

2018

JANSSEN U.S. TRANSPARENCY REPORT

[A Message from Our Leaders](#) ▶

[Our Investments](#) ▶

[Pricing & Patient Costs](#) ▶

[Advancing a Better Way](#) ▶

[Resources for Patients](#) ▶

[References](#) ▶

A MESSAGE FROM OUR LEADERS

A Message From Our Leaders

About This Report

- Our Investments ▶
- Pricing & Patient Costs ▶
- Advancing a Better Way ▶
- Resources for Patients ▶
- References ▶

Scott White (pictured left) is Company Group Chairman, North America, Janssen Pharmaceutical Companies of Johnson & Johnson, and **Anastasia G. Daifotis, M.D.** (pictured right) is Chief Scientific Officer, Janssen North America Pharmaceuticals

A MESSAGE FROM OUR LEADERS

WE KNOW THAT IN TODAY'S COMPLEX HEALTHCARE SYSTEM, patients and families are increasingly concerned about their ability to access and afford healthcare, including prescription medicines. These concerns have rightfully led to calls for greater transparency into the world of healthcare.

We are therefore pleased to present the 2018 Janssen U.S. Transparency Report—a window into how, at the Janssen Pharmaceutical Companies of Johnson & Johnson, we discover, develop, and make available medicines that treat and cure some of the world's most challenging diseases.

With this year's Report, we are building on a legacy of leadership in transparency and responsible business practices. We continue to make disclosures related to our research and development investment, our approach to pricing, and the support programs we make available for eligible patients, and we reiterate our support for a more results-based healthcare system that rewards value over volume. In the spirit of open dialogue that delivers workable ideas for system change, this year we also share our ideas and perspectives on policy proposals, with the goal of building on what is working in our healthcare system while fixing what is not.

As you read the 2018 Janssen U.S. Transparency Report, you'll learn that:

1. **For the second year in a row, the average net price of our medicines decreased.**

In 2018, our average net price declined 6.8 percent.¹ This is because the approximately \$21 billion in discounts and rebates we provided to payers and providers outweighed our single-digit list price increase.²

2. **Our investment in research and development is 86 percent more than what we spent on marketing and sales.³**

In 2018, we invested \$8.4 billion in global R&D.⁴ And we have more than 100 potential new medicines in development.

A MESSAGE FROM OUR LEADERS

A Message From Our Leaders

About This Report

- Our Investments ▶
- Pricing & Patient Costs ▶
- Advancing a Better Way ▶
- Resources for Patients ▶
- References ▶



3. We've developed a common-sense way to make clearer for patients what they may pay for our medicines.

Starting with our most frequently prescribed medicine, XARELTO®, we're voluntarily including list price and typical out-of-pocket costs in our U.S. pharmaceutical TV advertising, with additional information available online at janssen.com/dtcdisclosures.

4. We helped approximately 1 million patients with access, affordability, and treatment support through the Janssen CarePath program.⁵

This includes approximately 550,000 commercially insured patients who reduced their out-of-pocket costs through the Janssen CarePath Savings Program.⁶

5. We worked with stakeholders to advance our ideas for a better healthcare system.

We've forged value-based contracts with payers, participated in partnerships to explore value-based care models, and proposed practical policy solutions to bring down costs for patients.

We make these disclosures at a critical moment in the history of U.S. healthcare. In recent years, increased transparency has yielded important insights about why patients feel they're paying more out-of-pocket for their medicines. Government leaders are translating those insights into action, taking steps intended to lower costs. The current moment offers an unprecedented opportunity to minimize the barriers that stand between patients and affordable access to their medicines.

Historic medical advances add to the urgency of the task. It is now possible to treat diseases once thought beyond a cure, and new scientific insights promise advances yet to come. In decisions we as a society make about the future of healthcare, we need to remember the full value such advances ultimately deliver. For example, over the last two decades patient outcomes for diseases including HIV, heart disease, and lung cancer have improved substantially, while the cost of treating those diseases has decreased or risen only modestly. The fact that this progress is due largely to medicines⁷ is yet another reminder that all patients should have access to the medicines they need.

The status quo is not acceptable, and we are committed to generating sustainable solutions. We want these solutions to give hope to patients today—and foster the life-changing innovation that will give ever-increasing hope to patients tomorrow.

In the meantime, greater transparency is a critical step toward giving patients the clarity they need about their healthcare options and out-of-pocket costs (and patients need greater transparency from every stakeholder in the system). We want this Report to be useful to them—and to anyone who shares our commitment to developing a more results-based healthcare system that delivers what we all want: greater access to care, at more manageable cost, and, most importantly, better health for all.

Sincerely,

Scott White
Company Group Chairman
North America Pharmaceuticals
Johnson & Johnson

Anastasia G. Daifotis, M.D.
Chief Scientific Officer
Janssen North America
Pharmaceuticals

ABOUT THIS REPORT

A MESSAGE FROM OUR LEADERS

A Message From Our Leaders

About This Report

- Our Investments ▶
- Pricing & Patient Costs ▶
- Advancing a Better Way ▶
- Resources for Patients ▶
- References ▶

The 2018 Janssen U.S. Transparency Report is our third annual report providing greater transparency into our business operations. The report provides an inside look at how we at the Janssen Pharmaceutical Companies of Johnson & Johnson put our values into practice across our U.S. business, from how we choose to invest our resources in the development of new treatments, to how we value and price our medicines, to how we work to support access to our medicines.

The information provided in this report pertains to Janssen's U.S. operations, except where indicated otherwise. In June 2017, Johnson & Johnson completed the acquisition of Actelion Ltd, a leader in pulmonary arterial hypertension. Actelion information is incorporated into the 2018 Janssen U.S. Transparency Report, which reflects Actelion's first full year as part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

All financial data in this report reflects our fiscal year, which covers the period between January 1, 2018 and December 30, 2018. Other disclosures in this report cover the period between January 1, 2018 and December 31, 2018; any exceptions are noted. Analyses conducted for the purposes of this report may be different from the methodologies used by other companies. The data have not been audited and the report is not intended to address all our corporate disclosures.

Throughout this report we refer to additional resources where readers can find more information about specific Janssen and Johnson & Johnson programs and disclosures. Financial performance information of our parent company, Johnson & Johnson, and its subsidiaries, as well as its "Cautionary Note Regarding Forward-Looking Statements," can be found in Johnson & Johnson Annual Reports, available at jnj.com/about-jnj/annual-reports. Information on Johnson & Johnson environmental, social, and governance measures can be found in the Johnson & Johnson Health for Humanity Report, available at healthforhumanityreport.jnj.com.

This report and a one-page executive summary are also available to read and download at janssen.com/ustransparencyreport.



BY THE NUMBERS: JANSSEN IN 2018

\$8.4 billion

invested globally in research and development⁸

86% more

invested in R&D than we spent on marketing and sales⁹



100+

medicine candidates in development as a result of our investments in R&D

6

new medicines approved by the FDA over the past 5 years^{10,11}



~140

active collaborations in 2018 with academia, pharmaceutical and biotech peers, and public/private sector partners

24

clinical data transparency requests to the Yale Open Data Access (YODA) project, all approved¹²

~\$21 billion

total discounts and rebates¹³



6.3%

average list price change¹⁴

-6.8%

average net price change¹⁵



4

value principles that help us define the value of our medicines

550,000

commercially insured patients helped with out-of-pocket costs through the Janssen CarePath Savings Program¹⁶

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

OUR INVESTMENTS

AT JANSSEN, WE ARE COMMITTED TO delivering transformational medical innovation that can change the trajectory of health for humanity. We focus our research and development (R&D) on preventing and treating diseases in areas of medicine where we can make the most meaningful impact. In 2018, Janssen invested \$8.4 billion in R&D globally,¹⁷ making us one of the top R&D investors in any industry, anywhere in the world.¹⁸ This investment in R&D far exceeds what we spent to market our medicines.¹⁹

In this chapter, we describe our investments in R&D and our efforts to improve the R&D process by collaborating with patients and other partners throughout the healthcare system.

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

**Johnson & Johnson
Innovation—JLABS**

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

Resources
for Patients ▶

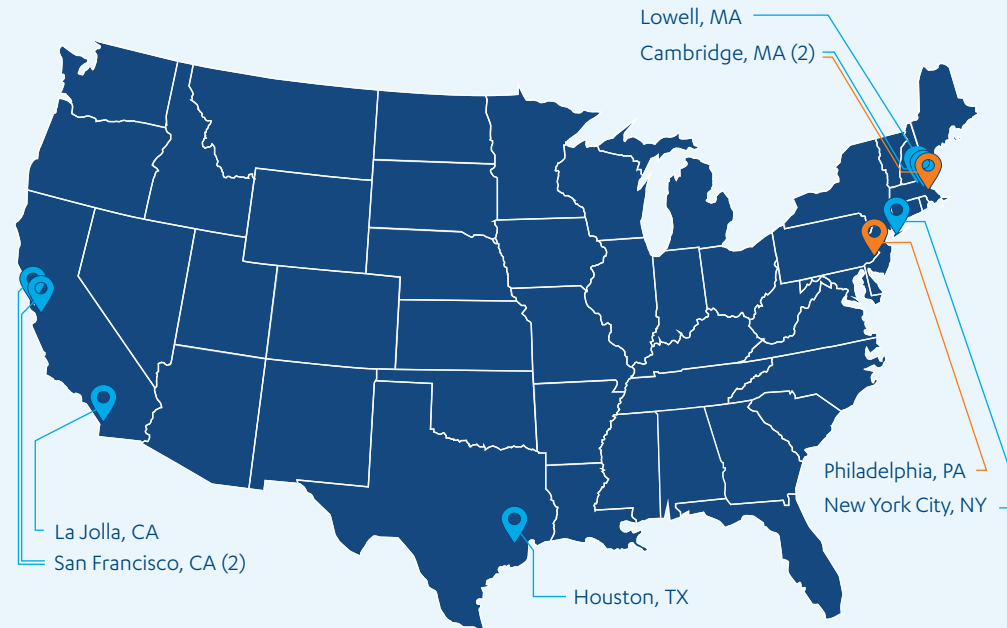
References ▶

JOHNSON & JOHNSON INNOVATION—JLABS

Getting a life sciences company up and running is a challenge. We are passionate about helping healthcare startups succeed. Our mission is to remove hurdles and empower life science innovators through access to infrastructure, community, and specialized expertise.

JLABS, the Johnson & Johnson network of open innovation health sciences incubators, provides life science startup companies access to the tools they need to take their ideas

from concept to commercialization. JLABS now has a total of 12 facilities, nine located in the U.S., each with varied access to state-of-the-art equipment, prototype labs, and a year-round innovator curriculum focused on commercial and business development. JLABS is a “no-strings-attached” model, which means entrepreneurs are free to develop their science while holding on to their intellectual property.



JLABS Locations JPOD Locations

Over six years,

JLABS has grown to support 450+ companies. In 2018 alone, there was a 44 percent increase in the total number of companies we supported.

100+ companies

participated in JLABS “Inside Scoop” pitch day events, at which more than 1,100 attendees gained access to venture capitalists, angel investors, and other funding sources.

Approximately \$6 million

in grant funding and residency costs were awarded in more than 30 Quickfire Challenges focused on key issues like health tech wearables and lung cancer treatments.³⁷

170 JPALs,

which include industry experts and business leaders from the Johnson & Johnson Family of Companies, coached and mentored JLABS companies throughout the year.

Startups now have access

to JPODs, networking hubs that connect life sciences innovators to Johnson & Johnson. These first-of-their-kind connection points are meant to accelerate the development of early-stage healthcare solutions that address significant unmet needs in medical devices, pharmaceuticals, consumer, and health technologies.

To learn more about JLABS, visit jabs.jnjinnovation.com.

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

**Expert Q&A: Partnering with
Patients to Bring Better Solutions**

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

**Pricing &
Patient Costs** ▶

**Advancing a
Better Way** ▶

**Resources
for Patients** ▶

References ▶

EXPERT Q&A: PARTNERING WITH PATIENTS TO BRING BETTER SOLUTIONS

Katherine Capperella, Janssen Global Patient Engagement Leader (pictured left), discusses how we incorporate the perspectives of patients and caregivers as we develop and deliver medicines and solutions that meet their needs.

What does patient engagement mean at Janssen and how does it help provide better solutions for patients?

Patients have always been at the heart of everything we do. Patient engagement means partnering directly in an ongoing dialogue with patients and caregivers to develop solutions that better meet their needs and improve outcomes. It is important to engage early and often throughout the entire lifecycle of a medicine's development, so we can better meet patient needs. Patients and caregivers are involved in many ways: they help us shape the medicines we develop, and ensure we understand and measure what matters to them. They help us build better clinical trial experiences and they provide feedback on educational materials and support programs.

How have you used patient input to improve the way Janssen develops medicines?

Input from patients helps us develop medicines in ways that reflect what's most important to them. Take inflammatory bowel disease (IBD), a chronic condition that can be debilitating. Our researchers wanted to learn as much as possible about what it's like to live with the disease and what getting better means for patients in terms of improvements to everyday life. We met directly with patients for an open dialogue about what it is like to live with the condition and to hear firsthand how people feel and what they are looking for in a therapy. Patients said the most important thing was to feel normal, which is as important as—and sometimes more important than—things like how easy it is to take the medicine.

We then asked ourselves, “how do we tailor the development process to ensure our medicines reflect these preferences?” From a scientific standpoint, “how do we translate patient input into the measurable goals that a development program should aim for?” Their input informed a target product profile (TPP), which is the recipe for the endpoints the clinical development process aims to meet. The team modified the TPP to make it clear that effectiveness is more important than convenience. They are now seeking to develop a medicine that works faster or to find a way to predict if the medicine will work so that patients don't have to wait in frustration or suspense.

Another example comes from our researchers who were developing a plaque psoriasis medicine. In clinical studies of moderate to severe plaque psoriasis, clinician-reported outcomes were typically used to assess the extent and severity of the disease as well as the patients' response to therapy. But plaque psoriasis often comes with symptoms that are best assessed by patients themselves, such as itching, pain, stinging, burning, and skin tightness. Our researchers worked with patients and other stakeholders to create the Psoriasis Symptoms and Signs Diary (PSSD), a tool that measures symptoms that matter to patients and lets them record their own symptoms.

The information we gathered from patients who used PSSD in clinical trials is now part of the FDA-approved U.S. Prescribing Information for the medicine. The PSSD instrument has also been made available publicly for other researchers to use.

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

**Pricing &
Patient Costs** ▶

**Advancing a
Better Way** ▶

**Resources
for Patients** ▶

References ▶



Sharing Clinical Trial Data

Making clinical trial results available allows other researchers to learn from our efforts. This advances science and benefits public health in important ways.

Like others in our industry, we disclose information about our clinical trials on clinicaltrials.gov, the largest U.S. public registry, and we seek to publish the results of company-sponsored trials and health economic studies in peer-reviewed medical journals. But we don't stop there.

In a first-of-its-kind agreement with the Yale University School of Medicine, we share pharmaceutical, device, and consumer product clinical trial data through the Yale Open Data Access (YODA) Project. Its mission is to advocate for the responsible sharing of clinical research data, open science, and research transparency.

Launched in 2014, the YODA Project serves as an independent review panel, evaluating researchers' requests for access to participant-level trial data

and research reports, which provide extensive details about the methods and results of a clinical trial. Researchers can use these clinical trial data in their own scientific or medical research to increase medical knowledge and improve public health.

The YODA Project informs and enhances future initiatives to promote clinical trial data-sharing.³⁸ For example, a recent study allowed outside researchers to look at gender differences in weight gain in patients with inflammatory bowel disease treated with one of our medications. Another study conducted by the World Health Organization compared different therapies used to treat multidrug-resistant tuberculosis, including one we produce, to inform global treatment guidelines. Data sharing and data transparency, helped significantly by the YODA Project, are quickly becoming the new standard in pharmaceutical and medical device science and in clinical research more broadly.

In 2018, the YODA Project received 24 requests for data from researchers and physicians at institutions and academic centers in the U.S. and around the world, all of which were approved by the YODA Project.³⁹ Additionally, 11 papers were published this past year as a result of data we shared.⁴⁰ For more information about the YODA Project and to request access to data from Janssen's clinical trials, please visit yoda.yale.edu.

BY THE NUMBERS: 2018 YODA RESULTS⁴¹

24
requests for data

100%
requests approved

11
papers were published
using YODA data

Our leadership in clinical trial data transparency has been recognized by external organizations like Bioethics International. In 2017, Johnson & Johnson achieved the highest overall clinical trial transparency score—100 percent—from Bioethics International in its Good Pharma Scorecard (GPS), an annual index that ranks the top 20 biopharmaceutical companies and new FDA-approved drugs on key ethics, human rights, and public health criteria.⁴² The GPS report evaluated clinical trial registration, results reporting, clinical study report synopsis sharing, and journal article publication rates for new drugs approved by the FDA in 2014 that were sponsored by large drug companies.⁴³

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

Janssen R&D by the Numbers

We are at a pivotal moment in the history of medicine. It is now possible to prevent, manage, and even cure diseases that were once severely debilitating or even fatal. And more advances lie ahead.

That's why we have continued our industry-leading investment in discovering and developing transformational medicines for patients facing some of the world's most challenging diseases.

In 2018, Janssen increased to \$8.4 billion our investment globally in R&D; this amount represents a significant portion of Johnson & Johnson's overall 2018 R&D investment of \$10.8 billion.⁴⁴ Our R&D expenditures enable us to discover, test, and develop new medicines as well as to demonstrate the efficacy, safety, and regulatory compliance of our medicines prior to approval. R&D resources are also used to improve existing, FDA-approved products.

This investment has enabled us to advance more than 100 medicine candidates. Over the past five years (2014-2018), we have had a total of six new medicines approved by FDA.^{45, 46} Five of these six new medicines were granted priority review by FDA. Priority review is an expedited review program reserved for products that treat a serious condition and would provide a significant improvement for patients in terms of safety or effectiveness.⁴⁷ During this same time period, we received eight FDA Fast Track designations, which facilitate development and expedite review of drugs that treat serious conditions and fill unmet medical needs. We also received approvals for more than 30 expanded indications or new product formulations that enable new groups of patients to benefit from our medicines.⁴⁸

Since the FDA established the Breakthrough Therapy Designation in 2012, we have received nine FDA Breakthrough Therapy Designations for indications for five of our investigational medicines.^{49, 50} A Breakthrough Therapy Designation is a process that expedites the development and review of an investigational medicine that is intended to address a serious condition when preliminary clinical evidence indicates that the medicine may demonstrate a substantial improvement over other available treatments.⁵¹

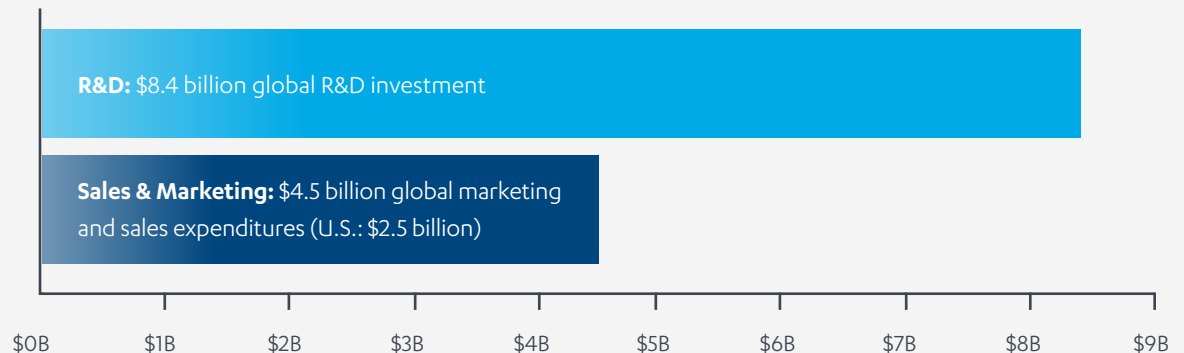
Our global investment in R&D significantly exceeds our investment in global marketing and sales activities. In 2018, we invested \$8.4 billion in our global R&D⁵² and we spent \$4.5 billion on global marketing and sales activities, which means we spent 86 percent more on R&D than we did on marketing and sales.⁵³ We make this comparison using global figures because our investment in R&D cannot be segmented by region. The R&D activities we undertake around the world collectively contribute to medicine development, regardless of location.

The marketing and sales figures in this report are even more specific than what is described in Johnson & Johnson financial statements. Johnson & Johnson financial statements do not separate marketing and sales expenses from other expenses associated with running the company. They combine marketing and sales expenses with other items in a line item described as "Selling, Marketing and Administrative Expenses" (SM&A). This SM&A figure accounts for much more than pharmaceutical marketing and sales expenses. It includes administrative and overhead activities that are not related to marketing or sales, such as expenses for insurance, legal, finance, and product distribution. It also pertains to all of the businesses in the Johnson & Johnson Family of Companies, which, in addition to pharmaceuticals, include medical devices and consumer products; finally, it is a global, not U.S., figure.

FAST FACT



In 2018, we invested
86% more
in R&D
than we spent on
marketing and sales.⁵⁴



OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

**Bringing Our Approved Medicines
to Patients: Sales & Marketing**

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

**Pricing &
Patient Costs ▶**

**Advancing a
Better Way ▶**

**Resources
for Patients ▶**

References ▶

Bringing Our Approved Medicines to Patients: Sales & Marketing

After we have FDA approval for an innovative medicine, we invest in providing accurate, up-to-date information about the medicine to healthcare professionals and patients. In 2018, we spent \$2.5 billion in the U.S. for pharmaceutical marketing and sales activities,⁵⁵ including communications with healthcare professionals about the medicines' approved uses, effectiveness, side effects, benefits, and risks. The expenditures also include patient education and direct-to-consumer communication.

The patients and healthcare professionals who rely on our medicines place their trust in the reliability of our clinical research, the rigor of our scientific publications, the independence of the medical education we fund, and the integrity of our professional relationships.

Healthcare providers with real-world clinical experience in specific therapeutic areas are uniquely qualified to provide education and insights into new advancements regarding our products. Known as "peer-to-peer" education, this type of interaction can address potential treatment gaps as it allows providers to objectively discuss important medical information with expert colleagues regarding the appropriate use of our products. We work with healthcare providers for peer-to-peer education with the goal of improving the health of patients and driving improved clinical outcomes through transparent, compliant activities.

Our marketing and sales activities adhere to a high level of legal requirements and ethical standards.

We follow all laws and regulations regarding the promotion of prescription medicines and submit promotional materials to the FDA. Our marketing and sales activities adhere to industry ethics standards and codes of conduct, including the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Healthcare Professionals and the [PhRMA Guiding Principles on Direct-to-Consumer \(DTC\) Advertisements about Prescription Medicines](#). We view these guidelines as a starting point and challenge ourselves to deliver even more for patients. For more information about how we are implementing the recently enhanced PhRMA principles regarding DTC advertisements, see the chapter titled "[Pricing & Patient Costs.](#)"

When we market our medicines, we ensure that the information we share with patients and healthcare professionals is accurate and current. Our review process, which is governed by an internal team of medical, compliance, and legal experts, evaluates all information about our medicines that we share with physicians or patients to ensure it is accurate and credible. ■



OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

**Open Payments: R&D
Accounts for 75 Percent of
Our Payments to Physicians**

Frequently Asked Questions

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

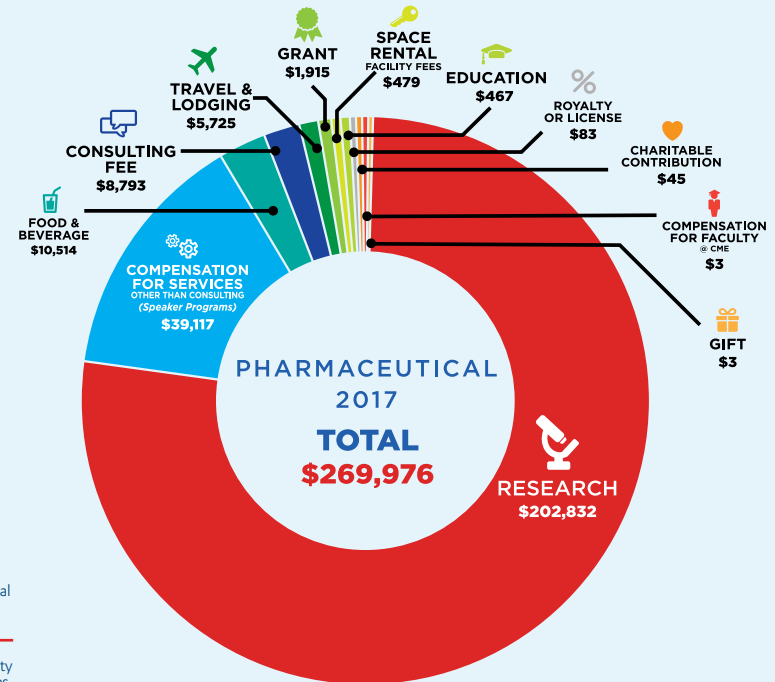
OPEN PAYMENTS: R&D ACCOUNTS FOR 75 PERCENT OF OUR PAYMENTS TO PHYSICIANS

In accordance with the Physician Payment Sunshine Act, we disclose to the U.S. Centers for Medicaid and Medicare Services (CMS) the compensation or transfers of value that we provide as a part of our sales and marketing outreach to educate healthcare professionals about our medicines. These transfers of value include, but are not limited to, meals, travel expenses, medical textbooks, and scientific articles. We make this information available on jn.com. The information is also available to the public through the CMS Open Payments database.

These “Sunshine Act” disclosures also include payments we make to physicians for their guidance during the R&D process, including assistance with the design and conduct of clinical trials. In fact, these research-related payments account for approximately 75 percent of our 2017 payments to physicians and teaching hospitals.⁵⁶

We anticipate that 2018 Open Payments data will be available through CMS on June 30, 2019.

Numbers contained in the chart below are shown in \$1,000s.



RESEARCH

Clinical studies and research that provide valuable scientific and clinical information about the medicines and medical devices that improve patients' lives



COMPENSATION FOR SERVICES OTHER THAN CONSULTING (Speaker Programs)

Compensation for services other than consulting, including serving as faculty or a speaker at a venue other than a continuing education program • Fees for speaking at program on our company's behalf • Acquisition payments



FOOD & BEVERAGE

Meals, whether paid directly or reimbursed, may be provided in conjunction with: • Consulting services • Training • Educational and other business discussions with physicians



CONSULTING FEE

Product development • Training • Development of educational materials and disease management programs • Unblinded market research



TRAVEL & LODGING

Travel, whether paid directly or reimbursed, in conjunction with: • Consulting services • Product training



GRANT

Sponsorship of an educational event, patient advocacy event, or publication • Sponsorship of fellowships for fellow and resident training • Certified independent educational activities (i.e., activities certified by a continuing medical education provider) • Non-certified medical education activities



SPACE RENTAL FACILITY FEES

Space Rental or Facility Fees (Teaching Hospital Only) • Booth or exhibit space rental • Facility rental for product training or clinical studies



EDUCATION

Medical textbooks • Scientific journal articles



ROYALTY OR LICENSE

Payment of royalty or license fees for inventions or significant contributions towards the development of a new innovation, often based on product sales over a pre-determined period of time



CHARITABLE CONTRIBUTION

Monetary donation (only represents charitable contributions required to be disclosed under Open Payments); for more on J&J charitable contributions, visit: jn.com/our-giving



COMPENSATION FOR FACULTY @ CME

Indirect payment by a third party organization to speakers at an accredited educational program, funded by an educational grant from a J&J company



GIFT

Open Payments categories are specified by regulation and do not provide for an "other" category; the gifts category may be used when there is no appropriate category available

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

FREQUENTLY ASKED QUESTIONS (FAQ)

What role does the National Institutes of Health (NIH) play in developing medicines and do pharmaceutical companies benefit from government funded research?

The National Institutes of Health (NIH) and other U.S. government agencies play an important role in medical research, primarily funding and conducting basic research, namely the exploration of the cellular and molecular changes involved in the development of disease.⁵⁷ This important work furthers our understanding of disease and can help identify potential targets for medicine development. The knowledge generated by public investments in basic science is critical for laying the foundation for future pharmaceutical innovation.⁵⁸

Research by government institutions like the NIH sometimes leads directly to the discovery of a molecule or technology platform that has the potential to become a novel medicine or vaccine, although this happens infrequently.⁵⁹ Basic research is rarely specific enough to yield an investigational molecule that could be turned into a medicine.

While the NIH funds research to understand the problem, we fund research on solutions—treatments for the problem. The vast majority of the long, financially risky, and costly process to discover and develop

new medicines that meet the stringent safety and efficacy requirements of the FDA is conducted and funded by the biopharmaceutical industry. In 2017 alone, industry investments were approximately \$97 billion, triple NIH's \$32.4 billion spending on research in the same year.⁶⁰ In fact, the amount of research U.S. biopharmaceutical companies undertake to bring new medicines to patients makes us one of the most research-intensive sectors in the country, and the source of the majority of industry spending on R&D worldwide.⁶¹

There is no straight line from government-funded basic research to a marketable medicine or medical device. A study of NIH grants awarded over a 27-year period (1980-2007) showed that only 8.4% of NIH grants were directly acknowledged in a patent for a medicine, device, or other technology, and less than 1% were directly acknowledged in a patent associated with a marketed medicine.⁶²

Further, sometimes public institutions hold intellectual property rights to research that a pharmaceutical company carries forward. In cases where a collaboration leads to intellectual property held by a partner, pharmaceutical companies pay royalties, and when the risks of drug discovery are shared, partners receive milestone payments and/or royalties paid on revenues of marketed medicines.



Continued on next page ▶

OUR INVESTMENTS

Research & Development at
Janssen: Our Approach

Disease Area Strongholds
and Pathway Area Strongholds

Meet Our R&D Colleagues

Enabling Innovation at Janssen

Research Continues After
FDA Approval

Collaborating with Experts and
Entrepreneurs Outside Janssen

Johnson & Johnson
Innovation—JLABS

Expert Q&A: Partnering with
Patients to Bring Better Solutions

Sharing Clinical Trial Data

Janssen R&D by the Numbers

Bringing Our Approved Medicines
to Patients: Sales & Marketing

Open Payments: R&D Accounts
for 75 Percent of Our Payments
to Physicians

Frequently Asked Questions

**Pricing &
Patient Costs** ▶

**Advancing a
Better Way** ▶

**Resources
for Patients** ▶

References ▶

FREQUENTLY ASKED QUESTIONS (FAQ)

What is the difference between Janssen's expenditures on R&D and sales and marketing highlighted in this report and expenditures for Sales, Marketing and Administration that Johnson & Johnson reports in financial filings?

Johnson & Johnson is a healthcare company comprised of three business segments: pharmaceuticals (Janssen), medical devices and consumer products. In its financial statements, Johnson & Johnson reports a total figure for Sales, Marketing & Administration (SM&A) which combines marketing, sales, and administrative expenses such as insurance, legal, finance and product distribution across all three business segments.

The figures we disclose in this report are for Janssen-specific sales and marketing and do not include administrative expenses. In order to help address questions about Janssen investments in R&D and Janssen sales and marketing expenditures, we detail this information on pages 14 and 15 of this report. Specifically, Janssen spent \$8.4 billion on R&D globally⁶³ and \$4.5 billion on marketing and sales globally in 2018. This means Janssen invested 86% more in R&D than sales and marketing.⁶⁴

Does Janssen work with generic manufacturers to provide access to medicine samples for testing?

We support intellectual property protections that encourage medical innovation as well as policies that enable generic medicines to be broadly available at a low cost. We cooperate with generic manufacturers so they have access to samples of our medicines at reasonable, market-based prices.

For certain medicines, FDA has required a Risk Evaluation and Mitigation Strategy (REMS) that restricts distribution of the medicine so that its safe use can be more closely managed. In those cases, before providing testing samples to generic manufacturers, we request that they seek an FDA determination that they have protocols in place to protect patient safety that are comparable to our REMS programs. We rely on FDA's determination that safety protections are comparable when working with generic manufacturers. We then establish supply



agreements with the manufacturer and provide samples. We have entered into supply agreements and provided samples to all companies whose safety protocols are determined to be sufficient, and we plan to continue to do so in the future.

Are acquisitions of pharmaceutical companies included in your R&D spending that you disclose?

No. When we acquire a pharmaceutical company, related acquisition expenses are considered a business transaction and are not included in our total R&D investment. R&D expenditures relate to the processes of discovering, testing and developing new products, upfront and milestone payments made to partners in connection with R&D collaborations, improving existing products, and ensuring product efficacy and regulatory compliance prior to launch. We invest in these activities to fulfill our commitment to delivering transformational medical innovation.

A Message from
Our Leaders ▶

Our
Investments ▶

PRICING & PATIENT COSTS

Our Pricing Approach

List Price vs. Net Price

Discounts and Rebates from
Pharmaceutical Companies

An Example of the
Pharmaceutical Supply Chain

Expert Q&A: List Price
vs. Net Price

Our Net Prices Declined
6.8% in 2018

Our Commitment to Providing
Meaningful Information on
Prescription Drug Costs

Patient Out-of-Pocket Costs

Benefit Design and the
Patient Experience

Examples of the Impact of
Benefit Design on Patient Out-
of-Pocket Costs

Utilization Management and
Cost Containment Tools

Frequently Asked Questions

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

PRICING & PATIENT COSTS

WE UNDERSTAND CONCERNS ABOUT THE COST OF MEDICINES

expressed by patients and other healthcare stakeholders.

That's why at Janssen, we take a responsible approach to pricing our medicines. This chapter covers our pricing approach, how we negotiate with insurers and pharmacy benefit managers in the U.S. to support access to our products, and how patient out-of-pocket costs are determined. We also disclose how the average net price of our medicines decreased for the second year in a row as a result of the discounts and rebates we provided to payers, providers, and the government.



A Message from
Our Leaders ▶

Our
Investments ▶

PRICING & PATIENT COSTS

Our Pricing Approach

List Price vs. Net Price

Discounts and Rebates from
Pharmaceutical Companies

An Example of the
Pharmaceutical Supply Chain

**Expert Q&A: List Price
vs. Net Price**

Our Net Prices Declined
6.8% in 2018

Our Commitment to Providing
Meaningful Information on
Prescription Drug Costs

Patient Out-of-Pocket Costs

Benefit Design and the
Patient Experience

Examples of the Impact of
Benefit Design on Patient Out-
of-Pocket Costs

Utilization Management and
Cost Containment Tools

Frequently Asked Questions

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

EXPERT Q&A: LIST PRICE VS. NET PRICE

Blasine Penkowski, Chief Strategic Customer Officer (pictured left), shares more about the difference between list and net price and how discounts, rebates, and fees work.

Can you provide more detail about how list price becomes net price?

The list prices we set are reduced by a combination of discounts and rebates. Some of these are mandated by the government. Others we negotiate with commercial payers.

To government insurers, such as state Medicaid departments and the U.S. Department of Veterans Affairs, we are required to give substantial discounts. The government requires that pharmaceutical companies provide specific mandatory discounts on medicines in order to participate in these programs; manufacturers are also required to provide discounts to certain hospitals.

In addition, we provide discounts and rebates through negotiations with the private health insurance companies and pharmacy benefit managers (PBMs) who administer benefits for Medicaid and Medicare.

We also work with the commercial health insurance companies and PBMs that manage the purchase of medicines for those with private insurance coverage. They determine what medicines will be included on their formulary (the list of products they cover) and the out-of-pocket amounts patients will pay for those medicines. Formulary determinations are based, in part, on payers' negotiations with pharmaceutical companies. These negotiations result in rebates from the pharmaceutical company to the payer.

We also pay fees to pharmaceutical wholesalers and distributors—companies that buy medicines in bulk and distribute them to pharmacies and other healthcare providers.

Why does Janssen negotiate with private payers?

Commercial payers like PBMs and health insurers have lists of prescription medicines they will cover and help pay for called drug formularies, which are updated regularly. Within the formularies, medicines are placed on "tiers" that correspond with patients' out-of-pocket costs. For example, a medicine on tier one will have a lower out-of-pocket cost than a medicine on tier three. Because multiple treatments exist for many conditions, payers create

competition among pharmaceutical companies who want their medicine to be placed on a tier with a lower copay. Products on tiers with lower copays are called "preferred" products.

In contract negotiations, we give payers information they can use to evaluate the overall value of our medicines. We offer discounts and rebates on our medicines with the objective of gaining payer coverage and favorable formulary placement so that our medicines are accessible and affordable to patients.

We are competitive in our negotiations so that payers enable patients to have access to our medicines. However, what patients pay may not reflect the discounts and rebates we provide to payers.

How do net prices affect what patients ultimately pay for their medicines?

It's important to keep in mind that payers decide where medicines belong on their formularies and the type of health insurance benefits patients have. These decisions determine what patients pay for medicines, often referred to as out-of-pocket costs.

Recent IQVIA research found that many patients' cost-sharing is based on list—not net—price, particularly when patients pay for prescriptions in their deductible period—in the beginning of the year—or when their medicines are subject to coinsurance—in other words, when they pay a percent of the medicine cost rather than a flat copay. Out-of-pocket costs in the deductible period or for coinsurance account for half of all patient out-of-pocket spending on branded medicines.⁶⁵ Recently, some payers have announced that they will start applying a portion of manufacturer rebates to the price patients pay.^{66, 67} While this benefits only a small percentage of commercially insured patients,⁶⁸ it is an important first step.

Further, despite the tremendous value medicines deliver, in the U.S., patients typically pay a greater share of the cost for medicines than they do for other forms of healthcare. On average, patients pay 13 percent of prescription drug costs compared to three percent of hospital care costs⁶⁹—even though the medicine could help keep the patient out of the hospital.

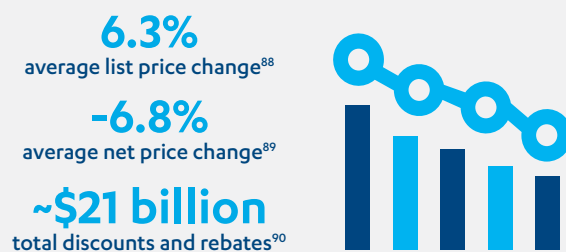
Frequently Asked Questions

Patient Out-Of-Pocket Costs

While the estimated net prices for branded medicines across the industry have increased below the rate of medical inflation in three of the past four years,^{81, 82, 83, 84} these pricing trends are not reflected in many patients' experiences at the hospital, doctor's office, or pharmacy counter. The average out-of-pocket burden has risen dramatically. In fact, out-of-pocket costs for branded medicines increased 48 percent from 2013 to 2016.⁸⁵

One reason patients' out-of-pocket spending has grown is a change in how health insurance is designed and pharmaceutical benefits are managed. Over the last decade, high-deductible health plans—plans that require large, upfront deductibles and higher rates of cost-sharing in exchange for lower premiums—have become more common. Enrollment in high-deductible health plans has expanded from 4 percent in 2006 to 29 percent in 2018.⁸⁶ The use of coinsurance, where insurers in some plans charge patients a percentage of the medicine's list price instead of a fixed dollar copayment, has also increased.⁸⁷

BY THE NUMBERS: OUR PRICING IN CONTEXT



However, the average out-of-pocket burden has risen dramatically. In fact, from 2013 to 2016, out-of-pocket costs for branded medicines increased 48%.⁹¹

These changes in benefit design make affordability significantly more challenging for some patients. High deductibles expose patients to larger upfront out-of-pocket expenses for medicines and other services. And coinsurance often leaves them responsible for larger payments, especially for specialty or highly innovative

medicines, than traditional flat-rate copays.⁹² Indeed, among patients covered by large employers, much of the increase in total out-of-pocket spending for healthcare can be attributed to increasing cost-sharing. The average payment toward deductibles and coinsurance rose 176 percent and 67 percent, respectively, between 2006 to 2016.⁹³ For medicines specifically, deductibles and coinsurance represent a significantly larger share of out-of-pocket spending than they did more than a decade ago, growing from 7 percent in 2004 to 49 percent in 2016.⁹⁴

FAST FACT

For medicines specifically, deductibles and coinsurance represent a significantly larger share of out-of-pocket spending than they did more than a decade ago, growing from 7 percent in 2004 to 49 percent in 2016.⁹⁵

Benefit Design and the Patient Experience

Benefit design can dramatically affect patient access to, and the affordability of, medicines. The hypothetical examples on the following page feature patients taking the same specialty medicine for a chronic condition under different types of insurance plans. The medicine has a negotiated monthly net price of \$300 (\$3,600 annual) and a monthly list price of \$500 (\$6,000 annual). For additional examples, please visit phrma.org.

Research shows that when patients pay a greater share for their medicines, patient health can suffer, and there can be negative consequences.⁹⁶ Patients with higher out-of-pocket costs are more likely to abandon their new prescriptions at the pharmacy: 69 percent of commercial patients did not start therapy when faced with out-of-pocket costs exceeding \$250.⁹⁷ Similarly, high out-of-pocket costs can contribute significantly to medication or treatment “non-adherence” in patients with chronic or serious illnesses, such as rheumatoid arthritis⁹⁸ or breast cancer.⁹⁹

When patients do not fill and adhere to their medicines, the result can be higher costs for other healthcare services.¹⁰⁰ Such decisions may reduce payer and health system pharmacy costs in the short term, but over the long term, lack of adherence results in poorer health outcomes and can lead to higher overall system costs.¹⁰¹ According to one study, the U.S. could save \$213 billion annually if medicines were used appropriately.¹⁰² The Congressional Budget Office has estimated that for every 1 percent increase in the number of prescriptions filled by Medicare beneficiaries, spending on medical services decreases by about 0.2 percent.¹⁰³

EXAMPLES OF THE IMPACT OF BENEFIT DESIGN ON PATIENT OUT-OF-POCKET COSTS



Example 1: Emily

Emily has health insurance through her employer. In an effort to distribute her healthcare costs evenly over the year, Emily selected a Preferred Provider Organization (PPO) plan that features smaller copay costs and no deductible in exchange for a higher premium.

When Emily goes to the pharmacy to fill her prescription, she learns that because her medicine is in a specialty tier, it is subject to her insurer's coinsurance rate of 20 percent instead of a flat copayment rate. If her coinsurance were based on the insurer's negotiated net price, her monthly cost would be \$60. However, because her insurer bases coinsurance rates on list price, Emily's monthly out-of-pocket payment at the pharmacy is \$100.

Total annual out-of-pocket cost for Emily's medicine under a PPO plan with no deductible and smaller copays: \$1,200

List Price	\$500	Deductible	\$0
Manufacturer Rebates	\$200	Copay	\$0/mo
Net Price	\$300	Co-insurance	\$100/mo

- **Co-insurance costs: \$100 x 12 months = \$1,200**
Paying 20 percent co-insurance that is based on \$500 list price
- **Emily's total annual out-of-pocket cost: \$1,200 (\$100 x 12 months)**



Example 2: Chris

Chris gets health insurance through his state's exchange plan. Chris wanted the most affordable health insurance option, so he selected a plan with a high \$2,000 deductible and lower monthly premiums.

When Chris goes to the pharmacy at the beginning of the year, he is still in his deductible period, so he must pay the full cost of his medicine upfront. Chris's insurer bases his medicine cost on list price, not the net price it negotiated with the manufacturer. For the first four months, until he reaches his deductible of \$2,000, Chris must pay the full \$500 list price of the treatment. Once his deductible is met, Chris's insurer covers the treatment for a monthly copay of \$75.

Total annual out-of-pocket cost for Chris's medicine under a high deductible health plan: \$2,600

List Price	\$500	Deductible	\$2,000
Manufacturer Rebates	\$200	Copay	\$75/mo
Net Price	\$300	Co-insurance	\$0/mo

- **Deductible costs: \$500 x 4 months = \$2,000**
Paying full list price for medicine until deductible is met
- **Copay costs: \$75 x 8 months = \$600**
After deductible is met, paying monthly copay set by insurer for remainder of year
- **Chris's total annual out-of-pocket cost: \$2,600 (\$500 x 4 months + \$75 x 8 months)**



Example 3: Sydney

Sydney has health insurance through her employer. To balance premium and out-of-pocket costs, she chose a PPO plan with a moderate \$500 deductible and slightly lower premiums.

When Sydney visits the pharmacy at the beginning of the year, she learns her insurance provider will not cover the specialty medicine her doctor prescribed until she tries a similar treatment, a common practice called step therapy. The similar treatment is in a lower tier, meaning her insurer likely pays a lower net price and therefore prefers that Sydney use this treatment. Because Sydney is in her deductible period, she pays the full list cost of the approved treatment, \$500, for one month. When she reaches her deductible, her insurer covers her medicine in exchange for a flat \$30 copay.

Sydney tries the insurer's preferred treatment for several months, but it doesn't manage her symptoms well, and her condition regresses. She has more doctor's visits and is evaluated by a specialist, all of which cost her additional money in the form of copays. After six months, Sydney qualifies for coverage of the originally prescribed treatment because she has tried and failed on the insurer's preferred treatment. Now she can get her treatment at the pharmacy for a flat copay of \$30.

Total annual out-of-pocket cost for Sydney's preferred medicine under a PPO plan with moderate deductible and smaller premiums: \$830

List Price	\$500	Deductible	\$500
Manufacturer Rebates	\$200	Copay	\$30/mo
Net Price	\$300	Co-insurance	\$0/mo

- **Deductible costs: \$500 x 1 month = \$500**
Paying full list price of manufacturer's preferred medicine until deductible is met
- **Copay costs: \$30 x 11 months = \$330**
After deductible is met, paying monthly copay set by insurer for remainder of year. Copay stays the same when Sydney switches back to her originally prescribed medication.
- **Sydney's total annual out-of-pocket cost: \$830 (\$500 x 1 month + \$30 x 11 months) plus additional copays for doctor visits, lab tests, and a specialist evaluation**

A Message from
Our Leaders ▶

Our
Investments ▶

PRICING & PATIENT COSTS

Our Pricing Approach

List Price vs. Net Price

Discounts and Rebates from
Pharmaceutical Companies

An Example of the
Pharmaceutical Supply Chain

Expert Q&A: List Price
vs. Net Price

Our Net Prices Declined
6.8% in 2018

Our Commitment to Providing
Meaningful Information on
Prescription Drug Costs

Patient Out-of-Pocket Costs

Benefit Design and the
Patient Experience

Examples of the Impact of
Benefit Design on Patient Out-
of-Pocket Costs

**Utilization Management and
Cost Containment Tools**

Frequently Asked Questions

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

Utilization Management and Cost Containment Tools

In addition to implementing benefit designs that shift more of a financial burden to patients, insurers employ various “utilization management tools” to contain the total amount they pay for medicines. Aimed at steering patients to lower-cost therapies, utilization management tools include:

- **Prior authorization requires doctors to obtain approval** from an insurer before a patient can receive a particular medicine. Prior authorization helps make sure patients get the insurer-preferred medicine, but the practice can result in delays that cause some patients to forego their treatment altogether.
- **Step therapy requires patients to try medicines on an insurer’s preferred list of prescriptions** before the insurer will cover the cost of another medicine. Step therapy is also known as “fail first.”
- **Non-medical switching happens when insurers eliminate coverage for a patient’s current medicine**, switching them to treatment that has a lower cost for the insurer. While some patients can switch to a different treatment without issue, this practice can be harmful to some patients, especially those with complex, chronic, or rare conditions, who have found that one medication works better than another.
- **Accumulator adjustment programs prevent savings cards offered by pharmaceutical manufacturers from applying** toward patients’ out-of-pocket maximums or deductibles. When an accumulator adjustment program is in effect, patients may be surprised to learn that the reduced out-of-pocket costs they’ve been paying—thanks to their savings card—are not counting toward their deductible or out-of-pocket maximum. This can result in additional and unexpected costs for the patient, which make it harder for patients to stay on their medications.¹⁰⁴

Physicians find that these tools can interfere with their ability to deliver care. In a survey of physicians, 91 percent of respondents reported that prior authorization delayed patient access to necessary care and had a significant or somewhat negative impact on patients’ clinical outcomes.¹⁰⁵ Regarding step therapy, 90 percent of primary care physicians report that it is a serious issue with respect to their ability to deliver quality care to patients.¹⁰⁶ Patients have expressed dissatisfaction with non-medical switching. In a survey of patients, approximately 70 percent of respondents reported that when they were switched to different medications for non-medical reasons, those medications were less effective than the drugs they had been on.¹⁰⁷ In another survey, 40 percent of patients reported that frustrations with non-medical switching led them to stop taking their medicines altogether.¹⁰⁸ ■



OUR POSITION ON NON-MEDICAL SWITCHING: OUR FIRST RESPONSIBILITY IS TO OUR PATIENTS

We believe treatment decisions belong in the hands of patients and their healthcare professionals, which is why we are concerned about clinically stable patients being switched to other therapies for non-medical reasons.

Because our first responsibility is to patients who use our medicines, we oppose non-medical switching even when it works to our advantage—as in instances where, for a given condition, a Janssen medicine is the lowest-cost therapy on a payer’s formulary. We do not proactively seek arrangements with payers that require patients who are clinically stable on a medicine to switch to a different medicine.

A Message from
Our Leaders ▶

Our
Investments ▶

PRICING & PATIENT COSTS

Our Pricing Approach

List Price vs. Net Price

Discounts and Rebates from
Pharmaceutical Companies

An Example of the
Pharmaceutical Supply Chain

Expert Q&A: List Price
vs. Net Price

Our Net Prices Declined
6.8% in 2018

Our Commitment to Providing
Meaningful Information on
Prescription Drug Costs

Patient Out-of-Pocket Costs

Benefit Design and the
Patient Experience

Examples of the Impact of
Benefit Design on Patient Out-
of-Pocket Costs

Utilization Management and
Cost Containment Tools

Frequently Asked Questions

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

FREQUENTLY ASKED QUESTIONS (FAQ)

Why does Janssen increase the prices of medicines?

Many factors contribute to price increases. After we receive FDA approval, we continue to conduct research on our medicines, including studies to understand how the medicines work in a real-world setting. We continue to monitor for safety and to secure regulatory approval for new indications, dosages, or improved product formulations—investments that enhance the value of our medicines for patients and society. Additional regulatory requirements, upgrading or building new manufacturing facilities, an increase in the cost of goods, and other market dynamics also play a role. And finally, we must continue to generate returns to invest in R&D.

Biopharmaceutical innovation paves the way for the introduction of generic medicines, which enables medicine costs to be reduced

over time. In the U.S., medicines lose market exclusivity, on average, about 12 years after they are introduced.¹⁰⁹ When that happens, prices generally drop significantly—an average of 90 percent within two and a half years for oral generic medicines¹¹⁰—giving patients ongoing access to effective therapies at a lower cost.

Do medicine price negotiations occur in Medicare?

Yes. Pharmaceutical companies negotiate rebates on medicines purchased by Medicare through the Part D benefit and through Medicare Advantage plans. Negotiations occur with private health insurance companies and PBMs that administer benefits for these public programs. The payers that administer Part D benefits represent as many as 40 million covered lives,¹¹¹ meaning they are powerful negotiators with leverage to secure large discounts and rebates.



Continued on next page ▶

A Message from
Our Leaders ▶

Our
Investments ▶

PRICING & PATIENT COSTS

Our Pricing Approach

List Price vs. Net Price

Discounts and Rebates from
Pharmaceutical Companies

An Example of the
Pharmaceutical Supply Chain

Expert Q&A: List Price
vs. Net Price

Our Net Prices Declined
6.8% in 2018

Our Commitment to Providing
Meaningful Information on
Prescription Drug Costs

Patient Out-of-Pocket Costs

Benefit Design and the
Patient Experience

Examples of the Impact of
Benefit Design on Patient Out-
of-Pocket Costs

Utilization Management and
Cost Containment Tools

Frequently Asked Questions

Advancing a
Better Way ▶

Resources
for Patients ▶

References ▶

FREQUENTLY ASKED QUESTIONS (FAQ)

Negotiation also takes place in Medicare Part B, albeit indirectly. The Part B benefit generally covers outpatient services received at a hospital, doctor's office, or clinic, including medicines that are injected or infused. The price that Medicare Part B reimburses is based on a calculation known as the Average Sales Price (ASP). ASP is the weighted average of all manufacturer sales prices, net of rebates and discounts. As a result, prices in Medicare Part B reflect aggressive market-based negotiations in the private, competitive market. In recent years, this market-based model has delivered multiple breakthrough drugs and biologics—therapies that are improving and saving the lives of U.S. patients every day.

Why do U.S. medicine prices differ from prices in other countries?

We are sometimes asked why patients in the U.S. pay more for medicines than patients in other countries. In fact, most cross-country comparisons focus solely on the list prices of medicines and do not account for the significant discounts required for participation in U.S. public programs, such as Medicaid, the 340B Drug Discount Program, and the Federal Supply Schedule (for U.S. Department of Veterans Affairs and Department of Defense), as well as the discounts and rebates negotiated by private payers. For this reason, most of these international comparisons are not “apples to apples.”

In the U.S., we have a market-based system that provides financial incentives for innovation while managing access and cost through intense competition, payer negotiations, and the high use of generics. In other countries, medicine prices are achieved through national regulation, which often restricts or delays access to innovative medicines and limits patient and physician choice. For example:

- Compared to patients in the U.S., the typical wait time for patients in five European Union countries to gain access to cancer medicines ranges from seven months to a year and a half longer.^{112, 113}
- Of 45 cancer medicines approved by the FDA from 2009 to 2013 and available through Medicare, only 58 percent were made available by



government health authorities in the U.K., 42 percent in France, 29 percent in Canada, and 24 percent in Australia.¹¹⁴

- In three major developed countries outside the U.S., it took one of our breakthrough medicines for multiple myeloma approximately 22 months to reach patients after local approval. In some cases, negotiations are still ongoing. Government reimbursement for another breakthrough medication for B-cell cancers took 12 months to nearly three years longer in those same major developed countries.

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

ADVANCING A BETTER WAY

WE BELIEVE GOOD HEALTH IS AT THE HEART OF HUMAN PROGRESS.

Together, our challenge is to develop a healthcare system that delivers what all of us want: greater access to care at more manageable cost and, most importantly, better health for all.

Ensuring that every American has access to affordable healthcare, including the medicines they need, means changing how we pay for medical care. Our current system rewards the quantity or volume of care delivered, regardless of results. Shifting to an approach that prioritizes value rather than volume means that everyone who plays a role in the healthcare system is held accountable for the results or outcomes they deliver, including pharmaceutical manufacturers like Janssen. This approach prioritizes healthcare interventions—whether medicines, surgeries, in-office visits, or other forms of care—that deliver the best results at the lowest possible cost. By spending less on care that doesn't work, we will have more to spend on care that does, now and in the future. Greater efficiency today also promises more innovation tomorrow as well as more affordable access to that innovation.

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

BY THE NUMBERS: THE VALUE OF MEDICINES

Reduction in direct
medical costs attributable
to cardiovascular
medicines like statins:

27%¹¹⁵

Amount of potential
savings from correct
use of medications for
chronic conditions:

\$213 billion¹¹⁶



Total healthcare dollars spent on medicines:

14%¹¹⁷



Decline in cancer deaths between 1991 and 2016:

An overall decline of 27%

in 25 years, meaning an estimated 2.6 million fewer
cancer deaths than expected if death rates had
remained at their peak.¹¹⁸

For patients with early-stage HIV, lifetime cost savings
after the introduction of antiretroviral therapies:

\$402,000¹¹⁹



Percentage of
prescriptions that are for
generic medicines:

90%¹²⁰

Proportion of recent
gains in life expectancy
attributable to medicines:

70%¹²¹

Assessing the Value of Our Medicines

Part of being accountable for the value we deliver means being transparent about how we assess the value we bring to patients and to the healthcare system more broadly. When we assess the value of our medicines, we follow four principles:

1. What matters most in determining a medicine's value is its impact on patients.¹²²

First, we look at a medicine's clinical profile—its effectiveness, ability to improve health-related quality of life, tolerability, side effects, etc.—compared with alternative treatments for the same condition or disease. We also look at how the medicine will be administered and in what clinical setting, the length or difficulty of the regimen, and whether the treatment requires any diagnostic tests—all factors that matter to patients. We consider the importance patients and their families place on having additional months or years of life; being able to avoid disability, hospitalization, and extensive medical procedures; and not having to depend on others for daily care. And because patients respond differently to different medicines, even those within the same class, we think about the benefit of having a variety of treatment options from which to choose.

2. The value of a medicine should include its impact on the healthcare system and society.¹²³

Medicines have effects that go beyond patient health. They can generate healthcare savings by reducing the need for future doctor visits, emergency room use, hospitalizations, nursing home stays, and procedures or operations. Medicines can add value to the broader society by improving workplace productivity, reducing disability, and preventing health-related interruptions in work or education. And in cases of serious mental illness like schizophrenia, some medicines can delay or reduce relapses, which may result in less frequent use of law enforcement or justice system resources.¹²⁴

3. Treatment outcomes should be assessed over an appropriate timeframe to capture all the benefits and risks for patients, the healthcare system, and society.¹²⁵

Some medicines have an immediate benefit that lasts a lifetime. Some medicines significantly extend a lifetime. Others have a more moderate benefit or a benefit over a shorter period. Our assessment of a medicine's value considers the time needed to fully realize all of its outcomes for all stakeholders, not just the first few months or a year or two.

4. Evidence considered in assessing the value of a medicine should be high-quality, current, and relevant.¹²⁶

We evaluate clinical trial data and real-world evidence from a variety of sources, including academic medical centers, government agencies, and healthcare systems, as well as from our own research. Evidence can vary in quality and reliability, which is why for everything we evaluate we

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

strive to confirm its credibility, identify ambiguities, and determine how best to address differences in conclusions. Some evidence is available immediately, while other evidence becomes available only after a longer period of time. Quality evidence, regardless of its source, makes clear the study methods, assumptions, and limitations, and it is transparent about any uncertainties in the data.

FAST FACT

When we assess the value of our medicines, we follow four principles:



1.

What matters most in determining a medicine's value is its impact on patients.¹²⁷



2.

The value of a medicine should include its impact on the healthcare system and society.¹²⁸



3.

Treatment outcomes should be assessed over an appropriate timeframe to capture all the benefits and risks for patients, the healthcare system, and society.¹²⁹



4.

Evidence considered in assessing the value of a medicine should be high-quality, current, and relevant.¹³⁰



take a short-term view of value. For example, they consider only the period in which the patient is being treated or the time it takes to see if a treatment is working, both of which fail to reflect the full benefits a medicine can provide to a patient over a lifetime.¹³² And some frameworks focus heavily on the impact a medicine has on healthcare budgets, not on the value it brings to individual patients, their families, or society.¹³³

Most importantly, value assessment frameworks need to measure value according to factors that truly matter to patients. These include improved quality of life, the ability to be productive at work, or the chance to remain independent for a longer period of time. These types of factors are not reflected in many of the current value frameworks.¹³⁴

Value assessment frameworks are still evolving, and developers should address these and other important limitations before they are widely adopted in healthcare decision making. Doing so will allow us to have more informed conversations about health system costs and the respective value of healthcare interventions, including medicines.^{135, 136}

Another consideration is that advances like personalized medicines and gene and cell therapies have the potential to dramatically reduce the burden of—and even cure—serious, life-altering, or life-threatening diseases. As these treatments become available, it is critical that evaluation of their clinical benefits and potential to offset costs over the long term remain independent of discussions about their immediate impact on the budgets of health systems. It is also important to strive to accelerate the access to these life-changing therapies as the FDA has done through approaches meant to make such medicines available as quickly as possible, such as Accelerated Approval.

We look forward to working with developers of value frameworks to improve their usefulness in healthcare decision-making and, importantly, to help ensure they reflect appropriate value principles.

Value Frameworks

Measuring and defining the value of medicines has been the subject of much discussion. In the U.S., several organizations have introduced frameworks and methodologies to assess the relative value of medicines.¹³¹ These approaches, or “value assessment frameworks,” can supply useful perspectives on the value of medicines. However, many of the current frameworks fail to include factors that are critical to fully assessing value. No single framework captures the complete range of factors that makes a medicine valuable.

Most of these frameworks consider important measures like how well the medicine works compared to other existing treatments and how much the medicine drives down more costly forms of healthcare spending. But some

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

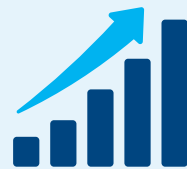
Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

REAL-WORLD VALUE AND EVIDENCE

To better understand and show the value our medicines bring to patients and the healthcare system, we generate clinical information on the use, risks, and benefits of a medicine derived from data on how a medicine is being used in the real world, outside of a clinical trial. Known as “real-world evidence” this data allows us to see how our medicines affect people in their everyday lives and gives us a more complete view of the safety and effectiveness of our medicines. Through real-world studies, we have shown that our medicines can:



Improve long-term health outcomes.

Patients taking our medicine for diabetes were less likely to stop taking the medicine as prescribed, to change to another medicine, or to need a second medicine in order to achieve the desired health outcome. This is important because adherence—taking a medicine as prescribed—can result in better long-term health outcomes.



Better manage side effects.

We found that patients who began treatment with one of our medicines for Crohn's disease were able to decrease use of the corticosteroids and opioids often prescribed to manage symptoms—treatments that come with significant side effects. By analyzing an anonymized database of health records of patients with Crohn's disease, we found that within eight weeks of being treated with one of our medicines, patients' use of opioids and steroids decreased.



Reduce costs to patients.

For patients with HIV, we know starting anti-retroviral therapy (ART) immediately after diagnosis leads to better health outcomes. What we didn't know was whether cost would prevent payers from adopting this clinical best practice. When we analyzed Medicaid databases in six states, we found that patients who started ART immediately had better health outcomes as well as lower costs for care. As it turned out, the best treatment was also the most economical.



Reduce costs to healthcare systems.

Patients taking one of our medicines for schizophrenia were hospitalized less frequently than patients taking different medications for the same serious mental illness. The reduced rate of hospitalizations produced savings of greater than \$8,500 per patient per year for the healthcare system that partnered with us on this research.¹³⁷



A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

**Innovative, Value-Based
Contracting Models**

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶



A Value-Based System

As we work to more clearly define and measure the value of our medicines, we are taking steps to advance a more results-based approach in three distinct ways: through the establishment of innovative contracting models, also known as value-based contracts; through partnerships that explore value-based care models; and through population health research that seeks to address quality and cost challenges in today's healthcare system.

FAST FACT

Janssen is advancing a more results-based approach through:



Innovative
Contracting Models



Value-Based
Partnerships



Population
Health Research

Innovative, Value-Based Contracting Models

An important part of the shift to a value-based system is innovation in the way contracts between payers and manufacturers are structured. By creating common incentives to deliver value for patients, innovative contracting models can provide better outcomes at lower costs.¹³⁸ They can take a variety of forms, including:

- **Contracts tied to measurable medical outcomes:** In this type of contract, the pharmaceutical company and payer agree on a measurable medical outcome that both parties are trying to achieve. The contract is based on achieving this shared goal, which would result in beneficial outcomes for the payer's patient population. If the medicine doesn't meet the goal, the pharmaceutical company will pay a rebate to the insurer.
- **Contracts to help insurers better predict costs:** Pharmaceutical companies might cover unexpected costs of providing a medicine to a patient. For example, if a patient needs a higher dose of a medicine than the average patient, the pharmaceutical company might agree to cover part of the cost of the additional medication. This type of arrangement allows insurers to better anticipate costs and manage risk over a large population of patients and, as a result, enables them to provide better access to that medicine.
- **Contracts tied to offsets of other healthcare expenditures:** The insurer provides better access to a medicine with the expectation the medicine will reduce the need for other costly healthcare interventions, such as surgeries, physician visits, and hospital stays. If such healthcare expenditures are reduced, the pharmaceutical company is paid more; if they increase, the pharmaceutical company agrees to provide more rebates.

We are enthusiastic about the potential for expanding the use of innovative value-based contracting models. Nevertheless, a number of technological and policy barriers can make these agreements challenging to implement. To address technological barriers, we advocate for modernizing our healthcare data system to make it easier to track patient outcomes. To address policy barriers, we support the following approaches: establishing safe harbors to better enable manufacturers to partner with payers and share risk; clarifying the treatment of value-based contracts in government price calculations, including in the complex Medicaid Best Price determination; and making comparative formulary and cost-sharing information readily available so patients have the information they need to make better decisions.

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Examples of Janssen's Value-Based Contracts

We have established several innovative, value-based contracts with insurers and continue to explore new opportunities. Here are some examples:

- **Immunology:** In 2018, Janssen partnered with payers to create an agreement in which the price of a medicine for chronic immune conditions varies based on how well it works for patients. Immune conditions often require long-term treatment with a medicine. The agreement measures how long patients who are newly treated with an immunology medicine stay on treatment. If they stop treatment, we return a portion of the cost of that treatment to the payer. In this case, treatment duration is being used in lieu of an outcomes-based measurement of efficacy.
- **Oncology:** We have partnered with public and private payers on novel contracts for patients with prostate cancer. In one contract, we agreed to provide additional rebates to the insurer for plan members who meet eligibility criteria and whose treatment duration is shorter than a predetermined period of time. Similar to the immunology example above, the insurer receives a price concession if the patient stops treatment.
- **Diabetes:** We have partnered with a leading payer on a contract under which we are paid more if data show our medicine that treats adults with type 2 diabetes contributed to lowering other identified healthcare costs, such as the use of additional medicines. If those costs increase, we pay additional rebates. We have also partnered with several payers on results-based contracts tied to clinical outcomes for that medicine. Under such agreements, we provide additional rebates if the agreed-upon health outcome is not achieved.

Value-Based Partnerships

Beyond value-based contracts with payers, we continue to participate in partnerships to explore value-based care models with others in the system. For example, we are pleased to support a multi-stakeholder effort established by Value Based Insurance Design (VBID) Health. This is an effort to identify, measure, and eliminate low-value healthcare services—defined as care that yields few benefits but comes with a high cost. Value-based insurance design bases patient out-of-pocket costs on the value of medical services, favoring the high-value care that provides important benefits (clinical or societal) relative to their cost. In other words, underused but high-value services have lower out-of-pocket costs, while overused but low-value services have higher out-of-pocket costs. Value-based insurance design has the potential to improve patient adherence to medicines and

lower costs. For example, the state of Connecticut implemented value-based insurance design for its employees who opted in, raising copays for low-value services like non-emergency visits to urgent care and eliminating them for routine doctor visits related to chronic conditions. It eliminated copays for diabetes medication and eliminated or lowered them for medications used to treat asthma, COPD, heart disease, hypertension, and hyperlipidemia. As a result, use of high-value services and adherence to medications for chronic conditions increased, and emergency room visits decreased.¹³⁹



A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

Population Health Research

We are also working to advance results-based healthcare at the population level. In an effort to contribute to the “Triple Aim” goals of improving patient care and population health while improving efficiency,¹⁴⁰ our Population Health Research team is engaged in a number of research partnerships with a variety of healthcare stakeholders to find evidence-based solutions to population health challenges. Here are some examples:

- **Hospital readmissions are a significant health system cost driver.** We collaborated with Sharp Healthcare to use real-world data to better understand how to proactively identify patients at higher risk for readmissions.
- **Costs to the healthcare system are also driven by hospital use and emergency room visits** that could have been prevented by lower-cost interventions and the early delivery of primary care. We are working with a large regional health system in northern California to understand “super-utilizers”—the 5-10 percent of high-need, high-cost patients who use a disproportionate number of healthcare services. These patients often have multiple chronic illnesses and complex psychological and social needs.^{141, 142} We are trying to understand how these patients are impacted by serious mental illness.¹⁴³ This research can help identify at-risk patients and inform the design of interventions that improve patient health.
- **Type 2 diabetes is a chronic and progressive disease.** Patients with type 2 diabetes often do not reach recommended HbA1c targets, a measure of diabetes control. In partnership with researchers at the University of Utah and SelectHealth, the insurance division of Intermountain Healthcare, we identified a broad set of patient factors associated with failure to achieve HbA1c goals. This analysis of real-world data will enable better identification of high-risk patients and help guide patient care and physician education.
- **We have entered into a research study with Apple Inc.** to investigate whether a new heart health program can accelerate the diagnosis of atrial fibrillation (AFib) and improve health outcomes for the approximately 33 million people living with the condition,¹⁴⁴ which can lead to stroke and other devastating complications. Using an app from Johnson & Johnson in combination with Apple Watch's irregular rhythm notifications as well as its ECG app, the study aims to analyze the impact of Apple Watch on the early detection and diagnosis of AFib. A multi-year research program will begin later in 2019. AFib is responsible for approximately 130,000 deaths and 750,000 hospitalizations every year in the U.S. alone.¹⁴⁵

We are also investing in improving population health and quality in the health system at large. We sponsored the National Committee for Quality Assurance's



(NCQA) Population Health Management Resource Guide,¹⁴⁶ a tool to support health plans in implementing best practices for achieving their population health management goals. The guide lays out five elements of a population health strategy that plans can use to improve the overall health of their members.

We are engaged in these efforts because we believe a more value-based healthcare system has tremendous potential to improve patient health, increase access to care, and curb the increase in healthcare spending. The transition to this value-based approach will require pharmaceutical companies, payers, providers, and policy makers to work together, and we will continue to look for ways to help lead in this effort. ■

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

CONTRIBUTING POLICY SOLUTIONS FOR A BETTER WAY

We have a long history of contributing policy ideas and working with policymakers on both sides of the aisle to find practical solutions that maintain what's distinctive about American healthcare: access to innovative therapies, personal choice, and doctors and patients making decisions based on what is right for each individual. Guided by the belief that policy solutions should first and foremost aim to improve healthcare for patients, we consider the following principles in evaluating and developing policy proposals:

- **Access.** Policies should support broad patient access to appropriate, affordable, and high-quality treatment options.
- **Choice.** Policies should safeguard the physician-patient relationship and keep treatment decisions in the hands of patients and their healthcare professionals; and clinically stable patients should not be switched to other therapies for non-medical reasons.
- **Patient Safety.** Policies should ensure patient safety by applying consistently rigorous clinical and manufacturing quality standards.
- **Sustainability.** Policies should lower overall costs to the system while sustaining a biomedical research ecosystem that continues to deliver transformative medical advances.

When the government asks for ideas about how to improve the healthcare system, we share our perspective and provide practical solutions based on the principles above. Amid the current conversation about healthcare spending in the U.S., the Administration has issued calls for ideas to reduce medicine prices. We have actively responded with solutions. Below are examples of the solutions we've offered in the specific policy areas the Administration is focused on:

Reducing Patient and Program Costs in Medicare Part B

The Administration has sought policy ideas to reduce costs in Medicare Part B while minimizing disruption to the supply chain and eliminating potential financial incentives for high-cost drugs.

In response, we crafted a policy solution to address these incentives while maintaining patient access to appropriate treatments. Under our



model—participation in which would be voluntary—Medicare would reduce Part B acquisition costs and reimburse all stakeholders for the value of the services they provide. Our solution leverages the benefits of the existing ASP mechanism, which captures the savings of open competition and should continue to play a role in any reform.

Critically, any Part B reform must also maintain the levels of access and innovation that are crucial for patients today and in the future. Part B covers medicines that treat diseases that are often irreversible, progressively damaging, or life-threatening. At the same time, innovations in development promise treatments for diseases once thought beyond cure. Access to all current and future Part B medicines is therefore paramount, as is fostering conditions that support continued medical advances.

Continued on next page ▶

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

ADVANCING A BETTER WAY

Assessing the Value of
Our Medicines

Value Frameworks

Real World Value and Evidence

A Value-Based System

Innovative, Value-Based
Contracting Models

Examples of Janssen's
Value-Based Contracts

Value-Based Partnerships

Population Health Research

Contributing Policy Solutions
for A Better Way

Resources
for Patients ▶

References ▶

CONTRIBUTING POLICY SOLUTIONS FOR A BETTER WAY

Capping Patient Out-of-Pocket Costs in Medicare Part D

While Medicare Part D is working for many seniors and has been effective in containing costs, we believe a cap on patient out-of-pocket costs in Medicare Part D is a needed protection. Without a cap, Medicare beneficiaries face unlimited out-of-pocket expenses, and, as research shows, high out-of-pocket costs reduce patient adherence to prescribed treatments and make them more likely to abandon their prescriptions.¹⁴⁷ Poor patient outcomes related to lack of adherence or abandonment of prescribed treatments can lead to an increase in overall healthcare costs.¹⁴⁸

Individual and group health insurance policies are already required to have out-of-pocket caps. Medicare, which serves some of the sickest and most vulnerable patients, should also have that protection. We support policy approaches that would make it possible to implement an out-of-pocket cap in a fiscally responsible way without creating new costs or access barriers for patients.

Rebate Reforms

Too often the rebates and discounts pharmaceutical manufacturers negotiate are not directly shared with the patients who use the medicines for which they are provided, leaving the sickest patients paying higher out-of-pocket costs to subsidize those who are healthier. This is not how health insurance is supposed to work. A competitive marketplace should deliver lower out-of-pocket costs to patients. To ensure it does, we support reforms to the system of incentives currently in the supply chain.

We anticipate eliminating rebates could result in lower list prices, provided these rebates and discounts are not replaced with equally high fees or other payments. As reforms take shape, we also strongly advocate that beneficiary copays be based on the final price payers receive from manufacturers.

Altering the current rebate structure would be a major change to the entire pharmaceutical supply chain. In order to minimize disruption for patients, any change should be implemented thoughtfully. We look forward to providing ongoing feedback should the Administration put these changes into effect.

Transparency in Direct-to-Consumer (DTC) Advertising

Consumers deserve to better understand what they can expect to pay out-of-pocket for their medicines. When including list price information in DTC TV ads was proposed in the American Patients First blueprint, we embraced the challenge to think about what additional transparency around medicine costs would benefit patients. After listening to



patients and consumers, we are introducing a common-sense approach to share meaningful and relevant information about medicine costs. We will begin to voluntarily include the list price and typical patient out-of-pocket costs in our U.S. pharmaceutical TV advertising, starting with our most frequently prescribed medicine, XARELTO®. This approach builds on our legacy of leadership in transparency and on our commitment to the PhRMA DTC Advertising Principles. (For more about our DTC advertising, please see the [“Pricing & Patient Costs”](#) chapter.)

We stand ready to continue to offer solutions to the Administration and other stakeholders as the conversation continues about how to reduce healthcare costs while improving the quality and efficiency of care for patients.



A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

RESOURCES FOR PATIENTS

Janssen CarePath

Independent Program
and Foundation Support

Other Patient Programs and
Resources We Support

Requests for Access to
Medicines in Development

References ▶

RESOURCES FOR PATIENTS

PATIENTS SHOULD HAVE AFFORDABLE ACCESS TO MEDICINES.

In the previous chapter, we discussed how we negotiate with insurers to support the availability of our medicines. We also help patients obtain appropriate access to our medicines, because we know that insurance coverage can be complicated and finding financial assistance can be challenging.

In this chapter, we describe the resources we provide to patients, caregivers, and healthcare providers through our Janssen CarePath program. We also include information about our support for charitable organizations and foundations that help patients get the medicines they need.

While we recognize these programs are not a long-term solution for all patients, they are one way we strive to meet the needs of the patients we serve and the healthcare professionals who care for them.

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

RESOURCES FOR PATIENTS

Janssen CarePath

Independent Program
and Foundation Support

Other Patient Programs and
Resources We Support

Requests for Access to
Medicines in Development

References ▶

Janssen CarePath

Even with health insurance, some patients face high prescription medication out-of-pocket expenses. Others are limited in the types of medicines they can access due to medication management measures like prior authorization and step therapy. (See [“Utilization Management and Cost Containment Tools”](#) in the [“Pricing and Patient Costs”](#) chapter for more information.) For patients facing these challenges, we’ve created some tools to help.

Janssen CarePath provides access, affordability, and treatment support resources to help patients get started on, and stay on, the Janssen medications their healthcare providers prescribe. Janssen CarePath Care Coordinators offer various forms of patient access support: they answer questions about insurance coverage for Janssen medications and potential patient out-of-pocket costs; locate nearby treatment centers for certain medications; provide resources to help patients take the Janssen medications as prescribed; and, if needed, identify options that may help make the medications more affordable. These resources are available for patients who are prescribed Janssen products in the following therapeutic areas: cardiovascular and diabetes, dermatology, gastroenterology, infectious diseases, neuroscience, oncology, and rheumatology.

For commercially insured patients who meet the program requirements, we also offer our Janssen CarePath Savings Programs to reduce patient out-of-pocket medication costs. Such programs—sometimes referred to as “copay cards” or “copay coupons”—are an important tool for helping patients gain access to the medicines prescribed by their healthcare provider. Copay coupons continue to play a critical role in making out-of-pocket costs more manageable for patients.¹⁴⁹

Janssen CarePath also helps healthcare providers focus their time on treating patients. For healthcare providers, navigating complex insurance benefits adds to their administrative burden. According to a survey by the American Medical Association, physicians and staff spend more than 16 hours a week seeking pre-approval from insurers to prescribe medicines—also known as prior authorization—from insurers, with 75 percent of physicians saying requests impose a “high” or “extremely high” burden.¹⁵⁰ Janssen CarePath helps by verifying patients’ health insurance benefits to make sure providers are familiar with their patients’ coverage for Janssen medicines and any requisite prior authorization, step therapy, or other payer policies.

In 2018, we helped approximately 1 million patients through the Janssen CarePath program.¹⁵¹ This includes approximately 550,000 commercially insured patients who reduced their out-of-pocket expenditures through the Janssen CarePath Savings Program.¹⁵²



WHY WE CAN'T OFFER COPAY CARDS TO SENIORS

The Social Security Act restricts the kinds of benefits pharmaceutical manufacturers can provide patients enrolled in federal and state-subsidized healthcare programs, including Medicare. Savings card programs are one such restriction. As a result, only patients who are privately and commercially insured are eligible for pharmaceutical savings cards.

While we can't help seniors through savings program cards, we contribute to foundations and independent charitable organizations that can assist seniors with medication-related copays. (See more information on our charitable contributions later in this chapter.)

In addition, Medicare patients may be eligible for one or more programs not affiliated with Janssen, such as the Medicare Savings Program, Medicare Extra Help (Part D), and state-sponsored programs. More information is available at [medicare.gov](https://www.medicare.gov).

A Message from
Our Leaders ▶

Our
Investments ▶

Pricing &
Patient Costs ▶

Advancing a
Better Way ▶

RESOURCES FOR PATIENTS

Janssen CarePath

**Independent Program
and Foundation Support**

**Other Patient Programs and
Resources We Support**

Requests for Access to
Medicines in Development

References ▶



MEET OUR JANSSEN CAREPATH COLLEAGUE



GINA GIORDANO

Director of Patient Access Solutions
for Oncology

MANY PATIENTS FACE HIGH OUT-OF-POCKET costs and understanding their health insurance coverage for medicines can sometimes be difficult. As mothers, fathers, caregivers, and patients ourselves,

we understand the challenges our patients may face, and we're poised to listen and to provide the best experience we can.

Gina Giordano helps patients who have been prescribed Janssen medicines start and stay on their medicine. Her goal is to empower patients to take their medication as their healthcare provider prescribed.

"Many patients face high out-of-pocket costs and understanding their health insurance coverage for medicines can be difficult," said Giordano. "As mothers, fathers, caregivers, and patients ourselves, we understand the challenges our patients may face, and we're poised to listen and to provide the best experience we can."

Janssen created a one-stop shop for patients called Janssen CarePath. The dedicated Care Coordinators try to simplify the process by showing patients the programs that are most likely to help, given the patient's coverage and financial situation. For example, commercially insured patients may be able to use the Janssen CarePath Savings Program to help reduce their out-of-pocket costs for Janssen medications. The program also offers resources and information to patients that help them understand their condition and take their medications as their physician has prescribed, including treatment reminders and information on where infusion centers are located.

To learn more, please visit janssencarepath.com or call 1-877-CarePath.

Independent Program and Foundation Support

We also support independent programs and foundations that help patients in the U.S.:

- **We donate medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc.**, an independent, nonprofit organization that is committed to helping eligible patients without insurance coverage receive prescription products donated by Johnson & Johnson operating companies. More information about the Johnson & Johnson Patient Assistance Foundation is available at jjpaf.org or by calling 1-800-652-6227.

In 2018, we donated approximately \$1 billion¹⁵³ in free product and financial support to the Johnson & Johnson Patient Assistance Foundation, enabling the Foundation to provide medicines at no cost to approximately 76,000 patients.¹⁵⁴

- **We also make financial donations to independent charitable foundations** that assist underinsured and financially needy patients with treatment-related expenses.

In 2018, we donated approximately \$200 million to independent charitable foundations,¹⁵⁵ enabling them to assist an estimated 30,000 patients with medication-related copays for any physician-prescribed medicines that treat certain diseases covered by the foundations.¹⁵⁶

Other Patient Programs and Resources We Support

In addition to the programs described above, patients and providers should be aware of the many other resources available to help patients access medicines. Some include:

The Partnership for Prescription Assistance (PPA): This organization helps patients who are uninsured or underinsured access the medicines they need through a program that is right for them. Since 2005, PPA has helped more than 10 million people get their prescriptions for free or nearly free.¹⁵⁷ Visit pparx.org to find out whether PPA can help you or someone you know.

Healthcare Ready: Through collaboration between the public health and private sectors, Healthcare Ready helps address pressing health issues before, during, and after major natural disasters. Visit healthcareready.org to learn about the resources that may be available to help those affected by hurricanes and other natural disasters. ■

RESOURCES FOR PATIENTS

Janssen CarePath

Independent Program
and Foundation Support

Other Patient Programs and
Resources We Support

[Requests for Access to
Medicines in Development](#)

REQUESTS FOR ACCESS TO MEDICINES IN DEVELOPMENT

Pre-approval Access Programs (also known as Expanded Access or Compassionate Use)

Pre-approval access (PAA) is the overarching term used at Johnson & Johnson for access to an investigational medicine outside of a clinical trial and prior to health authority approval. The main pathway for gaining access to Janssen's investigational medicines is for a patient to enroll in a clinical trial.

For patients with serious or life-threatening illnesses who cannot enroll in clinical trials, pre-approval access programs, such as "expanded access" programs and "named patient" programs for multiple patients, or "single-patient access" requests for individual patients, can be considered.

Our policy for considering pre-approval access to investigational medicines is grounded in key ethical principles, including:

1. All requests for pre-approval access are considered in a fair and just manner;
2. Sufficient understanding of the potential benefits and risks of the investigational medicine has been established through the conduct of a rigorously designed, scientifically and medically sound clinical trial program;
3. Patients are not put at risk of unnecessary harm;
4. Fulfillment of pre-approval access will not jeopardize the clinical trial program that may lead to broader public access through marketing authorization; and
5. Fulfillment of pre-approval access fully complies with applicable laws and regulations.

We typically consider making pre-approval access available when our clinical studies are complete, or sufficient scientific evidence is available to inform careful review of requests prior to health authority approval.

The list of agents available for evaluation in the pre-approval setting for the Janssen Pharmaceutical Companies of Johnson & Johnson can be found at clinicaltrials.gov. For more information on our pre-approval access program and policy, please visit janssen.com/compassionate-use-pre-approval-access.

The Compassionate Use Advisory Committee (CompAC)

The Compassionate Use Advisory Committee, or CompAC, is a group of global external advisors that provide a fair, ethical evaluation of our plans to consider and support potential pre-approval access requests, including "single patient access" requests. Developed in collaboration with New York University Langone Health, CompAC facilitates the review of compassionate use requests by an independent, external body of internationally recognized medical experts, bioethicists, and patient representatives. After a successful pilot that began in 2015, CompAC was expanded to include additional investigational medicines in development at Janssen.

For each single-patient (compassionate use) request, our physicians conduct an initial review to identify patients who may be immediately eligible for a clinical trial or "expanded access" and "named patient" program, and they direct those requests accordingly. If a patient has exhausted all available treatment options and does not qualify for any established clinical trial or pre-approval access program, the request will be assessed internally according to pre-established criteria which have been approved by CompAC. Some cases may also be forwarded to CompAC based on these pre-established criteria. CompAC evaluates such requests and provides a recommendation to Janssen. A Janssen physician makes the final decision on patient access for all compassionate use requests.

In 2018, Janssen provided access to 717 patients via single-patient request and named patient programs.¹⁵⁸

How to Get More Information

The best and fastest way to get more information on how to access Janssen investigational medicines, or to submit a request for access is for the patient's physician to call 1-800-JANSSEN or email janssenmedinfo@its.jnj.com. For information about how we process requests, please visit janssen.com/compassionate-use-pre-approval-access.



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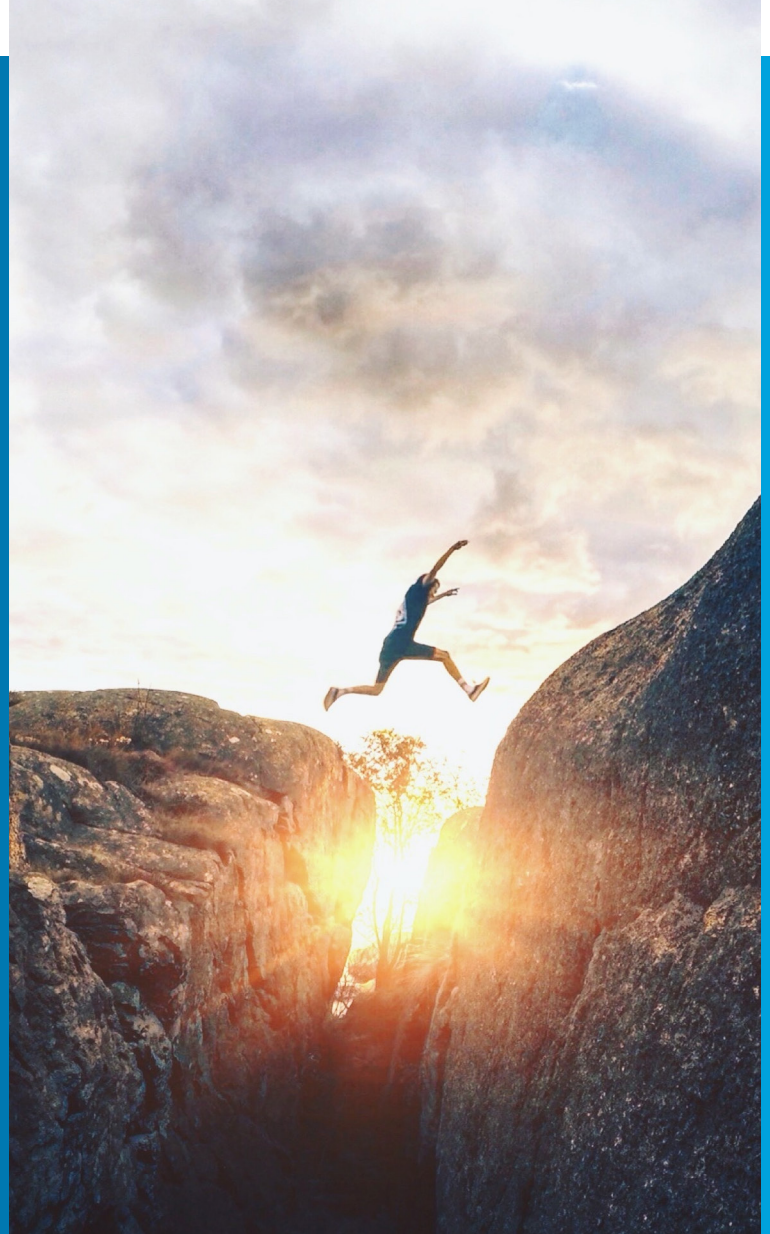
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154. Data is an approximate number as reported by the Johnson & Johnson Patient Assistance Foundation, Inc.
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