Pharmaceutical Costs for Cost-Effectiveness Analysis

Mark Bounthavong

2 March 2022





Disclosures

The author has no relevant financial or nonfinancial relationships to disclose. During the development, analysis, and preparation of this presentation, the author was an employee of the Veterans Health Administration, U.S. Department of Veterans Affairs.

The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of any agency of the U.S. government.

Pharmaceutical Costs

Pharmaceutical costs are commonly used for:

- Cost Analysis
- Cost-Effectiveness Analysis
- Budget Impact Analysis

Poll Question:

Do you believe that pharmaceutical costs are transparent?

- Yes
- ■No
- No idea

Acquisition price is what we want but...

Acquisition price is not readily available

Other sources of pharmaceutical price data are available

AWP = "Ain't What's Paid"

THE WALL STREET JOURNAL.

English Edition ▼ February 2, 2020 Print Edition Video

Home World U.S. Politics Economy Business Tech Markets Opinion Life & Arts Real Estate WSJ. Magazine

How Quiet Moves by a Publisher Sway Billions in Drug Spending

Lawsuit Forces Hearst Unit To Lower Prices on List Widely Used as Benchmark

By Barbara Martinez

Updated Oct. 6, 2006 12:01 am ET

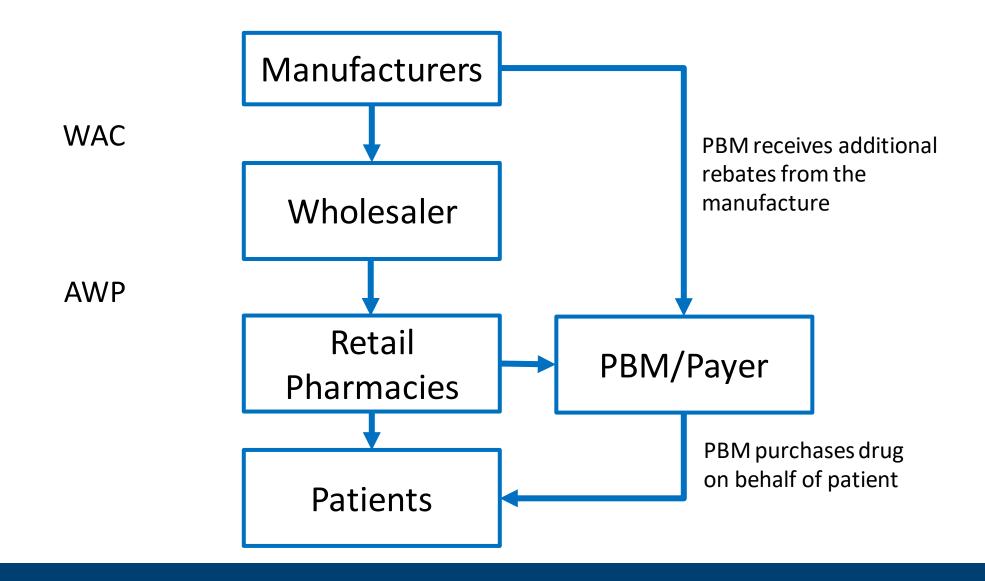
First DataBank and McKesson Corporation artificially increased AWPs using multipliers

Class action lawsuit resulted in the discontinuation of AWP by the two largest publishers in 2011

Landscape of Pharmaceutical Costs

Term	Definition
Federal upper	A price ceiling used by the Centers for Medicare and Medicaid Services
limit (FUL)	(CMS) to control prices for certain medications paid to pharmacies
Maximum allowable cost (MAC)	A price ceiling, similar to the FUL, established at the state level
Usual and customary price (U&C)	The average cash price paid at a retail pharmacy
Average wholesale	An estimate of the price retail pharmacies pay for drugs from
price (AWP)	their wholesale distributor. This price is calculated and published
	by companies such as Medi-Span and First Databank
Wholesale acquisition	An estimate of the manufacturer's list price for a drug to
cost (WAC)	wholesalers or other direct purchasers, not including discounts
	or rebates. This price is defined by federal law
Average manufacturer	The price a manufacturer charges wholesalers or pharmacies that
price (AMP)	purchase directly from the manufacturer after discounts. This price
	is defined by federal law
Average sales	A calculation of the weighted average of manufacturer's sales price
price (ASP)	for a drug for all purchasers, net of price adjustments. This price is defined by federal law
Estimated acquisition	An estimate of the price generally paid by providers for a drug.
cost (EAC)	Formula specific for each state as defined by the state Medicaid agency
Average Actual	An estimate of retail pharmacy acquisition costs for drugs through
cost (AAC)	a review of actual pharmacy invoices
Dispensing fee	The amount reimbursed to the pharmacy to cover the charge for
	professional services and overhead costs
National Drug	An 11-digit code used by Medicaid to identify a drug based on its
Code (NDC)	manufacturer, strength, and package size

Diagram of pharmaceutical transactions



Poll Question:

Which of the following source for pharmaceutical costs have you used in the past year?

- **AWP**
- **■** WAC
- **I**FSS
- Other
- None

Average Wholesale Price

Average Wholesale Price (AWP):

- An estimate of the price retail pharmacies pay for drugs from their wholesale distributor
- Prices are estimated and published by companies such as: Gold Standard Drug Database (Elsevier), Medi-Span, First DataBank, Micromedex Red Book
- Access is limited to subscriptions
- Mired in controversy

Wholesale Acquisition Cost

Wholesale Acquisition Cost (WAC):

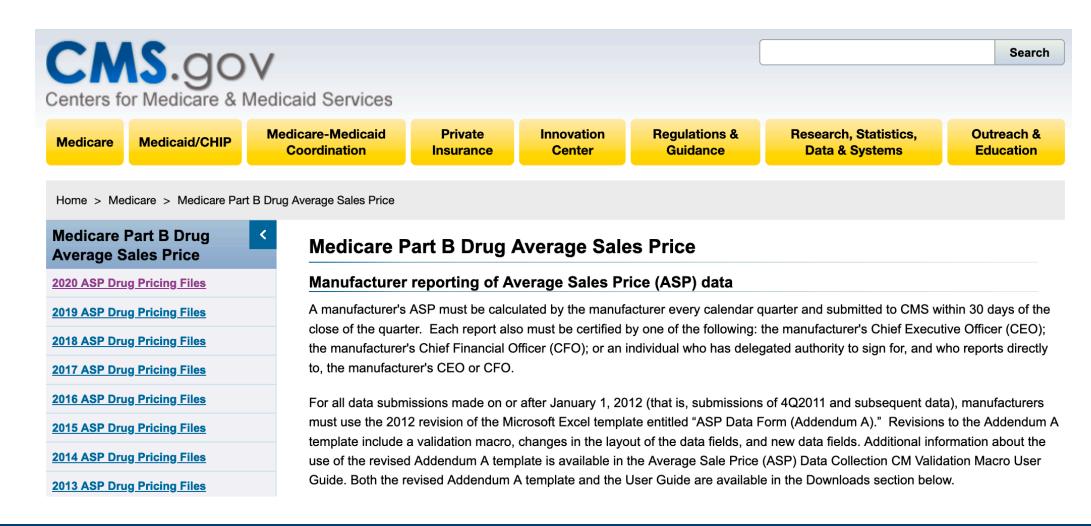
- An estimate of the drug manufacturer's list price to wholesalers or other direct purchasers
- Does not include discounts or rebates
- Price is determined by Federal Law

Average Sales Price

Average Sales Price (ASP):

- A calculation of the weighted average of manufacturer's sales price for a drug for all purchasers, net of price adjustments
- This price is determined by Federal Law
- Only available for Medicare Part B drugs

Average Sales Price



Average Actual Cost

Average Actual Cost (AAC):

- An estimate of retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices
- This what we would like to get

Alabama AAC list



Average Acquisition Cost (AAC) Reimbursement

The purpose of the Average Acquisition Cost (AAC) Program is to establish a transparent, timely and accurate pharmacy reimbursement system based on actual acquisition cost (invoice) data and a statistically validated cost of dispensing survey, and do so with all stakeholder involvement and support. CMS approved implementation of the AAC/COD reimbursement method effective September 22, 2010.

Click on this link to download the AAC for generic and brand drugs

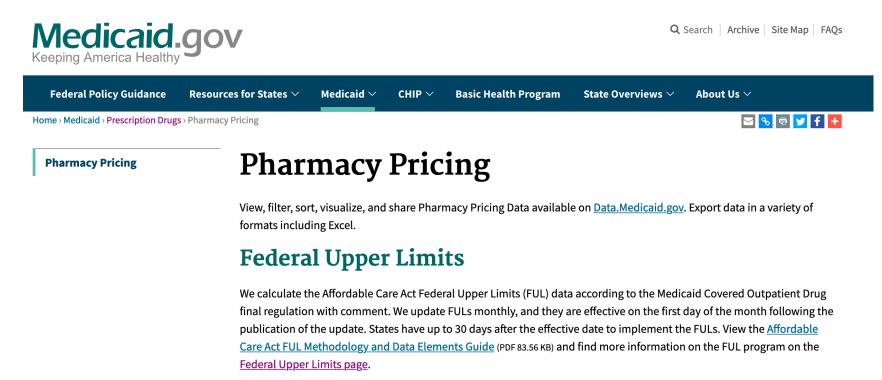
AAC Website

 AAC Website - Link to the Alabama Medicaid Pharmacy Average Acquisition Cost (AAC) / Myers and Stauffer web page - 8/24/16

Federal Upper Limits (FUL)

Federal Upper Limit (FUL)

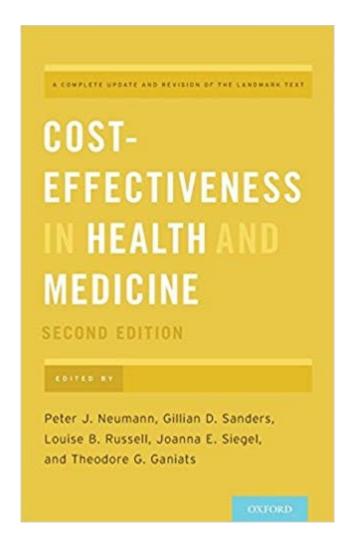
Price ceiling used by CMS to control prices paid to pharmacies



What do other folks recommend?

Second Panel on Cost-Effectiveness in Health and Medicine recommends using the FSS price

"While there is no consensus on what is the most accurate measure of transaction prices for pharmaceuticals, we recommend using the Federal Supply Schedule (FSS), a publicly available source of information of the cost paid for drugs by many federal agencies in the United States"



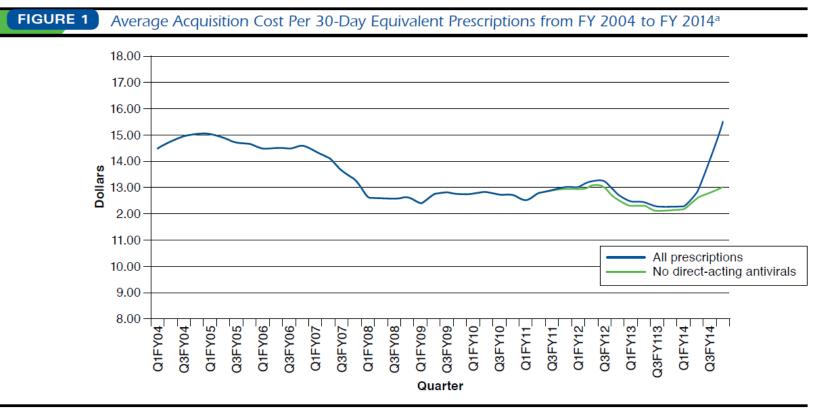
VA contracted prices (Public Law 102-585, Veterans Health Care Act of 1992)

- FSS (Federal Supply Schedule) is a multiple award, multi-year federal contract that is available for use by any Federal Government agency. It satisfies all Federal contract laws and regulations. Pricing is negotiated based on how vendors do business with their commercial customers
- Big 4 prices are only available to VA, Department of Defense, Public Health Service (Indian Health Service), and U.S. Coast Guard customers and are based on pricing calculations outlined under the Public Law.
- Actual acquisition costs is the "actual" cost that the VA PBM spends on a medical product after rebates and discounts (e.g., Blanket Purchase Agreements). Not available to the public.

VA contracted prices (cont.)

- By law, VA gets an approximately 24% discount from the Average Manufacturer Price (Most Favored Commercial Customer Price)
- Federal Supply Schedule 65-IB includes "Drugs and Biologics" and "Medicated Cosmetics and Toiletries"
- Contracting is performed by the National Acquisition
 Center

J Manag Care Spec Pharm. 2016;22(9):1058-63



aThese data are not broken down by the number of unique pharmacy users; therefore, they do not illustrate the influence of an increasing number of users on cost. Average 30-day drug cost is defined as the sum (prescription costs) \div sum (30-day prescriptions); for each prescription, cost equals the quantity multiplied by the unit cost. Thirty-day prescription = 1 for \le 30 days of supply; 30-day prescription = 2 for > 30 and \le 60 days of supply, and 30-day prescription = 3 for > 60 days of supply. Data are from VA Pharmacy Benefits Management Services prescription database, version 3.0, for FY 2004-FY 2014. FY= fiscal year; Q = quarter; VA=Veterans Affairs.

Anticipate drug prices changing

Introduction of generic drugs

- Simvastatin price decreased by 89% in 5 years after loss of patent exclusivity[1]
- Clopidogrel price decreased by 46% in 1 month after loss of patent exclusivity[2]
- Generic medications price decreased by 66% 5 years after loss of patent exclusivity and 80% 10 years after loss of patent exclusivity[3]
- 1. McKeller, et al. Forum Health Econ Policy. 2012;15(2):1-13.
- Aitken, et al. NBER paper # 19487
- Ladwadala, et al. Am J Manag Care. 2017;23(8):488-493.

HERC Guidance

Perspective of the average U.S. Payer getting the average cost

For brand name drugs:

121% of the FSS

152% of VA cost

64% of AWP

For generic drugs:

27% of AWP

Sources of VA drug costs

Managerial Cost Accounting (MCA)

Pharmacy Benefits Management (VistA Drug File)

Managerial Cost Accounting (MCA) Data

Formally Decision Support System (DSS)

Table 4. Cost Elements: What did it cost to purchase the medication and provide it to the patient?

Column Name	Brief Description
act_cost	Cost of the drug product itself, supply component of Actual Total Cost
dispcost	Dispensing fee, labor component of Actual Total Cost
fixdir	Fixed direct costs assigned to the Pharmacy Service
fixind	Fixed indirect cost allocated to the drug product
sprice	Contracted price paid for the drug product, confidential data may not be disclosed
var	Variable direct cost
vs_cost	Variable supply cost, confidential data may not be disclosed

Actual Total Costs = act_cost + dispcost

Confidential: sprice and vs_cost

Due to confidentiality, aggregate costs are presented instead of unit price

HERC recommends using FSS when presenting unit price

VIReC. VIReC Research User Guide: Pharmacy Managerial Cost Accounting National Data Extract (PHA MCA NDE). Hines IL: U.S. Department of Veterans Affairs, Health Services Research & Development Service, VA Information Resource Center; November, 2017.

Pharmacy Benefits Management Cost Data

PBM dataset include the cost of the drug only Drug cost comes from the VistA Local Drug File

Variable: **Drug Cost Per Unit**

Definition: Average cost per Drug Unit

Remarks: For solutions, this will be the average cost per milliliter. For additives, this will be

the average cost per Drug Unit. The Average Cost Per Unit is calculated and entered by the Pharmacy ADPAC. The Average Cost Per Unit may not reflect the actual price of the dispense unit of the drug product dispensed. This will occur if

VistA files specified below have not been updated to reflect the price of the

currently stocked supply at the time the drug was dispensed.

The total cost of the IV order from the **Start Date of Order** until the **Stop Date of Order** will equal the sum of the Average Cost Per Unit multiplied by the **Total Units Dispensed** for each solution and additive in the IV preparation.

US Department of Verterans Affairs, VA Information Resource Center (VIReC). VIReC Research User Guide: VHA Pharmacy Prescription Data, 2nd Edition. Hines, IL: VIReC; September 2008. Available at http://www.virec.research.va.gov/References/RUG/RUG.htm.

FSS price tutorial

Demonstrate how to find the FSS price using existing public facing websites

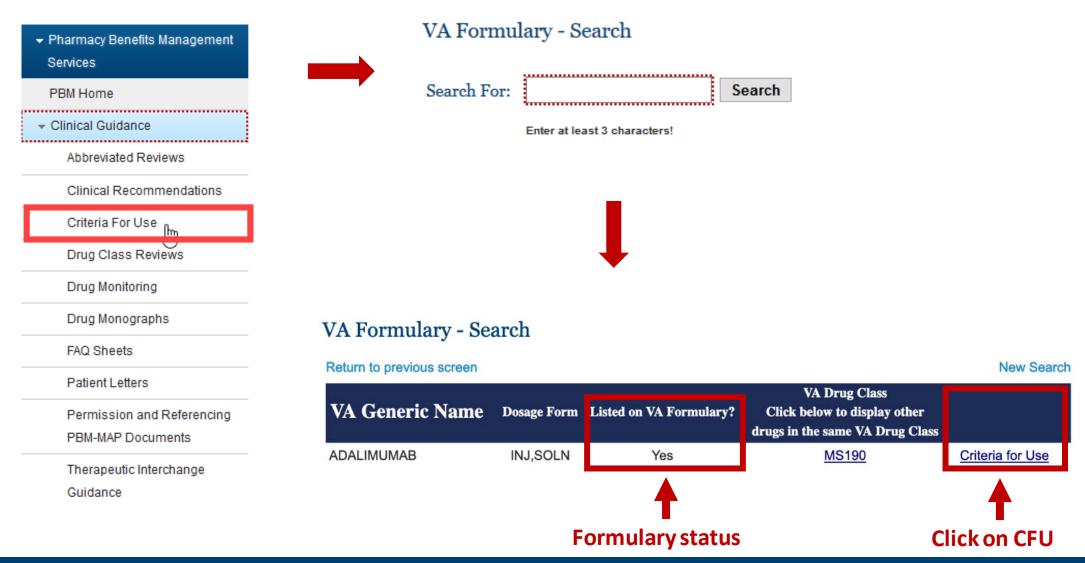
Look up a VA formulary status and drug price

Go to the VA PBM formulary page and find adalimumab (Humira):

Answer the following questions:

- Is adalimumab on the VA National Formulary?
- What does the VA criteria for use recommend providers use for patients with RA?
- How much does it cost compared to certolizumab?

Step 1: Search for the drug and CFU



Step 2: Review the CFU

VHA FORMULARY POLICIES

The formulary TNFIs – adalimumab, etanercept, and infliximab-dyyb – are available through facility prior authorization. Certolizumab pegol, golimumab, and infliximab are available through the nonformulary process in VHA.

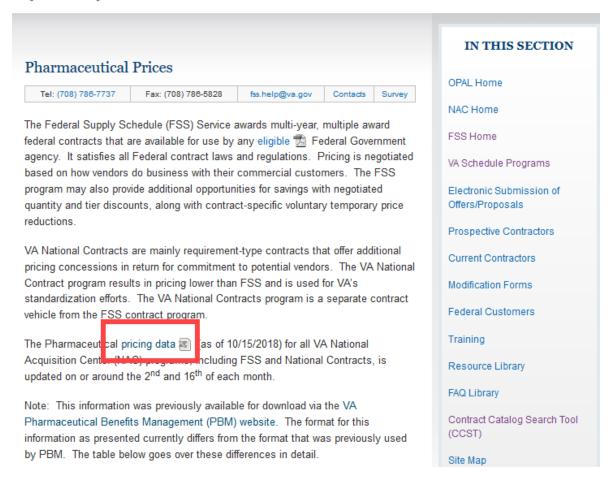
This guidance may serve as a <u>reference</u> for facility prior authorizations for the formulary TNFIs and for requests for the nonformulary TNF inhibitors. The intent of using facility prior authorizations is to simplify access to TNF inhibitor therapy.

of TNFIs
Nonformulary
Without CFU
Certolizumab
Golimumab
Infliximab

Step 3: Download pricing data

Method 1: Download entire drug price table and look for adalimumab

Office of Procurement, Acquisition and Logistics (OPAL)



Step 4: Look up the price

Method 1: Download entire drug price table and look for adalimumab

00074-4339-07	NDC With Dashe	Sub-Iter Package Descripti	o Generic	Trade Name	VA Class	Covered	Prime Ve	Price	Price Start Da	Price Stop Dat	Price Type
00074-4339-07 4 ADALIMUMAB 40MG/0.8ML INJ,PEN,KIT HUMIRA 40MG/0.8 MS190 T T 9597.17 09/01/2018 08/31/2023 FSS	00074-4339-07	4	ADALIMUMAB 40MG/0.8ML INJ,PEN,KIT	HUMIRA 40MG/0.8	MS190	T	T	2870.09	09/01/2018	08/31/2023	Big4
	00074-4339-07	4	ADALIMUMAB 40MG/0.8ML INJ,PEN,KIT	HUMIRA 40MG/0.8	MS190	T	T	9597.17	09/01/2018	08/31/2023	FSS

There are two prices for the syringe kit (**FSS** and **BIG4**)

BIG4 price = **\$2,871**

Step 5: Use the NAC portal

Method 2: Look the price up at the National Acquisition Center

National Acquisition Center (CCST)

Welcome to the National Acquisition Center (NAC) Contract Catalog Search Tool (CCST)

	UPDATE DATE	UPDATE TIME
Search Menu	10/31/2018	01:52:52 AM

What is the CCST?

The CCST (updated daily) is the most comprehensive online listing of the Department of Veterans Affairs (VA) NAC's active nation-wide healthcare-related contract vehicles, open to VA and other Government agencies. The CCST contains over 1,700 active contract vehicles and over 1 million catalog line items pertaining to VA's Federal Supply Schedule contracts and national standardization contract vehicles including contracts, Blanket Purchase Agreements (BPAs) and Basic Ordering Agreements (BOAs). Get quick access to the National Acquisition Center, including the Federal Supply Schedule (FSS) Service and National Contract Service (NCS) and the programs they offer such as MedSurg Catalog and Pharmaceutical Catalog products and services.



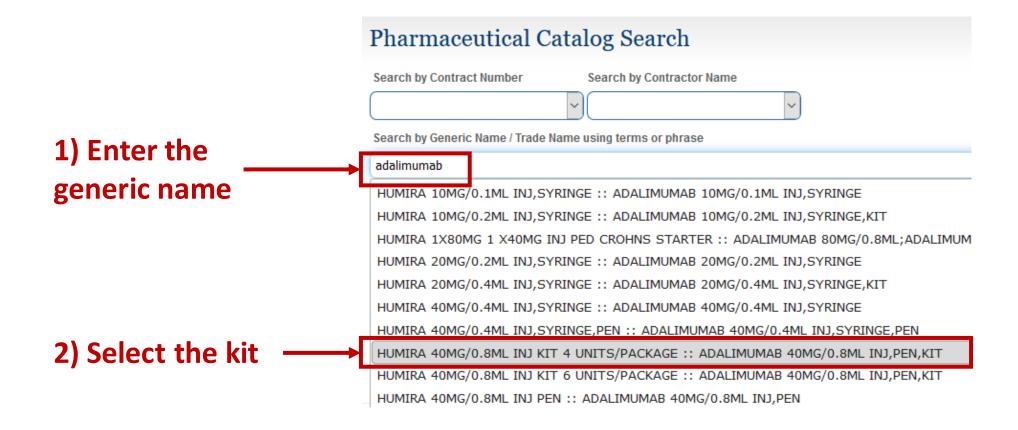
Search Pharmaceutical catalog

Includes:

- Pharmaceuticals (65 I B)
- Big 4, National Contracts

Step 6: Find the price

Method 2: Look the price up at the National Acquisition Center



Step 7: Compare the prices

Method 2: Look the price up at the National Acquisition Center

00074-4339-07 4 36F79718D0528 X Abbvie US ADALIMUMAB 40MG/0.8ML HUMIRA 40MG/0.8ML INJ KIT 4 \$9,597.17 \$0.00 \$2,870 UNITS/PACKAGE	NDC		PKG	CONTRACT NUMBER	PV	VENDOR	GENERIC NAME	TRADE NAME	FSS PRICE	NC PRICE	BIG 4 PRICE
	0007	4-4339-07	4	36F79718D0528	X	Abbvie US			\$9,597.17	\$0.00	\$2,870.09

There are two prices for the syringe kit (FSS and BIG4)

BIG4 price = **\$2,871**

Step 8: Compare adalimumab and certolizumab prices

Price comparison

Adalimumab

FSS price = **\$9,597** BIG4 price = **\$2,871**

Price per dose = \$2,871 / 4 = **\$718**

Certolizumab

FSS price = **\$991**

Price per dose = \$991 / 2 = **\$495**

Why does the price favor certolizumab even though it is not on the VANF? **Need to consider the rebates that are hidden from the public**

Conclusions

- Perspectives matter
- Use FSS prices with adjustments
- Perform sensitivity analyses

Poll Question:

Do you have a better understanding of pharmaceutical costs?

- Yes
- No
- ☐I think so?

References

Links to VA Pharmacy Sites

VA PBM Main Site

VA Copayment Rates

VA Service Connection Priority Groups

VA Formulary Management FAQ

VA Drug Monograph List

VA National Formulary List

VA Drug Class Reviews

VA Criteria For Use

References

Oehsen, Ashe, Duke. Executive Summary: Pharmaceutical Discounts Under Federal Law: State Program Opportunities. Am J Health Syst Pharm. 2003:60(6):551-53.

A Congressional Budget Office Paper. Prices for Brand-Name Drugs Under Selected Federal Programs. The Congress of the United States. Congressional Budget Office. June 2005. [link]

Office of Procurement, Acquisitions, and Logistics (OPAL). Public Law 102-585, Veterans Health Care Act of 1992. [link]

Mattingly J. Understanding Drug Pricing. U.S. Pharmacist. 2012;37(6):40-45. [link]

Aspinal S, et al. Pharmacy Benefits Management in the Veterans Health Administration Revisited: A Decade of Advancements, 2004-2014. J Manag Care Spec Pharm. 2016;22(9):1058-63. [link]

McKeller, et al. Forum Health Econ Policy. 2012;15(2):1-13. [link]

Aitken, et al. NBER paper # 19487. [link]

Ladwadala, et al. Am J Manag Care. 2017;23(8):488-493. [link]

References

US Department of Veterans Affairs, VA Information Resource Center (VIReC). VIReC Research User Guide: VHA Pharmacy Prescription Data, 2nd Edition. Hines, IL: VIReC; September 2008. Available at http://www.virec.research.va.gov/References/RUG/RUG.htm

Gonsoulin, M. VIReC Factbook: Corporate Data Warehouse (CDW) Non-VA Meds 1.0. Hines IL: U.S. Department of Veterans Affairs, Health Services Research & Development Service, VA Information Resource Center; February, 2016.

VIReC. VIReC Research User Guide: Pharmacy Managerial Cost Accounting National Data Extract (PHA MCA NDE). Hines IL: U.S. Department of Veterans Affairs, Health Services Research & Development Service, VA Information Resource Center; November, 2017

Health Economics Resource Center: Pharmacy Data. URL: https://www.herc.research.va.gov/include/page.asp?id=pharmacy

Questions?

For more information visit the HERC website at www.herc.research.va.gov

Email us at HERC@va.gov

Call us at (650) 617-2630

Email me at: mark.bounthavong@va.gov





Appendix





National Average Drug Acquisition Cost

https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html

The National Average Drug Acquisition Cost (NADAC) is based on the retail price survey and focuses on the retail community pharmacy acquisition costs. CMS has mandated that Medicaid pharmacy programs reimburse the actual acquisition cost (AAC) of drugs plus a professional dispensing fee

National Average Drug Acquisition Cost

We update the National Average Drug Acquisition Cost (NADAC) data and comparison data weekly. Each month we post new data, including findings from the previous month's survey and weekly price changes that have occurred before the release of the next month's NADAC data. For more information on the fields in the NADAC data, please review the NADAC data Field Definitions (PDF 24.97 KB). Find more NADAC information on the Survey of Retail Prices page.

Showing 1 to 10 of 323 en	ıtries		
Name	♦ Year	♦ Month	♦ Date
All	♦ All	♦ All	♦ All ♦
<u>NADAC</u>	2020	February	2020-02-12
NADAC	2020	February	2020-02-05
NADAC	2020	January	2020-01-29
NADAC	2020	January	2020-01-22

Average Manufacturer's Price

The Average manufacturer price (AMP) is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts. The AMP is statutorily defined and its calculation is based on actual sales transactions. Drug manufacturers must report AMP data for all Medicaid-covered drugs to the Centers for Medicare & Medicaid Services (CMS) quarterly as a requirement of the Medicaid drug rebate program. Most State Medicaid agencies do not have access to AMP data, which is proprietary.

Average Manufacturer's Price

At the median, AMP is 59 percent lower than AWP.

Forty-nine States use AWP to estimate pharmacy acquisition costs.

The median State EAC formula is AWP minus 12 percent.

For 98 percent of Medicaid-reimbursed NDCs, this median State EAC formula would reimburse at a price higher than AMP.

At the median, AMP is 25 percent lower than WAC.

Among the eight States that use WAC in their EAC, the median State EAC formula is WAC plus 8.5 percent.

For 96 percent of NDCs, this median EAC would reimburse at a price higher than AMP.

Accessibility Tips

- Tables, charts, and images must have a text description or be described orally by the speaker. Do not use "visual references"
 - Bad: "The yellow box contains data from..."
 - Bad: "The arrows indicate..."
 - Good: "Data flows in real time from the client CPRS computer to..."
 - Good: "The chart show that women Veterans are just as likely to use VA primary care..."
- All info conveyed with color should be available without color
 - For graphs, add text labels (e.g. male vs. female), use grayscale (e.g. black vs. grey), or use non-text indicators (e.g. a solid versus dotted line)
 - Print your slides in B&W and see if the slides are readable
- Avoid complicated notations on figures, screenshots, etc
 - Use a simple text description or describe orally
- Handouts should also be compliant with Section 508
 - Check the documentation for the software used to make these documents
- Please give all tables, images, figures, etc. an alternate text
 - Right click table > Format Shape > Alt Text > Enter description of table, image, figures, etc.
 > Close