PRICENTRIC ONE
BY EVERSANA™

INSIGHTS Newsletter

Issue 24 | April 2021

Pricentric INSIGHT: NICE's 5-year Strategy Focuses on "Flexible" and "Innovative" Methods

The strategy aims to keep ahead of the challenges of a rapidly changing healthcare landscape, allowing NICE to evolve from producing full guidelines to adopting a more modular, living style of recommendations, allowing rapid updates that incorporate the latest evidence to reach healthcare professionals faster than ever before.

Pricentric INSIGHT: How the New GVWG Law Could Change Healthcare in Germany

Health Technology Assessment (HTA) bodies are under increasing scrutiny to control healthcare expenditure and enhance the sustainability of healthcare systems, as pressure on healthcare budgets continue to increase due to various factors such as aging populations and innovative therapies.

FDA's ODAC Decides Fate of Recently Withdrawn PD-1, PD-L1 Inhibitors

The United States Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee has been reviewing six indications in breast, urothelial, gastric, and hepatocellular cancers that were granted accelerated approval but have since reported confirmatory trial results that have no verified clinical benefit.

Follow us on LinkedIn
https://www.linkedin.com/showcase/pricentric-one-by-eversana/

Table of Contents

(Click on title to jump to page)

Pricentric INSIGHT: NICE's 5-year Strategy Focuses on "Flexible" and "Innovative" Methods

PRICENTRIC BRIEF:

- On Monday April 19, the National Institute for Health and Care Excellence (NICE) launched its 5-year strategy with a virtual webinar
- The strategy aims to keep ahead of the challenges of a rapidly changing healthcare landscape, allowing NICE to evolve from producing full guidelines to adopting a more modular, living style of recommendations, allowing rapid updates that incorporate the latest evidence to reach healthcare professionals faster than ever before
- The key elements have been divided into four pillars of work - Rapid, robust, and responsive technology evaluation, dynamic, living guideline recommendations, effective guidance uptake to maximize impact and leadership in data, research, and science

THE DETAILS

LONDON, United Kingdom - On Monday April 19, the National Institute for Health and Care Excellence (NICE) launched its 5-year strategy with a virtual webinar.

The strategy aims to keep ahead of the challenges of a rapidly changing healthcare landscape, allowing NICE to evolve from producing full guidelines to adopting a more modular, living style of recommendations, allowing rapid updates that incorporate the latest evidence to reach healthcare professionals faster than ever before.

Speaking at the event, NICE Chief Executive, Professor, Gillian Leng, called it an "exciting time," but noted that the "pandemic response created challenges for all of us."

"As we move forward, we will absolutely ensure that we protect or robust independent approach to evidence evaluation, and we are committed to ensuring that NICE continues to be a world leader so that we can play our part in ensuring improvement in health and wellbeing across the UK but also globally. But our dedicate to speed and efficiency as well as robustness and independence means that we will have to transform some key elements of how we work."

The key elements have been divided into four pillars of work:

- Rapid, robust, and responsive technology evaluation
- Dynamic, living guideline recommendations
- Effective guidance uptake to maximize impact
- Leadership in data, research, and science

Gillian continued, "The key to delivering this strategy will be collaboration. Working with partner organizations – building on the existing relationships that we already have in place and forging new ones to expand our skills and capabilities. It will be a busy but a positive future."

Meindert Boysen, Deputy Chief Executive and Director of the Centre for Health Technology Evaluation also spoke at the panel, noting: "that the plan positions NICE at the forefront of anticipating and evaluating emerging and new technologies. It will lead to world-leading assessments of value and improved access for patients."

"We will work closely with colleagues in the MHRA and NHS England to develop a runway for innovative new technologies, drawing on the experience of the work we have done during COVID-19 and the launch of the Innovative Licensing and Access Pathway (ILAP)."

"We will increase access to promising and valuable new

technologies by managing uncertainty and risk, and invest in our data and analytics capacity, our interest in real-world evidence, and participation in managed access funds – drawing on the great success of the UK's Cancer Drugs Fund."

For industry, these changes could entail a new "front door" for life sciences that will help guide industry to the relevant programs to support a company's journey to market access. This will include a dedicated office for digital health, Boysen confirmed, additional collaboration with other healthcare players and commissioning flexibilities to enable earlier patient access.

The Strategy

NICE recently published the 2021-2026 strategy, which outlines the agency's trajectory over the next five years in consideration of lessons learned during the COVID-19 Pandemic.

According to the group, the pandemic "provided a catalyst for the type of change that we already knew we needed to make," including expediting access to new treatments and technologies and integrating real world data (RWD) into evaluations.

With this strategy, NICE has a "A renewed determination to prioritize our work to reduce those health inequalities that have been highlighted during the pandemic, to work seamlessly across boundaries, to reduce bureaucracy, and to speed up access to the latest and most effective treatments," explained NICE Chair Sharmila Nebhrajani and Leng.

Below is an overview of NICE's strategic roadmap, including key measures, for 2021-2026.

1. Rapid, robust, and responsive technology evaluation

2021-2022	2023-2024	2025-2026
• Implement revised NICE process and methods manual for technologies with Innovative Licensing and Access Pathway (ILAP) and Innovative Medicines Fund arrangements • Launch new Office for Digital Health • Develop beta version of the Life Sciences Hub	• Develop targeted processes and methods for cell and gene therapies, artificial intelligence, and genomics • Build on joint working with national and international HTA bodies • Develop managed access pathways for medical technologies (including digital)	• Improve rapid access to new technologies, aiming for an equivalent approach for medical devices, diagnostics, and digital technologies • Realize a new, dynamic approach to health technology evaluation and management, fully aligned with living guidelines and data analytics

2. Dynamic, living guideline recommendations

2021-2022	2023-2024	2025-2026
• Identify and adopt selected guidance authoring tool • Products selected guidelines in new interactive format • Establish cross-agency panel on priority topics	• Incorporate HTAs into practice recommendations • Present recommendations in interactive format • Establish advisory committees for all key topic suites	• Publish consolidated portfolio of high priority recommendations that are rapidly updated, interactive, and easy to access • Publish integrated guidelines on key topics

3. Effective guidance uptake to maximize our impact

2021-2022	2023-2024	2025-2026
• Develop new implementation strategy • Complete patient safety review and policy • Explore a partnership to improve access to guidelines	• Embed NICE guidance in partners' regulation, monitoring, and improvement frameworks • Build links with academic units to be at forefront of implementation science and support evaluation	• Embed NICE guidance in decision support systems • Ensure fully automated monitoring of device compliance, impact, and value

4. Leadership in data, research, and science

2021-2022	2023-2024	2025-2026
• Establish research and data partnerships • Establish "NICE Listens" program • Explore options for citable publications platform	• Develop RWD data methods and standards program • Develop approach to considering environmental impact • Publish evidence reviews and economic analyses	• Develop position as a though leader and research active organization in health technology assessment (HTA) methods and guidelines, including environmental impact • Consolidate role as a global leader in patient and public engagement

The Future

Opening the virtual event, Sharmila Nebhrajani OBE, NICE chairman said: "The healthcare of the future will look radically different from today – new therapies will combine pills with technologies, genomic medicine will make early disease detection a reality and AI and machine learning will bring digital health in disease prevention and self-care to the fore.

"Our new strategy will help us respond to these advances, finding new and more flexible ways to evaluate products and therapies for use in the NHS, ensuring that the most innovative and clinically effective treatments are available to patients at a price the taxpayer can afford."

Later in the discussion, she further elaborated on the point: "We are on the cusp on a big change in not just the care model, but in what we mean by health. We've touched a little bit on prevention, and we have touched a little bit on diagnostics, early detection and screening. What we're seeing is the health system is changing from care for sickness and tackling illness, to thinking about wellness and tackling prevention as well as early diagnostics.

"Those things are critical for NICE, and I think we are reflecting them in our technology approvals and guidelines in the new strategy. They also speak to the change care model, the shift to self-care and the critical drive to tackle inequalities."

Keeping up with Pharma

NICE's methods of health technology appraisal (HTA) have often been under scrutiny for remaining broadly unchanged for the past 20 years, despite increasing sophistication of innovative treatments within the modern medicine pipeline.

Now, the organization is undergoing the largest ever review of its processes for producing guidance on health technologies.

The drug-pricing group often still uses a cost-effectiveness threshold of £20,000 - £30,000 per quality-adjusted life year (QALY), a number that has not moved since NICE came into being, despite inflation over the last two decades as well as advancements in drug technologies.

It is particularly important that NICE brings itself up to speed at this moment in time, as since January 2021 the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

has been autonomous from the European Union, giving the group potentially even more gravitas and responsibility than it had before.

Here to Help

EVERSANA™ has the people, methods, and tools to assist businesses in navigating any changing pharmaceutical policies, even in such unsure times. This expertise is built on our combined decades of experience solving problems in and building tools for global pricing intelligence, global visibility, and product launch expertise, which puts us in a trusted position to advise clients on how to handle these changes.

At the same time, Pricentric Insights strives to deliver accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in over 100+ markets around the world. Our team of researchers checks a database of over 700+ reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape. In addition, we provide conference coverage and utilize our team of consultants to detail how major policy changes, such as NICE's plans, can impact market access and the global pricing landscape.

Pricentric INSIGHT: How the New GVWG Law Could Change Healthcare in Germany

PRICENTRIC BRIEF

- At the tail end of 2020, Germany's Federal Health Minister, Jens Spahn, announced the adoption of a new law to help ensure quality and transparency, better services and stronger networking in care for the key European Union (EU) country
- The law, which is dubbed Health Care Further Development Act (GVWG), does not require approval from the Federal Council and is currently in the process of being implemented before the first half of 2021 is over
- Overall, the draft bill contains 80 new proposals for the healthcare landscape in Germany, ranging from transparency to insurance amendments and healthcare professionals' liability

THE DETAILS

At the tail end of 2020, Germany's Federal Health Minister, Jens Spahn, announced the adoption of a new law to help ensure quality and transparency, better services and stronger networking in national healthcare.

The law, which is dubbed Health Care Further Development Act (GVWG), does not require approval from the Federal Council and is currently in the process of being implemented before the first half of 2021 is over.

Overall, the draft bill contains 80 new proposals for the healthcare landscape in Germany, ranging from transparency to insurance amendments and healthcare professionals' liability.

On the release of the plan, the Minister noted how "Especially in the pandemic," it is important to "strengthen our health system and make it fit for the future."

He added, “With this law we ensure more networking, quality and transparency in care. All insured persons will benefit from this.”

Quality & Transparency Changes

Under the law, the Federal Ministry of Health (BMG) is tightening the requirements for the establishment of minimum quantities by the Federal Joint Committee (G-BA), meaning that the G-BA must conduct its deliberations in two years. Additionally, the authority of the G-BA and the federal states to provide for exemptions is being revoked.

Patient surveys are set to be developed further, with increased development of digital patient surveys, consideration of national and international survey instruments and commissioning of the G-BA to develop barrier-free patient surveys.

Under the law, quality contracts will replace the previous quality surcharges and deductions. The G-BA will now have to define four further services or service areas by the end of 2023, in which the quality contracts will be tested.

The law also requires specification of an annual volume of expenditure per insured person in order to achieve a “sufficient number” of contracts, as well as commissioning the G-BA to continuously publish an overview of the contracts concluded.

Public & Private Insurance Amendments

As for insurance amendments under the law, for the first time, people in Germany will be entitled to corresponding benefits in the event of pregnancy and maternity, regardless of gender. Additionally, a new structured treatment program (DMP) will be introduced for the treatment of obesity.

The law also entitles all individuals covered by statutory health insurance to reimbursement for certain digital health applications (DiGA); something that Germany is placing increased focus on going forward.

It’s anticipated that under the law, the GBA will have the right to determine whether a second opinion is warranted for further interventions. Further, both outpatient and inpatient services in recognized facilities will be converted from discretionary to compulsory services.

Why Does it Matter?

Germany is often seen as a pharmaceutical and healthcare policy leader in the European Union. It was one of the first countries to implement health technology assessments (HTA) and continues to be one of the biggest spenders on healthcare in the bloc.

Germany spends 11.1% of its annual gross domestic product (GDP) on its healthcare system annually; third only to Switzerland and France in terms of percentage.

Additionally, Germany’s statutory health insurance companies reported a total deficit of around EUR 2.65 billion in 2020, according to available financial results.

Federal Health Minister Jens Spahn has reminded that the pandemic "shaped the development of the health insurance balance sheets in the past year. However, the figures for last year also show that thanks to the additional federal subsidy and the reduction in financial reserves, we have succeeded in ensuring that contributors and employers are not excessively burdened. Keeping the contributions stable - that is our goal also with a view to the current year."

The income of the health insurances, which they receive primarily through pre-determined allocations from the health fund, rose by 4% to EUR 260 billion. However, expenditures for services and administrative costs also recorded an increase of 4% to EUR 262.6 billion with an increase in the number of insured persons of 0.3%.

Germany's Current Landscape

G-BA is a key decision-making body in the German healthcare system that assesses new methods of medical treatment and diagnosis, as well as the benefits and efficiency of new products, and determines whether they should be reimbursed by public health insurance (SHI).

In general, any drug approved by the European marketing authorization agency (EMA) is automatically reimbursed in Germany. The manufacturer is free to set a price for the first 12 months. After this period, a revised reimbursed price will take place as a result of pricing negotiations. This new price is heavily influenced by G-BA or the Institute for Quality and Efficiency in Health Care's (IQWiG) clinical benefit assessment.

With the introduction of the Pharmaceutical Market Restructuring Act (AMNOG) in 2011, new originator medicines and subsequent indications have been required to go through a clinical benefit assessment process. This has had a direct impact on the ability to demand a premium price in the German market.

"Half-hearted" Reform Step?

Despite the comprehensive points of reform, Germany's largest statutory health insurance fund, AOK, believes that there is still work to be done on the bill before it is fit for implementation.

Speaking at a hearing in the Bundestag in April, Martin Litsch, Chairman of the AOK Federal Association, explained that the organization is "critical" of the plans.

He added, "The proposed regulation is nothing more than a half-hearted reform step. Structural problems are not solved with it. The implementation of sector-independent emergency care, as proposed by the German Council of Economic Experts in 2017, is still not foreseeable and will remain on the to-do list for the next legislative period."

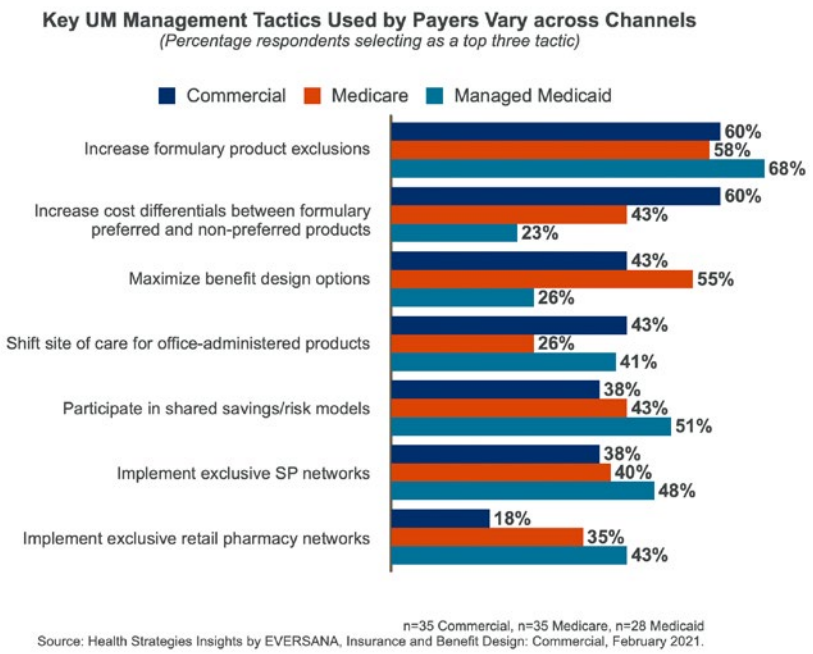
"In order to further develop quality contracts, framework conditions must be made less bureaucratic and the possibilities for patient management improved."

"The draft law also omits a very important point: the double financing of statutory medical services. A correction is only in sight with the Health Care and Care Act (GPVG) in the fourth quarter of 2021."

Here to Help

EVERSANA™ is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science services for a healthier world. To learn more about EVERSANA, visit eversana.com.

Insurance, Benefit and Design: Commercial (IBDC)



n=35 Commercial, n=35 Medicare, n=28 Medicaid
Source: Health Strategies Insights by EVERSANA, Insurance and Benefit Design: Commercial, February 2021.

Do you need to develop a deeper understanding of how commercial and government payer benefit designs are changing, and how COVID-19 is affecting the healthcare landscape?

Our newest research from the Insurance, Benefit and Design: Commercial (IBDC) product line, entitled Coverage Landscape, explores these topics along with how payer use of utilization management tactics in pharmacy and medical benefit designs is evolving, and how these market events impact opportunities for biopharma partnerships.

Spoiler Alert:

- **Despite the COVID-19 pandemic, the commercial health plan landscape remains relatively unchanged with 3 leading payers managing most lives**
- **Recent policy rules increasingly affect care delivery, Medicare Advantage and Medicaid benefit designs**
- **As payers exhaust use of traditional management strategies, they set their sights on new tactics to control costs**

Across channels, payers consider brand exclusions the most effective cost-saving tool. This tactic is increasing in crowded therapeutic areas where products are viewed as therapeutically equivalent.

Without evidence demonstrating clinical and economic superiority over competitors, companies with brands in crowded classes may need to offer pricing concessions in exchange for product access.

Commercial and Medicare payers adjust benefit designs to increase member cost shares for drug therapy. Although this tactic aims to promote cost-conscious consumer decisions, it jeopardizes adherence. Companies should educate payers on the cost-adherence tradeoff, providing data linking OOP increased to adherence decreases.

Since Medicaid payers have limited ability to increase patient cost shares, they rely on narrow pharmacy network strategies Companies must evaluate their distribution networks to ensure this population can access contracted pharmacies.

Please contact EVERSANA Client Services at hsiclientservices@eversana.com if you are interested in learning more about this report and our IBDC product line; or if you have any other payer needs that we can assist you with.

FDA's ODAC Decides Fate of Recently Withdrawn PD-1, PD-L1 Inhibitors

PRICENTRIC BRIEF:

- The United States Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee has been reviewing six indications in breast, urothelial, gastric, and hepatocellular cancers that were granted accelerated approval but have since reported confirmatory trial results that have no verified clinical benefit
- The committee voted:
    - 7 to 2 in favor of maintaining accelerated approval of Tecentriq (atezolizumab), following a review of follow-up clinical evidence in unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) whose tumors express PD-L1, as determined by an FDA-approved test
    - 5 to 3 to keep Merck's Keytruda (pembrolizumab) under approval for cisplatin-ineligible and carboplatin-ineligible locally advanced or metastatic urothelial carcinoma
    - 6 to 2 against maintaining Keytruda's gastric or gastroesophageal junction adenocarcinoma indication, pending the completion of additional post-approval trials
    - 5 to 4 against maintaining the accelerated approval for Bristol Myers Squibb's Opdivo (nivolumab) as monotherapy in hepatocellular carcinoma (HCC) patients previously treated with Nexavar, after it failed to significantly prolong overall survival (OS) when used as a first-line treatment for patients in the Phase III CheckMate -459 study against Nexavar

THE DETAILS

WASHINGTON, D.C., United States - The U.S. Food and Drug Administration (FDA) has announced an official Oncology Drugs Advisory Committee (ODAC) meeting to review six indications across a group of PD-1 and PD-L1 inhibitors that have recently had their indications withdrawn in the U.S. due to an accelerated approvals crackdown.

The panel assessed a group of inhibitors that were granted under the agency's accelerated approval pathway with confirmatory trials that have not verified clinical benefit, such as Bristol Myers Squibb's Opdivo (nivolumab), Merck's Keytruda (pembrolizumab) and Roche's Tecentriq (atezolizumab) across six different indications in breast, urothelial, gastric and hepatocellular cancers.

Richard Pazdur, MD, director of FDA's Oncology Center of Excellence, noted that the committee is "committed to ensuring the integrity of the accelerated approval program, which is designed to bring safe and effective drugs to patients with unmet medical needs as quickly as possible.

"The program allows the FDA to approve a drug or biologic product intended to treat a serious or life-threatening condition based on an outcome that can be measured earlier than survival that demonstrates a meaningful advantage over available therapies. However, when confirmatory trials do not confirm clinical benefit, a reevaluation must be performed to determine if the approval should be withdrawn."

Genentech recently announced that it was voluntarily withdrawing the U.S. indication for Tecentriq in prior-platinum treated metastatic urothelial carcinoma, in a joint decision made in consultation with the FDA.

Merck also voluntarily withdrew its U.S. indication for Keytruda for patients with metastatic small-cell lung cancer (SCLC) who experience disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy earlier in March, and in December 2020, Bristol Myers Squibb also announced its withdrawal from the FDA of an application regarding Opdivo (nivolumab) in SCLC.

BMS issued a note of support for the FDA's decision, stating that "In HCC, despite evolution of the treatment landscape over the past few years, we believe Opdivo continues to address an unmet medical need for patients in the post-sorafenib setting, and we appreciate the opportunity to discuss this in more depth with the Committee."

ODAC's decisions:

Tecentriq

- ODAC voted seven to two in favor of maintaining accelerated approval of Tecentriq (atezolizumab), following a review of follow-up clinical evidence
- The drug will remain under approval with chemotherapy (Abraxane, albumin-bound paclitaxel; nab-paclitaxel) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) whose tumors express PD-L1, as determined by an FDA-approved test

Keytruda

- ODAC voted five to three to keep Merck's Keytruda (pembrolizumab) under approval for cisplatin-ineligible and carboplatin-ineligible locally advanced or metastatic urothelial carcinoma

Opdivo

- On the final day of its meeting, ODAC voted that Merck's Keytruda (pembrolizumab) and Bristol Myers Squibb's Opdivo (nivolumab) should have two of their indications rescinded
- The panel voted six to two against maintaining Keytruda's gastric or gastroesophageal junction adenocarcinoma indication, pending the completion of additional post-approval trials
- Members of the committee also voted five to four against maintaining the accelerated approval for Bristol Myers Squibb's Opdivo (nivolumab) as monotherapy in hepatocellular carcinoma (HCC) patients previously treated with Nexavar, after it failed to significantly prolong overall survival (OS) when used as a first-line treatment for patients in the Phase III CheckMate -459 study against Nexavar

According to the FDA, only 6% of accelerated approvals for oncology drugs have been withdrawn over the whole duration of the pathway's use, including the four recent withdrawals.

End Price Gouging Act to Base U.S. Prescription Drug Prices on Median Price in 11 Countries

Date: April 27, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Editor's Choice, Policy, Reference Pricing (IRP) | Keywords: #americanfamiliesplan #averageinternationalmarket-price #cancer #drugprices #elijahcummingslowerdrugcostsnowact #endpricegougingformedications-act #fda #hhs #hr3 #innovation #insulin #lowercostsmorecuresact #medicare #nih #outofpocket

PRICENTRIC BRIEF:

- United States Senator Jeff Merkley (D-OR) and Representative Peter Welch (D-VT) have together introduced the End Price Gouging for Medications Act that would make sure Americans pay no more for prescription drugs than the median price found among 11 reference countries
- The Act would require the Secretary of Health and Human Services (HHS) to establish a reference price for prescription drugs based on the median price per drug in Australia, Canada, Germany, France, Italy, Japan, the Netherlands, Spain, Sweden, Switzerland, and the United Kingdom, and this price would be made available to all individuals in the U.S. market
- Both legislators are pushing for the End Price Gouging for Medications Act to be included in the White House's American Families Plan package when it moves through Congress, however, their Act is running against the Elijah J. Cummings Lower Drug Costs Now Act (HR 3), which was reintroduced by the House Energy and Commerce, Ways and Means, and Education and Labor Committees last week to likewise leverage the negotiating power of Medicare and make these prices available to all commercial plans as well

THE DETAILS

WASHINGTON, D.C., United States – United States Senator Jeff Merkley (D-OR) and Representative Peter Welch (D-VT) have together introduced the End Price Gouging for Medications Act that would make sure Americans pay no more for prescription drugs than the median price found among 11 reference countries.

The Act would require the Secretary of Health and Human Services (HHS) to establish a reference price for prescription drugs based on the median price per drug in Australia, Canada, Germany, France, Italy, Japan, the Netherlands, Spain, Sweden, Switzerland, and the United Kingdom, and this price would be made available to all individuals in the U.S. market.

Companies that object would be penalized for each year they do not offer a drug at the established reference price; the penalties will equal five times the difference between the retail list price and the reference price, and will go toward drug research and development (R&D) at the National Institutes of Health (NIH).

According to Merkley's press release, the Act would see the cost of insulin drop by approximately 497%, the cost of DPP-4 inhibitors for diabetes by approximately 670%, the cost of corticosteroids for asthma by approximately 628%, the cost of medicine for chronic myeloid leukemia patients by 304%, and the cost of medicine for arthritis, psoriasis, Crohn's disease, and ulcerative colitis by approximately 196%.

Both legislators are pushing for the End Price Gouging for Medications Act to be included in the White House's American Families Plan package when it moves through Congress. Welch was one of 20 representatives who signed a letter to U.S. President Joe Biden urging him to include critical drug pricing reforms in the Plan.

Policymakers Rally to Include Drug Pricing Legislation in Biden's American Families Plan

Merkley and Welch's Act is not the only piece of legislation targeting prescription drug pricing for which policymakers are seeking inclusion in Biden's forthcoming Plan. The House Energy and Commerce, Ways and Means, and Education and Labor Committees have reintroduced the Elijah J. Cummings Lower Drug Costs Now Act (HR 3) to leverage the negotiating power of Medicare and make these prices available to all commercial plans as well.

As with the End Pricing Gouging Act, under HR 3 Medicare—specifically the Department of Health and Human Services (HHS) Secretary—would be empowered to negotiate drug prices directly with pharmaceutical

companies, and these negotiated drug prices would be made available to Americans with private insurance. A maximum price would be applied, based on the drug's average price (dubbed the "Average International Market (AIM) price") among Australia, Canada, France, Germany, Japan, and the United Kingdom.

Any savings reaped from lowering drug prices would be reinvested in innovation and the search for new cures and treatments at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), a common thread between both bills. Further, Medicare beneficiaries would have a $2,000 out-of-pocket (OOP) limit on prescription drug spending, and companies that have raised their drug prices in Medicare Parts B and D above the rate of inflation since 2016, have the option to either lower their prices or pay the entire price above inflation in a rebate back to the U.S. Treasury.

Republican Alternative Seeks to Protect Innovation, Cut Costs for Consumers

On the contrary, Republicans remain against the bill, and Energy and Commerce Committee Republican Leader Cathy McMorris Rodgers, Ways and Means Committee Republican Leader Kevin Brady, and Education and Labor Committee Republican Leader Virginia Foxx in response released legislation—the Lower Costs, More Cures Act (HR 19)—to lower drug costs for Americans without limiting access to cures.

According to the Leaders, the Lower Costs, More Cures Act would:

- lower costs without jeopardizing cures;
- leads to lifesaving new cures and innovation;
- promote more low-cost options for patients who need them, and stop drug companies from gaming the system;
- avoid increased reliance on China;
- provide first-ever out-of-pocket cap for seniors in the Medicare Part D program;
- cap the cost of insulin for seniors in the Medicare Part D program;
- empower patients with more drug price transparency and removes uncertainty at the pharmacy counter;
- cut the cost of cancer treatment and other drug administration for Medicare beneficiaries by as much as half; and
- enable strong, pro-America trade agreements to end American subsidizing of other developed countries' health care.

In a letter sent to Republican colleagues, the Leaders underscored, "All the provisions in HR 19 are bipartisan and are ready to become law as soon as possible, including two that already passed the People's House last week."

Biden Signs Advancing Education on Biosimilars Act

Date: April 28, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Editor's Choice, Biosimilar, Policy | Keywords: #advancingeducationonbiosimilarsact #biosimilarsforum #fda #interchangeability #savings

PRICENTRIC BRIEF:

- United States President Joe Biden has signed into law the Advancing Education on Biosimilars Act of 2021 (S. 164), thus authorizing the Food and Drug Administration (FDA) to educate consumers and health care providers on biologics, including their biosimilar counterparts
- As part of the Act, information to be shared on a biosimilar-specific website will include regulatory details on the approval and classification of biosimilars, as well as their interchangeability with their branded biologic counterparts, and comparative data for biologics and their biosimilars will be made available, with continuing educational programs established for health care providers
- Meaghan Rose Smith, Executive Director of the Biosimilars Forum, said, "These life-saving drugs and their cost-savings capabilities can play a key role in the nation's path to economic recovery, with the potential to save the U.S. up to $100 billion over the next five years, but only if their use increases"

THE DETAILS

WASHINGTON, D.C., United States – United States President Joe Biden has signed into law the Advancing Education on Biosimilars Act of 2021 (S. 164), thus authorizing the Food and Drug Administration (FDA) to educate consumers and health care providers on biologics, including their biosimilar counterparts.

The Advancing Education on Biosimilars Act requires that educational materials aimed at improving confidence in the safety and efficacy of Food and Drug Administration (FDA)-approved biosimilars be provided to patients and care providers.

Information to be shared on a biosimilar-specific website would include:

- Explanations of key statutory and regulatory terms, including "biosimilar" and "interchangeable," and clarification regarding the use of interchangeable biosimilar biological products;
- information related to the development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers;
- an explanation of the process for reporting adverse events and
- an explanation of the relationship between biosimilars biological products and interchangeable biosimilar biological products license under section 351 (k) and reference products, including standards for review and licensing

It is hoped that improved confidence in biosimilars will encourage increased use, thus generating savings in the health care field.

In response to Biden signing the Act, Meaghan Rose Smith, Executive Director of the Biosimilars Forum, said, "The Biosimilars Forum thanks President Biden for his swift action in signing the Advancing Education on Biosimilars Act into law and looks forward to continuing to work with the administration to ensure that patients and providers have all of the educational resources and materials they need to be assured of the safety and efficacy of biosimilars."

Smith highlighted the financial benefits of promoting the use of biosimilars, saying, "These life-saving drugs and their cost-savings capabilities can play a key role in the nation's path to economic recovery, with the potential to save the U.S. up to $100 billion over the next five years, but only if their use increases. As the administration approaches its 100th day in office, we encourage them to continue to prioritize smart policy solutions that will increase stakeholder confidence and access to biosimilars while lowering costs for the entire health care system."

U.S. Reps Reintroduce Bipartisan Ensuring Access to Lower-Cost Medicines for Seniors Act

Date: April 30, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Editor's Choice, Policy, Regulation | Keywords: #associationforaffordablemedicines #biosimilars #branddrugs #costsharing #ensuringaccesstolowercostmedicinesforseniorsact #formulary #generics #medicare #outofpocketcosts #partd

PRICENTRIC BRIEF:

- United States Representatives David B. McKinley (R-WV) and Annie Kuster (D-NH) have reintroduced the Ensuring Access to Lower-Cost Medicines for Seniors Act that aims to leverage generic drugs to help Medicare beneficiaries with medicine affordability
- While generics and biosimilars saved Medicare beneficiaries over $90 billion in 2018, the savings provided by these drugs are at risk due to their grouping in the same pricing tier as branded drugs; thus, the Act seeks to reverse this practice that is "unnecessarily increasing" what beneficiaries pay out-of-pocket (OOP) for generics
- The Act would ensure automatic coverage of lower-cost generic and biosimilar medications on plan formularies immediately after launch, place generic drugs on "generic-only" formulary tiers so patients are not charged the higher brand rate, and create a dedicated specialty tier for specialty generics and biosimilars with significantly lower patient cost-sharing than the brand specialty tier

THE DETAILS

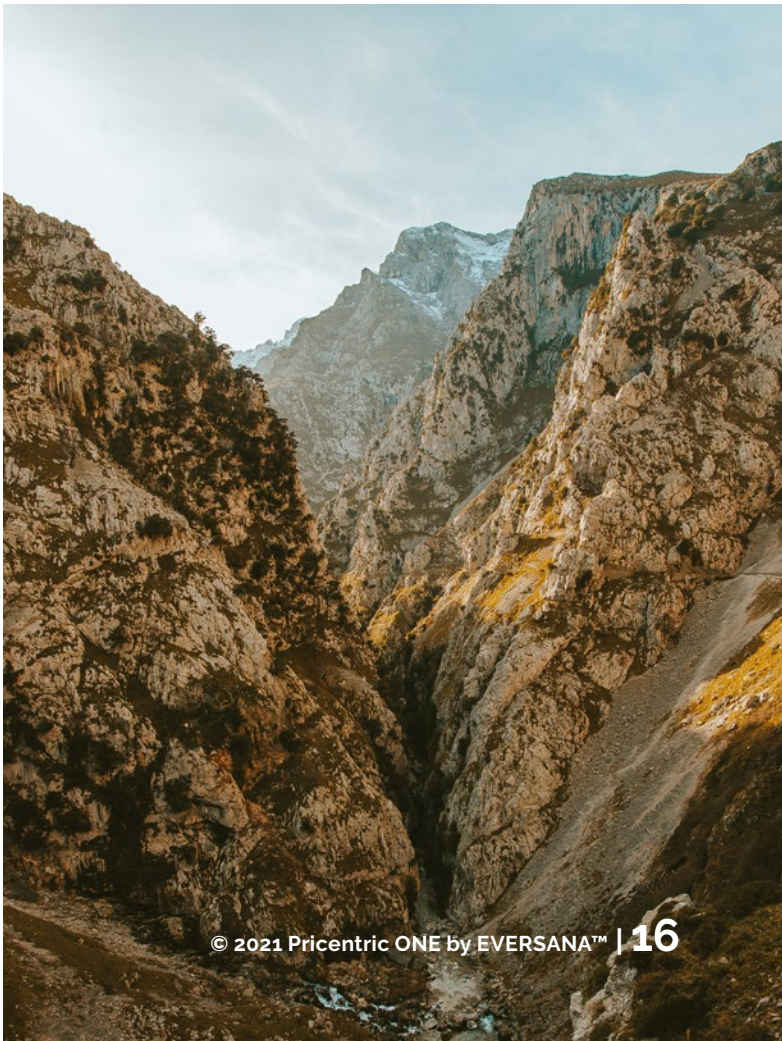
WASHINGTON, D.C., United States – United States Representatives David B. McKinley (R-WV) and Annie Kuster (D-NH) have reintroduced the Ensuring Access to Lower-Cost Medicines for Seniors Act that aims to leverage generic drugs to help Medicare beneficiaries with medicine affordability.

While generics and biosimilars saved Medicare beneficiaries over $90 billion in 2018, the savings provided by these drugs are at risk due to their grouping in the same pricing tier as branded drugs; thus, the Act seeks to reverse this practice that is "unnecessarily increasing" what beneficiaries pay out-of-pocket (OOP) for generics.

The Act would ensure automatic coverage of lower-cost generic and biosimilar medications on plan formularies immediately after launch, place generic drugs on "generic-only" formulary tiers so patients are not charged the higher brand rate, and create a dedicated specialty tier for specialty generics and biosimilars with significantly lower patient cost-sharing than the brand specialty tier.

Rep McKinley explained, "Our bill would ensure seniors can benefit from lower-cost generic medicine and limit the amount they have to pay out of pocket. This is a common-sense bill that will help seniors access the medicine they need at a reasonable price."

The Association for Affordable Medicines has endorsed the Act, saying it could save American's seniors benefiting from Medicare Part D more than $4 billion a year by lowering OOP spending.



Colorado Gov. Approves Expanding Canadian Prescription Drug Import Plan to Allow Imports from Other Nations

Date: April 30, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy, Regulation | Keywords: #canadianprescriptiondrugimportplan #hhs #import #manufacture #pharmacy #prescriptiondrug #savings #sb21123 #wholesale

PRICENTRIC BRIEF:

- Colorado Governor Jared Polis has signed into law SB21-123, expanding the state's Canadian Prescription Drug Import Plan to allow the import of prescription drugs from suppliers from nations other than Canada
- SB21-123 expands Colorado's prescription drug importation program so that the state can import medicines from countries such as Japan, France, and Australia—manufacturers, wholesalers, or pharmacies from other countries would be permitted to export drugs to Colorado
- Prescription drug imports from Canada have led to savings of 63%-80% for Coloradans, and the expansion of this program is forecasted to achieve 73% savings on many other life-changing prescription drugs, according to Governor Polis

THE DETAILS

DENVER, Colorado – Colorado Governor Jared Polis has signed into law SB21-123, expanding the state's Canadian Prescription Drug Import Plan to allow the import of prescription drugs from suppliers from nations other than Canada.

SB21-123 expands Colorado's prescription drug importation program so that the state can import medicines from countries such as Japan, France, and Australia—manufacturers, wholesalers, or pharmacies from other countries would be permitted to export drugs to Colorado.

It is an extension to Senate Bill 19-005 of 2019 that allowed Colorado to request a waiver from the United States Department of Health and Human Services (HHS) to import medicines from Canada. According to one of the bill's sponsors, Colorado State Senator Joann Ginal, "We are taking into account the fact that Canada is one-tenth of the size of the United States, and they were very worried about us getting most of their drugs, which we don't want to happen."

Prescription drug imports from Canada have led to savings of 63%-80% for Coloradans, and the expansion of this program is forecasted to achieve 73% savings on many other life-changing prescription drugs, according to Governor Polis.

According to Governor Polis, SB21-123 improves Colorado's return on investing in imports from Canada, as it allows other countries to export to the state, thus increasing Colorado's negotiating leverage so Coloradans can "get the best deal." Lieutenant Governor Dianne Primavera added that the Bill increases access to more affordable medication while not compromising safety.

Brazil Authorizes J&J's COVID-19 Vaccine for Emergency Use

Date: April 1, 2021 | Country: BRAZIL | Region: SOUTH AMERICA | Type: Breaking News, Drug Approval | Keywords: #anvisa #covid19 #emergencyuseauthorization #janssen #johnson&johnson #vaccine

PRICENTRIC BRIEF:

- The Collegiate Board of the National Health Surveillance Agency (ANVISA) has granted temporary authorization for emergency use to Johnson & Johnson's COVID-19 vaccine
- After analyzing all submitted study data—the company also carried out a Phase 2 study in Brazil, the regulator concluded that the vaccine protects against severe forms of COVID-19 and is effective in preventing the virus in adults
- Earlier in March, Brazil's Ministry of Health announced the signing of a contract with the company for the purchase of 38 million doses of the vaccine

THE DETAILS

BRASILIA, Brazil – The Collegiate Board of the National Health Surveillance Agency (ANVISA) has granted temporary authorization for emergency use to Johnson & Johnson's COVID-19 vaccine.

After analyzing all submitted study data—the company also carried out a Phase 2 study in Brazil, the regulator concluded that the vaccine protects against severe forms of COVID-19 and is effective in preventing the virus in adults.

Earlier in March, Brazil's Ministry of Health announced the signing of a contract with the company for the purchase of 38 million doses of the vaccine.

Brazil is the second South American country to authorize J&J's COVID-19 jab, following Colombia, where it was approved by the National Institute for Drug and Food Surveillance of Colombia (INVIMA).

So far, Brazil's ANVISA has approved five vaccines, including those from Pfizer/BioNTech and AstraZeneca, the India-produced version of AZ's vaccine, CoviShield, and Sinovac's CoronaVac.

Health Strategies Insights by Eversana™

Actionable insights to validate and inform your strategies & tactics across the product lifecycle

Market Access

- Alternative Payment Models
- Customer Relationships with IDNs
- Customer Relationships with MCOs
- Employer Trends and Management Decisions
- Insurance and Benefit Design
  - Commercial
  - Government
- Leading Payer
- Account Trends
- Medical Group Trends
- Organized Customer Account Trends
- Quality Performance and Priorities
- Regional Account Trends
- Value- Based Contracting Evolution

Brand Access

- Marketplace Dynamics
  - Autoimmune
  - Multiple Sclerosis
  - Therapeutic Area of Choice
- Oncology Pathways Engagement
- Specialty Pharmacies and Distributors

Account Access

- Cancer Center Profiles
- Health System Profiles
- Hospital Sales Force Effectiveness
- National Account Profiles
- Regional and Blues Health Plan Profiles
- **SP**OPTIMIZER BY EVERSANA™

Patient Access Consumer Trends

- Patient Services and Hubs
  - Autoimmune
  - Oncology
  - Rare Disease
  - Therapeutic Area of Choice

Custom Access

- **ACCESS**EXPRESS® by EVERSANA

Please contact EVERSANA Client Services at hsiclientservices@eversana.com to learn more.

South Korea Authorizes Johnson & Johnson's COVID-19 Jab

Date: April 8, 2021 | Country: SOUTH KOREA | Region: ASIA & SOUTH PACIFIC | Type: Breaking News, Drug Approval | Keywords: #covid19 #janssen #janssencovid19vaccine #johnson&johnson #mfda #vaccine

PRICENTRIC BRIEF:

- The Ministry of Food and Drug Safety (MFDS) of South Korea has authorized use of Johnson & Johnson's one-shot COVID-19 Vaccine for the prevention of moderate to severe COVID-19 infections in adults aged 18 years and up
- At the beginning of April, the MFDS' advisory board comprised of outside experts as well as agency officials recommended approving J&J's COVID-19 jab after reviewing its safety and efficacy
- South Korea has inked a deal for 6 million doses of the vaccine, which are scheduled to be provided in Q3 of 2021

THE DETAILS

SEOUL, South Korea – The Ministry of Food and Drug Safety (MFDS) of South Korea has authorized use of Johnson & Johnson's one-shot COVID-19 vaccine for the prevention of moderate to severe COVID-19 infections in adults aged 18 years and up.

At the beginning of April, the MFDS' advisory board comprised of outside experts as well as agency officials recommended approving J&J's COVID-19 jab after reviewing its safety and efficacy rate of 66% in preventing moderate to severe COVID-19 infection in adults.

The COVID-19 vaccine will be subject to additional monitoring and the company will need to submit a final report on study results in the future.

South Korea has inked a deal for 6 million doses of the J&J vaccine, which are scheduled to be provided in Q3 of 2021, according to South Korea-based Yonhap News Agency.

J&J's COVID-19 jab is the third to gain approval from South Korea's regulator following green lights for the vaccines from AstraZeneca and U Oxford and Pfizer and BioNTech.

China's Fifth Round of Volume-Based Procurement Seeks 60 Products for 207 Specifications

Date: April 16, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Editor's Choice, Policy | Keywords: #bidding #centralizedprocurement #tender #volumebasedprocurement

PRICENTRIC BRIEF:

- Updates on the upcoming round of volume-based procurement (VBP) in China have started to surface, revealing that China seeks to include 60 drug products (31 of which are injectables), covering as many as 207 specifications in the fifth round—it would be the largest VBP go to date, with a reported market size of over CNY 50 billion
- Volume submission will be initiated April 19, and bidding for the 5th round will be in late May or early June and conclude by July 1, 2021
- China's national, centralized procurement has expanded significantly since its pilot known as the "4+7 tender trial" launched in 11 select cities in 2018, and, on average, China has secured medicines through VBP at price cuts of 53%-54%

THE DETAILS

The number of specifications has been updated to say "207".

BEIJING, China – Updates on the upcoming round of volume-based procurement (VBP) in China have started to surface, revealing that China seeks to include 60 drug products (31 of which are injectables), covering as many as 207 specifications in the fifth round—it would be the largest VBP go to date, with a reported market size of over CNY 50 billion.

Volume submission will be initiated April 19, and bidding for the 5th round will be in late May or early June and conclude by July 1, 2021.

At the beginning of 2021, China's General Office of the State Council formally issued "Opinions on Promoting the Normalized and Institutionalized Development of Centralized and Volume Procurement of Drugs," thereby officially announcing the normalization and institutionalization arrangements for centralized drug procurement.

According to Premier Li Keqiang, "The bulk-buying program has worked well," said Li. "It is a major step in reforming medical institutions. The scheme has helped to lower, over time, medical costs for the public, and keep the operation of medical insurance funds sustainable."

China's national, centralized procurement has expanded significantly since its pilot known as the "4+7 tender trial" launched in 11 select cities in 2018. On average, China has secured medicines through VBP at price cuts of 53%-54%. At the start of February, China's fourth round of VBP commenced, seeking 45 drugs across a variety of therapeutic areas including hypertension, diabetes, gastrointestinal diseases, mental illnesses, and malignant tumors.

Going forward, VBP could take place twice a year, and the initiative will expand to cover all types of clinically necessary drugs, including Chinese-patented medicines and biosimilars. At a January meeting during which Chinese officials laid out the trajectory of the initiative, it was agreed that VBP will expand nationwide to cover the top 250 drugs by national purchase value in 2021 and then 80% of leading drugs by national purchase value – a list that includes over 500 products – in 2022.

Shanghai Introduces Huhuibao Supplementary Medical Insurance

Date: April 28, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Policy | Keywords: #healthinsurance #hospital #huhuibao #oncology #orphandrug #radiation #raredisease #supplementalinsurance

PRICENTRIC BRIEF:

- Through a partnership with nine insurance companies, the Shanghai city government has unveiled Huhuibao, a new customized, supplementary medical insurance program available to all people who use the city's current medical insurance
- At an annual fee of only 115 yuan, Huhuibao offers medical compensation up to 2.3 million yuan and covers payments beyond the ambit of the city's current insurance scheme
- Huhuibao offers additional perks, including compensation for hospitalization fees, 21 undisclosed but "expensive" medicines for cancer and rare diseases, and proton and heavy ion radiation treatments—plus, there is no threshold for insured conditions and people with past illnesses can be insured and compensated for their illness

THE DETAILS

SHANGHAI, China – Through a partnership with nine insurance companies, the Shanghai city government has unveiled Huhuibao, a new customized, supplementary medical insurance program available to all people who use the city's current medical insurance.

At an annual fee of only 115 yuan, Huhuibao offers medical compensation up to 2.3 million yuan and covers payments beyond the ambit of the city's current insurance scheme; the percentage of compensation is based on the needs of the insured.

Huhuibao offers additional perks, including compensation for hospitalization fees, 21 undisclosed but "expensive" medicines for cancer and rare diseases, and proton and heavy ion radiation treatments. There is no threshold for insured conditions, people with past illnesses can be insured and compensated for their illness, and personal medical insurance accounts can be tapped to pay the annual fee for Huhuibao.

Payments for the first year of Huhuibao run until June 30 and take effect on July 1.

More Insurance Options Predicted for China

A recent study conducted by Fudan University and Shanghai-based health insurer Shanzhen Haiwei predicted a rise in more diversified, low-cost, and inclusive health insurance plans in China this year to make up for the lack of coverage for certain populations in China.

The report asserts that coverage will gradually expand from first- and second-tier cities to smaller ones, with the prices of products and scope of protection diversifying.

Overall, the Basic Medical Insurance (BMI) scheme has been tweaked to cover more outpatient medical bills, and a special commercial medical insurance scheme covering 49 imported innovative drugs was recently launched in Hainan's Boao Lecheng International Medical Tourism Pilot Zone to lower costs and boost access for patients.

China Issues Guidance on Expanding BMI Scheme for Outpatient Services

Date: April 29, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Editor's Choice, Policy | Keywords: #basicmedicalinsurance #chronicdisease #compensation #outpatient #paymentstandard #personalaccount #pharmacy #poolingfund #rationaldruguse #reimbursement

PRICENTRIC BRIEF:

- The General Office of the State Council has issued "Guiding Opinions on Establishing and Improving the Outpatient Mutual Aid Guarantee Mechanism for Basic Medical Insurance for Employees" seeking to expand outpatient coverage under China's Basic Medical Insurance (BMI) scheme, including increasing compensation, to gradually reduce the financial burden on patients
- Measures include boosting compensation for outpatient chronic diseases (e.g. hypertension and diabetes) and reconfiguring personal accounts and their proper use for outpatient mutual aid protection and improving outpatient benefits of insured persons, including allowing them to be tapped to cover other immediate family members
- In the guidance, it was detailed that relevant parties should explore pay per capita for primary medical services and the combination of per capita payment with chronic disease management, among other measures, and that payment standards for medical insurance drugs should be determined scientifically and reasonably to guide medical institutions and patients to actively use drugs with definite curative effects and reasonable prices

THE DETAILS

BEIJING, China – The General Office of the State Council has issued "Guiding Opinions on Establishing and Improving the Outpatient Mutual Aid Guarantee Mechanism for Basic Medical Insurance for Employees" seeking to expand outpatient coverage under China's Basic Medical Insurance (BMI) scheme, including increasing compensation, to gradually reduce the financial burden on patients.

China aims to establish and improve the overall insurance mechanism for general outpatient expenses, particularly for outpatient chronic diseases and special diseases such as hypertension and diabetes. General outpatient expenses shall be included in the payment scope of the overall planning fund, and compensation will gradually increase with the increase in the affordability of medical funds. It is hoped that the scope of covered outpatient chronic diseases will include expenses for diseases with long treat cycles that lead to great health damage and heavy costs.

Ultimately, continuous improvement will lead to cost protection from disease protection, and medication protection services provided by qualified designated retail pharmacies will be included under the largesse of outpatient protection, with support and full play for the convenience and accessibility of designated retail pharmacies. Further, China will explore covering internet medical services.

The crediting level of personal accounts will be determined scientifically and reasonably; the crediting standard of personal accounts through the BMI is controlled, in principle, at 2% of the BMI paid by the unit. The specific allocation ratio or standard of the personal account shall be determined by the provincial medical insurance department in conjunction with the financial department, and after adjusting the pooling fund and personal account structure, the increased pooling fund is to be mainly used for outpatient mutual aid protection and improving outpatient benefits of insured persons.

As personal accounts are primarily used to pay for out-of-pocket (OOP) expenses incurred by insured persons in designated medical institutions or designated retail pharmacies (including expenses incurred by individuals for purchasing drugs, medical equipment, and medical consumables in designated retail pharmacies), China will explore allowing personal accounts to cover spouses, parents, and children participating in the BMI for urban and rural residents.

In the guidance, it was detailed that relevant parties should explore pay per capita for primary medical services and the combination of per capita payment with chronic disease management, the implementation of payment by disease type or grouping related to disease diagnosis. Payment standards for medical insurance drugs will be determined scientifically and reasonably, and authorities will guide medical institutions and patients to actively use drugs with definite curative effects and reasonable prices.

Further measures aim to improve the management of funds, including curbing fraud and misuse and setting up monitoring and evaluative methods.

European Commission Releases Pharmaceutical Strategy Roadmap

Date: April 7, 2021 | Country: BELGIUM | Region: EUROPE | Type: Editor's Choice, Policy | Keywords: #commission #europe #pharmaceuticalstrategy #policy

PRICENTRIC BRIEF:

- The European Commission has released an official roadmap for its Pharmaceutical Strategy, which was announced in November 2020
- In the roadmap, which will be open for feedback until April 27, the Commission outlines key areas of interest such as the life cycle of medicines from R&D to authorization and patient access and how to fill market gaps (e.g. new antimicrobials)
- The Commission adopted the new Pharmaceutical Strategy for Europe last year, covering everything from access and affordability to competition support and frameworks for innovation

THE DETAILS

BRUSSELS, Belgium – The European Commission has released an official roadmap for its Pharmaceutical Strategy, which was announced in November 2020.

In the roadmap, which will be open for feedback until April 27, the Commission outlines key areas of interest such as:

- The life cycle of medicines from R&D to authorization and patient access
- How to put scientific and technological advances into practice
- How to fill market gaps (e.g. new antimicrobials)
- Lessons learned from COVID-19 on how to better prepare for future pandemics

On the announcement of the new roadmap, the Commission noted: "People across the EU expect to benefit from equal access to safe, modern and affordable therapies. Medicines play an important role in this regard, as they offer therapeutic options for diagnosis, treatment and prevention of diseases. Europe's pharmaceutical sector is a major contributor to the EU economy in terms of creation of highly skilled jobs and investment in innovation.

"Digitalization and innovation in the use of real-world data open new possibilities in how medicines are developed and used. However, innovative therapies do not reach all patients across Europe at the same speed and patients might not have access to medicines they need due to shortages. The unprecedented coronavirus pandemic further demonstrated how important it is to have a crisis-resistant system and ensure the availability of medicines under all circumstances.

"At the same time, Europe's population is ageing and the EU faces a rising burden of diseases and emerging health threats such as COVID-19. Moreover, health systems and patients have difficulty bearing the cost of medicines. The EU is also becoming increasingly dependent on non-EU countries for importing medicines and their active ingredients; and issues such as antimicrobial resistance and environmental sustainability of medicines is also a concern.

"The strategy, through its objectives described above, is a policy instrument that aims to tackle these important challenges and adapt the EU pharmaceuticals system in the years to come."

Pharmaceutical Strategy for Europe

The Commission adopted the new Pharmaceutical Strategy for Europe last year, covering everything from access and affordability to competition support and frameworks for innovation.

The plan is based on four specific pillars, which include legislative and non-legislative action:

- Ensuring access to affordable medicines for patients, and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, rare diseases);
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;
- Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages;
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

On the release of the plan President of the European Commission, Ursula von der Leyen, underlined how the ongoing pandemic has "highlighted the vital need to strengthen our health systems," including access to safe, effective and high-quality medicines at an affordable price.

The plan is primarily a crisis response outline, building on lessons learned from COVID-19, in order to better prepare for future potential pandemics and other crises.

Since its implementation, the Commission notes that the revision of the legislation on rare diseases and medicines for children is already underway.

Pricentric INSIGHTS: Accurate, Comprehensive and On-Time

Pricentric INSIGHTS delivers accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in over 100 markets around the world.

Our team of researchers checks a database of over 700 reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape.

We also provide conference coverage and utilize our team of consultants to detail how major policy changes can impact market access and the global pricing landscape.

Accurate

Our team verifies every news story and works from a database of validated sources, providing links to the original source where possible.

Comprehensive

Our team provides detailed insights on daily policy and reimbursement updates for products around the globe, covering more than 100 countries to ensure a full overview of every change.

On-time

Our team delivers the news daily and covers trends to encompass the trajectory of policy and regulatory updates, releasing 3000+ articles a year to keep you informed when making company decisions.

Country-Level Decisions Roll in as EMA's PRAC Finds "Possible Link" Between AZ Jab and Rare Blood Clots

Date: April 9, 2021 | Country: AUSTRALIA, BELGIUM, BRAZIL, CHINA, FRANCE, GERMANY, HONG KONG, ITALY, MEXICO, SOUTH AFRICA, SWEDEN, UNITED KINGDOM, UNITED STATES | Region: AFRICA, ASIA & SOUTH PACIFIC, CENTRAL AMERICA, EU27 + UK, EUROPE, NORDICS, NORTH AMERICA, SOUTH AMERICA | Type: Editor's Choice, Regulation | Keywords: #astrazeneca #covid #ema #prac #regulation #review #rollout #safety #vaccination

PRICENTRIC BRIEF:

- Following a European Medicines Agency (EMA) briefing in which the regulatory body officially requested that rare blood clotting should be listed as an extremely rare potential side effect of the AstraZeneca (AZ) vaccine, various countries have made regulation changes to the way the vaccine is to be used
- European Health Ministers met on Wednesday April 7 to try and formulate common guidance on the use of the shot, but no decision was reached - Due to the lack of coordination across Europe, the EMA stated that countries should make their own decisions about how to "handle the risk"
- Pricentric is keeping track of updates in real-time and will update this article as more information comes through from each country

THE DETAILS

BRUSSELS, Belgium – Following a European Medicines Agency (EMA) briefing in which the regulatory body officially requested that rare blood clotting should be listed as an extremely rare potential side effect of the AstraZeneca (AZ) vaccine, various countries have made regulation changes to the way the vaccine is to be used.

Despite the "possible link" between the vaccine – now dubbed Vaxzevria - and unusual blood clots with low blood platelets, the EMA's safety committee (PRAC) stressed that the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.

The World Health Organization (WHO) has also confirmed that, based on current information, a "causal relationship is considered plausible but is not confirmed," before adding that further specialized studies are needed to fully understand the potential relationship between vaccination and possible risk factors.

AstraZeneca responded to the regulators' decisions, stating: "Overall, both of these reviews reaffirmed the vaccine offers a high-level of protection against all severities of COVID-19 and that these benefits continue to far outweigh the risks.

European Health Ministers met on Wednesday April 7 to try and formulate common guidance on the use of the shot, but no decision was reached. Due to the lack of coordination across Europe, the EMA stated that countries should make their own decisions about how to "handle the risk."

What You Need to Know by Country
(this will be updated in real-time as Pricentric finds more information on the matter)

EUROPE

The UK's Joint Committee on Vaccination and Immunization (JCVI) has said that "based on the available data and evidence," it is "preferable for adults aged under 30 with no underlying conditions to be offered an alternative to the AstraZeneca vaccine where available."

Both Spain and Italy have decided to limit the use of the vaccine to over-60s.

Health Officials in Germany have urged under-60s who have received the first dose of the AZ vaccine to get a different second dose.

France has previously recommended reserving the AZ vaccine for over-65s, and following the briefing has said that those who are under-55 and had a first shot of the AZ vaccine should get a second shot with a different vaccine – preferably mRNAs such as Pfizer or Moderna.

The Polish Health Ministry has stated that the vaccine is "safe" and as such will not restrict use. Wojciech Andrusiewicz, Spokesperson for Poland's Ministry of Health "As of today, Poland and the Health Ministry also confirm that the AstraZeneca vaccine is very effective and safe. In Poland we don't have any confirmed deaths after inoculation with AstraZeneca."

Belgium's Health Ministers have chosen to restrict the vaccine to the over-55s for at least one month.

The Netherlands halted the use of the vaccine in the week before the briefing and has now limited its use to over-60s.

Portugal, similarly, will only administer the AZ vaccine to those over 60 according to Health Minister Hugo de Jonge.

Sweden is currently standing by its previous recommendation to give the vaccine only to those aged 65 and above, but will undergo an additional assessment to be sure.

AMERICAS

The U.S. has not yet approved the AZ jab, and has not made comment on the reports.

Mexico and Brazil have chosen not to limit the use of the vaccine in any way following the report.

Costa Rica will continue to use AZ's COVID-19 vaccine under its COVAX contract after assessing the guidance, according to the Health Ministry.

ASIA & SOUTH PACIFIC

Australia has doubled its order of the Pfizer COVID-19 vaccine in a bid to "overhaul" its vaccination drive, based on the information the EMA provided. New South Wales, the country's most populous state, has also temporarily suspended the use of AZ.

Australia has also abandoned a goal to vaccinate nearly all of its 26 million population by the end of 2021, advising that people under 50 should take Pfizer's COVID-19 vaccine instead.

The Philippines has suspended doses for those under 60.

Hong Kong has said it will delay shipments of the AZ COVID-19 vaccine this year, based on the briefing.

South Korea said on Wednesday it will temporarily suspend the use of the vaccine for those under 60.

AFRICA

Africa's CDC has recommended that African Union Member States should continue to roll out the AstraZeneca vaccine as part of their vaccination campaigns. It added that AU Member States should ensure the routine monitoring, reporting and evaluation of Adverse Events Following Immunization and that policy decisions pertaining to vaccination roll-out be based on evidence and thorough regulatory review processes.

CDC will "continue to monitor the adverse events following immunization with all the COVID-19 vaccines and provide evidence-based recommendations as the situation evolves."

Mercosur's Drug Policy Commission Meeting Pushes for Price Transparency, Increased Access, and Collaboration on High-Priced Medicines

Date: April 12, 2021 | Country: ARGENTINA, BRAZIL, PARAGUAY, URUGUAY | Region: SOUTH AMERICA | Type: Editor's Choice, Policy | Keywords: #access #acquisition #bolivia #crossbordercollaboration #essentialmedicine #highpricedmedicine #intergovernmentalcommissionondrugpolicies #mercosur #pharmacy #pricetransparency #regulation #vaccine

PRICENTRIC BRIEF:

- Health authorities from Argentina, Brazil, Bolivia, Paraguay, and Uruguay convened this past week for a meeting of Mercosur's Intergovernmental Commission on Drug Policies to discuss proposals related to price transparency, access to drugs for neglected diseases, and the prosecution of specialty and high-priced medicines
- Attendees analyzed how they could work together on different tools that would make transparent the prices of medicines, vaccines, and other health technologies, and define and develop strategies targeting the acquisition of medicines for neglected diseases
- When it comes to specialty and high-priced medicines, Emiliano Melero, National Director of Medicines and Health Technology for Argentina, underscored the importance of Mercosur collaboration to "show ourselves as a bloc on this issue"— Thus, "the possibility of carrying out a joint diagnosis that helps us establish common policies would be essential," added Melero

THE DETAILS

BUENOS AIRES, Argentina – Health authorities from Argentina, Brazil, Bolivia, Paraguay, and Uruguay convened this past week for a meeting of Mercosur's Intergovernmental Commission on Drug Policies to discuss proposals related to price transparency, access to drugs for neglected diseases, and the prosecution of specialty and high-priced medicines.

Essentially, the Intergovernmental Commission on Drug Policies of Mercosur seeks to promote, design and propose actions and policies aimed at improving access and rational use of drugs.

Attendees analyzed how they could work together on different tools that would make transparent the prices of medicines, vaccines, and other health technologies, and define and develop strategies targeting the acquisition of medicines for neglected diseases.

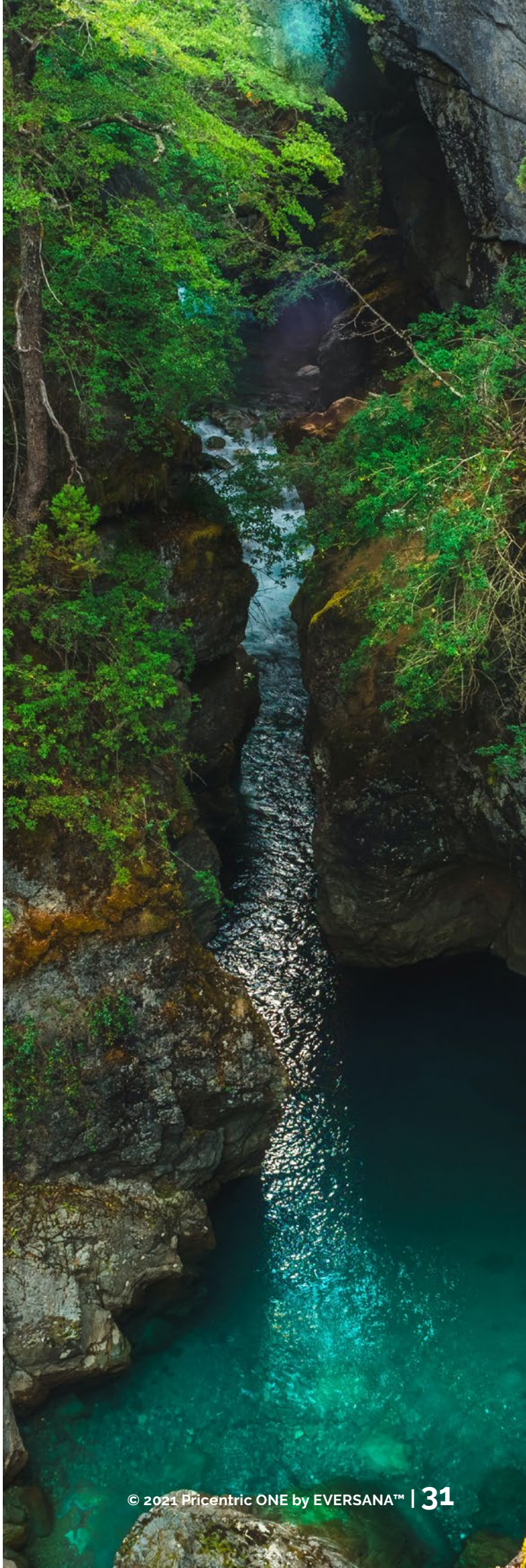
Mauricio Muraca, Argentina's Director of Essential Medicines, Supplies, and Technologies for the national portfolio, said, "It is necessary to change the approach in order to achieve a declaration by the ministers of health that expresses the will of the States parties to highlight the importance of working together with different tools that make price transparent."

Meeting attendees detailed their experiences so far regarding price transparency for medicines, vaccines, and other health technologies and agreed that joint work, common strategies, and diagnosis would behoove Mercosur.

When it comes to specialty and high-priced medicines, Emiliano Melero, National Director of Medicines and Health Technology for Argentina, underscored the importance of Mercosur collaboration to "show ourselves as a bloc on this issue." Thus, "the possibility of carrying out a joint diagnosis that helps us establish common policies would be essential," added Melero.

The push for joint work was well received among attendees.

Lastly, Mercosur's Brazilian representative put forth a strategy on popular pharmacies, a government initiative calling for public-private partnership to expand access to safe, essential, and free medicines.



PRICERIGHT®
BY EVERSANA

PriceRight® by EVERSANA

Create Value Across Your Product's Lifecycle

Take control of your pricing strategy across the globe with **PriceRight,** the **first comprehensive software suite** to help you set the optimal price and navigate the complexities of global pricing.

LAUNCH WITH CONFIDENCE.

Use our comprehensive reference-pricing tool to track global pricing by markets, predict revenue trends and easily identify risks and opportunities. Save time and focus your team on what matters by letting our software do the data crunching for you.

MAKE SMARTER DECISIONS.

Our international reference pricing (IRP) simulation software enables you to:

- Enhance your go-to-market strategy and maximize your ROI with our proprietary launch sequence optimization (LSO) algorithm.
- Automatically detect issues that can affect compliance with IRP rules
- Understand risks and forecast impacts of proposed changes on revenue
- Produce presentation-ready graphs and output analyses
- Free up internal resources to focus on other issues

MANAGE TENDERS WITH GREATER CONFIDENCE.

Gain visibility into bids and contract prices in more than 30 countries. Model a full range of discounts with easy-to-set terms and built-in flexibility.

STAY CONNECTED WHEREVER YOU ARE.

Access up-to-date pharmaceutical pricing, price governance proposals and breaking news with the PriceRight mobile app. Customizable notifications and other tools keep you informed and focused on your top priorities.

ACCURATE PRICES.

Monitor prices in over 100 markets and flag when countries are out of compliance.

LAUNCH SEQUENCE.

Our LSO has been used in over 20 major product launches

REFERENCE RULES.

List of all changes to reference rules in over 100 markets.

SECURE.

SOC-2 and ISO 27001 certification.

LEARN MORE AND REQUEST A DEMO AT INFO@EVERSANA.COM

NICE Strategy 2021-2026 Seeks to Cross Boundaries, Reduce Bureaucracy, Accelerate Access to New Treatments

Date: April 6, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Editor's Choice, Policy | Keywords: #access #cellandgenetherapy #covid19 #crossbordercollaboration #digitaltechnology #hta #ilap #innovativemedicinesfund #nice #r&d #realworlddata #regulation

PRICENTRIC BRIEF:

- The National Institute for Health and Care Excellence (NICE) has published its 2021-2026 strategy, which outlines agency's trajectory over the next five years in consideration of lessons learned during the COVID-19 Pandemic
- With this strategy, NICE has a "A renewed determination to prioritize our work to reduce those health inequalities that have been highlighted during the pandemic, to work seamlessly across boundaries, to reduce bureaucracy, and to speed up access to the latest and most effective treatments," explained NICE Chair Sharmila Nebhrajani and NICE Chief Executive Professor Gillian Leng
- The strategy consists of four pillars: 1) Rapid, robust, and responsive technology evaluation; 2) Dynamic, living guideline recommendations; 3) Effective guidance uptake to maximize our impact; and 4) Leadership in data, research, and science

THE DETAILS

LONDON, United Kingdom – The National Institute for Health and Care Excellence (NICE) has published its 2021-2026 strategy, which outlines the agency's trajectory over the next five years in consideration of lessons learned during the COVID-19 Pandemic.

According to NICE, the Pandemic "provided a catalyst for the type of change that we already knew we needed to make," including expediting access to new treatments and technologies and integrating real world data (RWD) into evaluations.

With this strategy, NICE has a "A renewed determination to prioritize our work to reduce those health inequalities that have been highlighted during the pandemic, to work seamlessly across boundaries, to reduce bureaucracy, and to speed up access to the latest and most effective treatments," explained NICE Chair Sharmila Nebhrajani and NICE Chief Executive Professor Gillian Leng.

The strategy consists of four pillars: 1) Rapid, robust, and responsive technology evaluation; 2) Dynamic, living guideline recommendations; 3) Effective guidance uptake to maximize our impact; and 4) Leadership in data, research, and science.

Below is an overview of NICE's strategic roadmap, including key measures, for 2021-2026.

Rapid, robust, and responsive technology evaluation

2021-2022

- Implement revised NICE process and methods manual for technologies with Innovative Licensing and Access Pathway (ILAP) and Innovative Medicines Fund arrangements
- Launch new Office for Digital Health
- Develop beta version of the Life Sciences Hub

2023-2024

- Develop targeted processes and methods for cell and gene therapies, artificial intelligence, and genomics
- Build on joint working with national and international HTA bodies
- Develop managed access pathways for medical technologies (including digital)

2025-2026

- Improve rapid access to new technologies, aiming for an equivalent approach for medical devices, diagnostics, and digital technologies
- Realize a new, dynamic approach to health technology evaluation and management, fully aligned with living guidelines and data analytics

Dynamic, living guideline recommendations

2021-2022

- Identify and adopt selected guidance authoring tool
- Products selected guidelines in new interactive format
- Establish cross-agency panel on priority topics

2023-2024

- Incorporate HTAs into practice recommendations
- Present recommendations in interactive format
- Establish advisory committees for all key topic suites

2025-2026

- Publish consolidated portfolio of high priority recommendations that are rapidly updated, interactive, and easy to access
- Publish integrated guidelines on key topics

Effective guidance uptake to maximize our impact

2021-2022

- Develop new implementation strategy
- Complete patient safety review and policy
- Explore a partnership to improve access to guidelines

2023-2024

- Embed NICE guidance in partners' regulation, monitoring, and improvement frameworks
- Build links with academic units to be at forefront of implementation science and support evaluation

2025-2026

- Embed NICE guidance in decision support systems
- Ensure fully automated monitoring of device compliance, impact, and value

Leadership in data, research, and science

2021-2022

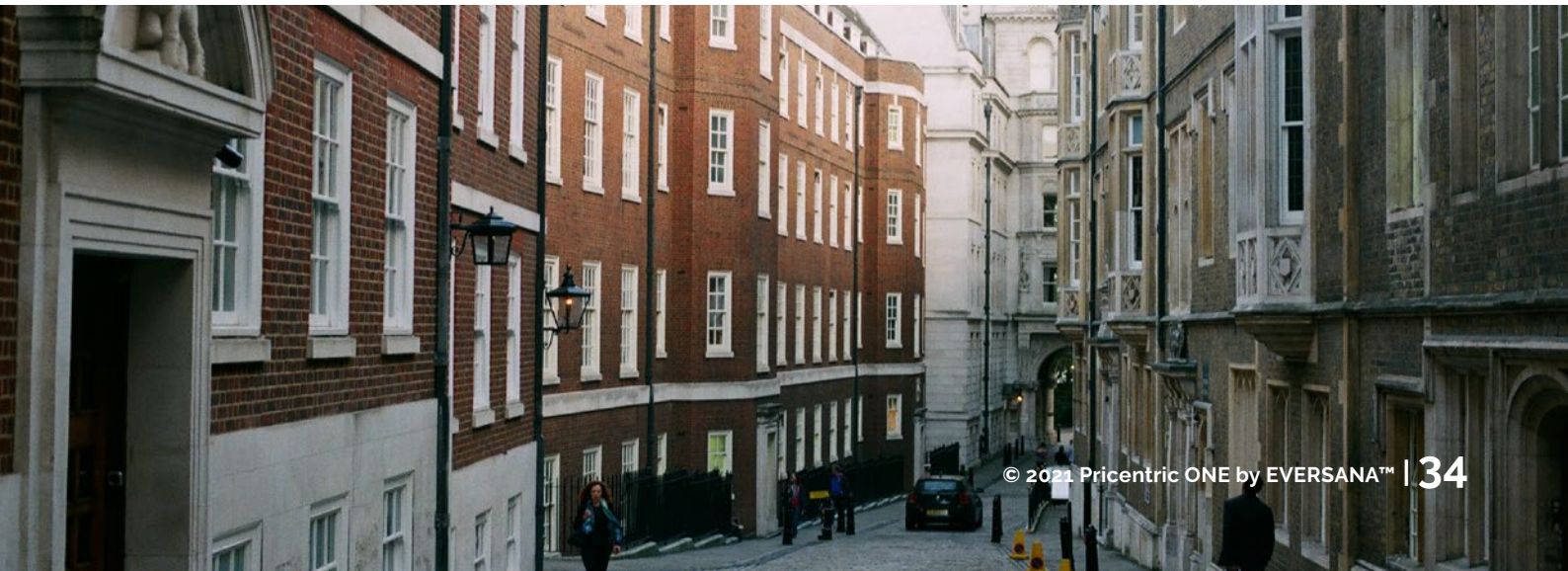
- Establish research and data partnerships
- Establish "NICE Listens" program
- Explore options for citable publications platform

2023-2024

- Develop RWD data methods and standards program
- Develop approach to considering environmental impact
- Publish evidence reviews and economic analyses

2025-2026

- Develop position as a though leader and research active organization in health technology assessment (HTA) methods and guidelines, including environmental impact
- Consolidate role as a global leader in patient and public engagement



IQWiG Tasked by G-BA to Collect Application-Related Data on CAR-T Therapies

Date: April 2, 2021 | Country: GERMANY | Region: EUROPE | Type: Editor's Choice, Regulation | Keywords: #carttherapy #celland genetherapy #datacollection #gba #iqwig #leukemia #postlaunchdata #realworldevidence

PRICENTRIC BRIEF:

- The Federal Joint Committee (G-BA) has tasked the Institute for Quality and Efficiency in Health Care (IQWiG) to come up with new ways to collect application-related data for new drugs, specifically CAR-T cell therapies, and its first concept should be ready in six months
- IQWiG will develop its own concept for collecting and evaluating data for these drugs—To start, IQWiG is developing a scientific concept for CAR-T cell therapies for the treatment of hemo-oncological diseases (including leukemia), which will be compared to existing therapy alternatives
- Post-launch data collection in Germany has always been for one drug, not several new products

THE DETAILS

BERLIN, Germany – The Federal Joint Committee (G-BA) has tasked the Institute for Quality and Efficiency in Health Care (IQWiG) to come up with new ways to collect application-related data for new drugs, specifically CAR-T cell therapies.

Post-launch data collection in Germany has always been for one drug, not several new products.

In February, G-BA asked Novartis to gather data on the use of spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec) in clinical practice, in order to evaluate it for additional benefit assessment. Further, G-BA wanted Novartis to plan and implement a corresponding registry study to help close evidence gaps.

Given the uncertainty regarding the long-term use of such products, the collection of "care-related" data allows for the creation of a better database which can be used to assess the additional benefit of these products, according to certain criteria.

IQWiG will develop its own concept for collecting and evaluating data for these drugs. To start, IQWiG is developing a scientific concept for CAR-T cell therapies for the treatment of hemo-oncological diseases (including leukemia), which will be compared to existing therapy alternatives.

Its first concept should be ready in six months, said G-BA.

Germany's G-BA Publishes 2021 Work Plan

Date: April 12, 2021 | Country: GERMANY | Region: EUROPE | Type: Editor's Choice, Policy | Keywords: #atmp #collection #committee #evaluation #evidence #federal #funding #gba #germany

PRICENTRIC BRIEF:

- Germany's Federal Joint Committee (G-BA) has published its "Work Plan" for 2021, including a "wide range of statutory orders and consultations on new topics"
- According to the group, the "unifying element of the individual work assignments is to improve health care in Germany," and as such the organization will work on the outlined selection of topics in addition to the routine updating and updating of the guidelines
- As the number of advanced therapy medicinal products (ATMPs) going through assessment is increasing, G-BA "will now adopt the framework directive for its quality-assured application," as "so far, quality assurance for the individual ATMPs has been regulated in separate resolutions"

THE DETAILS

BERLIN, Germany – Germany's Federal Joint Committee (G-BA) has published its "Work Plan" for 2021, including a "wide range of statutory orders and consultations on new topics."

According to the group, the "unifying element of the individual work assignments is to improve health care in Germany," and as such the organization will work on the outlined selection of topics in addition to the routine updating and updating of the guidelines.

Drug Evaluation

As the number of advanced therapy medicinal products (ATMPs) going through assessment is increasing, G-BA "will now adopt the framework directive for its quality-assured application," as "so far, quality assurance for the individual ATMPs has been regulated in separate resolutions."

Additionally, experience gained from G-BA's data-collection process regarding Novartis' Zolgensma (onasemnogene abeparvovec) will be "incorporated into the examination of further drug candidates."

G-BA expects that "in this calendar year at least one other active ingredient will probably receive such a requirement in order to record data from practical application."

In February, G-BA asked Novartis to collect data on Zolgensma when used in routine clinical practice, in order to evaluate it for an additional benefit assessment.

This is because there is no direct comparison available for Zolgensma in the treatment of spinal muscular atrophy (SMA), due to the nature and the novelty of the treatment, and as such the G-BA says that its comparison to treatment alternatives cannot yet be conclusively assessed.

In order to mitigate these gaps in data, the G-BA wants Novartis to plan and implement a corresponding registry study in order to close the evidence gaps.

As such, to help the group form the basis for a new additional benefit assessment, all doctors who want to use Zolgensma are obliged to take part in the data collection.

Interchangeability of Biologics

G-BA has outlined plans to develop the "Annex VIIa of the Drugs Directive," which has the potential to provide information about the authorization relationships for active substances that are biotechnologically produced and have at least one similarly biotechnologically produced product.

Funding

The Innovation Fund has been allocated an annual volume of EUR 200 million until 2024, of which 80% goes into promoting new forms of care and 20% goes into health services research.

A detailed outline of G-BA's plans is available here.

.

GKV-SV, BVDW Settle on Initial Framework for Health App Reimbursement

Date: April 20, 2021 | Country: GERMANY | Region: EUROPE | Type: Policy, Pricing & Reimbursement | Keywords: #amnog #arbitration #bfarm #bvdw #diga #gba #gkvsv #healthapps #frameworkagreement #hta #maximumprice #negotiation

PRICENTRIC BRIEF:

- Germany's Federal Association of the Digital Economy (BVDW) and umbrella payer, the National Association of Statutory Health Insurance Funds (GKV-SV) have concluded a framework agreement for the reimbursement of health apps (DiGAs) prescribed to patients by physicians
- DiGAs were first eligible for reimbursement in October 2020 following the passing of the Digital Supply Act (DGV) in December 2019, pending approval from evaluative body, the Federal Institute for Drugs and Medical Devices (BfARM); however, in January of this year, GKV-SV outlined why it was less than keen on the way in which DiGAs would be reimbursed, specifically taking aim at the medical benefit of these apps versus comparable apps or not using an app at all, the fast-track procedure provided to these apps, and their pricing—GKV-SV backed a maximum price to be fixed for apps, set on the first day of reimbursement
- Under the framework agreement, the price of DiGAs is set to commence six months after listing by BfARM, and the framework provides room for necessary renegotiations considering product changes and allows for arbitration in the event of any disagreement during negotiations

THE DETAILS

BERLIN, Germany – Germany's Federal Association of the Digital Economy (BVDW) and umbrella payer, the National Association of Statutory Health Insurance Funds (GKV-SV) have concluded a framework agreement for the reimbursement of health apps (DiGAs) prescribed to patients by physicians.

DiGAs were first eligible for reimbursement in October 2020 following the passing of the Digital Supply Act (DGV) in December 2019, pending approval from Germany's evaluative body, the Federal Institute for Drugs and Medical Devices (BfARM). Apps would be subject to the same one year of free pricing privilege for new drugs under Germany's AMONG procedure while their level of

added benefit is evaluated by Germany's drug assessor, the Federal Joint Committee (G-BA).

However, in January of this year, GKV-SV outlined why it was less than keen on the way in which DiGAs would be reimbursed, specifically taking aim at the medical benefit of these apps versus comparable apps or not using an app at all, the fast-track procedure provided to these apps, and their pricing—GKV-SV backed a maximum price to be fixed for apps, set on the first day of reimbursement.

Appmakers were opposed to maximum prices for apps, given that these stakeholders have underscored the innovativeness of their apps and the benefits they offer the health care system. Plus, BfARM evaluates apps based on data security, data protection, functionality, efficacy, and safety.

As such, the framework aims to simplify how reimbursed is agreed on between an appmaker and GKV-SV by codifying the basis for negotiation.

Under the framework agreement, the price of DiGAs is set to commence six months after listing by BfARM, and the framework provides room for necessary renegotiations considering product changes and allows for arbitration in the event of any disagreement during negotiations.

Chairman of BVDW's working group on prescription apps Philipp Butzbach said, "As BVDW, we have repeatedly placed the negotiations in the context of innovation and digitization. We have succeeded in taking the interests of the digital economy into account as much as possible. The jointly found solution is new territory for everyone involved and is certainly a good starting point for the widespread introduction of digital health applications in the German health system."

Butzbach added, "Even if it is only a beginning and many adjustments will certainly be necessary due to experience gained, with the framework agreement there is now a solid basis to start with DiGA in Germany."

BfARM has a registry of DiGAs approved for use in Germany, which can be found here.

Ukraine to Adopt National Rare Disease Strategy, Announces Health Minister Stepanov

Date: April 1, 2021 | Country: UKRAINE | Region: EUROPE | Type: Editor's Choice, Policy | Keywords: #access #earlydiagnosis #healthministry #nationalstrategy #orphandrug #patientgroup #patientregistry #raredisease

PRICENTRIC BRIEF:

- At the recent National Health, Medical Care, and Medical Insurance meeting, Ukraine Minister of Health Maksym Stepanov announced that Ukraine is initiating the adoption of the National Strategy for Prevention, Diagnosis, and Treatment of Rare (Orphan) Diseases
- Key components of the National Strategy include: collecting statistical information on the frequency and spectrum of rare diseases in Ukraine; introducing effective methods of early diagnosis of rare diseases; introducing effective methods of treatment of rehabilitation for affected patients to reduce disability and mortality; and training qualified specialists in the diagnosis and treatment of rare diseases, among other steps
- The Ministry of Health has also backed proposals from patient groups requesting that working groups on medicines for patients with rare diseases include specialists and consider recommendations from patient groups, including Orphan Diseases of Ukraine, the All-Ukrainian Association of Cystic Fibrosis, and Patients with Pulmonary Hypertension

THE DETAILS

KYIV, Ukraine – At the recent National Health, Medical Care, and Medical Insurance meeting, Ukraine Minister of Health Maksym Stepanov announced that Ukraine is initiating the adoption of the National Strategy for Prevention, Diagnosis, and Treatment of Rare (Orphan) Diseases.

Not yet fully implemented, the National Strategy is a nominative act, and rare diseases were first acknowledged at the state-level in 2014. Ukraine still lacks a register of citizens suffering from rare diseases, although, according to approximated data, one in 2,000 Ukrainians are affected by a rare disease.

Stepanov said, "I consider that it is necessary to adopt a National Strategy for the prevention, diagnosis, and treatment of orphan diseases. Because its absence threatens access to continuous adequate treatment of orphan patients, as well as providing them with vital medicines and special food, it is necessary to adopt a National Strategy for the prevention, diagnosis, and treatment of orphan diseases. Every life is invaluable, so the attitude of the government and society to orphan patients is a litmus test for the civilization of the state."

Key components of the National Strategy include:

- Collecting statistical information on the frequency and spectrum of rare diseases in Ukraine;
- Introducing effective methods of early diagnosis of rare diseases;
- Introducing effective methods of treatment of rehabilitation for affected patients to reduce disability and mortality;
- Training qualified specialists in the diagnosis and treatment of rare diseases;
- Increasing doctor and patient awareness of these diseases;
- Ensuring patients with rare diseases access to treatment;
- Meeting the specific needs of those suffering from rare diseases; and
- Developing national and international cooperation in the field of prevention, diagnosis, and treatment of rare diseases.

The Ministry of Health has also backed proposals from patient groups requesting that working groups on medicines for patients with rare diseases include specialists and consider recommendations from patient groups, including Orphan Diseases of Ukraine, the All-Ukrainian Association of Cystic Fibrosis, and Patients with Pulmonary Hypertension.

RWE-focused "GetReal Institute" Made Up of HTA Bodies and Stakeholders Launches in Europe

Date: April 29, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Cost Effectiveness, European Union, HTA, Pricing & Reimbursement | Keywords: #europe #getreal #hta #imi #institute #nice #rwd #rwe

PRICENTRIC BRIEF:

- A group of health technology assessment (HTA) bodies and stakeholders throughout Europe have come together to create the new "GetReal Institute": a not-for-profit multi-stakeholder organization with a focus on implementing real-world evidence (RWE) in health care decision-making in Europe
- The group, which will launch 28 April 2021, builds on the work of the existing Innovative Medicines Initiative (IMI) GetReal Initiative
- Dr Felix Greaves, director of Science, Evidence and Analytics at NICE, said: "NICE is highly regarded around the globe and is seen as a world leader in health technology evaluation and the development of clinical guidelines. Our involvement in the GetReal Institute fits very well with our newly launched five-year strategy and will benefit work in the Science, Evidence and Analytics directorate"

THE DETAILS

AMSTERDAM, The Netherlands – A group of health technology assessment (HTA) bodies and stakeholders throughout Europe have come together to create the new "GetReal Institute": a not-for-profit multi-stakeholder organization with a focus on implementing real-world evidence (RWE) in health care decision-making in Europe.

The group, which will launch 28 April 2021, builds on the work of the existing Innovative Medicines Initiative (IMI) GetReal Initiative.

According to a release, the initiative will act as:

- A convening platform for key stakeholder groups in Europe – including regulatory agencies, health technology assessment (HTA) bodies, health care systems, patient organizations, academia, industry, and data partners – to reach a common understanding and prioritization of critical opportunities and challenges in the generation, evaluation, and use of RWE
- An incubator and design lab for demonstration projects to clarify scientific and operational uncertainties in RWE approaches and methods and for development of practical tools to facilitate the adoption of RWE
- A hub for sharing learnings among initiatives, consortia, and organizations working to strengthen the use of RWE in health-care decision-making in Europe, and
- A source of trusted, high quality RWE education and training resources through the established and highly regarded GetReal Academy.

Additionally, the project will be initially prioritising three core focus areas in:

1. Reducing barriers to the secondary use of data sources for health care decision-making, including challenges with real world data discoverability, quality, and accessibility
2. Bridging the gap between RWE and conventional randomized controlled trial (RCT) approaches through, for example, incorporation of "real world" elements in RCT design and implementation, use of real world data-based external comparator arms in clinical trials, and use of non-interventional study designs
3. Addressing the evidence needs of "downstream" decision-makers — HTA bodies, payers, clinical guideline developers, clinicians, and patients — whose perspectives and decision contexts are as important as those of regulatory agencies

No official contracts have been signed, however the below organizations have expressed previous interest in joining the initiative:

- Clinical Practice Research Datalink (CPRD) (UK)
- Eli Lilly and Company
- F. Hoffmann-La Roche
- GlaxoSmithKline
- International Alliance of Patients' Organizations (IAPO)
- Janssen, Pharmaceutical Companies of Johnson & Johnson

- National Institute for Health and Care Excellence (NICE) (UK)
- Norwegian Medicines Agency (NoMA)
- University Medical Center Utrecht (UMCU)

Dr Felix Greaves, director of Science, Evidence and Analytics at NICE, said: "NICE is highly regarded around the globe and is seen as a world leader in health technology evaluation and the development of clinical guidelines.

"Our involvement in the GetReal Institute fits very well with our newly launched five-year strategy and will benefit work in the Science, Evidence and Analytics directorate.

"As well as looking at evidence generation for pharmaceuticals, the GetReal Institute will have an opportunity to expand its remit to incorporate medical technologies and digital health interventions. These are two areas where NICE shares a mutual interest of better data and research.

Earlier this year EUCope, a trade body for small to medium-sized innovative pharma companies, published a "Position Paper on New Payment & Funding Approaches for ATMPs."

The paper goes on to explain how a coherent approach with the scientific community could benefit healthcare systems, as well as increased use of real-world evidence (RWE) and potentially specific ATMP funds.

Options such as RWE-collection, outcome-based models and annuity payments are being debated more and more in order to help mitigate affordability issues and get patients the fastest access to ATMPs across Europe.

Speaking at the recent EPA World Congress, Bernard Hamelin MD, Former Global Head of Medical Evidence Generation, Sanofi, noted how with the introduction of RWE and advanced analytics, the traditional framework for using randomized clinical trial (RCT) data in economic evaluations and HTA will change over the next years.

HTAs, Approvals, Launches & Price Changes

HTA Decisions: Germany

- G-BA in Germany has conducted an assessment of Imfinzi (Durvalumab; Astrazeneca) for Small Cell Lung Cancer (etoposide And Carboplatin Or Cisplatin). Result: Durvalumab in combination with chemotherapy leads to a statistically significant increase in overall survival compared to chemotherapy, the extent of which is rated as a small improvement. In the overall assessment, durvalumab in combination with etoposide and either carboplatin in the first-line treatment of adult patients with advanced small-cell lung cancer appears to have a minor added benefit.
- G-BA in Germany has conducted an assessment of Imbruvica (Ibrutinib; Janssen) for CII. Result: An added benefit has not been proven for ibrutinib in combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia with 17p deletion and/or TP53 mutation or for whom chemoimmunotherapy is not indicated for other reasons.
- G-BA in Germany has conducted an assessment of Epclusa (Sofosbuvir; Gilead Sciences Inc) for Chronic Hepatitis C. Result: The company has not provided data for the assessment of the added value of sofosbuvir/velpatasvir compared to the appropriate comparative therapies for this population.
- G-BA in Germany has conducted an assessment of Imbruvica (Ibrutinib; Janssen) for CII. Result: An added benefit has not been proven for ibrutinib in combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia for whom treatment with fludarabine in combination with cyclophosphamide and rituximab is not an option.
- G-BA in Germany has conducted an assessment of Epclusa (Sofosbuvir; Gilead Sciences Inc) for Chronic Hepatitis C. Result: The submitted single-arm STUDY 1143 is not suitable for the assessment of an additional benefit due to the lack of comparison with the respective comparative therapy. Overall, no added value can be derived based on the data provided.
- G-BA in Germany has conducted an assessment of Epclusa (Sofosbuvir; Gilead Sciences Inc) for Chronic Hepatitis C. Result: The company has not provided data for the assessment of the added value of sofosbuvir/velpatasvir compared to the appropriate comparative therapies for this population.
- G-BA in Germany has conducted an assessment of Epclusa (Sofosbuvir; Gilead Sciences Inc) for Chronic Hepatitis C. Result: The company has not provided data for the assessment of the added value of sofosbuvir/velpatasvir compared to the appropriate comparative therapies for this population.
- G-BA in Germany has conducted an assessment of Imbruvica (Ibrutinib; Janssen) for CII. Result: Overall, there is a clear advantage in overall survival and, at the same time, predominantly advantages in the side effects category. Based on the available data for ibrutinib in combination with rituximab for adult patients with previously untreated chronic lymphocytic leukemia for whom treatment with fludarabine in combination with cyclophosphamide and rituximab is an option, a considerable additional benefit compared to fludarabine in combination with cyclophosphamide and rituximab therapy can be derived.

HTA Decisions: Germany (cont.)

- G-BA in Germany has conducted an assessment of Crysvita (Burosumab; Kyowa Kirin) for Hypophosphatemia (x-linked). Result: Uncertainties regarding the validity of the evidence arise due to the 24-week treatment duration for the assessment of the sustainability of the effects, about the adjustment and stratification factors of the randomization for the responder analyzes of the WOMAC as well as due to deviations in the study documents on endpoints of the side effects category. Also, it remains unclear whether the results of the UX023-CL303 study can also be applied to patients who have no symptoms in the form of bone pain. Overall, the G-BA concludes that there is a hint of a minor additional benefit of burosumab for the treatment of adult patients with XLH.

- G-BA in Germany has conducted an assessment of Nustendi (Bempedoic Acid + Ezetimibe; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: The patients included do not adequately reflect the approved field of application according to the product information, as only 1.4% of the patients had prior ezetimibe treatment, which, according to the product information, is a prerequisite for treatment with bempedoic acid / ezetimibe. Hence, an added benefit has not been proven.

- G-BA in Germany has conducted an assessment of Epidyolex (Cannabidiol; Gw Pharmaceuticals) for Dravet Syndrome. Result: Due to the duration of the study, uncertainties remain in the present application area and against the background of the possible pharmacokinetic interactions of cannabidiol with clobazam is to be regarded as short, the small study population, and thereby, that a patient-specific titration was not shown in the studies. The subpopulation conforming to the technical information (combination with clobazam) was not a prior planned and also not stratified randomized. No adult data were obtained patient presented. For the frequency of convulsive seizures and the reduction of convulsive seizures by 75%, at 20 mg/kg / d also for the reduction by 25% and 50%, and at 20 mg/kg / d for the increase the frequency of convulsive seizures, there were statistically significant and relevant advantages of cannabidiol. Overall, a hint of a considerable added benefit is found.

- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.

- G-BA in Germany has conducted an assessment of Ozempic (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.

- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis who have no adverse prognostic factors 2 and who responded insufficiently to previous treatment with a disease-modifying antirheumatic drug (classic DMARDs, including methotrexate (MTX)) or who did not tolerate it, the added benefit of filgotinib (as monotherapy or in combination with MTX) compared to the ACT is not proven.

HTA Decisions: Germany (cont.)

- G-BA in Germany has conducted an assessment of Ozempic (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.

- G-BA in Germany has conducted an assessment of Crysvita (Burosumab; Kyowa Kirin) for Hypophosphatemia (x-linked). Result: Uncertainties regarding the validity of the evidence arise due to the 24-week treatment duration for the assessment of the sustainability of the effects, about the adjustment and stratification factors of the randomization for the responder analyzes of the WOMAC as well as due to deviations in the study documents on endpoints of the side effects category. Also, it remains unclear whether the results of the UX023-CL303 study can also be applied to patients who have no symptoms in the form of bone pain. Overall, the G-BA concludes that there is a hint of a minor additional benefit of burosumab for the treatment of adult patients with XLH.

- G-BA in Germany has conducted an assessment of Epidyolex (Cannabidiol; Gw Pharmaceuticals) for Dravet Syndrome. Result: Due to the duration of the study, uncertainties remain in the present application area and against the background of the possible pharmacokinetic interactions of cannabidiol with clobazam is to be regarded as short, the small study population, and thereby, that a patient-specific titration was not shown in the studies. The subpopulation conforming to the technical information (combination with clobazam) was not a prior planned and also not stratified randomized. No adult data were obtained patient presented. For the frequency of convulsive seizures and the reduction of convulsive seizures by 75%, at 20 mg/kg / d also for the reduction by 25% and 50%, and at 20 mg/kg / d for the increase the frequency of convulsive seizures, there were statistically significant and relevant advantages of cannabidiol. Overall, a hint of a considerable added benefit is found.

- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No study was presented that would assess the added benefit of a semaglutideMonotherapy when diet and exercise alone in adult patients with Diabetes Mellitus type 2 without manifest cardiovascular disease2 the blood sugar is insufficient to control and the use of metformin due to intolerance considered unsuitable compared to the ACT(Sulfonylurea: glibenclamide or glimepiride) would have been suitable.

- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.

- G-BA in Germany has conducted an assessment of Ozempic (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No study was presented that would assess the added benefit of a semaglutideMonotherapy when diet and exercise alone in adult patients with Diabetes Mellitus type 2 without manifest cardiovascular disease2 the blood sugar is insufficient to control and the use of metformin due to intolerance considered unsuitable compared to the ACT(Sulfonylurea: glibenclamide or glimepiride) would have been suitable.

- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis for whom initial therapy with biotechnologically manufactured DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated, the added benefit of filgotinib as monotherapy over the ACT is not proven.

HTA Decisions: Germany (cont.)

- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.
- G-BA in Germany has conducted an assessment of Nustendi (Bempedoic Acid + Ezetimibe; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: No data were presented compared to the appropriate comparator therapy. Hence, an added benefit has not been proven.
- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.
- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis who have inadequate prior treatment with one or more bDMARDs and / or tsDMARDs responded or did not tolerate them, the added benefit for filgotinib (as monotherapy or in combination with MTX) compared to the ACT is not proven.
- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.
- G-BA in Germany has conducted an assessment of Nilemdo (Bempedoic Acid; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: No data was present for comparator study. Hence, an added benefit has not been proven.
- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.
- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis for whom initial therapy with biotechnologically manufactured DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated, the added benefit of filgotinib in combination with MTX compared to the ACT adalimumab + MTX derived a hint of a minor added benefit.

HTA Decisions: Germany (cont.)

- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors3)would have been suitable.
- G-BA in Germany has conducted an assessment of Epidyolex (Cannabidiol; Gw Pharmaceuticals) for Seizures (lennox-gastaut Syndrome-pediatric). Result: Due to the duration of the study, uncertainties remain in the present application area and against the background of the possible pharmacokinetic interactions of cannabidiol with clobazam is to be regarded as short, the small study population, and thereby, that a patient-specific titration was not shown in the studies. The subpopulation conforming to the technical information (combination with clobazam) was not a prior planned and also not stratified randomized. No adult data were obtained patient presented. For the frequency of convulsive seizures and the reduction of convulsive seizures by 75%, at 20 mg/kg / d also for the reduction by 25% and 50%, and at 20 mg/kg / d for the increase the frequency of convulsive seizures, there were statistically significant and relevant advantages of cannabidiol. Overall, a hint of a considerable added benefit is found.
- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis who have no adverse prognostic factors 2 and who responded insufficiently to previous treatment with a disease-modifying antirheumatic drug (classic DMARDs, including methotrexate (MTX)) or who did not tolerate it, the added benefit of filgotinib (as monotherapy or in combination with MTX) compared to the ACT is not proven.
- G-BA in Germany has conducted an assessment of Rybelsus (Semaglutide; Novo Nordisk) for Diabetes Mellitus (type 2). Result: No direct comparative studies were presented that were useful for the assessment of the added benefit of semaglutide monotherapy when diet and exercise are used alone adult patients with type 2 diabetes mellitus with overt cardiovascular disease 2 insufficient control of blood sugar and an application of metformin is considered unsuitable due to intolerance to appropriate comparator therapy (sulfonylurea: glibenclamide or glimepiride in combination with other medicines to treat cardiovascular risk factors) would have been suitable.
- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis who have no adverse prognostic factors 2 and who responded insufficiently to previous treatment with a disease-modifying antirheumatic drug (classic DMARDs, including methotrexate (MTX)) or who did not tolerate it, the added benefit of filgotinib (as monotherapy or in combination with MTX) compared to the ACT is not proven.
- G-BA in Germany has conducted an assessment of Nustendi (Bempedoic Acid + Ezetimibe; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: No data were presented compared to the appropriate comparator therapy. Hence, an added benefit has not been proven.
- G-BA in Germany has conducted an assessment of Ayvakyt (Avapritinib; Blueprint) for Gastrointestinal Stromal Tumor. Result: The reliability of the conclusions is assessed with a reference point because only a one-armed study is available and a comparative assessment is not possible. Overall, a hint of a non-quantifiable added benefit was determined for avapritinib because the scientific data basis does not allow quantification.
- G-BA in Germany has conducted an assessment of Nilemdo (Bempedoic Acid; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: No data was present for comparator study. Hence, an added benefit has not been proven.

HTA Decisions: Germany (cont.)

- G-BA in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For adult patients with moderately to severely active rheumatoid arthritis who have inadequate prior treatment with one or more bDMARDs and / or tsDMARDs responded or did not tolerate them, the added benefit for filgotinib (as monotherapy or in combination with MTX) compared to the ACT is not proven.
- G-BA in Germany has conducted an assessment of Nilemdo (Bempedoic Acid; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: The vast majority continued their lipid-lowering therapy, which was inadequate at the start of the study. The treatment in the comparator arm therefore does not correspond to the ACT. Hence, an added benefit has not been proven.
- G-BA in Germany has conducted an assessment of Nustendi (Bempedoic Acid + Ezetimibe; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: The patients included do not adequately reflect the approved field of application according to the product information, as only 1.4% of the patients had prior ezetimibe treatment, which, according to the product information, is a prerequisite for treatment with bempedoic acid / ezetimibe. Hence, an added benefit has not been proven.

HTA Decisions: France

- HAS/TC in France has conducted an assessment of Vocabria (Cabotegravir; Viiv Healthcare) for Hiv. Result: The actual benefit of VOCABRIA (cabotegravir) 30 mg tablet and VOCABRIA (cabotegravir) 600 mg suspension for injection in combination with rilpivirine is significant only in virologically controlled adults (viral load <50 copies / mL) on stable antiretroviral therapy for at least 6 months, with more than 200 CD4 / mm 3 , without evidence of current or previous resistance and without history of virological failure to agents of the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs) and integrase inhibitors (INI). SMR (IMPORTANT); ASMR V (ABSENCE).
- HAS/TC in France has conducted an assessment of Rekambys (Rilpivirine; Viiv Healthcare) for Hiv. Result: The actual benefit of REKAMBYS (rilpivirine) 900 mg suspension for injection, in combination with cabotegravir injection, is significant only in virologically controlled adults (viral load <50 copies / mL) on stable antiretroviral therapy for at least 6 months, having more than of 200 CD4 / mm 3 , without evidence of current or previous resistance and without history of virological failure to agents of the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs) and integrase inhibitors (INIs). SMR (IMPORTANT); ASMR V (ABSENCE).
- HAS/TC in France has conducted an assessment of Rekambys (Rilpivirine; Viiv Healthcare) for Hiv. Result: The actual benefit of REKAMBYS (rilpivirine) 900 mg suspension for injection, in combination with injectable cabotegravir, is insufficient to justify coverage by national solidarity in other populations in the Marketing Authorization. SMR (INSUFFICIENT).
- HAS/TC in France has conducted an assessment of Vocabria (Cabotegravir; Viiv Healthcare) for Hiv. Result: The actual benefit of VOCABRIA (cabotegravir) 30 mg tablet and VOCABRIA (cabotegravir) 600 mg suspension for injection in combination with rilpivirine is insufficient to justify coverage by national solidarity in the other populations in the marketing authorization. SMR (INSUFFICIENT).

HTA Decisions: United Kingdom

- NICE in United Kingdom has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: Acalabrutinib as monotherapy is recommended, within its marketing authorisation, as an option for previously treated CLL in adults. It is recommended only if the company provides the drug according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: Acalabrutinib as monotherapy is recommended as an option for untreated chronic lymphocytic leukaemia (CLL) in adults, only if there is no 17p deletion or TP53 mutation, and fludarabine plus cyclophosphamide and rituximab (FCR), or bendamustine plus rituximab (BR) is unsuitable, and the company provides the drug according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: Acalabrutinib as monotherapy is recommended as an option for untreated chronic lymphocytic leukaemia (CLL) in adults, only if there is a 17p deletion or TP53 mutation and the company provides the drug according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Bavencio (Avelumab; Merck) for Merkel Cell Carcinoma. Result: Avelumab is recommended as an option for treating metastatic Merkel cell carcinoma in adults who have not had chemotherapy for metastatic disease. It is recommended only if the company provides avelumab according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Bavencio (Avelumab; Pfizer) for Merkel Cell Carcinoma. Result: Avelumab is recommended as an option for treating metastatic Merkel cell carcinoma in adults who have not had chemotherapy for metastatic disease. It is recommended only if the company provides avelumab according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Lynparza (Olaparib; Astrazeneca) for Ovarian Cancer (brca Mutation) (bevacizumab). Result: Olaparib plus bevacizumab is recommended for use within the Cancer Drugs Fund as an option for maintenance treatment of advanced (International Federation of Gynecology and Obstetrics [FIGO] stages 3 and 4) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in adults when there has been a complete or partial response after first-line platinum-based chemotherapy plus bevacizumab, and the cancer is associated with homologous recombination deficiency (HRD). It is recommended only if the conditions in the managed access agreement for olaparib are followed.
- NICE in United Kingdom has conducted an assessment of Nilemdo (Bempedoic Acid; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: Bempedoic acid with ezetimibe is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if: • Statins are contraindicated or not tolerated • Ezetimibe alone does not control low-density lipoprotein cholesterol well enough, and • The company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Nilemdo (Bempedoic Acid; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: Bempedoic acid with ezetimibe is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if: • Statins are contraindicated or not tolerated • Ezetimibe alone does not control low-density lipoprotein cholesterol well enough, and • The company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement.

HTA Decisions: United Kingdom

- NICE in United Kingdom has conducted an assessment of Nilemdo (Bempedoic Acid; Daiichi Sankyo) for Heterozygous Familial Hypercholesterolemia. Result: Bempedoic acid with ezetimibe is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if: • Statins are contraindicated or not tolerated • Ezetimibe alone does not control low-density lipoprotein cholesterol well enough, and • The company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Kyprolis (Carfilzomib; Amgen) for Multiple Myeloma (lenalidomide). Result: Carfilzomib plus lenalidomide and dexamethasone is recommended as an option for treating multiple myeloma in adults, only if: • They have had only 1 previous therapy, which included bortezomib, and • The company provides carfilzomib according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Keytruda (Pembrolizumab; Msd) for Urothelial Carcinoma (platinum Chemotherapy Treated). Result: Pembrolizumab is not recommended, within its marketing authorisation, for treating locally advanced or metastatic urothelial carcinoma in adults who have had platinum-containing chemotherapy.

PRICENTRIC ONE
BY EVERSANA™

Did you know Pricentric can help you with...

Monthly Reporting

Pricentric can help with custom monthly reporting based on you exact requirements and templates.

Source Validation

Source proofs / screenshots for regulatory reporting.

In a Hurry

Out of time, no problem. The Pricentric Support Team can pull the data for you.
Just send over your request and we will turn it around in a flash.

Launch Monitoring

Live monitoring is now available within the Pricentric portal with email and in-app notifications.
Pricentric can help you track important launches in real-time with precision.

Data Integration

Pricentric can be easily integrated into internal systems via the Pricentric Web API, XML, JSON, or custom formats. Pricentric integrates with the PriceRight Unity Suite (Price Governance / IPR / Launch Sequencing, Tender Management) in real-time!

Ready to get started?

Just message us on Live Chat or email: pricentric@eversana.com.

Note these services are free and included as part of your Pricentric INSIGHTS Subscription.

Drug Approvals: Europe

- VENCLYXTO (VENETOCLAX) was approved for AML by the EMA in combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.
  COMPANY: ABBVIE

- YERVOY (IPILIMUMAB) was approved by the EMA in combination with nivolumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.
  COMPANY: BRISTOL-MYERS SQUIBB

- OPDIVO (NIVOLUMAB) was approved by the EMA in combination with ipilimumab for the first line treatment of adult patients with unresectable malignant pleural mesothelioma.
  COMPANY: BRISTOL-MYERS SQUIBB

- ONUREG (AZACITIDINE) was approved by the EMA for the maintenance treatment of patients with acute myeloid leukemia.
  COMPANY: BRISTOL-MYERS SQUIBB

- KOSELUGO (SELUMETINIB SULFATE) was approved by the EMA for the treatment of paediatric patients with neurofibromatosis type 1 (NF1) plexiform neurofibromas (PN).
  COMPANY: ASTRAZENECA

- ENSPRYNG (SATRALIZUMAB) was approved by the EMA for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive.
  COMPANY: ROCHE

- JAYEMPI (AZATHIOPRINE) was approved by the EMA for prophylaxis against transplant rejection and as immunosuppressive antimetabolite either alone or in combination with other agents to influence the immune response in a variety of diseases.
  COMPANY: NOVA

- CELSUNAX (IODINE IOFLUPANE (123I)) was approved by the EMA for detecting loss of functional dopaminergic neuron terminals in the striatum.
  COMPANY: PINAX

- ADTRALZA (TRALOKINUMAB) was approved by the EMA for the treatment of moderate-to-severe atopic dermatitis.
  COMPANY: LEO

- EVKEEZA (EVINACUMAB) was approved by the EMA for the treatment of adult and adolescent patients aged 12 years and older with homozygous familial hypercholesterolaemia (HoFH).
  COMPANY: REGENERON

- ABIRATERONE KRKA (ABIRATERONE ACETATE) was approved by the EMA for the treatment of metastatic prostate cancer.
  COMPANY: KRKA

Drug Approvals: United States

- QELBREE (VILOXAZINE) was approved by the FDA for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age
COMPANY: SUPERNUS PHARMS

- ERBITUX (CETUXIMAB) was approved by the FDA for patients with K-Ras wild-type, EGFR-expressing colorectal cancer (mCRC) or squamous cell carcinoma of the head and neck (SCCHN).
COMPANY: IMCLONE LLC

- TRODELVY (SACITUZUMAB GOVITECAN) was approved by the FDA for patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
COMPANY: IMMUNOMEDICS INC

- NEXTSTELLIS (DROSPIRENONE & ESTETROL) was approved by the FDA for use by females of reproductive potential to prevent pregnancy.
COMPANY: MAYNE PHARMA

- OPDIVO (NIVOLUMAB) was approved by the FDA in combination with fluoropyrimidine- and platinum-containing chemotherapy for advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.
COMPANY: BRISTOL-MYERS SQUIBB

- JEMPERLI (DOSTARLIMAB-GXLY) was approved by the FDA for the treatment of adult patients with mismatch repair deficient 5.2) (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with • Complications of allogeneic HSCT after PD-1/L-1–blocking antibody: a platinum-containing regimen.
COMPANY: GLAXOSMITHKLINE

- ZYNLONTA (LONCASTUXIMAB TESIRINE-LPYL) was approved by the FDA for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.
COMPANY: ADC THERAPEUTICS

Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	MNF	OLD MNF PRICE	MNF AMOUNT CHANGE	MNF PERCENT CHANGE
MERCK	BAVENCIO	AVELUMAB	BAVENCIO INFUSION 1 VIAL 10 ML 200 MG	651.34	786.66	-135.32	-17.20%
NOVO NORDISK	ESPEROCT	COAGULATION FACTOR VIII	ESPEROCT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 1000 IU	584.38	820.00	-235.62	-28.73%
NOVO NORDISK	ESPEROCT	COAGULATION FACTOR VIII	ESPEROCT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 1500 IU	876.56	1230.00	-353.44	-28.73%
NOVO NORDISK	ESPEROCT	COAGULATION FACTOR VIII	ESPEROCT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 2000 IU	1168.75	1640.00	-471.25	-28.73%
NOVO NORDISK	ESPEROCT	COAGULATION FACTOR VIII	ESPEROCT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 3000 IU	1753.13	2460.20	-707.07	-28.74%
NOVO NORDISK	ESPEROCT	COAGULATION FACTOR VIII	ESPEROCT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 500 IU	292.19	410.00	-117.81	-28.73%
NOVARTIS	MAYZENT	SIPONIMOD	MAYZENT TABLETS 1 PACK 12 TABS 0.25 MG	164.38	330.36	-165.98	-50.24%
NOVARTIS	MAYZENT	SIPONIMOD	MAYZENT TABLETS 1 PACK 28 TABS 2 MG	920.55	1850.00	-929.45	-50.24%
NOVARTIS	MAYZENT	SIPONIMOD	MAYZENT TABLETS 1 PACK 84 TABS 0.25 MG	690.41	1387.50	-697.09	-50.24%
NOVARTIS	MAYZENT	SIPONIMOD	MAYZENT TABLETS 1 PACK 98 TABS 2 MG	3221.92	6475.00	-3253.08	-50.24%
NOVO NORDISK	NOVOEIGHT	COAGULATION FACTOR VIII	NOVOEIGHT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 1000 IU	520.63	830.00	-309.37	-37.27%
NOVO NORDISK	NOVOEIGHT	COAGULATION FACTOR VIII	NOVOEIGHT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 1500 IU	780.94	1245.00	-464.06	-37.27%
NOVO NORDISK	NOVOEIGHT	COAGULATION FACTOR VIII	NOVOEIGHT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 2000 IU	1041.25	1660.00	-618.75	-37.27%
NOVO NORDISK	NOVOEIGHT	COAGULATION FACTOR VIII	NOVOEIGHT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 250 IU	130.16	207.50	-77.34	-37.27%
NOVO NORDISK	NOVOEIGHT	COAGULATION FACTOR VIII	NOVOEIGHT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 3000 IU	1561.88	2490.00	-928.12	-37.27%
NOVO NORDISK	NOVOEIGHT	COAGULATION FACTOR VIII	NOVOEIGHT INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 500 IU	260.31	415.00	-154.69	-37.27%
ROCHE	POLIVY	POLATUZUMAB VEDOTIN	POLIVY INFUSION 1 LYOPHILIZED POWDER VIAL 1.5 ML 30 MG	2071.43	2635.61	-564.18	-21.41%
ROCHE	POLIVY	POLATUZUMAB VEDOTIN	POLIVY INFUSION 1 LYOPHILIZED POWDER VIAL 7.2 ML 140 MG	9666.66	12299.50	-2632.84	-21.41%
NOVO NORDISK	REFIXIA	COAGULATION FACTOR IX	REFIXIA INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 1000 IU	1498.13	1700.00	-201.87	-11.87%
NOVO NORDISK	REFIXIA	COAGULATION FACTOR IX	REFIXIA INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 2000 IU	2996.25	3400.00	-403.75	-11.88%
NOVO NORDISK	REFIXIA	COAGULATION FACTOR IX	REFIXIA INJECTION 1 LYOPHILIZED POWDER VIAL 4 ML 500 IU	749.06	850.00	-100.94	-11.88%
GILEAD SCIENCES INC	TYBOST	COBICISTAT	TYBOST TABLETS 1 PACK 30 TABS 150 MG	30.26	32.53	-2.27	-6.98%
GILEAD SCIENCES INC	TYBOST	COBICISTAT	TYBOST TABLETS 1 PACK 90 TABS 150 MG	90.78	97.59	-6.81	-6.98%
TESARO PHARMA	ZEJULA	NIRAPARIB	ZEJULA CAPSULES 1 PACK 56 CAPS 100 MG	3599.74	4462.50	-862.76	-19.33%
TESARO PHARMA	ZEJULA	NIRAPARIB	ZEJULA CAPSULES 1 PACK 84 CAPS 100 MG	5399.60	6693.75	-1294.15	-19.33%
GILEAD SCIENCES INC	TYBOST	COBICISTAT	TYBOST TABLETS 1 PACK 30 TABS 150 MG	30.26	32.53	-2.27	-6.98%
GILEAD SCIENCES INC	TYBOST	COBICISTAT	TYBOST TABLETS 1 PACK 90 TABS 150 MG	90.78	97.59	-6.81	-6.98%
TESARO PHARMA	ZEJULA	NIRAPARIB	ZEJULA CAPSULES 1 PACK 56 CAPS 100 MG	3599.74	4462.50	-862.76	-19.33%
TESARO PHARMA	ZEJULA	NIRAPARIB	ZEJULA CAPSULES 1 PACK 84 CAPS 100 MG	5399.60	6693.75	-1294.15	-19.33%

Drug Launches: Europe & U.S.

Country	Generic Name	Product Group	Company	Indication	Therapeutic Areas	Product Approval Date	Launch Date
GERMANY	FOSTEMSAVIR	RUKOBIA	VIIV HEALTHCARE	HIV	ANTIVIRALS	2/4/2021	01/04/2021
ITALY	CEFIDEROCOL	FETCROJA	SHIONOGI INC	BACTERIAL INFECTIONS	ANTIBACTERIALS	23/04/2020	12/04/2021
UNITED KINGDOM	INCLISIRAN	LEQVIO	NOVARTIS	HYPERCHOLESTEROLEMIA	CVS	09/12/2020	01/04/2021
UNITED KINGDOM	SELPERCATINIB	RETSEVMO	ELI LILLY	NSCLC (RET FUSION+), THYROID CANCER (RET FUSION+)	NA	10/12/2020	01/04/2021
UNITED STATES	ROSUVASTATIN & EZETIMIBE	ROSZET	ALTHERA PHARMA	HYPERLIPIDEMIA, HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA	CVS	23/03/2021	05/04/2021
UNITED STATES	DASIGLUCAGON	ZEGALOGUE	ZEALAND PHARMA	HYPOGLYCEMIA	NA	22/03/2021	05/04/2021

Price Changes: Europe & U.S.

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing date
FRANCE	ARIPIPRAZOLE	ABILIFY MAINTENA	OTSUKA PHARMACEUTICALS	NEUROLOGY	-8.50%	22/12/2014
FRANCE	GOSERELIN	ZOLADEX	ASTRAZENECA	ONCOLOGY	-11.54%	01/01/2002
FRANCE	SALMETEROL & FLUTICASONE	SERETIDE	GLAXOSMITHKLINE	RESPIRATORY	-10.46%	25/08/2001
SPAIN	PROPYPHENAZONE & BUTALBITAL & CAFFEINE	OPTALIDON	PERRIGO PHARMACEUTICALS	NEUROLOGY	+5.04%	01/01/2016
UNITED STATES	ERGOTAMINE	ERGOMAR	TERSERA	NEUROLOGY	+6.00%	01/11/2006
UNITED STATES	SONIDEGIB	ODOMZO	SUN PHARMACEUTICALS	ONCOLOGY	+5.00%	28/09/2015
UNITED STATES	HISTRELIN	SUPPRELIN LA	ENDO PHARMACEUTICALS	ONCOLOGY	+4.90%	18/06/2007
UNITED STATES	VALRUBICIN	VALSTAR	ENDO PHARMACEUTICALS	ONCOLOGY	+4.85%	31/10/2007
UNITED STATES	SELINEXOR	XPOVIO	KARYOPHARM THERAPEUTICS	ONCOLOGY	+4.90%	03/07/2019
ITALY	TINZAPARIN	INNOHEP	LEO	BLOOD AND BLOOD FORMING ORGANS	-10.45%	3/3/2020

EVERSANA™ is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers.

The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science services for a healthier world. To learn more about EVERSANA, visit eversana.com.

Pricentric ONE by EVERSANA™ is a powerful intelligence tool that provides near real-time updates to drug price (list/net), reimbursement, and cost of treatment information at the indication level across 95+ markets and 250+ therapeutic areas. Visit us at pricentric.alscg.com.

UNITED STATES

Alan Crowther

General Manager, Global Pricing & Access

+1 (917) 749-4610

alan.crowther@eversana.com

Andrew Hanhauser

Vice President, Pricentric Leader

+1 (843) 801-4808

andrew.hanhauser@eversana.com

UNITED KINGDOM

Alan Stewart

Director, Account Services

+44 (0)7901 002066

alan.stewart@eversana.com

SPAIN

Miguel Espinosa

Director, Account Services

+34 673005073

miguel.espinosa@eversana.com