



State of Utah

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

Insurance Department

JONATHAN T. PIKE
Insurance Commissioner

Utah Drug Transparency Report January 2022

The *Utah Drug Transparency Report – January 2022* was prepared by Jeffrey E. Hawley, Ph.D. and Heather Sandberg, B.S. of the Health & Life Insurance Division for the Utah Insurance Commissioner pursuant to Utah Code § 31A-48-103. Publication date: March 14, 2022.

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Overview

As required by Utah Code § 31A-48-103(1), drug manufacturers that are manufacturing a drug available for purchase by Utah residents with a wholesale acquisition cost (WAC) of at least \$100 or more for a 30-day supply are required to submit to the Utah Insurance Department (Department) the information described in § 31A-48-103(1)(b) when an increase in the wholesale acquisition cost of the drug is 1) greater than 16 percent over the preceding two calendar years, or 2) greater than 10 percent over the preceding calendar year.

The information provided to the Department may not be released in a manner that: 1) would allow for the identification of an individual drug, therapeutic class of drugs, or manufacturer, or 2) is likely to compromise the financial, competitive, or proprietary nature of the information (see § 31A-48-103(1)(f)).

The Department received 77 drug product reports during January 2022 that were in compliance with § 31A-48-103(1)(a). This report summarizes the following information received by drug manufacturers:

- 1) The effective date of the increase in the WAC price of the drug product,
- 2) The drug type (brand name drug or generic drug),
- 3) The manufacturer's aggregate company-wide research and development costs for the most recent year for which final audit data is available, and
- 4) A written description, suitable for public release, of the factors that led to the increase in the WAC price of the drug product and the significance of each factor.

The information has been de-identified to protect the identity of the individual drug, the therapeutic class of the drug, and the drug manufacturer as required by Subsection 31A-48-103(1)(f).

List of Manufacturer Drug Product WAC Price Increase Reports by Effective Date

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$23,012,000

Factors that led to the increase in the WAC price

<Drug product> is one of <manufacturer's> primary sources of revenue while the Company works to ensure the continued availability of its products to patients. <Drug product> has not been reformulated or changed.

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$0

Factors that led to the increase in the WAC price

Due to the rising cost of plasma and manufacturing cost.

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$0

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Due to the rising cost of plasma and manufacturing cost.

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$16,009,624

Factors that led to the increase in the WAC price

While <manufacturer's> business pricing model is both proprietary and confidential, the decision to increase the WAC for <drug product> included a broad range of financial and non-financial factors including changing market dynamics, costs of labor and goods, post market requirements, support for the marketing and sales of <drug product>, and reinvestment in the product. <Therapeutic class information>. As such, it represents a valuable therapeutic treatment option. We have incurred substantial costs to obtain and maintain regulatory approval and continue to incur the substantial costs described above as well as the more traditional, general and administrative costs associated with our operations, resulting in a deficit of over \$200 Million since our inception. In addition, we continue to reinvest in <drug product's> manufacturing infrastructure to maintain sufficient supply. These increases in costs and the ever-increasing demand for rebates to improve patient access, were all considered as part of this decision to permit the company to increase the wholesale acquisition cost of <drug product>.

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1/1/2022	Brand	\$290,780,226

Factors that led to the increase in the WAC price

This price is not reflective of discounts available to customers. This increase is the result of increased costs and other financial commitments of the company, including the recent launch of a <therapeutic class> to treat adults with <therapeutic class> and the potential launch of another therapy later this year. <Manufacturer> continues to invest in innovation that brings value to patients, providers, and the U.S. healthcare system through research and development, quality manufacturing, as well as through patient education and disease awareness.

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$114,763,969

Factors that led to the increase in the WAC price

<Manufacturer> is committed to discovering, developing and making available to patients and physicians medicines that treat serious disorders for which there are few – or no – good treatment options. In setting <drug product's> price, we weigh (i) the increased cost of administrative and commercial activities, (ii) the increased cost of discovering and developing innovative new drug candidates and (iii) our commitment that no patient be denied <drug product> for financial reasons.

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<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$9,405,000,000

Factors that led to the increase in the WAC price

After a medicine is approved for use by patients, our work doesn't end. There are a number of reasons that the price of medicines can change over time. These may include, among others: discovery of new uses and new patient populations through both trial data and real world evidence; new or expiring patents; improvements in the manufacturing and supply chain; new formulations; market-based factors; and changes in local laws and mandates. We continue to invest in a medicine through its entire lifecycle – monitoring for safety, analyzing real-world data, and often undertaking additional research and development. Our commitment and responsibility to quality and supply also continues after a medicine is available in a generic form.

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Generic	\$9,405,000,000

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<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$159,712,000

Factors that led to the increase in the WAC price

<Manufacturer> generally makes decisions on price revisions annually based on market conditions and corporate strategy, a common practice across the industry. These decisions are designed to help us invest in bringing new medicines to market to address unmet patient needs and improve the lives of patients. <Manufacturer> takes into account several market and business considerations when setting a list price for a product, including, but not limited to: - The clinical and health outcomes value of our products to patients and payors. -Not only the budget impact to payers but also patient out of pocket costs to ensure that products reach the patients who need them. -Responsible and competitive prices, in line with current treatment costs where other treatment options exist. -Corporate business strategy, including costs and profitability. - Consideration of other factors such as Annual CPI-U rates. -R&D investment priorities and budgets to identify future medicines to improve the lives of patients. <Manufacturer> does not maintain records that reflect how these factors were applied in the context of any particular product or price increase.

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<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/1/2022	Brand	\$997,000,000

Factors that led to the increase in the WAC price

<Manufacturer> considers various factors in deciding the price at which to set its prescription drugs, including: the competitive landscape and pricing environment; any exclusivities that might apply; manufacturing considerations; supply considerations; profitability; costs, including research and development costs; therapeutic class and patient population, as well as patient needs; class of trade, distribution channel, and nature of payer for the relevant product; contracts and relationships with customers; public policy considerations; and legal considerations, including compliance with rules and regulations governing sales to government and institutional purchasers.

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<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/5/2022	Generic	\$135,500

Factors that led to the increase in the WAC price

Increase cost of ingredients, shipping, and cGMP manufacturing. Serialization, stability, submitting pricing to states like Utah when the price is readily available through compendia publishers.

<i>Effective Date</i>	<i>Drug Type</i>	<i>Company-Wide Research & Development Costs</i>
1/17/2022	Brand	\$5,634,530

Factors that led to the increase in the WAC price

Cost of manufacturing has gone up.
