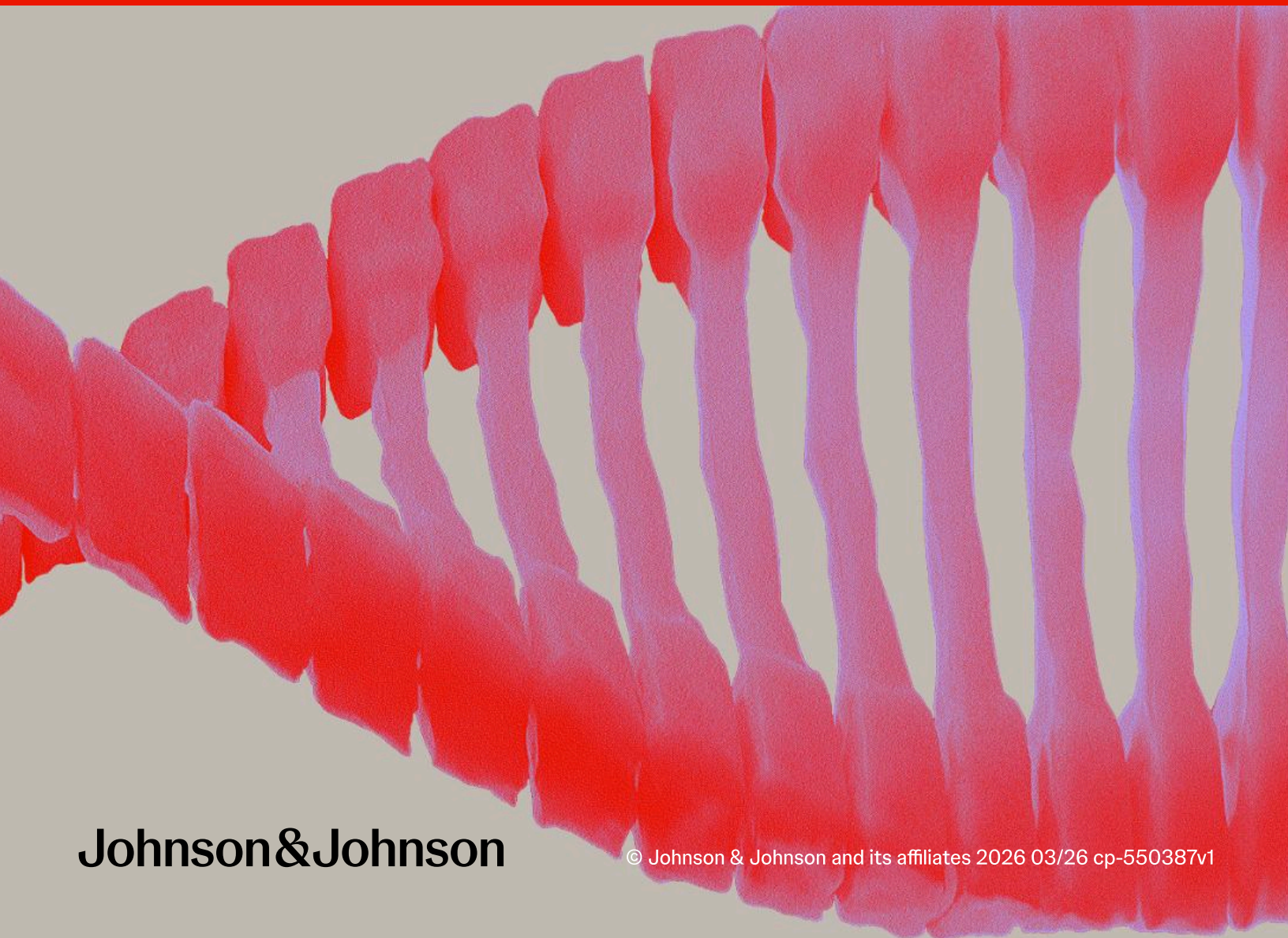
The value of medicines in the U.S.

Johnson & Johnson Issue Brief



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At a glance:

The value of medicines in the U.S.

A core principle of the U.S. healthcare system is that treatment decisions should be made through shared decision-making between patients and physicians.[1] This decision is informed by an individual's medical history, disease state and personal preferences and is influenced by the patient's insurance benefit design.[2]

The American approach to valuing medicines should reflect the diverse, decentralized U.S. system — a system that supports treatment decisions that fit the unique needs of each patient.

The flaws of one-size-fits-all value assessments

Some argue the U.S. should adopt top-down value assessment models used in some parts of the world with inherent flaws, including:

Strict decision rules relying upon **arbitrary predetermined thresholds**.[3]

Oversimplified metrics that embed discriminatory assumptions.[4]

Focus on a **hypothetical "average" patient**, not real patients with real needs.[5]

When the U.S. system works: a patient-centered approach to valuing medicines

The U.S. system is driven by a market-based approach to understanding the value of medicines that supports strong incentives for biopharmaceutical innovation and investments.[6] As a result, American patients benefit from the earliest availability and access to the broadest, most innovative set of therapies in the world, enabling patients to find treatments that work for them.[7]

Earliest availability of novel medicines

68%

25 of the 37 drugs the U.S. Food and Drug Administration (FDA) approved in 2022 (68%) were approved in the U.S. before any other country.[8]

Shorter wait times

2.5 years

In Canada from 2018–2022, publicly insured patients waited 2.5 years longer than Americans with Medicare for access to newly approved drugs.[9]

More treatment options

78%

78% of drugs launched by G20 nations from 2012–2021 were available in the U.S. within one year of launch, vs 38% in the U.K. and 21% in Canada.[7]

Value in healthcare is influenced by many factors, but assessments often overlook or underrepresent important drivers.[10, 11]

Some examples of the broader drivers include:[10, 11]

- The possibility for **scientific spillover** where medical innovations spark future research.
- Intangible but meaningful benefits like the **value of hope.**
- Allowing patients to return to normal life and **productivity**, reducing economic burden.
- The **severity of the disease** or condition being treated.

J&J supports valuations of medicines that adhere to the following principles:[12]

- **Patient-centered:** Focused on individual autonomy and outcomes.
- **Holistic:** Considers the full impact on patients, the healthcare system and society.
- **Deliberative and flexible:** Avoiding strict decision rules or oversimplified metrics.
- **Decentralized and locally relevant:** Reflective of local communities' specific needs.
- **Clinically driven:** Aimed at maximizing the health of every patient.

Overview

A core principle of the U.S. healthcare system is that treatment decisions should be made through shared decision-making between patients and physicians.[1] This decision is informed by an individual's medical history, disease state and personal preferences and is influenced by the patient's insurance benefit design.[2] The American approach to valuing medicines should reflect the diverse, decentralized U.S. system — a system that supports treatment decisions that fit the unique needs of each patient.

However, top-down methods and frameworks to determine value are increasingly being considered for use in the U.S.[13] For example, some countries with different systems and preferences than the U.S. rely on predetermined arbitrary monetary thresholds to determine a medicine's value.[3] If top-down value assessment models were applied to treatments for multiple myeloma, multiple sclerosis, and non-small cell lung cancer in Medicare Part B, many patients could be forced to switch from therapies that are currently working for them.[14] These one-size-fits-all approaches risk undervaluing medicines, fail to reflect patient and provider choice and ultimately undermine access and innovation.[5]

Part 1:

Putting patient values first

Every patient is unique. Their medical history, preferences and circumstances shape what treatments are best for them. In the U.S., valuations must be clinically nuanced and patient-centric to enable each individual to obtain the therapy that they and their doctor determine is best.

Ideally, assessments of value would support evidence-based, patient-centered decision-making about treatment choices. However, they often do not consider all elements of value, and are not sufficiently nuanced to capture the unmet needs and preferences of individual patients. If decision-makers consider this incomplete and misleading information, patients could be prevented from accessing the care that they need.

The flaws of one-size-fits-all value assessments

Some argue the U.S. should adopt top-down value assessment models used in some parts of the world with inherent flaws, including:

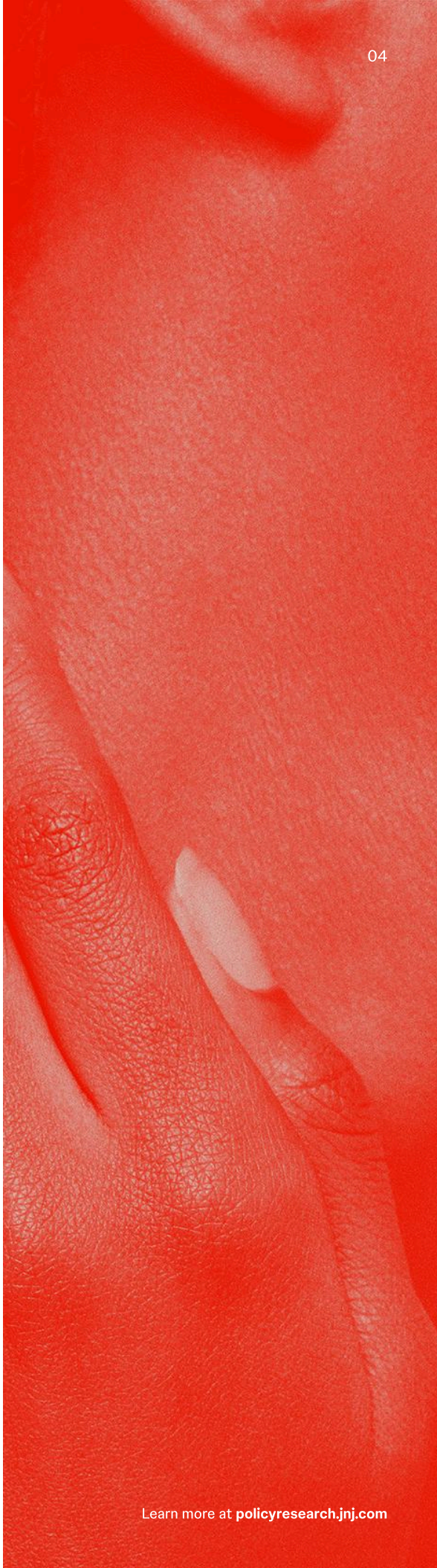
Strict decision rules relying upon arbitrary predetermined thresholds.[3]

Oversimplified metrics that embed discriminatory assumptions.[4]

Focus on a hypothetical "average" patient, not real patients with real needs.[5]

Too often, value assessment models fail to account for the unique needs of individual patients. These impersonal models can cause medicines to be excluded from coverage for entire populations, even if those medicines would help specific patients within those populations.[5]

Evidence from Europe illustrates how rigid, threshold-driven health technology assessment (HTA) frameworks can limit or delay access to innovative cancer therapies.[15] Similar issues are observed in Canada, where a complex and sequential HTA and reimbursement process frequently delays the availability of new oncology treatments compared with peer countries.[16]



Part 2:

When the U.S. system works: A patient-centered approach to valuing medicines

A national survey of practicing U.S. physicians found that pharmaceutical and biopharmaceutical innovations were considered the single largest driver of improved patient outcomes, accounting for over half (56%) of post-diagnosis health gains in diseases like breast cancer, HIV, diabetes and lung cancer between 1990 and 2015.[17] During this period, overall U.S. life expectancy increased by 3.3 years.[18] In a study estimating the factors contributing to this change between 1990 and 2015, pharmaceuticals were found to be the second-largest contributor, behind only public health improvements like reduced smoking and better vehicle safety.[18]

Delivering positive health outcomes can depend on timely and broad access to innovative therapies, an area where the U.S. system consistently outperforms other countries.[7] The U.S. system is driven by a market-based approach to understanding the value of medicines that supports strong incentives for biopharmaceutical innovation and investments.[6] As a result, American patients benefit from the earliest availability and access to the broadest, most innovative set of therapies in the world, enabling patients to find treatments that work for them.[7]

The U.S. advantage at a glance

- ☑ **A greater share of drugs is approved in the U.S.:** 25 of the 37 novel drugs the U.S. Food and Drug Administration approved in 2022 (68%) were approved in the U.S. before any other country.[8]
- ☑ **Longer wait times abroad:** From 2018-2022, publicly insured patients in Canada waited an average of 2.5 years longer than Americans with Medicare for access to newly approved drugs.[9]
- ☑ **Broader treatment options:** 78% of drugs launched by G20 nations between 2012 and 2021 were available in the U.S. within one year of their launch, compared to just 38% in the United Kingdom and 21% in Canada.[7]
- ☑ **U.S. cancer patients have more treatment options:** Of the 124 new cancer medicines approved globally from 2012 to 2021, American patients have access to 94% of these treatments, compared to the average of 46% in other G20 countries.[7]

The strength of the U.S. innovation ecosystem can be seen in the impact therapies have on patients.[19] Innovative medicines can provide value in many ways by extending lives, improving quality of life and reducing the burden on patients, their caregivers and the healthcare system.[18, 20, 21, 22, 23]

How medicines add value in many forms

Recognizing the importance of innovation when evaluating the value of new therapies is essential to understanding their full benefits. Innovative medicines can deliver improvements that extend beyond clinical outcomes, improving standards of care, enhancing patient quality of life and increasing healthcare system efficiency. [6, 20, 23, 24]

Long-acting injectable antipsychotics

Real-world data has shown that for adults with schizophrenia, treatment with long-acting injectables was associated with improved adherence and reduced hospitalizations compared with oral therapies.[21]

Development in oncology care

Real-world U.S. evidence suggests some innovative oncology treatments create additional value by "bridging" patients to later breakthroughs—helping more patients live long enough to benefit from subsequent innovations—an effect known as "real option value" and not captured in traditional value assessments.[25]

Multiple drivers of value in healthcare

Value in healthcare is influenced by many factors, but assessments often overlook or underrepresent important drivers.[10, 11]

Recognizing and incorporating broader drivers is essential to capturing the full spectrum of value to patients and society. Some examples include:[10, 11]

Scientific spillover

Medical innovations often lead to knowledge gains that benefit future research and treatment development.

Value of hope

Some treatments offer intangible but meaningful benefits, such as giving patients hope for longer survival or a future cure.

Productivity

Effective treatments can improve patients' ability to perform their daily tasks, reducing societal and economic burden.

Severity of disease

Treatments for more serious or life-threatening conditions tend to offer greater relative value due to the high burden they alleviate.

Assessments of value should also consider how treatments impact society outside of healthcare: for example, by increasing labor force participation and thereby economic growth.[26]

Part 3:

The path forward for value and access

Adopting one-size-fits-all value assessment models for decision-making in the U.S. risks undermining the benefits of a patient-centric approach to innovation.

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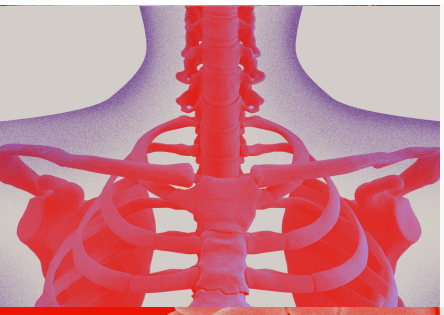
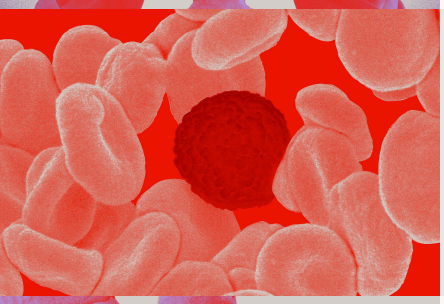


Patient-centered

A patient-centered approach is fundamental to achieving the most efficient and effective use of medicines and ensuring that access to treatment is nondiscriminatory. Without such an approach, providers may direct patients toward treatments that are inefficient and ineffective, resulting in wasted resources for the patient, provider and healthcare system. This approach respects patient autonomy by placing every patient's outcome at the forefront of decision-making.

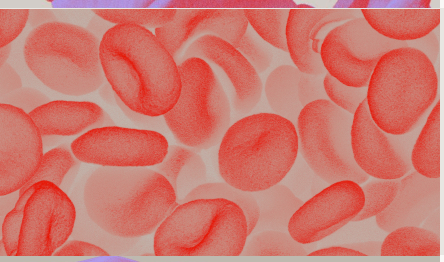


Holistic

Valuations must not rely on information from a small set of simple summary statistics, such as average life expectancy and average cost, but instead consider the full range of impacts to patients, the healthcare system and society. Valuations that are incomplete will distort the marketplace, resulting in both today's and tomorrow's patients receiving suboptimal care.

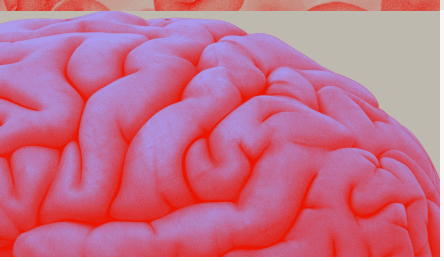
Deliberative and flexible

Using a deliberative decision-making process is critical, as is avoiding the use of strict rules or oversimplified metrics, such as discriminatory quality-adjusted life year (QALY), expected value of life years gained (evLYG) or healthy years in total (HYT). Instead, the full diversity of healthcare values must be considered, prioritizing those of patients.



Decentralized and locally relevant

Valuations must consider the specific needs of local health systems and local patients. Treatment needs in rural areas or underserved communities, for instance, may differ significantly from treatment needs in metropolitan areas or communities that are adequately resourced.



Clinically driven

Clinically driven valuations best preserve the opportunity to maximize the health of every patient. Financing of medicines should be considered separately and addressed through insurance solutions.

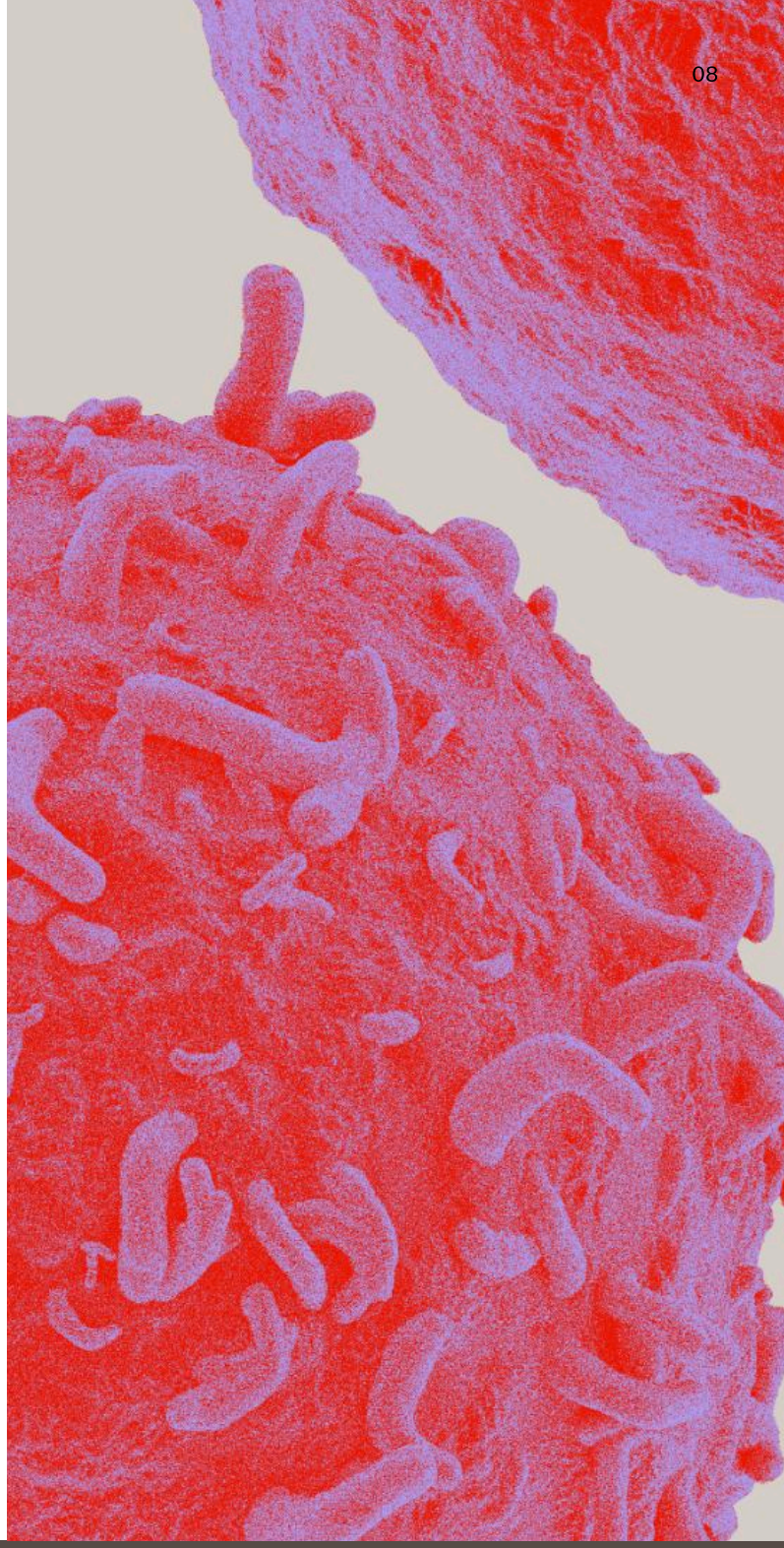
Policies to improve the U.S. healthcare system

Although the U.S. system supports patient-centered decision-making, opportunities for reform remain. Policymakers should support patients by:

01 Increasing transparency in the drug supply chain, including PBM reforms to bolster patient access and lower patient costs.

02 Ensuring that patient cost sharing is based on net prices and that cost-sharing assistance is counted toward patient out-of-pocket contributions.

03 Eliminating the ability of large health systems and for-profit middlemen to continue profiting from the 340B Drug Pricing Program while vulnerable patients are left behind.



The bottom line:

Johnson & Johnson supports value assessment that is patient-centered, locally relevant, deliberative, flexible, holistic and clinically driven. To make good decisions and avoid discrimination, it is important to look at all aspects of value and how different patients might be affected. Undervaluing medicines will not address access issues for today's patients. Instead, it can distort the innovation ecosystem needed to develop the treatments of tomorrow.

Citations

1. Daniel D. Matlock, Larry R. Jackson II, Amneet Sandhu, and Laura D. Scherer. “Past, Present, and Future of Shared Decision-Making.” *American Heart Association Journals*. July 2024.DOI: 10.1161/CIRCOUTCOMES.124.010584. Accessed January 2026.
2. U.S. Preventive Services Task Force. “Collaboration and Shared Decision-Making Between Patients and Clinicians in Preventive Health Care Decisions and US Preventive Services Task Force Recommendations.” *JAMA*. 2022 Mar 22;327(12):1171-1176. DOI: 10.1001/jama.2022.3267. Accessed October 2025.
3. Ruth Schwarzer, Ursula Rochau, et. al. “Systematic overview of cost-effectiveness thresholds in ten countries across four continents.” *Journal of Comparative Effectiveness Research*. October 22, 2015. DOI: 10.2217/cer.15.38. Accessed January 2026.
4. Alexa C. Klimchak, Lauren E. Sedita, Eleanor M. Perfetto, Katherine L. Gooch, and Daniel C. Malone. “Discriminatory Properties of the Quality-Adjusted Life Year Based Cost-Effectiveness Analyses for Patients With Disabilities: A Duchenne Muscular Dystrophy Case Study.” *Value in Health Journal.* 2024 Dec;27(12):1641-1647. DOI: 10.1016/j.jval.2024.07.008. Accessed October 2025.
5. Michael S. Willis, Andreas Nilsson, and Cheryl A. Neslusan. “A Review of Heterogeneity in Comparative Economic Analysis, with Specific Considerations for the Decentralized US Setting and Patient-Centered Care.” *PharmacoEconomics*. Published online March 8, 2025. 2025;43:601–616. DOI: 10.1007/s40273-025-01478-z. Accessed October 2025.
6. Stephen Ezell and Kelli Zhao. “The Economics of BioPharmaceutical Innovation: Symposium Report.” Information Technology & Innovation Foundation. March 2023. https://www2.itif.org/2023-biopharma-economics.pdf. Accessed January 2026.
7. PhRMA. “Global Access to New Medicines Report.” April 2023. https://cdn.aglty.io/phrma/global/resources/import/pdfs/2023-04-20%20PhRMA%20Global%20Access%20to%20New%20Medicines%20Report%20FINAL-1.pdf. Accessed October 2025.
8. U.S. Food and Drug Administration. “New Drug Therapy Approvals 2022.” Updated January 10, 2023. https://www.fda.gov/drugs/novel-drug-approvals-fda/new-drug-therapy-approvals-2022. Accessed October 2025.
9. Brett Skinner. “Waiting for new medicines in Canada, Europe, and the United States 2018-2023.” *Canadian Health Policy.* Updated April 2024. DOI: 10.54194/QQVC3893. Accessed October 2025.
10. Peter J. Neumann, Louis P. Garrison, and Richard J. Wilke. “The History and Future of the “ISPOR Value Flower”: Addressing Limitations of Conventional Cost-Effectiveness Analysis.” *PubMed Central.* 2022 Apr;25(4):558-565. DOI: 10.1016/j.jval.2022.01.010. Accessed October 2025.
11. Jason Shafrin, Jaehong Kim, et al. “Valuing the Societal Impact of Medicines and Other Health Technologies: A User Guide to Current Best Practices.” *Forum Health Economics Policy*. November 15. DOI: 10.1515/fhep-2024-0014. Accessed February 2026.
12. Johnson & Johnson Innovative Medicine. “2023 Johnson & Johnson Innovative Medicine U.S. pricing transparency report.” October 2024. https://policyresearch.jnj.com/download/2023-johnson-johnson-innovative-medicine-u-s-pricing-transparency-report-11-26-24-copy-pdf. Accessed October 2025.
13. World Health Organization. “Institutionalization of Health Technology Assessment.” June 2001. https://iris.who.int/server/api/core/bitstreams/fa9c5b5d-b434-44dd-89e2-1f8b578334b6/content. Accessed January 2026.
14. Cencora. “Government Reliance on Value Assessments in Medicare Part B: Implications for Access for Medicare Beneficiaries.” March 2024. https://biopharmaservices.amerisourcebergen.com/icer-brief-government-reliance-medicare. Accessed October 2025.
15. Lukasz Kaczyński, Beata Serafin, Patrycja Prząda-Machno, and Marcin Kaczor. “Is the cost-effectiveness threshold cost-effective in cancer therapy?” *Journal of Health Policy & Outcomes Research*. Published December 31, 2015. DOI: 10.7365. Accessed November 2025.
16. Sandeep Sehdev, Joanna Gotfrit, Martine Elias, and Barry D. Stein. “Impact of Systemic Delays for Patient Access to Oncology Drugs on Clinical, Economic, and Quality of Life Outcomes in Canada: A Call to Action.” *PubMed Central*. 2024 Mar 11;31(3):1460-1469. DOI: 10.3390/curroncol31030110. Accessed October 2025.
17. David Wamble, Michael Ciarametaro, and Robert DuBois. “The Effect of Medical Technology Innovations on Patient Outcomes, 1990-2015: Results of a Physician Survey.” *J Manag Care Spec Pharm*. 2019 Jan;25(1):10.18553/jmcp.2018.18083. DOI: 10.18553/jmcp.2018.18083. Accessed November 2025.
18. Jason Buxbaum, Michael Chernew, A Mark Fendrick, and David Cutler. “Contributions of Public Health, Pharmaceuticals, And other Medical Care to US Life Expectancy Changes, 1990-2015.” *Health Affairs*. 2020 Sep;39(9):1546-1556. DOI: 10.1377/hlthaff.2020.00284. Accessed January 2026.
19. IQVIA. “America's Greatness in the Biopharmaceutical Sector." May 2025. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/americas-greatness-in-the-biopharmaceutical-sector/iqvia-institute-greatness-in-biopharma-2025-web.pdf. Accessed February 2026.
20. Abdimutalib Mamasaidov, Kyazbek Sakibaev, et. al. “Impact of Biological Therapies on Quality of Life in Rheumatoid Arthritis: A Narrative Review.” *Open Access Rheumatology: Research and Reviews*. 2025 Apr 23;17:73–86. DOI: 10.2147/OARRR.S523778. Accessed April 2026.
21. Dee Lin, Philippe Thompson-Leduc, et al. “Real-world evidence of the clinical and economic impact of long-acting injectable versus oral antipsychotics among patients with schizophrenia in the United States: a systematic review and meta-analysis.” *CNS Drugs*. 2021;35(8):923. DOI: 10.1007/s40263-021-00850-9. Accessed March 2026.
22. Srihari Gopal, Haiyan Xu, et. al. “Caregiver burden in schizophrenia following paliperidone palmitate long acting injectables treatment: pooled analysis of two double-blind randomized phase three studies.” *Schizophrenia*. July 27, 2017. DOI: 10.1038/s41537-017-0025-5. Accessed April 2026.
23. Christopher Roebuck. “Impact of Direct-Acting Antiviral Use for Chronic Hepatitis C on Health Care Costs in Medicaid: Economic Model Update.” *The American Journal of Managed Care*. 2022;28(12):630-631. DOI: 10.37765/ajmc.2022.89273. Accessed April 2026.
24. Donald C Moore and Andrew S Gvuinigundo. “Revolutionizing Cancer Treatment: Harnessing the Power of Biomarkers to Improve Patient Outcomes.” *Journal of the Advanced Practitioner in Oncology*. 2023 Apr 1;14(Suppl 1):4–8. DOI: 10.6004/jadpro.2023.14.3.15. Accessed April 2026.
25. William Wong, Tu My To, et. al. “Real-world evidence for option value in metastatic melanoma.” *Journal of Managed Care & Specialty Pharmacy.* August 25, 2021. DOI: 10.18553/jmcp.2021.21192. Accessed March 2026.
26. Janet Currie and Brigitte Madrian. “Health, Health Insurance and the Labor Market.” In: Ashenfelter O, Card D, eds. *Handbook of Labor Economics*. Vol 3. Elsevier Science B.V.; 1999:3309–3416. Accessed February 2026.