

# PRESCRIPTION MEDICINE PRICING

## OUR PRINCIPLES AND PERSPECTIVES

At Sanofi, we work passionately to prevent, treat and cure illness and disease, understand and solve health care needs of people across the world, and transform the practice of medicine. Our focus spans a number of therapeutic areas in specialty care and general medicines, including immunology, oncology, rare diseases, rare blood disorders, diabetes and cardiovascular diseases, as well as vaccines. Sanofi has a long-standing commitment to promote health care systems that make our treatments accessible and affordable to patients in need.

Countries are increasingly seeking to achieve better value in health care spending. Sanofi understands and shares concerns about the affordability of medicines for patients while also recognizing that we are only one of many stakeholders in the health care system. In the United States, medicines are a small share — about 14%<sup>1</sup> — of total health care spending. In order to maintain an environment that will continue to bring new health care solutions to patients, we must encourage a transition to a value-driven health care system that provides incentives for the highest-quality care. This evolution will enable both affordable access to treatment and continued investment in medical innovation.

Sanofi is committed to helping address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are controlled by other stakeholders in the health care system, we believe we have a responsibility to be a leader in solving issues of patient access and system viability. For our part, we price our medicines according to their value, while contributing to broader solutions that improve patient outcomes and support affordability within the U.S. health care system.



### OUR PRICING PRINCIPLES: ADVANCING RESPONSIBLE LEADERSHIP

Pharmaceutical innovation brings value to our patients, our society and our health care systems. Given the growing concerns over rising health care costs, our approach to pricing reflects our commitment to patient access while minimizing our contribution to health care inflation. We therefore commit to continued transparency in how we price our prescription medicines and to limit any increase in prices in the United States to no more than the projected National Health Expenditure (NHE) growth rate.

The Pricing Principles we put forth focus on three pillars:



**CLEAR RATIONALE FOR PRICING**  
at the time of launch of a new medicine



**LIMITED U.S. PRICE INCREASES**  
on our medicines over time



**CONTINUED TRANSPARENCY IN THE U.S.**  
around our pricing decisions

<sup>1</sup>The Altarum Institute, Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail, June 2019.



## CLEAR RATIONALE FOR PRICING

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers the following factors:



**A holistic assessment of value**, including 1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; 2) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and 3) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA) and other analyses that help define or quantify value and include patient perspectives and priorities.



**Similar treatment options** available or anticipated at the time of launch, in order to understand the landscape within the disease areas in which the medicine may be used.



**Affordability**, including the steps we must take to promote access for patients and contribute to a more sustainable system for payors and health care systems.



**Unique factors** specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to reinforce the value of the product (e.g., longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care.



## LIMITED U.S. PRICE INCREASES

We acknowledge our role in preserving the sustainability of our health care system and in limiting our contribution to U.S. health care spending growth. Should we take a list price increase on one of our medicines, our guiding principle is to limit the total annual increase during our fiscal year (Jan. 1 to Dec. 31) to a level at or below the projected growth rate for National Health Expenditures for said year.

**Our benchmark, the projected U.S. National Health Expenditure (NHE) growth rate**, is estimated and published annually by the Centers for Medicare & Medicaid Services (CMS). The NHE projection provides a critical forward-looking view needed for business planning. NHE measures spending across all health care goods and services and reflects payments made by both public and private payors.

Once the NHE projection is updated each year, we will adjust any future planned pricing actions to reflect the projection. Given the need for

business planning, we will adopt the updated standard by April 1 each year.<sup>2</sup> More information about the NHE growth rate can be found [here](#).

**Should we take a price increase above the NHE growth rate for a given medicine** that results in a list price increase greater than \$15 for a full course of treatment per year, we will provide our rationale, highlighting clinical value, real-world evidence, regulatory change, new data or other circumstances that support our decision.

<sup>2</sup> As measured by National Health Expenditures, published annually by the Centers for Medicare & Medicaid Services.



## CONTINUED TRANSPARENCY IN THE UNITED STATES

We recognize calls for continued transparency in our pricing practices. Our principles reflect a desire to help our stakeholders better understand our pricing decisions.

Our principles reflect both a desire to help our stakeholders better understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines. To continue this dialogue and provide greater insights about this topic, we will disclose annually our average aggregate U.S. list and net price changes from the prior calendar year. These data may help illustrate how pricing changes accrue to manufacturers versus others in the value chain, highlighting our discrete role in the broader U.S. health care environment and enabling a better-informed discussion on solutions to improve patient access and affordability.

While list prices often receive the most attention, they reflect only the initial prices set for our medicines and are **not** the prices typically paid by the insurers, employers or pharmacy benefit managers who purchase our medicines on behalf of patients in their respective health plans. We negotiate discounts and rebates with these payors, which are designed to offer the

health care system lower prices in exchange for greater access and affordability for patients with insurance. List prices also fail to capture the substantial mandated discounts and rebates, sometimes required by law, provided to government programs, including those provided in Medicare Part D, Medicaid and the 340B drug-pricing programs.

The net price is what Sanofi receives after discounts, rebates and fees paid to health plans and other parts of the health care system.

While our efforts focus on securing affordable coverage of our medicines for patients, it is important to note that patient cost-sharing and coverage decisions are ultimately made by payors and employers, not manufacturers of the medicines.

Simply put, patients' out-of-pocket costs depend on how the plan is structured and the extent of the negotiated discounts passed on to patients.

These principles demonstrate Sanofi's commitment to patient access and affordability, a sustainable health care system and greater transparency in our pricing actions. Moreover, our position supports an environment that will enable us to continue to advance scientific knowledge and bring innovative treatments to patients worldwide.



**SANOFI 2020  
PRICING  
PRINCIPLES  
REPORT:**  
ADVANCING  
RESPONSIBLE  
LEADERSHIP

# SANOFI 2020 PRICING PRINCIPLES REPORT: ADVANCING RESPONSIBLE LEADERSHIP

In May 2017, Sanofi committed to further addressing concerns over rising health care costs with the introduction of our Pricing Principles, which remain the most comprehensive assessment of corporate pricing decisions in the industry. Our approach to the prices of our medicines reflects a continued effort to support patient access while minimizing our contribution to health care spending growth. The following report outlines key 2019 pricing decisions.



## CLEAR RATIONALE FOR PRICING

**Cablivi® (caplacizumab-yhdp):** Cablivi was launched in March 2019. It is used in combination with plasma exchange and immunosuppression and was approved in the United States specifically for the treatment of acquired thrombotic thrombocytopenic purpura or aTTP, a rare, life-threatening blood-clotting disorder that affects fewer than 2,000 people in the U.S. each year. The U.S. list price for treating a typical aTTP episode with Cablivi is \$270,000.

In the case of Cablivi, our holistic assessment of value primarily considered the clinical data for the medicine, notably our Phase 3 HERCULES study. In the HERCULES study, treatment with Cablivi in combination with plasma exchange and immunosuppression resulted in a significantly shorter time to platelet count response, the study's primary efficacy endpoint; in secondary endpoints, Cablivi showed a significant reduction on a composite endpoint of aTTP-related death, recurrence of aTTP, or a major thromboembolic event during study drug treatment; and a significantly lower number of aTTP recurrences in the overall study period.

Results of this study were published in the *New England Journal of Medicine* in January 2019. That publication also included data on reduction in use of hospital service. During the HERCULES study, patients receiving Cablivi experienced, on average, a 65% shorter duration of care in an intensive care unit (3.4 days vs. 9.7 days) and 5.8 days of plasma-exchange treatment as compared with 9.4 days of plasma-exchange treatment needed by patients in the placebo group.

We also considered similar treatment options and unique factors. In the case of aTTP, there was a lack of effective treatment options; it is estimated that up to 20% of patients die from aTTP episodes with plasma exchange and immunosuppression alone, with median time to death of nine days from diagnosis. aTTP is also an ultra-rare disease.

Finally, Sanofi is committed to ensuring those who are prescribed Cablivi have access to the medicine. For patients with aTTP who are prescribed Cablivi, [Cablivi Patient Solutions](#) provides support to eligible patients who require financial assistance, help in navigating insurance, benefits and reimbursement, as well as other at-home support services.



## LIMITED U.S. PRICE INCREASES

In February 2018, the U.S. National Health Expenditure projected growth rate for 2019 was 5.2%.<sup>3</sup> That figure was updated to 4.8% in February 2019.<sup>4</sup>

In 2019, Sanofi increased the price of 49 of our 85 prescription medicines. All of these increases were within our Pricing Principles guidelines.

<sup>3</sup> Health Affairs, 2018.  
<sup>4</sup> Health Affairs, 2019.

Recognizing our role in improving affordability within the U.S. health care system, Sanofi also meaningfully lowered the list price of two of our medications in 2019. In February 2019, Sanofi announced that Praluent® (alirocumab)<sup>5</sup> would be made available at the reduced list price of \$5,850 annually, a 60% reduction in the original price, for both the 75 mg and 150 mg doses. With the new price, Sanofi estimated that out-of-pocket costs for Medicare patients could be lowered to approximately \$25 to \$150 per month, a potential savings of up to \$345 per month, depending on their insurance plan.

In July 2019, Sanofi reduced the list price of Admelog® by 44%. This ensured Admelog retained the lowest list price for mealtime insulin in the United States. The new list prices of Admelog are \$130.76 per 10 mL vial, \$39.23 per 3 mL vial, and \$252.47 per box of five pens.

Based on our direct experience, as well as our observations of list price reductions by other manufacturers, simply lowering list prices does not address all the barriers to improving access and affordability challenges for patients and sometimes has little, if any, impact on a patient's out-of-pocket costs.



## CONTINUED TRANSPARENCY IN THE UNITED STATES

### U.S. Portfolio Annual Aggregate Price Change from Prior Year\*

Year	Average Aggregate List Price	Average Aggregate Net Price
2016	4.0% INCREASE	2.1% DECREASE
2017	1.6% INCREASE	8.4% DECREASE
2018	4.6% INCREASE	8.0% DECREASE
2019	2.9% INCREASE	11.1% DECREASE

\*Aggregated across Sanofi's prescription portfolio

In 2019, 55% of our gross sales were given back to payors as rebates, including \$5.5 billion in mandatory rebates to government payors and \$8.4 billion in discretionary rebates.

Rebates are a pricing concession that Sanofi offers to insurance companies, often through their pharmacy benefit managers, to help ensure that our products are covered by insurance and thus available to and affordable for patients. Many government programs require additional discounts or rebates that are defined by statute.

The price of a medicine after taking these rebates and discounts into account is known as the "net price" and most accurately reflects the price that Sanofi receives for its products.

Given the impact of rebates on the cost of medicines to payors, it is important to consider how net prices have changed over time to assess a medicine's true cost to the overall health care system.

Despite rhetoric about skyrocketing insulin prices, the net price of insulin has been falling for five consecutive years, making our insulins **significantly less expensive** for insurance companies.

**Since 2012, the net price of Sanofi insulins has declined by 41%. Over the same period, the net price for commercial and Medicare Part D plans of our most prescribed insulin, Lantus, has fallen 37%, while average out-of-pocket costs for patients with commercial insurance and Medicare has risen approximately 62%. For all the focus by health plans and others on the growth of list prices, today, the average net price of Lantus is below 2006 levels.**

<sup>5</sup> Collaboration program with Regeneron

The failure of declining net prices for four consecutive years, or of list price reductions, to *fix* patient access and affordability challenges demonstrates that focusing solely on the list price of medicines will not guarantee that patients will be able to access and afford the medicines they need.

## INSULIN COST OVER TIME



Given that insulin net prices are declining, patient out-of-pocket costs should be declining as well. However, that is not always the case, as benefit designs may result in patient out-of-pocket costs exceeding plans' net cost.

For high-value and highly rebated therapies such as insulin, plans should never impose cost-sharing at a level that creates a financial barrier for a patient to fill his or her prescription or potentially forces the patient to ration insulin.

We have worked to lower prices and improve access programs for our insulin products in a way that benefits patients first, part of **Sanofi's ongoing commitment to address affordability for people with diabetes.**

## PRIORITIZING PATIENT AFFORDABILITY

Our commitment to transparency extends beyond responsible launch pricing and limited price increases. We recognize that too many patients in the United States are struggling to afford their medications, and we therefore offer a suite of programs to address a range of patient needs.

We feel a special obligation to address pressing issues around access to, and affordability of, insulin. In order to address the needs of patients with diabetes, Sanofi was the first company to introduce a program in which uninsured patients could access insulin for a single, low monthly cost. With our Insulins Valyou Savings Program, introduced in 2018 and expanded in April 2019, all uninsured patients, regardless of income level, can access one or multiple Sanofi insulins (Lantus®, Toujeo®, Admelog® and Apidra®) for a fixed price of \$99 per month for up to 10 boxes of pens and/or 10 mL vials.

Additionally, our copay assistance programs for commercially insured patients, regardless of income level, limits out-of-pocket expenses for a majority of participating patients to \$0 or \$10. Through Sanofi Patient Connection, we provide free medications to eligible patients with a demonstrated financial need.

Every patient has unique circumstances. Sanofi has live support specialists at **(855) 984-6302** to answer patients' questions and help navigate their individual situations in an effort to find the best resources and programs to help lower their out-of-pocket costs.

### 2019 PATIENT SUPPORT: BY THE NUMBERS

**1.8 million**

# OF TIMES A **SANOFI COPAY ASSISTANCE CARD** WAS USED



**\$472 million**

PATIENT SAVINGS FROM USE OF **COPAY ASSISTANCE PROGRAMS**

**52,220**

# OF TIMES **INSULINS VALYOU SAVINGS PROGRAM** WAS USED



**\$17.6 million**

PATIENT SAVINGS FROM USE OF **INSULINS VALYOU SAVINGS PROGRAM**



**99,650** # OF PATIENTS WHO RECEIVED **FREE PRODUCT THROUGH PATIENT ASSISTANCE PROGRAMS**

**\$727 million** VALUE OF MEDICINE PROVIDED VIA **PATIENT ASSISTANCE PROGRAMS**

