	72,121,570	73,769,075	75,092,307	73,812,252	77,574,594	84,748,593
TOTAL US	111,955,393	114,151,888	112,360,540	114,692,671	120,435,920	128,214,841

	Percent of Total Commercial Population in Top 10 Accounts					
California	88%	86%	60%	82%	81%	80%
Florida	78%	75%	72%	70%	71%	70%
Illinois	79%	74%	74%	71%	69%	76%
New York	61%	60%	62%	70%	75%	69%
Texas	76%	73%	71%	70%	67%	72%
All Other	74%	73%	70%	71%	74%	77%
TOTAL US	76%	74%	69%	72%	74%	76%

Our percentage restrictions and tier assignments are weighted by covered lives. Therefore accounts and formularies with more lives have more influence over our results than accounts and formularies with fewer lives. However, all drugs in a therapeutic class are weighted equally.

CAVEATS

We relied upon formulary and covered lives data from Managed Markets Insight & Technology, LLC (MMIT), as provided to us by Pfizer. While we examined the data for reasonableness, we did not audit it. The average values presented in this report are estimates based on historical data and other assumptions, and does not represent results for specific plans, members, or therapeutic classes.

This report was commissioned by Pfizer, Inc. and reflects the authors' findings and opinions. It should not be interpreted as an endorsement of any particular legislation by Milliman. Because extracts of this report taken in isolation can be misleading, we ask that this report be distributed only in its entirety.

Gabriela Dieguez and Tia Goss Sawhney are Fellows of the Society of Actuaries and members of the American Academy of Actuaries, and meet its qualification standards to issue this report.

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