



Glossary: Drug Costs

Term	Acronym	Definition
21st Century Cures		A bill designed to promote the development and speed the approval of new drugs and devices.
340B Drug Pricing Program		A federal program that requires drug manufacturers participating in the Medicaid drug rebate program to provide medications at discounted prices to certain designated nonprofit hospitals and other providers.
Abbreviated New Drug Application	ANDA	A form submitted to FDA as part of the generic drug approval process. These applications are called “abbreviated” because a manufacturer is usually not required to include animal and human data to establish safety and effectiveness. Instead, a generic applicant must show that its product is bioequivalent—the same as a brand-name drug in dosage, quality, strength, intended use, and how it performs in the body.
Actual Acquisition Cost	AAC	The net cost of a drug paid by a pharmacy. A drug’s AAC includes discounts, rebates, chargebacks and other adjustments to the price of the drug, but excludes the pharmacy’s dispensing fees.
Average Manufacturer Price	AMP	The average price paid to a drug manufacturer by wholesalers and retailers who buy direct from manufacturers. AMP is a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available.
Average Sales Price	ASP	The average sales price paid to manufacturers by all purchasers. It includes practically all discounts but is limited in that it is only available for Medicare Part B covered drugs.
Average Wholesale Price	AWP	This is a measurement of the price paid by pharmacies to purchase drug products from wholesalers in the supply chain.
Biologics		Complex products made from living organisms that are considered a cutting-edge form of medicine, revolutionizing treatments for cancer, arthritis, multiple sclerosis and other conditions. Although these drugs can sustain and improve the quality of life for many patients, they are expensive—sometimes costing \$100,000 or more annually.

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Biosimilars		A biosimilar is a product that has the same general qualities of a biologic. Conceptually, a biosimilar is sometimes—incorrectly—said to be a “generic” of a biologic. A biosimilar does not have the precise replication of a biologic that a generic has for a chemical drug.
“Buy and Build”		Refers to physician management of certain medicines, primarily specialty medicines that require injection or infusion. The physician purchases the drug, manages the inventory, administers the drug, and then submits claims for reimbursement for both the drug and accompanying professional services.
Bona Fide Service Fees	BFSFs	Payments from drug manufacturers to PBMs, specialty pharmacies and other service vendors in Medicare Part D (and other government drug programs) for an array of patient and product support “services,” such as rebate administration, inventory, drug shipping, reimbursement/financial assistance, patient education, phone support and data reports. The only major financial item excluded from Part D “negotiated price” calculations.
Compounding		Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to an individual patient needs.
Formulary		List of drugs covered by insurance or PBM in a drug benefit plan. Products listed on a formulary are covered for reimbursement at varying levels.
Generic Drug User Fee Amendments	GDUFA	Legislation that allows FDA to collect fees to pay for the approval process for generic drugs.
Hatch-Waxman Act		A 1984 federal law that established a process for how generic drugs are approved by the FDA and manufactured by pharmaceutical industry. Also known as the Drug Price Competition and Patent Term Restoration Act.
List Price		The price of a drug that is shown in a pharmacist’s computer.
Maximum Allowable Cost	MAC	The upper limit or maximum amount that a plan will pay for generic and brand-name drugs that have generic versions available (multi-source brands).
Medicaid Best Price	BP	The lowest manufacturer price paid for a prescription drug, regardless of package size, by any purchaser. BP is reported to CMS and states, but is otherwise confidential. Included in BP are discounts, free goods that are contingent upon purchase, volume discounts and rebates. Excluded from BP are prices paid by the federal government.

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Medicare Part D	Part D	The federal-government program to subsidize the cost of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries. Also called the Medicare prescription drug benefit.
Pharmacy Benefit Managers	PBM	Companies that negotiate rebates and manage drug benefits for health plans, businesses and government programs.
Prescription Drug User Fee Act	PDUFA	PDUFA was created by Congress in 1992 and authorizes the Food and Drug Administration to collect fees from drug manufacturers to fund the new drug approval process. Must be reauthorized every five years.
Pricing Spreads		Price difference between what a PBM pays a pharmacy for a prescription drug and what it charges the health plan sponsor.
Product Hopping		A strategy drug makers use to stall the development of generic versions of a medication so they can keep brand-name drug prices high. (See Consumer Reports' <i>A Surprising Way Big Pharma Keeps Drug Prices High</i>).
Rebate		An incentive payment made by a drug manufacturer, to a drug wholesaler or other payer such as a PBM based on how much the entity increases the market share or actual "sales" of a drug.
Specialty Drugs		Drugs that treat chronic, complex, or life-threatening conditions, often manufactured through biologic processes and/or targeting a specific gene. Typically these medications are costly and require intensive clinical monitoring, complex patient actions, and/or special handling by the dispensing pharmacy. Although most commonly injected or infused, they may also be taken orally or inhaled.
State Drug Substitution Laws		State substitution laws provide authority to pharmacists to substitute lower-cost generics for higher-cost brand drugs. Some states require pharmacists to substitute generics for the brand, some allow pharmacists to do it, and other states require permission from consumers to substitute.
Single-Source Drug		Brand-name drugs still under patent protection.
Wholesale Acquisition Cost	WAC	This is the price set by the manufacturer. Pharmacies typically purchase drugs based on the Wholesale Acquisition Cost. The difference between what the pharmacy paid (based on WAC) and what insurers reimburse the pharmacy (based on AWP), is known as the "spread." The larger that difference, the larger the pharmacy's profit.