

Attorney General's Report on Prescription Drug Cost Transparency
Pursuant to 18 V.S.A. § 4635
December 30, 2020

OVERVIEW

This report is submitted pursuant to 18 V.S.A. § 4635 (“Prescription Drug Cost Transparency”). The statute requires that the Attorney General’s Office (“AGO”) provide a report to the General Assembly on an annual basis. This report focuses on information provided to the AGO by the Department of Vermont Health Access (“DVHA”), Blue Cross and Blue Shield Vermont (“BCBSVT”) and MVP Health Care (“MVP”) for calendar year 2019.¹

I. Information Provided by the Department of Vermont Health Access

Pursuant to 18 V.S.A. § 4635, DVHA and health insurers with more than 5,000 covered lives in Vermont for major medical health insurance (referred to below as “Health Insurers”) are required to provide certain information annually about the increase in the price of prescription drugs.

The statute requires that DVHA annually create two lists. The first, required by 18 V.S.A. § 4635 (b)(1)(A), is comprised of 10 prescription drugs (at least one generic and one brand name) on which the State “spends significant health care dollars” and for which the wholesale acquisition cost (“WAC”) ² has increased by 50 percent or more over the past five

¹ The AGO’s 2019 report was prepared after discussing with Legislative leaders the challenges of complying with the reporting requirements of the statute. Discussions about the statute continue and the same format is used in this report as was used in 2019. The AGO looks forward to working with the Legislature to address the compliance challenges presented by, among other things, federal law which prohibits Medicaid from providing drug-specific net cost information.

² WAC is defined under federal law as a manufacturer’s “list price” for a drug to wholesalers or other direct purchasers but does not reflect any prompt pay or other discounts, rebates, or reductions in price. 42 U.S.C. § 1395w-3a (c) (6).

calendar years or by 15 percent or more during the previous calendar year. DVHA must rank the drugs on the list from those with the largest to smallest increase, and state: whether it considers any of the drugs to be specialty drugs; whether the drugs were included based on their price increase over one year, five years or both; and provide DVHA's total expenditure for each drug. The WAC list provided by DVHA is attached as Exhibit A.

The second list, required by 18 V.S.A. § 4635 (b)(1)(B), is comprised of 10 prescription drugs (at least one generic and one brand name) on which the State "spends significant health care dollars" and for which DVHA's net cost³ has increased by 50 percent or more over the past five years or 15 percent or more during the previous calendar year. DVHA must rank the drugs on the list from those with the largest to smallest increase, state whether it considers any of the drugs to be specialty drugs, and whether they were included based on their price increase over one year, five years or both. (18 V.S.A. § 4635 (b)(1)(B)). The net cost list provided by DVHA is attached hereto as Exhibit B.

The methodology DVHA used to create its 2019 WAC and net price lists is attached as Exhibit C. Exhibit C also includes observations made by DVHA about drug price increases.

II. Information Provided by Vermont Health Insurers

Pursuant to 18 V.S.A. § 4635 (b)(1)(C), Health Insurers are also required to create a list of 10 prescription drugs (at least one generic and one brand name) on which the insurance plan

³ "Net cost" is defined in 18 V.S. A. § 4635 (b)(1)(B) as the cost to DVHA net of rebates and other price concessions.

“spends significant health care dollars” and for which the insurance plan’s net cost⁴ has increased by 50 percent or more over the past five years, 15 percent or more during the previous calendar year, or both. Each Health Insurer must rank the drugs on the list from those with the largest to smallest increase and state whether it considers any of the drugs to be specialty drugs. The public version of the 2019 net cost lists provided by BCBS and MVP are attached hereto as Exhibits D and E, respectively.⁵

III. Factors That Influence Manufacturers’ Drug Pricing

As observed by the AGO in previous Prescription Drug Cost Transparency reports, manufacturers have identified several factors they consider in making pricing decisions, although the weight they place on those factors seems to vary. The factors commonly mentioned as impacting manufacture’s decisions to increase prices are listed below, in no specific order:

- the value of innovative medicines;
- cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class);
- the size of the patient population for the drug;
- investments made (including in research and development) and risks undertaken;
- return on investment;
- fiduciary responsibilities;

⁴ “Net cost” is defined in 18 V.S. A. § 4635 (b)(1)(C) as the cost to the insurance plans net of rebates and other price concessions.

⁵ Health Insurers also provide the Attorney General’s Office with a list that includes the insurer’s actual net dollars spent on each drug. That list is exempt from public inspection pursuant to 18 V.S. A. § 4635 (b)(1)(C)(ii).

- post-marketing regulatory commitments and ongoing pharmacovigilance (safety surveillance);
- creation and maintenance of manufacturing facilities and capabilities, including the ability to address drug shortages caused by production issues;
- cost of ingredients;
- competition, including for drugs in the same class;
- the rate of inflation; and
- percentage of sales in commercial versus Medicare or other government channels, and the funds expended on assistance programs for people with limited resources or without insurance which, in some measure, offset drug sales income.

IV. Analysis of Cost Information Submitted by DVHA and Health Insurers

The Health Insurers provide the AGO with their net dollar expenditures on a confidential basis. Because federal law prevents DVHA from disclosing the net prices it pays for individual drugs, it is unable to provide the AGO with the prices actually paid, even on a confidential basis. 42 U.S.C. § 1396r-8(b)(3)(D). DVHA has provided the gross dollar amount (WAC) it paid for individual drugs, as depicted in Exhibit A, but those figures do not exclude any rebates or other price concessions it receives. As a result, it is not possible to compare DVHA's net drug costs to the Health Insurers' net drug costs. There is one drug that appears on both the DVHA and MVP net cost lists (Stelara), no overlap on the DVHA and BCBS net cost lists, and one drug that

appears on both the BCBS and MVP net cost lists (a Humira pen), albeit in different formulations.⁶

A. How DVHA and the Insurers Selected the Drugs on the Lists

As mentioned above, 18 V.S.A. § 4635 permits DVHA and the Health Insurers to compile their lists based on either drug price increases of 50 percent or more over the past five years or 15 percent or more during the previous calendar year. To be consistent and to maximize comparison of the lists, DVHA and the Health Insurers selected their 10 drugs based on an increase of 15 percent or more during calendar year 2019.

B. DVHA and the Health Insurer Drug Price Increases

1. DVHA

Since DVHA is prohibited from revealing drug-specific net cost information, its net cost list ranks the drugs from 1 through 10 but reflects the gross amount paid for those drugs. As DVHA observed in its footnote to the net cost chart, the gross amount paid “will not align in rank order with the net cost of the drug to the State.”

The drugs on DVHA’s WAC list and net cost lists did not overlap. DVHA listed one generic drug on its net cost list, as required by 18 V.S.A. § 4635. That drug had the lowest WAC spend and a 74.05% net price increase over the prior year. The branded drugs on the net cost list increased from a low of 15.15 % to a high of 744.14 %. There was a wide range of percentage cost increases among the 7 generic drugs on its DVHA’s WAC list- from 40.11 % to 666.67 %. The drug with the lowest WAC percentage increase reflected the second highest WAC amount

⁶ Drugs receive a universal product identifier which identify: the labeler (such as the manufacturer); the product code which identifies the strength, the dosage form (such as capsule, liquid, etc.) and formulation; and the package size which identifies package size and type.

paid (\$65,538) by DVHA. The WAC list showed the highest percentage price increases among the generic drugs. While there were also substantial increases among the 3 brand name drugs, the increases were far less, i.e. from 18.65% to 20.78%.

2. Health Insurers

BCBSVT's and MVP each selected one generic drug for inclusion on their list. The one-year generic net price increases were 252% and 114.1%, respectively. BCBSVT's brand name drug increases ranged from 43.6 % to 347.7% over one year and MVP's brand name drug increases ranged from 17.7% to 385%.

C. Specialty Drugs

The statute requires that DVHA and the Health Insurers identify any “specialty drugs” that appear on their lists. “Specialty drugs” are used to treat chronic, serious, or life-threatening conditions and are often far more costly than traditional drugs.⁷

Five of the BCBSVT and two of the MVP drugs were specialty drugs. Humira pens with different NDCs were common to the Health Insurers' lists, two on the BCBSVT list and one on the MVP list. Stelara, also a specialty drug appeared on both the DVHA and BCBSVT net cost lists, representing 20.09 % and 138% increases, respectively.

⁷ They can cost thousands of dollars per month and may exceed \$100,000 per year. There are few or no low-cost generics. “Although there is no accepted definition of *specialty pharmaceuticals*, they generally are drugs and biologics (medicines derived from living cells cultured in a laboratory) that are complex to manufacture, can be difficult to administer, may require special patient monitoring, and sometimes have Food and Drug Administration (FDA)-mandated strategies to control and monitor their use.” <https://www.healthaffairs.org/doi/10.1377/hpb20131125.510855/full/>. They may require specialized and temperature-controlled shipping, storage and handling.

Conclusion

Pharmaceutical drug pricing is extraordinarily complicated. Each party in the drug distribution chain (which includes manufacturers, wholesalers, pharmacy benefit managers, pharmacies, health/plans/payers) is governed by myriad requirements, and they also have a variety of interests. While it is clear there are ongoing sizeable drug price increases, the process of preparing this report - including communications with DVHA and the Health Insurers over many months - has demonstrated the challenges to providing the public with useable information about pharmaceutical pricing.

Exhibit A

TOP 10 GROSS AMOUNT PAID-CY 2019 (Chart 1)

Therapeutic Category	PRODUCT NAME	GENERIC NAME	LABELER NAME	Brand or Generic (B/G)	Rank by Gross Amount Paid 1= Highest Spend	PERCENT_INCREASE (Over One Year)	GROSS AMOUNT PAID	Specialty (Yes)	Appeared on Previous Year's List
ADHD	GUANFACINE HCL	guanfacine	AMNEAL PHARMACEUTICALS LLC	G	1	180.42%	\$84,306.34	-	No
ADHD	METHYLPHENIDATE HYDROCHLO	methylphenidate HCl	NORTHSTAR RX LLC	G	2	40.11%	\$65,539.30	-	No
Cancer	NERLYNX	neratinib	PUMA BIOTECHNOLOGY, INC.	B	3	20.78%	\$62,975.15	Yes	No
Gastrointestinal	RANITIDINE HYDROCHLORIDE	ranitidine HCl	STRIDES PHARMA INC.	G	4	134.21%	35,330.850	-	No
Antidepressant	FLUOXETINE HYDROCHLORIDE 20MG/5ML SOL	fluoxetine HCl	SILARX PHARMACEUTICALS, INC.	G	5	666.67%	\$24,604.36	-	No
ADHD	METHYLPHENIDATE HYDROCHLO	methylphenidate HCl	MAYNE PHARMA INC.	G	6	89.20%	\$16,082.10	-	No
Gastrointestinal	RANITIDINE HCL	ranitidine HCl	SILARX PHARMACEUTICALS, INC.	G	7	316.72%	\$11,353.92	-	No
Diabetes	AFREZZA	insulin, human, inhalation	MANNKIND CORPORATION	B	8	18.81%	\$10,211.55	-	No
Corticosteroid	PREDNISOLONE SODIUM PHOSP	prednisolone sodium	PHARMACEUTICAL ASSOCIATES, INC.	G	9	84.88%	\$9,850.37	-	No
Antiprotozoal	ALINIA	nitazoxanide	ROMARK LABORATORIES, L.C.	B	10	18.65%	\$6,952.65	-	No

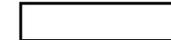


Exhibit B

TOP 10 NET AMOUNT PAID-CY 2019 (Chart 2)

Therapeutic Category	PRODUCT NAME	GENERIC NAME	LABELER NAME	Brand or Generic (B/G)	Rank by Net Amount Paid 1= Highest Net Spend	AVERAGE PERCENT INCREASE (Over One Year)	GROSS AMOUNT PAID*	Specialty (Yes)	Appeared on Previous Year's List (Yes/No)	Appeared on this year's GROSS (WAC) COST LIST
Psoriasis, Crohn's, UC	STELARA	Ustekinumab	JANSSEN BIOTECH, INC	B	1	20.09%	\$2,363,384.10	Yes	Yes	No
ADHD	CONCERTA	Methylphenidate HCl Tab ER (OSM)	JANSSEN PHARMACEUTICALS, INC	B	2	288.49%	\$6,645,616.14	-	No	No
ADHD	VYVANSE	Lisdexamfetamine Dimesylate	SHIRE US, INC.	B	3	24.95%	\$3,393,980.56	-	No	No
Asthma/COPD	ADVAIR DISKUS	Fluticasone-Salmeterol	GLAXOSMITHKLINE	B	4	744.14%	\$893,250.48	-	No	No
Antirheumatic	ACTEMRA	Tocilizumab	GENENTECH, INC.	B	5	42.66%	\$214,556.92	Yes	No	No
Cancer	RYDAPT	Midostaurin	NOVARTIS	B	6	16.69%	\$102,052.05	Yes	No	No
Blood Cancer	REVLIMID	Lenalidomide	CELGENE CORPORATION	B	7	27.99%	\$439,679.06	Yes	No	No
Atypical Antipsychotic	INVEGA	Paliperidone	JANSSEN PHARMACEUTICALS, INC	B	8	15.15%	\$121,947.37	-	Yes	No
Anticonvulsant	DIASTAT ACUDIAL	Diazepam (rectal gel delivery)	BAUSCH HEALTH US, LLC.	B	9	19.94%	\$82,552.13	-	No	No
Antidepressant	VENLAFAXINE HCL ER	Venlafaxine HCl	AUROBINDO PHARMA LTD.	G	10	74.05%	\$55,799.32	-	No	No

*DVHA is prohibited from publishing drug-specific net cost information. The gross cost to DVHA for each drug listed is provided as a benchmark. This will not align in rank order with the net cost of the drug to the State.

Exhibit C

18 V.S.A. § 4635- Pricing Transparency Drug List-DVHA Methodology

Date: July 1, 2020

Vermont law 18 V.S.A. § 4635, entitled “Prescription Drug Cost Transparency” requires the Department of Vermont Health Access (“DVHA”) to create two lists of 10 prescription drugs per the following statutory language:

(b)(1)(A) The Department of Vermont Health Access shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years **or** by 15 percent or more during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall include the percentage of the wholesale acquisition cost increase for each drug on the list; rank the drugs on the list from those with the largest increase in wholesale acquisition cost to those with the smallest increase; indicate whether each drug was included on the list based on its cost increase over the past five years or during the previous calendar year, or both; and provide the Department's total expenditure for each drug on the list during the most recent calendar year.

(B) The Department of Vermont Health Access shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the cost to the Department of Vermont Health Access, net of rebates and other price concessions, has increased by 50 percent or more over the past five years **or** by 15 percent or more during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall rank the drugs on the list from those with the greatest increase in net cost to those with the smallest increase and indicate whether each drug was included on the list based on its cost increase over the past five years or during the previous calendar year, or both.

DVHA’s Pharmacy Unit prepared data on drugs that meet the criteria per the following methodology.

Methodology used for selection of drug list for 18 V.S.A. § 4635:

To be consistent with other payers and allow the Attorney General’s office to maximize comparisons of the list among payers, DVHA developed the list based on the one-year increase in WAC and net cost. The data was supplied by DVHA’s Pharmacy Benefits Manager (PBM) Change Healthcare, based on criteria supplied by DVHA and produced a detailed listing of all drugs that exceeded a 15% increase in gross and net cost to DVHA. The final list of the top 10 drugs in each category was derived by reviewing these lists in detail, taking into consideration the previous year’s lists, and brand, generic and specialty status. Net spend was also considered when generating the ranking of the drugs in the “net cost” list.

TOP 10 GROSS AMOUNT PAID (Chart 1)

This list contains drugs for which the wholesale acquisition cost (WAC) increased by 15 percent or more in calendar year 2019. The WAC unit price for all years was pulled as of December 31st of the calendar year. The data was averaged and grouped at the product name level. The data was initially sorted based on the highest total gross cost to DVHA and an additional list was sorted for largest percent increase in WAC.

TOP 10-NET AMOUNT PAID (Chart 2)

This list contains drugs for which the net cost to DVHA increased by 15 percent or more in calendar year 2019. DVHA net cost was calculated as pharmacy reimbursement minus all rebates. The total net cost for each NDC was divided by the total quantity (ex. tablets or capsules) of the drug reimbursed by DVHA for that NDC to obtain the Net Unit Cost for each drug. The data was pulled by calendar year, then averaged and grouped at the product name level. The list was extracted using the highest net paid amount for each drug that met the 1 year 15% increase threshold.

Both drug lists were further refined to assure that at least one generic and one brand appeared on each list, and specialty drugs were identified. Specialty drugs were defined as per DVHA’s posted list of specialty drugs on the DVHA website at: [DVHA Specialty Drug List](#). Since DVHA is prohibited from publishing drug-specific net cost information, the gross cost to DVHA for each drug listed was provided as a benchmark. This will not align in rank order with the net cost of the drug to the State.

A summary of the drug NDC’s analyzed appears below:

2019 GROSS									
Category	Total # NDC's Evaluated	# of NDCs with Utilization Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC >= 50% last 5 Yr	11,677	475	4.07%	336	70.74%	240.60%	80.68%	\$1.58	\$17.09
WAC >= 15% last 1Yr	12,998	199	1.53%	166	83.42%	176.67%	32.18%	\$0.68	\$5.15

DRUG PRICE TRENDS

The following chart is a summary of the last four years of data on WAC price increases. Compared to 2016, there has been a 64% decline in the total number of drugs reaching the 15% per year threshold, and a 78% decline in the total number of drugs reaching the 50% per 5-year threshold. This indicates that fewer manufacturers are excessively increasing their wholesale acquisition costs for drugs. Compared to 2016, the percentage of generics drugs reaching the 15% per year threshold has increased from 35.2% to 83.4%, and the total percentage of brand drugs reaching the threshold has therefore declined from 64.8% to 16.6% of the total. Manufacturers of brand name drugs have moderated their price increases more effectively than generic manufacturers. However, the magnitude of the increase in brand drugs rose from an average of 22.3% to 32.2% and generics rose from 132% to 176.7%. Therefore, although prices are rising on fewer drugs, prices are increasing at a higher rate. The average dollar increase in generic prices has declined from an average of \$1.98 to \$0.68 which along with the other trends, indicates that lower priced generics are experiencing sharper price increases than higher priced generics.

2016 GROSS									
Category	Total # NDC's Evaluated	# of NDCs with Utilization Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC >= 50% last	11,542	2,204	19.10%	1,404	63.70%	447.93%	111.05%	\$2.63	\$40.48
WAC >= 15% last	12,972	548	4.22%	193	35.22%	131.99%	22.31%	\$1.98	\$12.49
2017 GROSS									
Category	Total # NDC's Evaluated	# of NDCs with Utilization Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC >= 50% last	12,035	1,644	13.66%	996	60.58%	325.01%	92.73%	\$2.51	\$51.55
WAC >= 15% last	13,747	323	2.35%	158	48.92%	86.81%	24.67%	\$1.70	\$14.59
2018 GROSS									
Category	Total # NDC's Evaluated	# of NDCs with Utilization Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC >= 50% last	12,934	992	7.67%	543	54.74%	253.27%	79.34%	\$3.45	\$51.94
WAC >= 15% last	14,348	202	1.41%	171	84.65%	148.16%	29.37%	\$0.90	\$19.15
2019 GROSS									
Category	Total # NDC's Evaluated	# of NDCs with Utilization Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC >= 50% last	11,677	475	4.07%	336	70.74%	240.60%	80.68%	\$1.58	\$17.09
WAC >= 15% last	12,998	199	1.53%	166	83.42%	176.67%	32.18%	\$0.68	\$5.15

Exhibit D

BCBSVT List of Drugs with Largest Net Price Increase Impact

Pursuant to 18 V.S.A. § 4635 (b)(C)(i)

2019

RANKING	NATIONAL_DRUG_CODE	DRUG_NAME	MANUFACTURER	Brand/Generic	Specialty?	1-yr % Increase
1	00074055402	HUMIRA(CF) PEN	AbbVie	Brand	Yes	76.3%
2	57894006103	STELARA	Janssen	Brand	Yes	138.0%
3	00074433902	HUMIRA PEN	AbbVie	Brand	Yes	43.6%
4	00088221905	LANTUS SOLOSTAR	Sanofi	Brand	No	294.8%
5	00002751001	HUMALOG	Eli Lilly & Company	Brand	No	347.7%
6	61958220101	EPCLUSA	Gilead Sciences	Brand	Yes	266.6%
7	58406044504	ENBREL SURECLICK	Immunex	Brand	Yes	64.0%
8	00002879959	HUMALOG KWIKPEN U-100	Eli Lilly & Company	Brand	No	271.4%
9	00186037020	SYMBICORT	Astrazeneca	Brand	No	247.1%
10	00093598627	EPINEPHRINE	Teva	Generic	No	252.00%

Note: Price increases were calculated after applying any manufacturer rebates and administrative fees.