

Pharmaceutical Costs for Cost-Effectiveness Analysis

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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

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”

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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 AWP's using multipliers

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

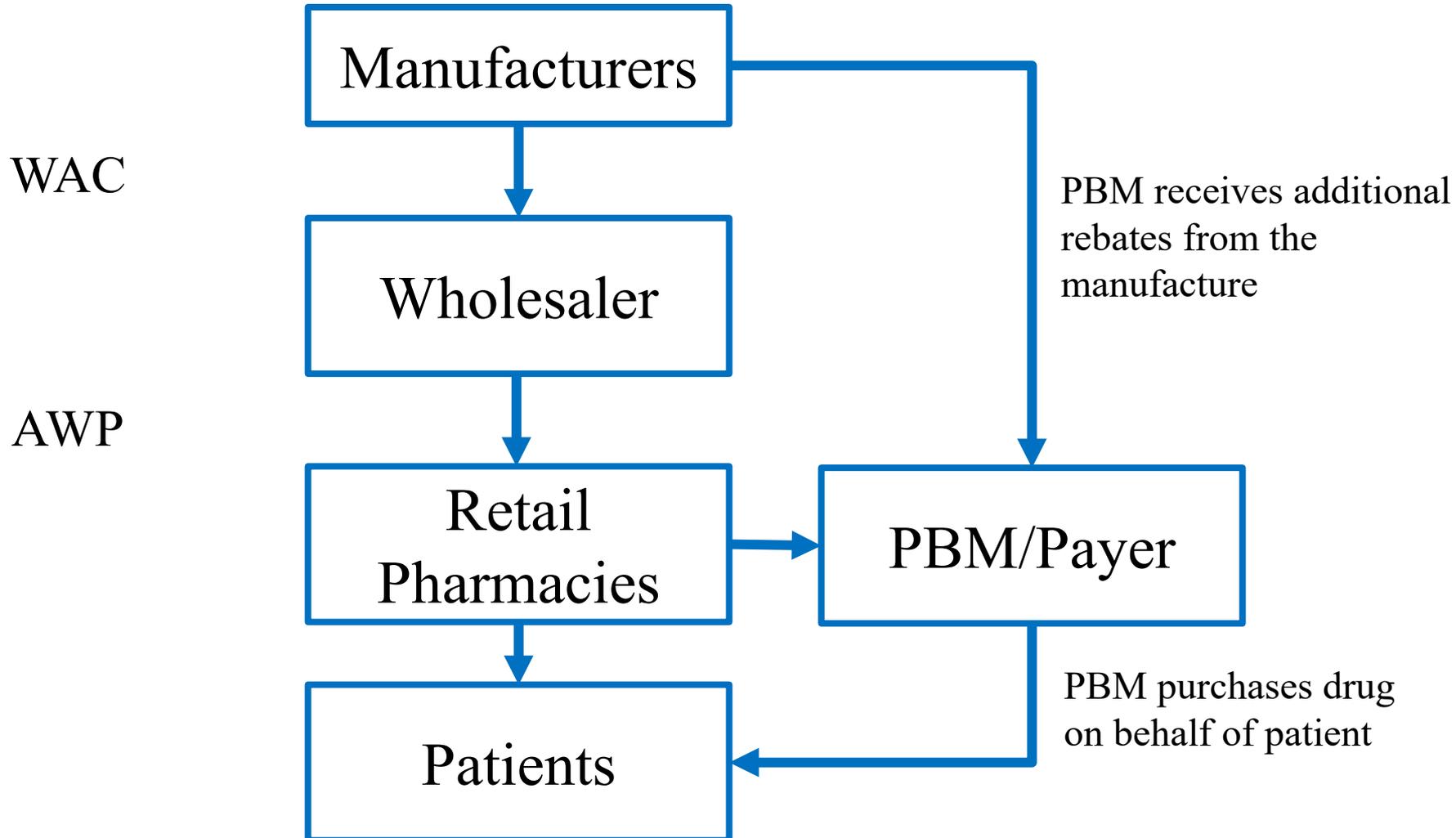
Landscape of Pharmaceutical Costs

Table 1. Common Terms and Acronyms Used in Drug Pricing

Term	Definition
Federal upper limit (FUL)	A price ceiling used by the Centers for Medicare and Medicaid Services (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 price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First Databank
Wholesale acquisition cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. This price is defined by federal law
Average manufacturer price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law
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 defined by federal law
Estimated acquisition cost (EAC)	An estimate of the price generally paid by providers for a drug. Formula specific for each state as defined by the state Medicaid agency
Average Actual cost (AAC)	An estimate of retail pharmacy acquisition costs for drugs through 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 Code (NDC)	An 11-digit code used by Medicaid to identify a drug based on its manufacturer, strength, and package size

Source: References 3-5, 7, 14.

Diagram of pharmaceutical transactions



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

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice>

The screenshot shows the CMS.gov website interface. At the top left is the CMS.gov logo with the tagline "Centers for Medicare & Medicaid Services". To the right is a search bar with a "Search" button. Below the logo is a navigation bar with eight yellow buttons: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, and Outreach & Education. Below the navigation bar is a breadcrumb trail: Home > Medicare > Medicare Part B Drug Average Sales Price. On the left side, there is a sidebar with a blue header "Medicare Part B Drug Average Sales Price" and a list of links for ASP Drug Pricing Files from 2013 to 2020. The main content area has a heading "Medicare Part B Drug Average Sales Price" and a sub-heading "Manufacturer reporting of Average Sales Price (ASP) data". The text explains that a manufacturer's ASP must be calculated every calendar quarter and submitted to CMS within 30 days of the close of the quarter. It also lists the required certifiers: the manufacturer's CEO, CFO, or an authorized individual. A final paragraph states that for data submissions made on or after January 1, 2012, manufacturers must use the 2012 revision of the Microsoft Excel template, and provides information about the revised Addendum A template and the User Guide available in the Downloads section.

Home > Medicare > Medicare Part B Drug Average Sales Price

Medicare Part B Drug Average Sales Price

Manufacturer reporting of Average Sales Price (ASP) data

A manufacturer's ASP must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. Each report also must be certified by one of the following: the manufacturer's Chief Executive Officer (CEO); the manufacturer's Chief Financial Officer (CFO); or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

For all data submissions made on or after January 1, 2012 (that is, submissions of 4Q2011 and subsequent data), manufacturers must use the 2012 revision of the Microsoft Excel template entitled "ASP Data Form (Addendum A)." Revisions to the Addendum A template include a validation macro, changes in the layout of the data fields, and new data fields. Additional information about the use of the revised Addendum A template is available in the Average Sale Price (ASP) Data Collection CM Validation Macro User Guide. Both the revised Addendum A template and the User Guide are available in the Downloads section below.

[2020 ASP Drug Pricing Files](#)

[2019 ASP Drug Pricing Files](#)

[2018 ASP Drug Pricing Files](#)

[2017 ASP Drug Pricing Files](#)

[2016 ASP Drug Pricing Files](#)

[2015 ASP Drug Pricing Files](#)

[2014 ASP Drug Pricing Files](#)

[2013 ASP Drug Pricing Files](#)

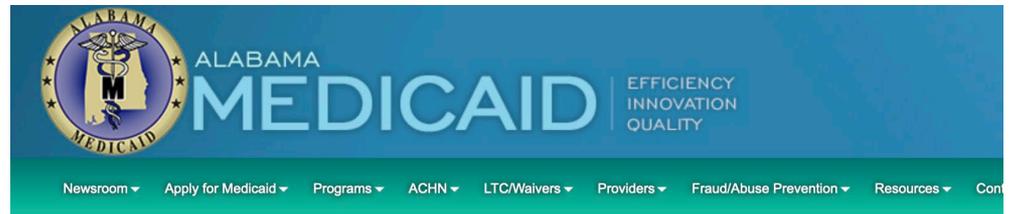
Average Actual Cost

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

https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.1_AAC.aspx



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.

AAC Website

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

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



Federal Upper Limits (FUL)

Federal Upper Limit (FUL)

- Price ceiling used by CMS to control prices paid to pharmacies

<https://data.medicaid.gov/Drug-Pricing-and-Payment/Federal-Upper-Limits-2020-01/dfsa-ug9f>

Medicaid.gov
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Home > Medicaid > Prescription Drugs > Pharmacy Pricing



Pharmacy Pricing

Pharmacy Pricing

View, filter, sort, visualize, and share Pharmacy Pricing Data available on [Data.Medicaid.gov](https://data.medicaid.gov). Export data in a variety of formats including Excel.

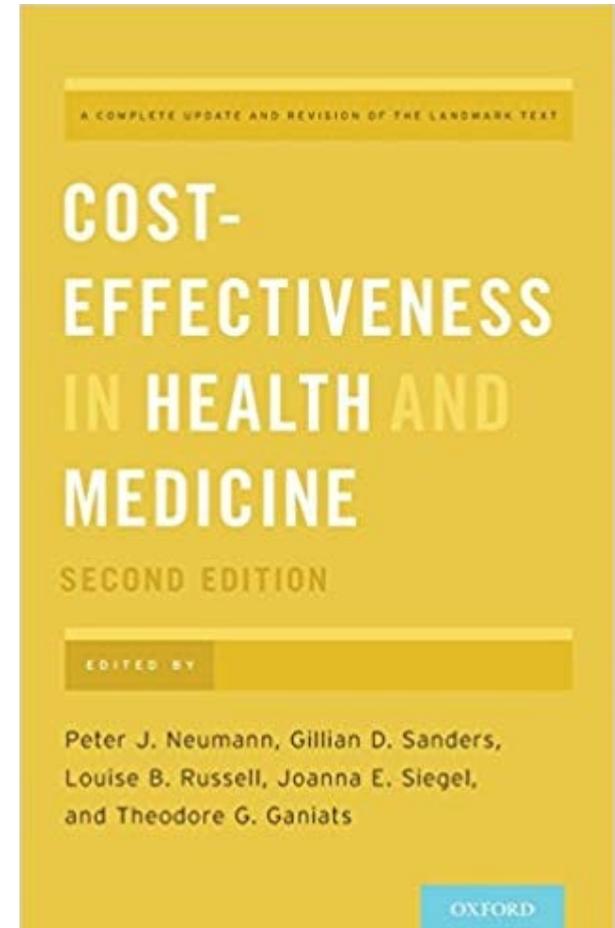
Federal Upper Limits

We calculate the Affordable Care Act Federal Upper Limits (FUL) data according to the Medicaid Covered Outpatient Drug final regulation with comment. We update FULs monthly, and they are effective on the first day of the month following the publication of the update. States have up to 30 days after the effective date to implement the FULs. View the [Affordable Care Act FUL Methodology and Data Elements Guide](#) (PDF 83.56 KB) and find more information on the FUL program on the [Federal Upper Limits page](#).

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

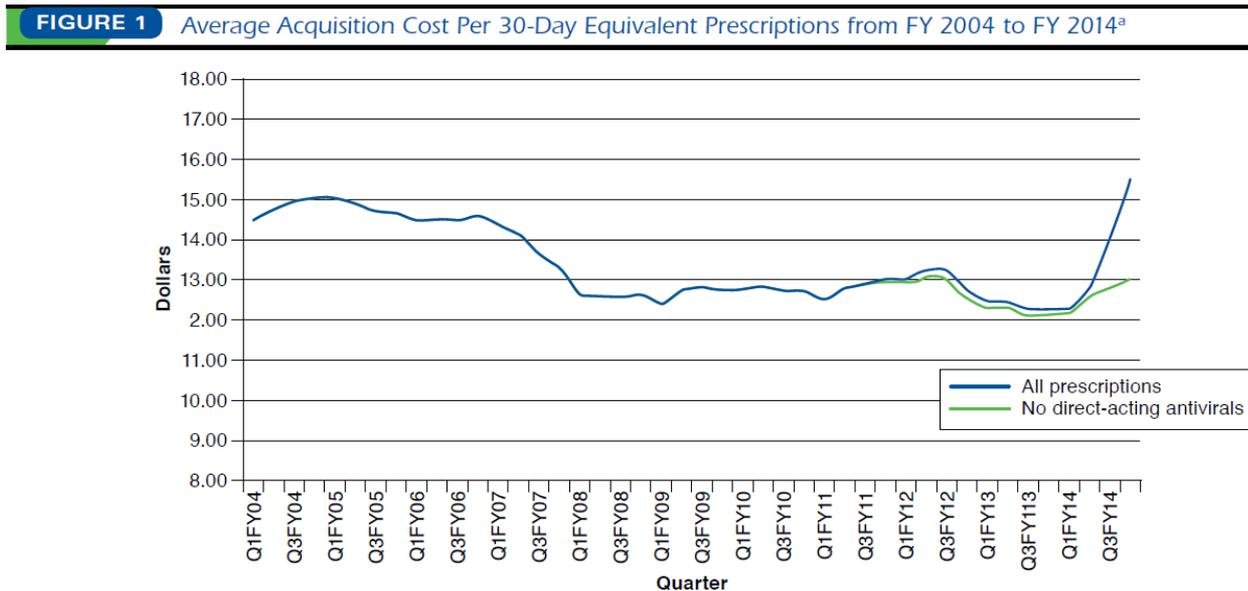
Big 4 prices are only available to VA, Department of Defense, Public Health Service (Indian Health Service), and U.S. Coast Guard customers and are based on pricing calculations outlined under the Public Law.

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.

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**



^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) ÷ sum (30-day prescriptions); for each prescription, cost equals the quantity multiplied by the unit cost. Thirty-day prescription = 1 for ≤ 30 days of supply; 30-day prescription = 2 for > 30 and ≤ 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.

2. Aitken, et al. NBER paper # 19487

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

HERC Guidance

<https://www.herc.research.va.gov/include/page.asp?id=pharmaceutical-costs>

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

<https://www.herc.research.va.gov/include/page.asp?id=data-overview>

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

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.

FSS price tutorial

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



Look up a VA formulary status and drug price

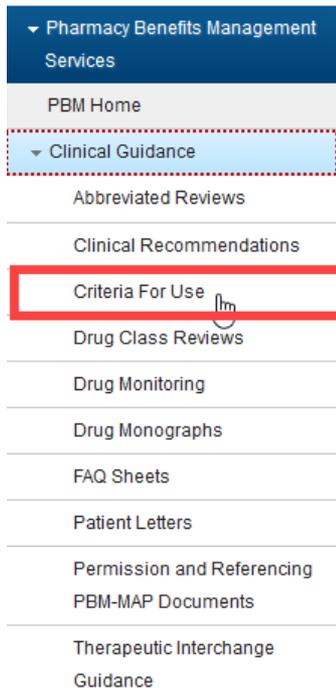
Go to the VA PBM formulary page and find adalimumab (Humira):

Answer the following questions:

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

Step 1: Search for the drug and CFU

<https://www.pbm.va.gov/apps/VANationalFormulary/>



VA Formulary - Search

Search For: Search

Enter at least 3 characters!



VA Formulary - Search

[Return to previous screen](#)

[New Search](#)

VA Generic Name	Dosage Form	Listed on VA Formulary?	VA Drug Class
ADALIMUMAB	INJ,SOLN	Yes	Click below to display other drugs in the same VA Drug Class MS190



Formulary status



Click on 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 reference 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.

Formulary Status	of TNFIs
Formulary With PA	Nonformulary Without CFU
Adalimumab Etanercept Infliximab-dyyb	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)

Pharmaceutical Prices

Tel: (708) 786-7737 Fax: (708) 786-5828 fss.help@va.gov [Contacts](#) [Survey](#)

The Federal Supply Schedule (FSS) Service awards multi-year, multiple award federal contracts that are available for use by any [eligible](#) Federal Government agency. It satisfies all Federal contract laws and regulations. Pricing is negotiated based on how vendors do business with their commercial customers. The FSS program may also provide additional opportunities for savings with negotiated quantity and tier discounts, along with contract-specific voluntary temporary price reductions.

VA National Contracts are mainly requirement-type contracts that offer additional pricing concessions in return for commitment to potential vendors. The VA National Contract program results in pricing lower than FSS and is used for VA's standardization efforts. The VA National Contracts program is a separate contract vehicle from the [FSS contract program](#).

The [Pharmaceutical pricing data](#) (as of 10/15/2018) for all VA National Acquisition Center (NAC) programs, including FSS and National Contracts, is updated on or around the 2nd and 16th of each month.

Note: This information was previously available for download via the [VA Pharmaceutical Benefits Management \(PBM\) website](#). The format for this information as presented currently differs from the format that was previously used by PBM. The table below goes over these differences in detail.

IN THIS SECTION

- [OPAL Home](#)
- [NAC Home](#)
- [FSS Home](#)
- [VA Schedule Programs](#)
- [Electronic Submission of Offers/Proposals](#)
- [Prospective Contractors](#)
- [Current Contractors](#)
- [Modification Forms](#)
- [Federal Customers](#)
- [Training](#)
- [Resource Library](#)
- [FAQ Library](#)
- [Contract Catalog Search Tool \(CCST\)](#)
- [Site Map](#)

Step 4: Look up the price

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

NDC With Dashes	Sub-Iter	Package Description	Generic	Trade Name	VA Class	Covered	Prime	Net Price	Price Start Date	Price Stop Date	Price Type
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.



Catalog search

[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

1) Enter the generic name

Pharmaceutical Catalog Search

Search by Contract Number Search by Contractor Name

Search by Generic Name / Trade Name using terms or phrase

HUMIRA 10MG/0.1ML INJ,SYRINGE :: ADALIMUMAB 10MG/0.1ML INJ,SYRINGE
HUMIRA 10MG/0.2ML INJ,SYRINGE :: ADALIMUMAB 10MG/0.2ML INJ,SYRINGE,KIT
HUMIRA 1X80MG 1 X40MG INJ PED CROHNS STARTER :: ADALIMUMAB 80MG/0.8ML;ADALIMUMAB 40MG/0.4ML
HUMIRA 20MG/0.2ML INJ,SYRINGE :: ADALIMUMAB 20MG/0.2ML INJ,SYRINGE
HUMIRA 20MG/0.4ML INJ,SYRINGE :: ADALIMUMAB 20MG/0.4ML INJ,SYRINGE,KIT
HUMIRA 40MG/0.4ML INJ,SYRINGE :: ADALIMUMAB 40MG/0.4ML INJ,SYRINGE
HUMIRA 40MG/0.4ML INJ,SYRINGE,PEN :: ADALIMUMAB 40MG/0.4ML INJ,SYRINGE,PEN
HUMIRA 40MG/0.8ML INJ KIT 4 UNITS/PACKAGE :: ADALIMUMAB 40MG/0.8ML INJ,PEN,KIT
HUMIRA 40MG/0.8ML INJ KIT 6 UNITS/PACKAGE :: ADALIMUMAB 40MG/0.8ML INJ,PEN,KIT
HUMIRA 40MG/0.8ML INJ PEN :: ADALIMUMAB 40MG/0.8ML INJ,PEN

2) Select the kit

Step 7: Compare the prices

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

<u>NDC</u>	<u>PKG</u>	<u>CONTRACT</u> <u>NUMBER</u>	<u>PV</u>	<u>VENDOR</u>	<u>GENERIC NAME</u>	<u>TRADE NAME</u>	<u>FSS PRICE</u>	<u>NC</u> <u>PRICE</u>	<u>BIG 4</u> <u>PRICE</u>
00074-4339-07	4	36F79718D0528	X	Abbvie US	ADALIMUMAB 40MG/0.8ML INJ,PEN,KIT	HUMIRA 40MG/0.8ML INJ KIT 4 UNITS/PACKAGE	\$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 = $\$2,871 / 4 = \mathbf{\$718}$

Certolizumab

FSS price = **\$991**

Price per dose = $\$991 / 2 = \mathbf{\$495}$

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
-

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](#)

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

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

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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?

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