PRICENTRIC ONE
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INSIGHTS Newsletter

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What Canada's IRP Changes Could Mean for the Industry

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BeNeLuxA Takes on AveXis & Novartis' Zolgensma

Now that AveXis, a Novartis company's gene therapy Zolgensma (onasemnogene abeparvovec) has been conditionally approved in Europe, the BeNeLuxA Initiative wants to enter discussions with the company on access and affordability.

Nordics to Jointly-Negotiate Access to Zynteglo with Bluebird

Bluebird bio has been invited to enter joint negotiations with Nordic countries Denmark, Finland, Iceland, Norway, and Sweden to ensure quick and equal access to its gene therapy Zynteglo (autologous cd34+ cells encoding βAT87Q-globin gene) for transfusion-dependent β-thalassemia.

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What Canada's IRP Changes Could Mean for the Industry

NOTE: Due to COVID-19, the impending PMPRB amendments will come into force on January 1, 2021 instead of the proposed July 1, 2020. Amendments to the Regulations will be published in Canada's Gazette II on June 10, 2020. The contents of the article are relevant as of May 2020 and have been updated appropriately in lieu of these recent developments.

Last August, Canada's Patented Medicine Prices Review Board (PMPRB) announced a set of amendments for its regulatory measures, in a bid to strengthen and modernize the country's pricing framework for patented drugs.

Following the initial proposal of the alterations, the PMPRB released its new draft guidelines in November 2019 and launched a 60-day consultation period with stakeholders and interested members of the public. The amendments, which empower the PMPRB to more strictly control drug prices and reorganize Canada's reference basket countries to include markets where drug prices are lower, received serious industry backlash, with certain pharmaceutical companies warning that Canada could experience severe launch delays, among other repercussions, if it were to adopt the proposed amendments.

In a statement, Canada's Minister of Health, Ginette Petitpas Taylor, said that the reforms are "the biggest step to lower drug prices in a generation," and that the changes "will lay the foundation" for universal drug coverage under Canada's Pharmacare program.

The Role of the PMPRB

The PMPRB holds the power to challenge the list price of any patented drug, and order companies to repay some revenue. Instead of bargaining with companies to bring drug prices down, it can declare some prices to be an "illegal abuse of patent rights" and challenge drugmakers at an internal tribunal.

For the price review, at introduction, an interim maximum List Price (iMLP) ceiling is set for the sale of the patented medicine in question, according to the median international list price gathered from the reference basket of countries. Patentees must ensure that the patented medicine's gross publicly available Canadian ex-factory price (List

Price) is no higher than the iMLP for the period during which it is applicable, failing which the price may be subject to additional review.

Proposed Changes

Going forward, Canada is dropping the US and Switzerland; the only two countries with higher drug prices than Canada. Now, he basket will be: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Amending the country's reference basket would allow the international reference price (IRP) to provide the PMPRB with the actual market price of medicines in Canada, as opposed to inflated list or "sticker" prices, according to the watchdog agency. On top of this, the change would ultimately let the PMPRB accurately assess whether a price is reasonable when setting a price ceiling, as the new list of countries was deemed to have more similar consumer protection priorities, economic wealth and marketed medicines as Canada.

In the original Draft Guidelines, the PMPRB also stated that patented medicines that received a Drug Identification Number (DIN) prior to August 21, 2019 are now to be categorized as "grandfathered" products, meaning they will be subject to a different price review process than non-grandfathered products.

However, patented medicines sold in Canada prior to August 21 under the Special Access Program are not assigned a DIN and, therefore, are not grandfathered.

The body explained that the Maximum List Price for grandfathered products would be the lower of (i) the median international price across the amended list of comparator countries, referred to as the "PMPRB11" after the removal of Switzerland and the US, for which the patentee has provided information, and (ii) the price ceiling set under the current PMPRB Guidelines.

Non-grandfathered products, however, would be further divided into two categories:

- Category I: A medicine for which either (i) its 12-month treatment cost is greater than 50% of GDP per capita, or (ii) its estimated or actual market size (revenue) exceeds the annual Market Size Threshold of CA$ 25 million.
- Category II: All other patented medicines.

Following this, Category I patented medicines would be subject to two price ceilings: The Maximum List Price, based on the median international list price in the PMPRB11 and adjusted before being eventually set, annually; and the Maximum Rebated Price, based on the pharmacoeconomic value of the drug and the market size for the patented medicine. Category II medicines, however, would be subject only to the Maximum List Price.

The proposed amendments also give new, more stringent powers to the PMPRB, allowing it to now consider the cost-effectiveness of new medicines from January 1, 2021, and in some cases, the ability to force pharmaceutical companies to disclose confidential discounts to the price regulator.

Henceforth, the PMPRB will consider the opportunity cost of a medicine in the health system when evaluating whether its price is excessive, as well as considering the economic impact of paying for the drug for all patients who need it, when evaluating whether the company's pricing is excessive.

As such, the Maximum Rebated Price (MRP) of a drug would be calculated as follows:

- The Incremental Cost-Effectiveness Ratio (ICER) measured in cost per quality-adjusted life years (QALYs) for each indication of the patented medicine will be identified from the cost-utility analyses filed by the patentee
- The ICER will be compared against the applicable Pharmacoeconomic Value Threshold (PVT) of $60,000 per QALY

Also, in terms of looking at market size, the PMPRB will consider gross domestic product (GDP) and GDP per capita as indicators of what Canada and individual Canadians can afford to pay for new patented medicines.

Effects

The new reference country basket will significantly impact both the highest international price and the median international price comparison metrics, and although Canada is a relatively small market for major drugmakers, lower prices in Canada could potentially spread into the US; a major market for pharma companies.

According to data compiled by EVERSANA analysts, the change in reference basket means that future manufacturer prices (MNF) of the 10 highest revenue drugs across all provinces in Canada could be slashed by over half in some cases.

For example, Bayer's Eylea (aflibercept), an anti-VEGF medication that's administered by an injection into the eye to treat wet age-related macular degeneration (AMD), would fall quite considerably by 21%.

MSD's immuno-oncology blockbuster, Keytruda (pembrolizumab), would also take a hit from the amendments, seeing a 10% reduction in MNF.

Most substantially, however, would be the 55% drop in MNF price for Januvia, another MSD drug that lowers blood sugar levels in adults with type 2 diabetes.

Drug	Current MNF Price	Future MNF Price	Percent Change
AVASTIN	$3.20	$3.05	4%
ENBREL	$5.69	$3.77	34%
ENTRESTO	$0.03	$0.03	10%
EYLEA	$507.40	$401.63	21%
HARVONI	$1.16	$0.95	19%
HUMIRA	$13.46	$10.89	19%
JANUVIA	$0.05	$0.02	55%
KEYTRUDA	$31.49	$28.41	10%
OPDIVO	$14.00	$13.52	3%
ORKAMBI	$0.38	$0.55	No upward revision (no change)

"We examined a selection of the top revenue generating drugs globally and applied the proposed IRP rule based on current global ex-manufacturer prices derived from Pricentric," explains Max Klietmann, Senior Consultant and Manager of EVERSANA's PriceXpress.

"On a cursory level, the impacts in Canada are significant (~20% drop in price for the products considered). This is a massive potential impact in Canada alone, not to mention the potential spillover effect into other markets that either reference Canada formally or look at Canadian prices as a basis for price negotiations."

Despite the country's federal government saying its amendments will not impact the way pharma companies view Canada as a business market, the sizeable margins mean that some manufacturers would have to reconsider launching certain drugs in Canada. A company's sustainability relies heavily on keeping profitability attractive to investors, and the changes would reduce Canada's appeal as a jurisdiction for manufacturers to seek regulatory and reimbursement approval for potential new drugs.

Industry Feedback

Multiple pharmaceutical executives have stated that they expect the amendments to the PMPRB to have a negative impact on their Canada business plan, according to results from a survey conducted by a Canadian not-for-profit life sciences organization.

The survey found the most significant anticipated impact will most likely be on product launches, commercialization, and the supply of current products in the Canadian market, followed by clinical research, patient support programs, compassionate use access programs, and manufacturing.

Respondents also said that drug launches for biologic medicines and oncology, rare disease, immunology, cell and gene therapy, and rheumatology drugs will be most affected by the amendments.

The effects are already being felt, as according to the study, some companies have already stopped plans to launch new medicines in Canada, with one company indicating that it may be forced to withdraw a first-line therapy because the new pricing formula will place the Canadian price far below those found in other developed countries.

In addition to the survey, the Canadian Organization for Rare Disorders (CORD) warned that the new maximum price calculations will slash prices so low, in some cases up to 40% and 90%, that no new medicines will come to market in Canada.

Where it Stands

Speaking recently at ISPOR, Director of Policy and Economic Analysis at the PMPRB, Tanya Potashnik pointed to evidence that many countries outperform Canada in terms of earlier drug launch times, despite having lower prices. She added that price is actually a weak determinate of time of launch while market size, wealth of country,

Nevertheless, PMPRB heard industry feedback. In a statement issued in February, PMPRB said, "The draft regulations remain just that—a draft. The PMPRB is contemplating significant changes to the document in light of stakeholder feedback."

Some patient advocacy groups have expressed their worry over being able to access the most innovative treatments poised to come to market, with Cystic Fibrosis Canada publishing a statement calling for the PMPRB to cease the plan, as according to the charity, those that suffer from cystic fibrosis are immuno-compromised, and 85 per cent will die from respiratory failure — that is, before the effects of COVID-19 are also considered.

The organization is concerned that the changes will block access to a therapy that is being hailed as the single biggest advancement in treating cystic fibrosis, while the therapy has been fast-tracked for approval in the United States, United Kingdom and Europe.

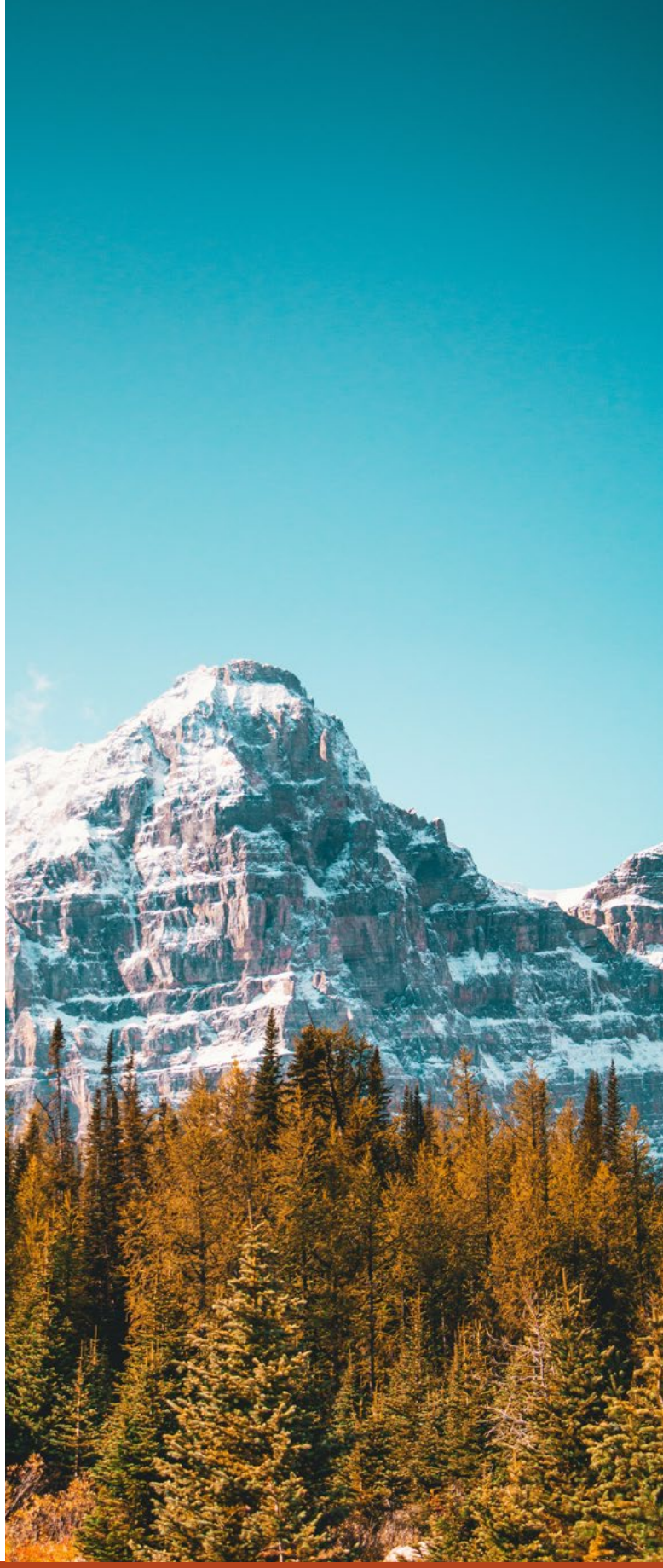
Additionally, on April 2, the PMPRB's Chairperson noted in a statement that in view of COVID-19, the organization would reassess the intended next steps closer to the date of their publication.

More recently, on June 1 it was officially announced that the amendments will be delayed by six months and come into force on January 1, 2021, as opposed to the initially proposed July 1, 2020, due to COVID-19.

How EVERSANA Can Help

EVERSANA is actively engaging with several clients to assess potential global price impacts resulting from this legislative change and is able to offer high level impact studies via PriceXpress, our tactical price consulting and analysis offering.

"These are very nebulous and challenging times for the industry" says Max Klietmann. "We've found that our clients are in a better position to make strategic decisions when armed with a holistic perspective of where potential impacts could manifest themselves and a solid mitigation plan."



PRICEXPRESS
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PriceXpress is used to answer questions about Launch, Pricing, Loss-of-Exclusivity, Trends, and Business Development needs using secondary research methods. The team uses the data in the Pricentric tool to conduct empirical analysis of price, reimbursement, cost-of-treatment and other information to answer common pricing questions quickly.

Examples of recent customer queries

- Average timeline to reimbursement for a product class
- Price differentials across markets for weight vs. non-weight based products
- Impact of indication expansion on pricing in the EU5 for oncology
- Price of rare analogues across Asia-Pacific for purpose of estimating launch price
- Analysis of linear pricing in biosimilars by EU markets
- Average 5-year price erosion since launch of a product class across EU15

For more details, contact Max Klietmann at max.klietmann@eversana.com

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BeNeLuxA Takes on AveXis & Novartis' Zolgensma

Originally published: May 20, 2020 | Country: AUSTRIA, BELGIUM, IRELAND, LUXEMBOURG, NETHERLANDS | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #avexis #beneluxa #crosscountrycollaboration #genetherapy #hta #jointhta #jointnegotiations #novartis

PRICENTRIC BRIEF:

- Now that AveXis, a Novartis company's gene therapy Zolgensma (onasemnogene abeparvovec) has been conditionally approved in Europe, the BeNeLuxA Initiative wants to enter discussions with the company on access and affordability
- Belgium, Ireland, and the Netherlands aim to undertake a joint health technology assessment (HTA) of Zolgensma as part of the application by the drugmaker, with Austria acting as expert reviewer during the procedure, and following HTA, the five countries will determine if the joint assessment will lead to a joint price negotiation
- AveXis/Novartis expressed its willingness to engage Zolgensma in joint assessment and dialogue on reimbursement in participating countries Belgium, the Netherlands, Luxembourg, Austria, and Ireland

THE DETAILS

BRUSSELS, Belgium – Now that AveXis, a Novartis company's gene therapy Zolgensma (onasemnogene abeparvovec) has been conditionally approved in Europe, the BeNeLuxA Initiative wants to enter discussions with the company on access and affordability.

According to BeNeLuxA, Belgium, Ireland, and the Netherlands aim to undertake a joint health technology assessment (HTA) of Zolgensma as part of the application by the drugmaker, with Austria acting as expert reviewer during the procedure.

AveXis/Novartis expressed its willingness to engage Zolgensma in joint assessment and dialogue on reimbursement in participating countries Belgium, the Netherlands, Luxembourg, Austria, and Ireland.

The HTA agencies of Belgium, Ireland, and the Netherlands will align the timing and content of their national HTA procedures, the first step for joint price negotiations within the BeNeLuxA initiative. Following HTA, the five countries will determine if the joint assessment will lead to a joint price negotiation.

Zolgensma is conditionally approved for the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1; or for patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene.

Initially, AveXis/Novartis announced the implementation of a global managed access program for Zolgensma, which would allow children diagnosed with SMA to receive treatment with the gene therapy before European approval.

Health ministers from Belgium, the Netherlands, Luxembourg, Austria, and Ireland expressed strong reservations in relation to this plan. The ministers were concerned over the "high level of uncertainty and the non-transparent approach," and lambasted the decision to provide Zolgensma this way through a lottery, as "Lotteries are by their nature a form of gambling and this is absolutely the wrong model to bring to healthcare."

To date, BeNeLuxA has completed around 15 HTAs and has only been successful with pricing and reimbursement negotiations related to Biogen's SMA treatment Spinraza (nusinersen). The Initiative twice failed to successfully complete negotiations for Vertex's cystic fibrosis (CF) medicines.

Europe Conditionally Approves AveXis' Zolgensma

Originally published: May 19, 2020 | Country: BELGIUM, FRANCE, GERMANY, NETHERLANDS | Region: EUROPE | Type: Drug Approval | Keywords: #accessprogram #atu #avexis #conditionalapproval #europeancommission #gene therapy #installments #novartis #outcomesbasedpayment #rebates

PRICENTRIC BRIEF:

- Zolgensma (onasemnogene abeparvovec) has received conditional approval from the European Commission for the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1; or for patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene
- AveXis, a Novartis company, met with over 100 stakeholder organizations to discuss its "Day One" access program, allowing rapid access to Zolgensma by babies and young children – immediately, Zolgensma will be accessible in France through a temporary authorized use (ATU) scheme, and it is expected that the gene therapy will be available in Germany very shortly
- Under the "Day One" program, the following will be offered: retroactive rebates to ensure early costs align with prices negotiated after clinical and economic assessment; deferred payments and installment options; outcomes-based rebates; robust training for treatment institutions on administration; and access to the global registry of SMA patients, RESTORE

THE DETAILS

BRUSSELS, Belgium – Zolgensma (onasemnogene abeparvovec) has received conditional approval from the European Commission for the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1; or for patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene.

Additionally, according to dosing guidance, the approval stipulates use of Zolgensma for babies and young children with SMA up to 21 kg.

Each year, upwards of 600 infants are born with SMA, for which Zolgensma is a one-time gene therapy designed to address the genetic root cause. Zolgensma delivers a new working copy of the SMN1 gene into a patient's cells, halting disease progression.

Dave Lennon, President of AveXis, said, "The EC approval of Zolgensma is a significant milestone for the SMA community, and further underscores the substantial clinical value of the only gene therapy for SMA, bringing new hope to those impacted by this rare, but devastating disease.

"Even under the current pandemic conditions, the urgent need to treat SMA has resulted in access pathways in France and Germany for Zolgensma, a potentially life-saving medicine delivered in a single dose. Additionally, we have met with more than 100 stakeholder organizations across Europe to discuss our "Day One" access program to enable rapid access with customizable options designed to work within local pricing and reimbursement frameworks."

According to a press release from Novartis, SMA burdens European healthcare systems with costs per child between €2.5 to €4 million within the first 10 years of life alone.

The "Day One" access program for Zolgensma offers ministries of health and reimbursement bodies a variety of flexible options that can be implemented right away to support swift access and broad reimbursement, explained Novartis. Through this program, it will be ensured that the cost of patients treated before national pricing and reimbursement are aligned with the value-based prices negotiated following clinical and economic assessment.

The program offers: retroactive rebates to ensure early costs align with prices negotiated after clinical and economic assessment; deferred payments and installment options; outcomes-based rebates; robust training for treatment institutions on administration; and access to the global registry of SMA patients, RESTORE.

Immediately, Zolgensma will be accessible in France through a temporary authorized use (ATU) scheme, and it is expected that the gene therapy will be available in Germany very shortly.

The cohort early access scheme (ATU) for Zolgensma (onasemnogene abeparvovec) by AveXis, a Novartis company, has started in France, according to the French Agency for the Safety of Health Products (ANSM).

Gene therapy Zolgensma is intended for the treatment of patients suffering from 5q spinal muscular atrophy (SMA) with a biallelic mutation of the SMN1 gene who have been clinically diagnosed with SMA Type 1, as well as patients with 5q SMA with a biallelic mutation in the SMN1 gene and up to three copies of the SMN2 gene.

Czech Republic Allows Pre-Authorized Use of Zolgensma

PRICENTRIC BRIEF:

- The Ministry of Health is allowing the implementation of a specific treatment program for pre-authorized use of spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec) by AveXis, a Novartis company
- Zolgensma will be allowed to treat pediatric patients under the age of two with SMA with a survival motor neuron 1 (SMN1) biallelic mutation regardless of type
- Adam Vojtech, Minister of Health, said, "We perceive the acute need for this experimental drug by patients, so we have allowed it to be used in the Czech Republic before the final decision of the European Medicines Agency is made"

Originally published: April 23, 2020

Country: CZECH REPUBLIC | Region: EUROPE |
Type: Regulation | Keywords: #avexis #chmp #earlyaccess #ema #genetherapy #novartis #pediatrics

THE DETAILS

PRAGUE, Czech Republic – The Ministry of Health is allowing the implementation of a specific treatment program for pre-authorized use of spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec) by AveXis, a Novartis company.

Zolgensma will be allowed to treat pediatric patients under the age of two with SMA with a survival motor neuron 1 (SMN1) biallelic mutation regardless of type.

Treatment will be administered in the Neuromuscular Center of the Department of Pediatric Neurology, 2nd Faculty of Medicine, Charles University and Motol University Hospital, explained the Ministry of Health.

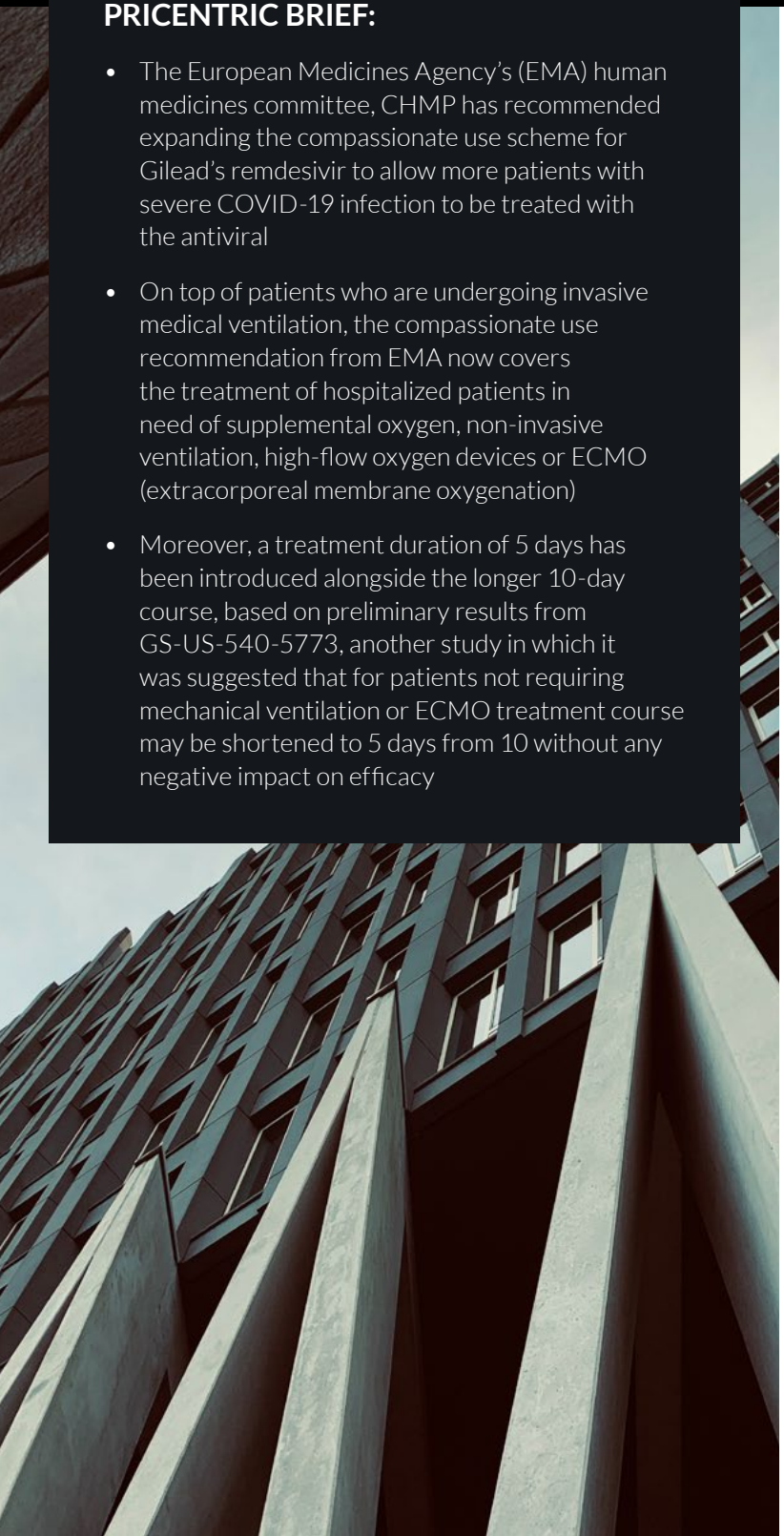
While the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHM) adopted a positive option recommending conditional marketing authorization for Zolgensma at its April meeting, the gene therapy has not yet been greenlighted.

In the meantime, the Czech Republic will allow the dispensation, distribution, and use of Zolgensma for patients under the age of two.

Adam Vojtech, Minister of Health, said, "We perceive the acute need for this experimental drug by patients, so we have allowed it to be used in the Czech Republic before the final decision of the European Medicines Agency is made."

EMA Recommends Expanded Compassionate Use Scheme for Remdesivir

Country: NETHERLANDS | Region: EUROPE | Type: Regulation | Keywords: #chmp #compassionateuse #covid-19 #ema #gilead #remdesivir | Originally published: May 12, 2020



PRICENTRIC BRIEF:

- The European Medicines Agency's (EMA) human medicines committee, CHMP has recommended expanding the compassionate use scheme for Gilead's remdesivir to allow more patients with severe COVID-19 infection to be treated with the antiviral
- On top of patients who are undergoing invasive medical ventilation, the compassionate use recommendation from EMA now covers the treatment of hospitalized patients in need of supplemental oxygen, non-invasive ventilation, high-flow oxygen devices or ECMO (extracorporeal membrane oxygenation)
- Moreover, a treatment duration of 5 days has been introduced alongside the longer 10-day course, based on preliminary results from GS-US-540-5773, another study in which it was suggested that for patients not requiring mechanical ventilation or ECMO treatment course may be shortened to 5 days from 10 without any negative impact on efficacy

THE DETAILS

AMSTERDAM, The Netherlands – The European Medicines Agency's (EMA) human medicines committee, CHMP has recommended expanding the compassionate use scheme for Gilead's remdesivir to allow more patients with severe COVID-19 infection to be treated with the antiviral.

On top of patients who are undergoing invasive medical ventilation, the compassionate use recommendation from EMA now covers the treatment of hospitalized patients in need of supplemental oxygen, non-invasive ventilation, high-flow oxygen devices or ECMO (extracorporeal membrane oxygenation).

EMA was able to issue this updated recommendation due to positive results from the NIAID-ACTT study of remdesivir in patients hospitalized with severe COVID-19.

Moreover, a treatment duration of 5 days has been introduced alongside the longer 10-day course, based on preliminary results from GS-US-540-5773, another study in which it was suggested that for patients not requiring mechanical ventilation or ECMO treatment course may be shortened to 5 days from 10 without any negative impact on efficacy.

As such, patients who receive 5-days' worth of remdesivir but show no clinical improvement will be permitted to continue their treatment for another 5 days. Shortening treatment duration is allowing for more people to take remdesivir.

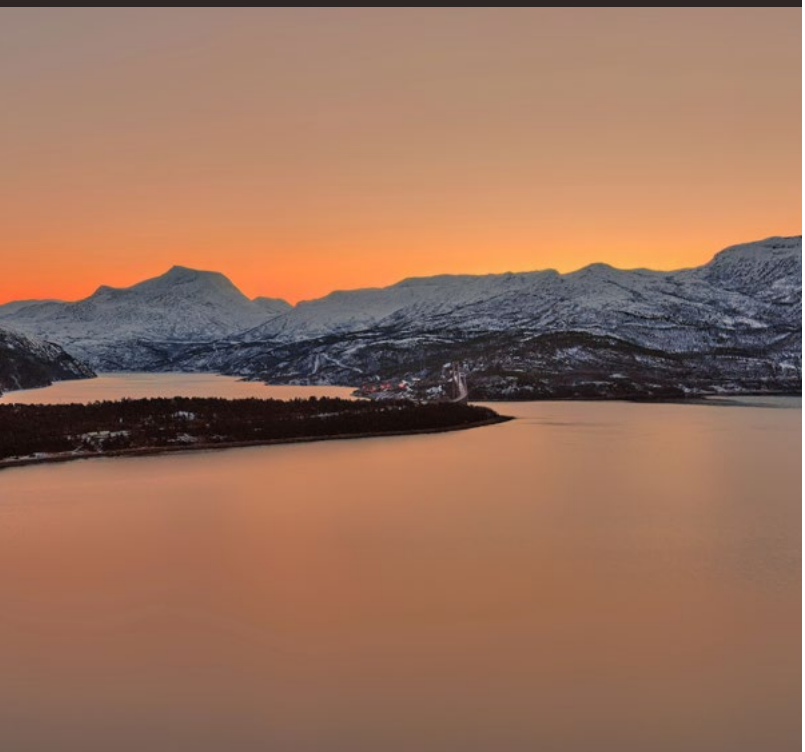
Currently, EMA is evaluating these data within the context of a rolling review of remdesivir, which has not yet been authorized for marketing in the European Union (EU). The compassionate use scheme is allowing for the drug to be made available while EMA evaluates its benefits and risks.

TLV Reviews Benefit Restrictions of High-Cost Protection Drugs

Originally published: May 15, 2020 | Country: SWEDEN | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #benefitrestrictions #druggroups #highcostsubsidy #interchangeability #medicinesbenefitsact #patientaccess #pharmacy #tlv

PRICENTRIC BRIEF:

- The Dental and Pharmaceutical Benefits Agency (TLV) has reviewed the benefit restrictions for a slew of drugs to allow for switching to high-cost protection without any complications from outdated benefit restrictions so that more patients can access medicines within this scheme
- In its review, TLV decided to remove limited subsidy – or benefit restrictions – from a number of drug groups, which were previously only included in high-cost protection for a particular area or specific patient group
- TLV decided to make benefit restrictions uniform within respective groups, meaning certain limitation texts were removed, added, or corrected, so that all restrictions would be uniform for all drugs with the same substance in a certain strength or form in time for updates to the Medicines Benefits Act, which is set to take effect on June 2, 2020



THE DETAILS

STOCKHOLM, Sweden – The Dental and Pharmaceutical Benefits Agency (TLV) has reviewed the benefit restrictions for a slew of drugs to allow for switching to high-cost protection without any complications from outdated benefit restrictions so that more patients can access medicines within this scheme.

All in all, the review resulted in a total of 48 decisions made for a total of 680 drugs.

In its review, TLV decided to remove limited subsidy – or benefit restrictions – from a number of drug groups, which were previously only included in high-cost protection for a particular area or specific patient group.

The agency concluded that previous benefit restrictions for these drugs could no longer be based on prior economic reasons since their prices had fallen upon the advent of generic competition. That said, the restrictions imposed no longer met their intended purpose, ergo the drugs received general subsidy.

TLV decided to make benefit restrictions uniform within respective groups, meaning certain limitation texts were removed, added, or corrected so all restrictions would be uniform for all drugs with the same substance in a certain strength or form.

The review was carried out in light of forthcoming amendments to the Medicines Benefits Act, set to take effect on June 2, 2020, which allow for medicines that have been prescribed that are not part of the high-cost protection scheme to be exchanged at pharmacies for an interchangeable alterative that is covered. But, if the drug that is included in the protection is marked with a restriction, exchange should not be carried out.

As such, the review conducted by TLV reduced the number of drugs with benefit restrictions within a generic exchange group.

IQWiG Urges EMA to Publish COVID-19 Study Reports on Day of Marketing Authorization

Country: GERMANY | Region: EUROPE | Type: Policy | Keywords: #authorizations #covid-19 #ema #iqwig #marketing | **Originally published: May 18, 2020**

PRICENTRIC BRIEF:

- Researchers from IQWiG and the Cochrane Collaboration have written an open letter to the European Medicines Agency
- The letter calls on the organization to publish all Clinical Study Reports on COVID-19 medicines and vaccines immediately on the day of marketing authorization.
- The EMA recently announced that it will accelerate its regulatory procedures so that marketing authorizations of safe, effective and high-quality COVID-19 related medicines can be granted as soon as possible

THE DETAILS

BERLIN, Germany – Researchers from IQWiG and the Cochrane Collaboration have written an open letter to the European Medicines Agency (EMA), calling on the organization to publish all Clinical Study Reports on COVID-19 medicines and vaccines immediately on the day of marketing authorization.

The letter, which is addressed to EMA Director Professor Guido Rasi, details how the international research community has joined forces to identify or develop, test and evaluate medicines and vaccines to fight the pandemic, and that "to assess these products further and to accelerate the development of additional products, the fast and full public availability of the information submitted to regulators is of utmost importance."

The letter comes after the recent announcement that the EMA has started an accelerated authorization process for Gilead's antiviral drug remdesivir. The Agency will also accelerate its regulatory procedures so that marketing authorizations of safe, effective and high-quality COVID-19 related medicines can be granted as soon as possible.

Procedures include:

- Rolling review: This procedure, used in a public health emergency, allows EMA to assess data for a promising medicine as they become available on a rolling basis. Under normal circumstances, all data supporting a marketing authorization application must be submitted at the start of the evaluation procedure. In the case of a rolling review, CHMP rapporteurs are appointed whilst development is still ongoing and the Agency reviews data as they become available.
- Rapid scientific advice, through which developers can receive prompt guidance and direction on the best methods and study designs to generate robust data on how well a medicine or vaccine works, how safe it is, as well as on the manufacturing and control process to establish its quality. In the context of COVID-19, fees for scientific advice are waived and the procedure is reduced to a maximum of 20 days, compared to normally 40-70 days.

The letter goes on to detail how "The international research community is undertaking coordinated efforts (e.g. the Living mapping and living systematic review of COVID-19 studies) to compile all emerging information on COVID-19 medicines and vaccines to ensure the optimal planning and conduct of research and to inform treatment decisions," and stresses that "To assess these products further and to accelerate the development of additional products, the fast and full public availability of the information submitted to regulators is of utmost importance."

The EMA's human medicines committee (CHMP) also recently recommended expanding the compassionate use scheme for remdesivir to allow more patients with severe COVID-19 infection to be treated with the antiviral.

UK Looks to the Future with "Smart Deals"

Originally published: May 22, 2020 | Region: EUROPE | Type: Regulation | Keywords: #access #complex #deals #nhs #reform #therapies

Pricentric Brief

- Over the last few years the NHS has begun a process to identify and pull transformative therapies and technologies into the NHS more quickly, hoping to change and modernize the way it treats disease
- Recent "smart deals" include an access deal for Bayer's histology independent cancer drug Vitrakvi (lartrectinib), as well as the securing of a deal with Vertex at the end of last year to make all three of their UK-licensed cystic fibrosis (CF) medicines available
- Off the back of the "smart deals", the implementation of several proposed policy initiatives during 2020, COVID-19 permitting, could help regulatory flexibility become a norm for the industry

The Details

LONDON, United Kingdom – As innovative therapies continue to develop at a rate faster than England's drug approval system can seem to keep up with, the approach to accessing innovation in the NHS becomes increasingly challenging. Over the last few years the NHS has begun a process to identify and pull transformative therapies and technologies into the organization more quickly, hoping to change and modernize the way it treats disease.

EVERSANA'S Market Access Data Analyst, Aatiqah Thanvi, explains, "Patient access schemes (PAS) are used by manufacturers to meet NICE incremental cost-effectiveness (ICER) threshold £30k QALY. In some cases, the price of the product is not cost effective therefore the PAS is used to meet the required ICER."

Following the recent news that the NHS struck an access deal for Bayer's histology independent cancer drug Vitrakvi (lartrectinib), we take a look back through the health service's previous "smart deals" and break down what the new settlements could mean for market access for similar innovative therapies in the UK.

NHS "Smart Deal" With Vertex

Potentially one of the most transformative agreements was the securing of a deal with Vertex Pharmaceuticals at the end of last year to make all three of their UK-licensed cystic fibrosis (CF) medicines available, following a tempestuous three-year back and forth between Vertex and the NHS. After The National Institute for Health and Care Excellence (NICE) rejected Orkambi (ivacaftor/lumacaftor) on cost-effectiveness grounds in 2016, the company refused the NHS' compromise of a £500 million, five-year funding deal. The two reached a seeming impasse, until the implementation of a managed access agreement (MAA).

Upon the sealing of the deal, NHS patients finally had full access to Vertex's CF portfolio; Orkambi, Symkevi (tezacaftor/ivacaftor) and Kalydeco (ivacaftor). Around 5,000 patients who had been waiting for access to Orkambi – priced by Vertex at £105,000 per patient per year – could now take up the life-changing treatment for the first time since it was approved for use in the UK in 2016.

Vertex's conditional reimbursement agreement via the MAA meant that the life-extending drugs could immediately be prescribed for all current licensed indications, as well as future license extensions, bringing the three-year battle between the company and the UK government closer to a definitive end.

The "smart deal" that ultimately gained patients access to the innovative drug was agreed under confidential commercial terms, but the NHS confirmed that the approach achieved was consistent with NHS England's other MAA reached with the pharmaceutical industry.

MAAs are already well established in the UK regulatory pathway, having been used as part of the Cancer Drugs Fund (CDF) system since 2016, but widening the scope of the use of MAAs can help unlock various new technologies for use on the NHS.

The flexible system allows patients who need a medicine to start being treated while at the same time allowing more information to be collected on how well the medicine works, providing a new way to bridge the gap between patient access and innovation that doesn't fit squarely in the established box of NICE's cost-effectiveness determinations.

CAR T-Cells, SMA, & Biosimilars

Other such "smart deals" include the health service's agreement to bring Gilead's Yescarta (axicabtagene ciloleucel) to lymphoma patients, the first agreement of its kind in Europe, and a comprehensive settlement to get Biogen's Spinraza (nusinersen) to patients living with spinal muscular atrophy (SMA).

As the former treatment is a CAR T-cell therapy, again the drug would have cost nearly £300,000 per patient at its full list price, but Gilead's Kite Pharma division secured a commercial agreement with NHS England that enabled NICE to approve its entry into England's Cancer Drugs Fund.

On the approval of Yescarta, Hilary Hutton-Squire, General Manager UK and Ireland, Gilead Sciences, said, "The speed of this decision shows how research-based life-sciences companies and the NHS can partner together for the benefit of patients in the UK," highlighting the ability of cooperation between the two to bring new generations of personalized treatments to patients.

The latter agreement, Spinraza for SMA, served as a reminder that "where companies show appropriate flexibility, it is possible to find a way to provide important treatments to patients in a way that is cost effective for the NHS and taxpayers", according to Meindert Boysen, director of the Centre for Health Technology Evaluation at NICE.

Not only do the "smart deals" show tangible benefit when used in relation to acquiring brand-name or patented drugs, but the group's abilities have also been used to negotiate deals with five manufacturers on low cost biosimilar versions of the health service's most costly drug; AbbVie's blockbuster Humira (adalimumab).

In 2018 AbbVie's exclusive patent to Humira expired, and the NHS wasted no time driving strong competition between biosimilar manufacturers and the manufacturer of the originator brand, resulting in huge cost discounts for the health service. NHS England accepted bids from four companies who manufacture biosimilar versions of the rheumatoid arthritis, inflammatory bowel disease and psoriasis drug – Amgen, Biogen, Mylan/Fujifilm Kyowa Kirin and Sandoz – as well as AbbVie.

From December 2018 biosimilar versions of adalimumab were available for use in England, and in August 2019 it was announced that the NHS had saved £110 million alone thanks to the 'smart procurement' of adalimumab.

Commercial Medicines Directorate

In 2016 NHS England released the Accelerated Access Review, detailing plans to establish an expert commercial drugs team – dubbed the Commercial Medicines Directorate. Since then, the team has worked closely with industry and particularly NICE to successfully negotiate a number of innovative deals, making new and promising treatments available for NHS patients.

The Directorate supports patient access to the most clinically effective medicines and treatments that don't adhere to the usual regulatory pathways, and at the same time, secures maximum value for the NHS and taxpayers from its ever growing spend on medicines and other healthcare treatments.

Looking at all the above deals, the overarching outcomes can be seen as driving both value for the taxpayer and benefits for patients, helping move the NHS and its structures forward in a timely manner to stay in pace with pharma's evolving R&D landscape.

In its most basic form, the relationship between pharmaceutical companies and the NHS is a supply and demand dynamic, but the symbiosis that holds the two so closely together is at risk of disintegrating should the two fall out of step with each other.

This potential disconnect is where the Commercial Medicines Directorate steps in. As an entity that undertakes the commercial arrangements that influence the price of medicines, the Directorate ensures patients have faster access to the most innovative new medicines, working collaboratively with industry and engaging early with pharmaceutical companies.

The group navigated all the above 'smart' negotiations, achieving major outcomes for patients in need by enabling the pharmaceutical industry and NHS to redefine and recalibrate the way they work together, carving out a new, adaptable path with the patients' needs at the heart of it.

Following the consistent success of the agreements, moving forward, the Commercial Directorate has announced that companies should work with NICE's Office for Market Access or NHSE as early as possible; as early as late-stage clinical trials in some cases.

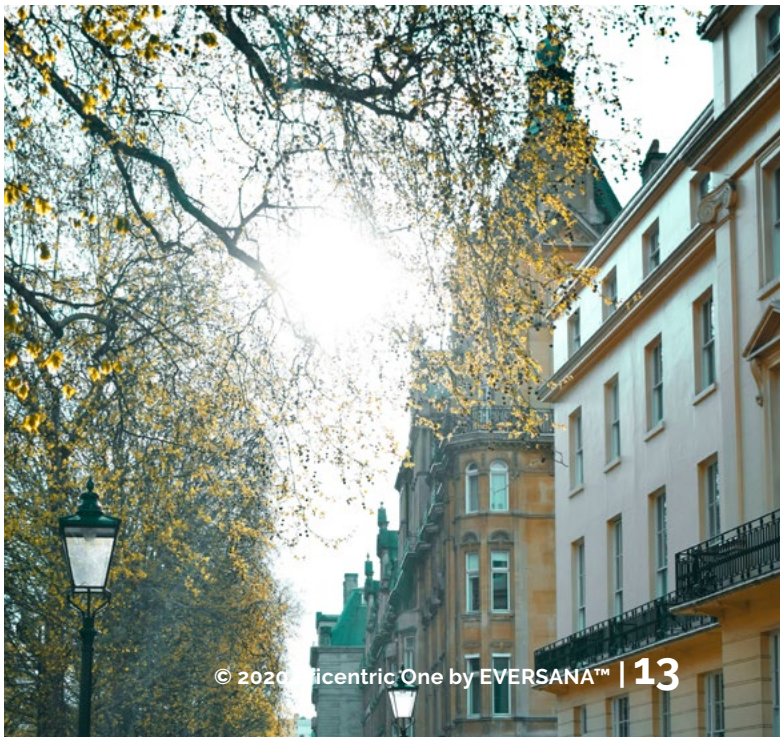
The systematic collection and understanding of real-world data through an MAA could serve as a beacon of shining light in addressing some of the UK's key pricing, funding and access issues for more unconventional, modern therapies.

UK Looks to the Future

Off the back of the "smart deals", the implementation of several proposed policy initiatives during 2020, COVID-19 permitting, could help regulatory flexibility become a norm for the industry, including:

- An expanded Accelerated Access Collaborative, promising quicker access to new breakthrough medicines: The collaborative expansion is set on developing alternative commissioning routes to expedite transformative medicine and technology uptake at pace and scale in the NHS
- A NICE Methodologies review, under which from June to September 2020 the organization will review a shortlist of topics: The 'major' overhaul is set to address complex therapies such as CAR-T and cell and gene, and delayed patient access due to issues determining the true value of therapies for rare diseases

If the rapidly growing pipelines are anything to go by, complex meds are only going to become more prevalent over time. Going forward, the UK pricing and reimbursement landscape can lean on the flexibility provided by "smart deals," which offer new pathways for accelerate approval, a step towards the future for the UK which relies on straightforward regulatory pathways in a time when innovative medicines are challenging standard protocol.



AIFA Announces Updates to OsMed Monitoring Reports

Region: EUROPE | Type: Policy | Keywords: #aifa #data #italy #osmed #reports #update

Originally published: May 26, 2020

PRICENTRIC BRIEF:

- The Italian Medicines Agency (AIFA) has revealed plans to update its Observatory on the Use of Medicines in Italy (OsMed) system, choosing to make it interactive
- The system will now return the overall consumption and expenditure data by region, with a greater level of detail than the reports published so far
- The data may now be filtered by classes of drugs and by dispensing methods, such as agreed assistance or purchases by the structures of the National Health Service

THE DETAILS

ROME, Italy – The Italian Medicines Agency (AIFA) has revealed plans to update its Observatory on the Use of Medicines in Italy (OsMed) system, choosing to make it interactive.

For years the reports have already been photographing the trend of consumption and expenditure on drugs in Italy, but will now return the overall consumption and expenditure data by region, with a greater level of detail than the reports published so far. The update will also allow users to view the comparison between regions and the deviations from the national average.

AIFA went on to explain that the data may now be filtered by classes of drugs and by dispensing methods, such as agreed assistance or purchases by the structures of the National Health Service.

The organization says that the new method of accessing OsMed data "facilitates and simplifies access to a series of useful information for the analysis of the use of drugs, monitoring of prescribing appropriateness, health planning, training and information," making it a useful tool for national and regional decision-makers, for those involved in programming, prevention and purchases in the pharmaceutical field.

Earlier this month, AIFA published a new set of rules for prescribing and dispensing conditions during COVID-19. Under the new guidance, information for chloroquine, hydroxychloroquine, lopinavir/ritonavir – also sold as Abbvie's Kaletra, darunavir/cobicistat – developed by Janssen as Prezcobix, and darunavir/ritonavir will be continuously updated in order to make them accessible for patients who need them.

On April 24th, AIFA also authorized three new clinical trials for the treatment of COVID-19 that are being coordinated at the University of Bologna, the University of Parma, and Pisan University Hospital.

Lithuania Government Gives Health Insurance Funds Consolidation the Go-Ahead

Originally published: May 22, 2020 | Country: LITHUANIA | Region: EUROPE | Type: Policy | Keywords: #consolidation #entities #funds #health #insurance #lithuania

PRICENTRIC BRIEF:

- Lithuania's Seimas, also known as its parliament, has approved the proposed project of consolidating the health insurance funds in order to optimize the Compulsory Health Insurance Fund's (PSDF) activities
- Following the approval, from the beginning of 2021, compulsory health insurance (PSD) will be provided by one legal entity - the State Health Insurance Fund (VLK) with regional branches
- The current insurance system has been under criticism from the National Audit Office since 2018, when leaders suggested that it could be worth merging all ICDs to simplify the management of the PSDF

THE DETAILS

VILNIUS, Lithuania - Lithuania's Seimas, also known as its parliament, has approved the proposed project of consolidating the health insurance funds in order to optimize the Compulsory Health Insurance Fund's (PSDF) activities, and simplify its management structure.

Following the approval, from the beginning of 2021, compulsory health insurance (PSD) will be provided by one legal entity - the State Health Insurance Fund (VLK) with regional branches. They would replace the current territorial health insurance funds (ICDs).

The current insurance system has been under criticism from the National Audit Office since 2018, when leaders suggested that it could be worth merging all ICDs to simplify the management of the PSDF.

Minister of Health Aurelijus Veryga commented at the time of the proposal: "Health insurance funds have always been reliable, their professional work has ensured the financial sustainability of the health system in the country.

"I have no doubt that these changes in the modernization of health insurance funds will only further strengthen the guarantees that everyone feels safe and can use the opportunities provided by compulsory health insurance,"

As it stands, the PSD is currently implemented in Lithuania by the PSD Council, VLK and five ICDs with the status of separate legal entities.

Merging them to create one larger legal entity would ensure the reduction of administrative burden, an increase in efficiency of the activities of the health insurance funds, the unification of the practice - which is what these changes are aimed at – all changes that are relevant for both medical institutions and patients.

By renouncing the status of the ICD as separate legal entities, the project proposes to clarify the functions and rights of the VLK, the provisions for concluding contracts with health care institutions.

WHO, Costa Rica Announce Tech Pooling for COVID-19 Products

Originally published: May 20, 2020 | Region: SOUTH AMERICA | Type: Policy | Keywords: #costa #covid-19 #pooling #procurement #rica #treatment #vaccine #who

PRICENTRIC BRIEF:

- WHO and Costa Rica have announced progress on a technology platform that aims to lift access barriers to effective vaccines, medicines and other health products against COVID-19
- The proposal would involve companies voluntarily pooling their intellectual property for treatment, vaccines, and diagnostics
- The platform will pool data, knowledge and intellectual property for existing or new COVID-19 health products to deliver "global public goods" for all people and all countries

THE DETAILS

SAN JOSÉ, Costa Rica - Presidents Carlos Alvarado Quesada of Costa Rica and Sebastián Piñera of Chile have joined WHO Director-General Dr Tedros Adhanom Ghebreyesus to announce progress on a technology platform that aims to lift access barriers to effective vaccines, medicines and other health products against COVID-19.

The idea was initially proposed by Costa at the beginning of the COVID-19 outbreak, and several countries are now backing the project.

WHO recently welcomed the proposal, which would involve companies voluntarily pooling their intellectual property for treatment, vaccines, and diagnostics.

The so-called Technology Intellectual Property Pool (TIPP) would accelerate scientific discovery, technology, and proof of safety, efficacy, and quality, and broad sharing of the benefits and scientific advancement of its application.

"Our proposal relies on solidarity," said President Alvarado of Costa Rica. "It's a Solidarity call to action to Member States, to academia, to companies, research institutions and cooperation agencies, based on global social responsibility, on a voluntary basis, promoting more global nonexclusive voluntary licensing."

"We need to unleash the full power of science, without caveats or restrictions, to deliver innovations that are scalable, usable, and benefit everyone, everywhere, at the same time," said WHO Director-General Dr Tedros Adhanom Ghebreyesus. "Traditional market models will not deliver at the scale needed to cover the entire globe. Solidarity within and between countries and the private sector is essential if we are to overcome these difficult times."

The platform will pool data, knowledge and intellectual property for existing or new COVID-19 health products to deliver "global public goods" for all people and all countries. Through the open sharing of science and data, numerous companies will be able to access the information they need to produce the technologies, thereby scaling up availability worldwide, lowering costs and increasing access.

WHO and Costa Rica will officially launch the platform on 29 May, and on that date, a Solidarity Call to Action will be published on WHO's website where governments, research and development funders, institutions and companies can express their support.

Previously, pharmaceutical companies joined intellectual property pools that allowed for HIV/AIDS, tuberculosis, and hepatitis C treatments to be extended to lower-income countries at affordable prices. The difference between the earlier pool and the COVID-19 pool is, all countries worldwide would be allowed to purchase treatments at lower prices.

NOK 5 Million Set Aside For Norway's New Methods Council Evaluation

PRICENTRIC BRIEF:

- NOK 5 million has been set aside for the evaluation of Norway's decision-making council for new methods
- In December 2019, the system was enacted in order to give regional health authorities responsibility for ensuring that there is a national system for deciding which methods are offered on the country's specialist health service
- The Ministry of Health and Care Services has said it intends to enter into an agreement at the end of October, November 2020; the evaluation will be delivered by 31 October 2021

Originally published: May 15, 2020

Country: NORWAY | Region: EUROPE | Type: Regulation | Keywords: #council #funding #methods #new #norway #storting #system

THE DETAILS

OSLO, Norway – Norway's Minister of Health, Bent Care Høie, has announced that NOK 5 million has been set aside for the evaluation of the country's decision-making council for new methods.

In December 2019 the system was enacted in order to give regional health authorities responsibility for ensuring that there is a national system for deciding which methods are offered on the country's specialist health service.

The Norwegian Storting has also asked the government to provide an evaluation of the current organization of case processing in the system for New Methods, stating "Medical developments give us new opportunities, but we also face difficult choices about which new drugs and treatment methods to use in our health service."

In a release, Care Bent Høie urged that "In order to ensure all patients equal, safe and effective access to new methods, the system must be continuously improved."

He continued, "It is important to me that patients, professional communities and providers be consulted. The experience and competence they have with them is important to listen to when we are preparing new methods for the future."

The Ministry of Health and Care Services has said it intends to enter into an agreement at the end of October, November 2020. The evaluation will be delivered by 31 October 2021.

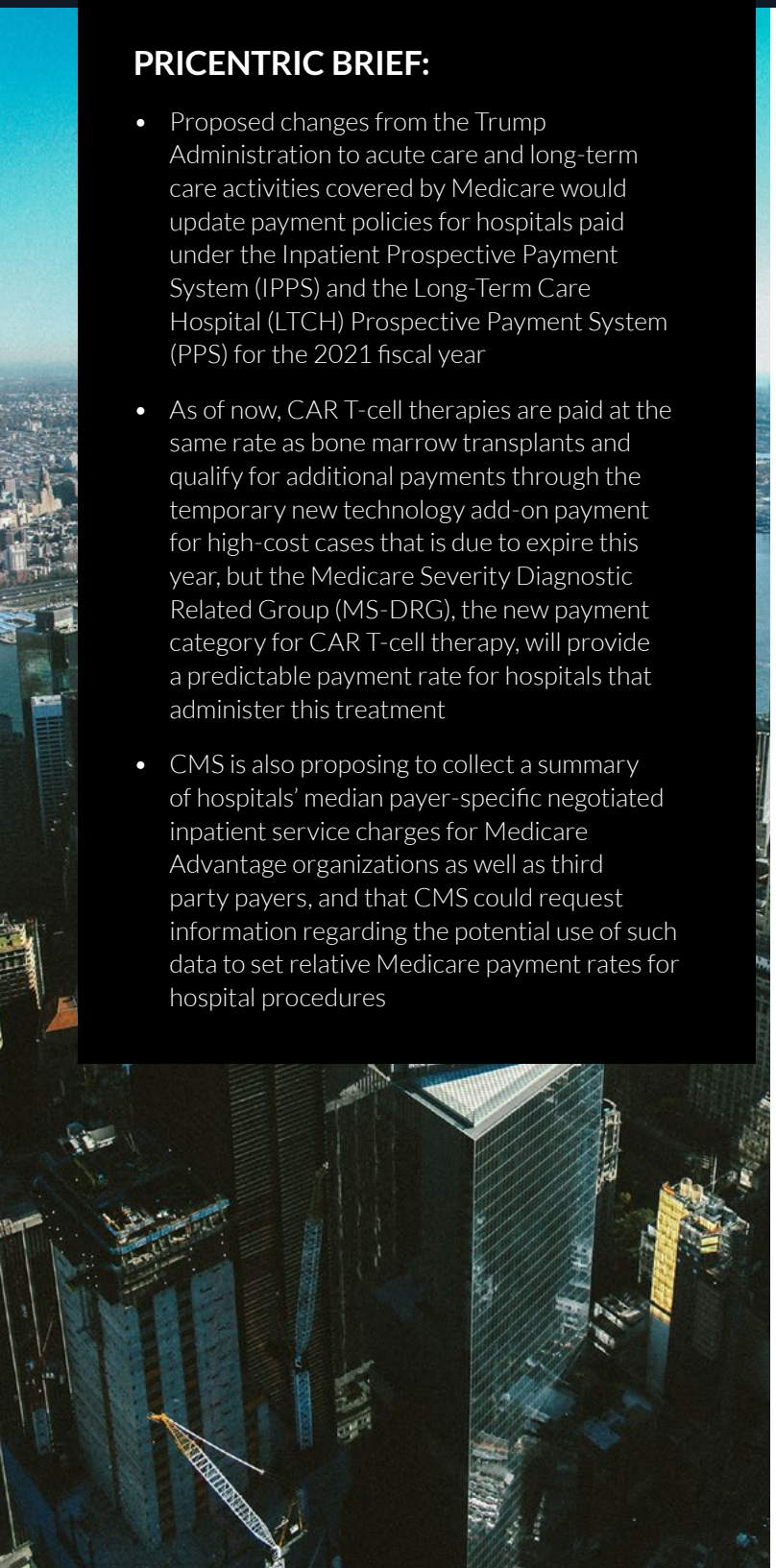
The evaluation intends to assess how the system is equipped organizationally and professionally for medical-technological development in the future, including special handling of personalized medicine.

It will also reevaluate how decisions are implemented in the health service, including information on health service decisions, updating national professional guidelines related to the decisions, and equal access to methods decidedly implemented for patients across the country.

At the end of last month, the decision-making council for new methods recommended the introduction of three new drugs to treat ovarian/peritoneal cancer, hemophilia A and gram-negative sepsis. Lynparza (olaparib), Esperoct (uroctokog alfa pegol) and Recarbrio (imipenem/cilastatin/relebactam) were among the decisions.

CMS Proposals Set CAR T-Cell Payment Rates, Increase Inpatient Rates Transparency

Originally published: May 14, 2020 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Regulation | Keywords: #cancer #cartcelltherapy #celltherapy #cms #medicaid #medicare #negotiations #oncology #paymentcategory #policy



PRICENTRIC BRIEF:

- Proposed changes from the Trump Administration to acute care and long-term care activities covered by Medicare would update payment policies for hospitals paid under the Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) for the 2021 fiscal year
- As of now, CAR T-cell therapies are paid at the same rate as bone marrow transplants and qualify for additional payments through the temporary new technology add-on payment for high-cost cases that is due to expire this year, but the Medicare Severity Diagnostic Related Group (MS-DRG), the new payment category for CAR T-cell therapy, will provide a predictable payment rate for hospitals that administer this treatment
- CMS is also proposing to collect a summary of hospitals' median payer-specific negotiated inpatient service charges for Medicare Advantage organizations as well as third party payers, and that CMS could request information regarding the potential use of such data to set relative Medicare payment rates for hospital procedures

THE DETAILS

WASHINGTON, D.C., The United States – Proposed changes from the Trump Administration to acute care and long-term care activities covered by Medicare would update payment policies for hospitals paid under the Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) for the 2021 fiscal year.

Through this, the Centers for Medicare and Medicaid Services (CMS) is proposing a separate new hospital payment category for CAR T-cell therapy, which modifies a patient's immune cells to fight certain types of cancer rather than relying on additional chemotherapy and other treatments paid for under the IPPS.

As of now, CAR T-cell therapies are paid at the same rate as bone marrow transplants and qualify for additional payments through the temporary new technology add-on payment for high-cost cases that is due to expire this year.

The Medicare Severity Diagnostic Related Group (MS-DRG), the new payment category for CAR T-cell therapy, will provide a predictable payment rate for hospitals that administer this treatment.

The proposals for regulatory changes to payments also address issues of transparency, henceforth allowing CMS to collect a summary of certain data already required by the agency's 2019 price transparency rule. Specifically, it addresses hospitals' median payer-specific negotiated inpatient service charges for Medicare Advantage organizations as well as third party payers.

Moreover, the proposal from CMS would request information regarding the potential use of such data to set relative Medicare payment rates for hospital procedures.

Nordics to Jointly-Negotiate Access to Zynteglo with Bluebird

Country: DENMARK, FINLAND, ICELAND, NORWAY, SWEDEN | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #access #bluebird #crosscountrycollaboration #finose #genetherapy #jointhta | **Originally published: May 20, 2020**

PRICENTRIC BRIEF:

- Bluebird bio has been invited to enter joint negotiations with Nordic countries Denmark, Finland, Iceland, Norway, and Sweden to ensure quick and equal access to its gene therapy Zynteglo (autologous cd34+ cells encoding βAT87Q-globin gene) for transfusion-dependent β-thalassemia
- Zynteglo will be the first new drug to enter into joint Nordic collaboration, and representatives from each country will participate to find common terms and conditions, but it will be up to each country to decide whether Zynteglo should be introduced for use within the health service
- Finland, Norway, and Sweden conducted a joint health economic assessment of Zynteglo through FiNoSe, their collaborative initiative

THE DETAILS

OSLO, Norway – Bluebird bio has been invited to enter joint negotiations with Nordic countries Denmark, Finland, Iceland, Norway, and Sweden to ensure quick and equal access to its gene therapy Zynteglo (autologous cd34+ cells encoding BAT87Q-globin gene).

Zynteglo will be the first new drug to enter into joint Nordic collaboration. Representatives from each country will participate to find common terms and conditions for the five countries, but it will be up to each country to decide whether Zynteglo should be introduced for use within the health service.

The Nordics hope to achieve acceptable and sustainable prices for medicines to offer new treatments to patients.

Zynteglo is a gene therapy for the treatment of transfusion-dependent β-thalassemia that does not have a β0 / β0 genotype in adults and children from 12 years of age.

Finland, Norway, and Sweden conducted a joint health economic assessment of Zynteglo through FiNoSe, their collaborative initiative. FiNoSe has primarily served to enable participating countries to jointly evaluate new medicines, not to engage in pricing and reimbursement negotiations together.

Previously, Denmark, Iceland, and Norway have entered into joint procurement of hospital pharmaceuticals, particularly those with expired patents that have been available on the market for some time and have little competition.

Negotiations with bluebird on the price of Zynteglo signal increased collaboration among the Nordics.

Slovenia Votes Against Funding Unauthorized Orphan Drugs

Country: SLOVENIA | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #authorization #funding #healthcommittee #orphandrugs #raredisease | Originally published: May 14, 2020

PRICENTRIC BRIEF:

- The Health Committee of Slovenia's parliament voted against legislative changes that would allow full state funding for medicines for rare diseases, regardless of whether they're on the list of drugs eligible for state funding
- These changes were first proposed by the upper chamber of parliament and sought for orphan drugs not eligible for state funding or not officially registered in Slovenia to be provided state funding
- In March of this year, the Health Committee was set to debate these amendments to the health care and health insurance act that would mandate public coverage for the cost of treatment of rare diseases, despite whether or not they were authorized for use

THE DETAILS

LJUBLJANA, Slovenia – The Health Committee of Slovenia's parliament voted against legislative changes that would allow full state funding for medicines for rare diseases, regardless of whether they're on the list of drugs eligible for state funding.

These changes were first proposed by the upper chamber of parliament and sought for orphan drugs not eligible for state funding or not officially registered in Slovenia to be provided state funding.

In March of this year, the Health Committee was set to debate these amendments to the health care and health insurance act that would mandate public coverage for the cost of treatment of rare diseases, despite whether or not they were authorized for use.

FiNoSe Publishes Joint Evaluation of Bluebird's Zynteglo

Originally published: May 13, 2020 | Country: FINLAND, NORWAY, SWEDEN | Region: EUROPE | Type: HTA | Keywords: #astellas #bluebird #fimea #finose #genetherapy #jointevaluation #noma #roche #tecentriq #tlv #xtandi

Pricentric Brief

- Along with the corresponding authorities in Norway and Finland, the Norwegian Medicines Agency (NoMA) and Finnish Medicines Agency (Fimea), respectively, the Dental and Pharmaceutical Benefits Agency (TLV) of Sweden has published an evaluation report on bluebird's Zynteglo (autologous CD34-positive cells expressing the βA-T87Q globin gene), the third joint evaluation under FiNoSe
- Relevant comparators to Zynteglo are regular blood transfusions and iron-binding drugs, which are lifelong treatments, whereas Zynteglo is a one-time administration that promises a cure; thus, the duration of the effect of Zynteglo is expected to be lifelong, counteracting the need for regular transfusions, but long-term data are limited
- According to TLV, the price for Zynteglo is approximated at SEK 17 million for one-time treatment, which was compared to the cost of life-long treatment with blood transfusions and iron-binding drugs—almost SEK 7.3 million with a discount rate of 3%

The Details

STOCKHOLM, Sweden – Along with the corresponding authorities in Norway and Finland, the Norwegian Medicines Agency (NoMA) and Finnish Medicines Agency (Fimea), respectively, the Dental and Pharmaceutical Benefits Agency (TLV) of Sweden has published an evaluation report on bluebird's Zynteglo (autologous CD34-positive cells expressing the βA-T87Q globin gene), the third joint evaluation under FiNoSe.

Through FiNoSe, the Scandinavian countries evaluated Zynteglo for the treatment of patients aged 12 years and up with transfusion-dependent beta-thalassemia who do not have a β0/β0 genotype for which allogeneic hematopoietic stem cell transplantation is suitable but lacking a donor.

For patients with beta-thalassemia who are eligible for treatment with Zynteglo, the severity level of their illness is considered moderate, because the impact of the disease on a person's health is generally moderate, despite current treatment with blood infusions and iron-binding drugs being lifelong.

Relevant comparators to Zynteglo are regular blood transfusions and iron-binding drugs, which are lifelong treatments, whereas Zynteglo is a one-time administration that promises a cure. Thus, the duration of the effect of Zynteglo is expected to be lifelong, counteracting the need for regular transfusions, but long-term data are limited.

According to TLV, the price for Zynteglo is approximated at SEK 17 million for one-time treatment, which was compared to the cost of life-long treatment with blood transfusions and iron-binding drugs—almost SEK 7.3 million with a discount rate of 3%.

TLV concluded that there are two scenarios, with and without survival gains, in which the cost per won quality-adjusted life year (QALY) amounts to SEK 1,761,000 and SEK 2,137,000, respectively.

FiNoSe is a pilot collaborative effort among Finland, Norway, and Sweden first launched in 2018 that allows for the joint evaluation of innovative therapies. FiNoSe does not pursue joint access and reimbursement decision making; rather, the objective of FiNoSe is to increase knowledge of a product through joint evaluation and align health technology assessment (HTA) methodologies and evidence requirements.

The first two medicines evaluated by FiNoSe were Astellas' Xtandi (enzalutamide), which was assessed under a grant application, and Tecentriq (atezolizumab), which followed submission from Roche. In each instance, TLV and NoMA were the assessors, with Fimea serving as reviewer.

EFPIA Highlights Importance of Data to Ensure Patients Get Needed Medicines

Region: EUROPE | Type: Policy | Keywords: #covid-19 #efpia #europe #supply | Originally published: May 11, 2020

PRICENTRIC BRIEF:

- The EFPIA has reiterated that ensuring the supply of medicines to the patients who need them is a top priority for the organization during COVID-19
- In a release, MSD's Dr Susanne Fiedler re-stated the importance of modelling data from the European Centre for Disease Control about the likely progression of the pandemic in each country
- This data can facilitate getting the right medicine to the right hospital in the right country at the right time as we prepare for any future waves of the disease

THE DETAILS

BRUSSELS, Belgium – Amid the COVID-19 pandemic, the EFPIA has reiterated that ensuring the supply of medicines to the patients who need them is a top priority for the organization.

In a release, MSD's Dr Susanne Fiedler re-stated the importance of modelling data from the European Centre for Disease Control about the likely progression of the pandemic in each country, as well as patient level and hospital level data in the Member States.

She reminded that ultimately, it is this data that will facilitate getting the right medicine to the right hospital in the right country at the right time as we prepare for any future waves of the disease.

Similarly to Dr Fiedler, both Commissioner Kyriakides and EFPIA Director General, Nathalie Moll underlined the importance of keeping the patients at the heart of Europe's coronavirus response with Ms Moll highlighting the public dialogue between EFPIA and the European Patients Forum as well as the European researched-based industry's commitments to fighting COVID-19.

Last week, the European Commission raised €7.4bn at the Coronavirus Global Response pledging event.

The EFPIA also stated that having instigated pandemic preparedness plans in January 2020, EFPIA member companies have been able to increase production to meet the needs of patients, however data holds the key to ensuring that this increased production can be allocated across Europe so that each patient gets the medicines they need.

In addition to the forecasting data and modelling, data held in national repositories, set up in the context of the EU Falsified Medicines Directive can show, at aggregate level, how and when critical treatments are delivered to countries and how quickly they are being used. If utilised, this data can be another powerful tool in helping to plan and manage the allocation of medicines to ensure patients get the treatments they need.

Danish Medicines Council Postpones Method Changes Until 2021

Country: DENMARK | Region: EUROPE | Type: Policy | Keywords: #medicinescouncil #method #postpone #qaly

Originally published: May 8, 2020

PRICENTRIC BRIEF:

- The Danish Medicines Council has issued an update on the implementation of its new methods following disruption due to COVID-19
- The council has confirmed that the changes will be moved from 1 October 2020 to 1 January 2021, when the organization will introduce QALY - quality adjusted life years - as the basis for its assessments of new medicines
- From January 2021 the QALY system will replace the current Council of Medicine methodology

THE DETAILS

COPENHAGEN, Denmark – The Danish Medicines Council has issued an update on the implementation of its new methods following disruption due to COVID-19.

The council has confirmed that the changes will be moved from 1 October 2020 to 1 January 2021, when the organization will introduce QALY - quality adjusted life years - as the basis for its assessments of new medicines.

QALY-based health economic analysis is already used in many other countries, and from January 2021 will replace the current Council of Medicine methodology with categorizations of value.
The Medicines Council confirmed that the postponement of the changes has been approved by the board of the Danish Regions.

Following the COVID-19 disruption, the council has announced its new timetable as following:

For ongoing cases of new medicines which were held prior to 1 January 2021, in which the company has already submitted a preliminary application, they will be finalized according to the current process and method. Companies are encouraged to contact the Secretariat if they have any doubts about how the transition to the new methods will affect their cases.

For the sake of backlog of tasks within and outside the Medical Council, teaching of specialist committees in the new methods will start after January 1, 2021. The teaching will be organized so that the specialist committees that work with the new methods will receive instruction first.

During the pandemic, the Council has introduced temporary work processes, endeavoring to complete as many cases as possible within the current case processing times, but has announced that there may be delays as the medical members of the council and the professional committees will have to prioritize their tasks in hospitals in the future in relation to COVID-19.

Germany's BfArM Issues Guidance for Evaluation, Approval of Digital Therapeutics Under DVG Law

Originally published: May 7, 2020 | Country: GERMANY | Region: EUROPE | Type: Regulation | Keywords: #bfarm #digitalsupplyact #digitaltherapeutics #dvg #gkvspitzenverband #gkvsv #healthapps #hta #policy #pricingandreimbursement

PRICENTRIC BRIEF:

- Following the passing of the Digital Supply Act (DVG) in Germany in December 2019, which allowed for a specific reimbursement scheme for digital health products, 14 medical technology associations commenced negotiation procedures with German umbrella payer GKV-Spitzenverband (GKV-SV) on how prices for digital therapeutics, or health apps, could be found
- While GKV-SV is charged with figuring out the pricing and reimbursement of digital therapeutics, the Federal Institute for Drugs and Medical Devices (BfArM) is the evaluative body, responsible for checking data security, data protection, and functionality, as well as efficacy and safety
- In the article, find a rundown of the evaluation and reimbursement process for digital therapeutics, as well as a link to a guide published by BfArM

THE DETAILS

BERLIN, Germany – Following the passing of the Digital Supply Act (DVG) in Germany in December 2019, which allowed for a specific reimbursement scheme for digital health products, 14 medical technology associations commenced negotiation procedures with German umbrella payer GKV-Spitzenverband (GKV-SV) on how prices for digital health apps could be found.

By Summer 2020, it is anticipated that over 70 million people with health insurance Germany could benefit from the new reimbursement scheme for health apps.

The Digital Health Ordinance under the DVG came into effect two weeks ago. Here is a rundown of the evaluation and reimbursement process for health apps, or digital therapeutics – both terms to be used interchangeably in this article. However, a full guide to the procedure can be found here.

While GKV-SV is charged with figuring out the pricing and reimbursement of health apps, the Federal Institute for Drugs and Medical Devices (BfArM) is the evaluative body.

Manufacturers must prove to BfArM that the app in question improves patient care. BfArM has published a list of procedures for the review of health apps to explain its process of checking the digital therapeutics for data security, data protection, and functionality, as well as efficacy and safety.

To be reimbursable, under the DVG law digital therapeutics, defined as low-risk medical devices (classified as either classes I or IIa) aimed at fulfilling a specific medical need or purpose, must be certified as a medical device and included in a BfArM register.

Digital therapeutics must meet requirements for safety, as mentioned before, and show proof of positive effects, including, but not limited to improvement in state of health or prolonged survival, in patient care. The benefits of using the digital therapeutic must be substantiated and made clearly evident by the manufacturer.

Comparative studies do not need to be necessarily set in Germany, but the effect of the digital therapeutics should be transferrable to Germany.

Digital therapeutics are listed in the BfArM register for a trial period, but the period may be extended if study results deem it necessary (long-term follow-up, etc.). However, in the case of a final admission to BfArM, the manufacturer has one chance for a review and reimbursement.

During this period, BfArM is allowed free access to the digital therapeutic.

Once backed by BfArM for use, the digital therapeutic is then subject to pricing negotiations between the manufacturer and GKV-SV. The German agency is to negotiate a reimbursement amount, which is performance related. If negotiations do not result in an agreement between both parties, then as with the AMNOG procedure, the reimbursement amount will then be decided by an arbitration board.

Association of Generic Medicines Calls Generics Spain's "Safety Net" During Pandemic

Country: SPAIN | Region: EUROPE | Type: Policy | Keywords: #aeseg #covid-19 #generics

PRICENTRIC BRIEF:

- Nearly 70% of the medicines that were declared essential by the Spanish Agency of Medicines and Health Products (AEMPS) for the treatment of COVID-19 have a generic presentation on the market, according to AESEG
- The general secretary of AESEG, Ángel Luis Rodríguez de la Cuerda, said much has been learned from dealing with the pandemic, lessons that should contribute to a better SNS…and the AESEG should be committed to the generic drug sector in order to minimize Spain's dependence on other countries
- Rodríguez de la Cuerda encourages "establishing minimum profitability thresholds that allow the generic drug industry in Spain to continue growing" and wants to "eradicate measures aimed at market exclusivity"

THE DETAILS

MADRID, Spain — The Spanish Association of Generic Medicines (AESEG) met to address the contribution of the generic drug sector to the health system amid the COVID-19 pandemic.

Present at the meeting were the president of the association, Raúl Díaz-Varela, and the general secretary, Ángel Luis Rodríguez de la Cuerda.

At the time of the colloquium, Díaz-Varela stated that "in this health crisis, generic drugs have been confirmed as the safety net that our National Health System has in order to guarantee access to most of the essential drugs and, in addition, in a cost efficient way."

"Manufacturing plants have worked at full capacity in these weeks "multiplying by ten the production of some highly demanded drugs in the treatment of patients with COVID-19 such as cisatracurium, propofol, midazolam, fentanyl or chloroquine and hydroxychloroquine," explained the president of AESEG.

Safety precautions in factories, mobility restrictions, access to raw materials, additional protection, and other factors have inflated costs of direct and indirect production, "which in no case have the companies affected in the final price of our drugs."

AESEG pointed out that almost 70% of the medicines that were declared essential by the Spanish Agency of Medicines and Health Products (AEMPS) for the treatment of COVID-19 have a generic presentation on the market and of them, 96% have a price lower than 10 euros.

Rodríguez de la Cuerda said much has been learned from dealing with the pandemic, lessons that should contribute to a better SNS…"our SNS needs to rearm, reformulate and establish new frameworks for relations in many plots, and without a doubt, pharmaceutical policy is one of them."

The general secretary added that the AESEG should be committed to the generic drug sector in order to minimize Spain's dependence on other countries

Rodríguez de la Cuerda encourages "establishing minimum profitability thresholds that allow the generic drug industry in Spain to continue growing and continue to be able to develop generic presentations of new drugs."

He also highlighted a "need to promote the free participation of all companies in the manufacture and supply of generic drugs and eradicate measures aimed at market exclusivity, such as those known as auctions or other restrictive measures."

Biosimilars Saved Spain 2,400 Million Euros Between 2009 and 2020

PRICENTRIC BRIEF:

- The Spanish Society of Hospital Pharmacists (SEFH) calculated that Spain has saved more than 2,400 million euros between 2009 and 2020 through the introduction of biosimilars for the treatment of inflammatory diseases and cancer
- In the article, published in the May/June issue of the journal Farmacia Hospitalaria, Dr. Miguel Ángel Calleja, former President of SEFH, said, "The use of monoclonal antibody biosimilars is endorsed by many scientific societies and allows additional innovation for the development of these molecules that adds value to patients and the Health System"
- Dr. Martinez Sesmero, Director of Innovation SEFH, too stressed that biosimilars represent a boost of "high value" in optimizing the management of health resources, reducing costs, increasing competitiveness and creating incentives to develop new and innovative therapeutic tools, monitoring and evaluation of health outcomes

Originally published: May 6, 2020

Country: SPAIN | Region: EUROPE | Type: Biosimilar | Keywords: #inflammatorydiseases #monoclonalantibodies #oncology #regulation #sefh

THE DETAILS

MADRID, Spain – The Spanish Society of Hospital Pharmacists (SEFH) calculated that Spain has saved more than 2,400 million euros between 2009 and 2020 through the introduction of biosimilars for the treatment of inflammatory diseases and cancer.

SEFH published their findings in the May/June issue of the journal Farmacia Hospitalaria.

In the article, SEFH details the approval process for these monoclonal antibody biosimilars in the European Union (EU), which is based on proven quality, efficacy, safety, and biosimilarity.

Dr. Miguel Angel Calleja, former President of SEFH, said, "The use of monoclonal antibody biosimilars is endorsed by many scientific societies and allows additional innovation for the development of these molecules that adds value to patients and the Health System.

"It is very important that the application in hospitals is carried out with the highest degree of consensus between pharmacy services and colleagues from other specialties."

Dr. Martinez Sesmero, Director of Innovation SEFH, stressed that biosimilars represent a boost of "high value" in optimizing the management of health resources, reducing costs, increasing competitiveness and creating incentives to develop new and innovative therapeutic tools, monitoring and evaluation of health outcomes.

ICER Suggests $10, $4,500 Prices for Remdesivir Based on Preliminary Trial Data

Region: NORTH AMERICA | Type: Cost Effectiveness | Keywords: #antiviral #costrecovery #covid-19 #gilead #icer #icercovid19models #pricingparadigms #remdesivir | Originally published: May 05, 2020

PRICENTRIC BRIEF:

- An initial analysis from the Institute for Clinical and Economic Review (ICER) has estimated that the ceiling price for Gilead's antiviral, which just received Food and Drug Administration (FDA) Emergency Use Authorization (EUA) designation, should be $4,500
- With the help of external academic partners, ICER developed ICER-COVID models for remdesivir and other future treatments for the coronavirus, which are comprised of two alternative pricing paradigms: cost-recovery, which details the minimum costs of production for a therapy, and traditional cost-effectiveness analyses, which consider incremental health benefits and costs within the health system
- The model for remdesivir is based on preliminary publicly available information for randomized clinicals trials and other sources, which for ICER suggests the preliminary cost recovery pricing for 10-day course of remdesivir to be estimated at $10, with cost-effectiveness pricing at a commonly used threshold for treatments of large patient populations estimated at a ceiling of $4,500

THE DETAILS

BOSTON, Massachusetts, The United States – An initial analysis from the Institute for Clinical and Economic Review (ICER) has estimated that the ceiling price for Gilead's antiviral, which just received Food and Drug Administration (FDA) Emergency Use Authorization (EUA) designation, should be $4,500.

With the help of external academic partners, ICER developed ICER-COVID models for remdesivir and other future treatments for the coronavirus. The models comprise two alternative pricing paradigms: cost-recovery, which details the minimum costs of production for a therapy, and traditional cost-effectiveness analyses, which consider incremental health benefits and costs within the health system.

The model for remdesivir is based on preliminary publicly available information for randomized clinicals trials and other sources, explained ICER. To keep pricing estimates as up-to-date as possible, ICER will continue tracking information and public input, which is always developing, to keep the models current.

Steven D. Pearson, MD, MSc, ICER's President, explained, "Our cost recovery estimate for remdesivir borrows directly from previous peer-reviewed work seeking to determine the 'minimum' costs of production by calculating the cost of active pharmaceutical ingredients, which is combined with costs of excipients, formulation, packaging and a small profit margin."

As noted by ICER, the preliminary cost recovery pricing for 10-day course of remdesivir is estimated at $10; cost-effectiveness pricing at a commonly used threshold for treatments of large patient populations estimated at a ceiling of $4,500.

Going forward, policymakers and the public will need to debate most appropriate development and pricing paradigms to be used to achieve rapid development and distribution of affordable treatments for a global pandemic, because, when it comes to COVID-19 treatments, "The results of a cost recovery approach and a cost-effectiveness approach are going to produce very different pricing estimates," said Pearson.

"Some may wish to view them as the low and the high end within which to frame a policy approach. We are releasing these estimates now, despite the fact that the evidence is highly uncertain and evolving, because now is the time when the public and policymakers should be actively debating how to link pricing to an overall platform to develop treatments for COVID-19.

"The consequential discussion about the tradeoffs and priorities involved with different pricing approaches cannot wait. All share the common goal of achieving rapid discovery, development, production, and distribution of effectiveness treatments. All share the understanding that treatments must be affordable in order for this goal to be realized. We hope our modeling results will help the public have a more transparent, explicit debate on treatment pricing for COVID-19, and we look forward to adapting our methods and results to provide an independent source of information to inform that debate," Pearson concluded.

U.S.-China Economic & Security Review Commission Hosts Hearing on China's Healthcare System

Originally published: May 11, 2020 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #commission #economic #healthcare #review #security #system

PRICENTRIC BRIEF:

- During a virtual hearing hosted by the U.S.-China Economic & Security Review Commission, Karen Eggleston, Senior Fellow, Freeman Spogli Institute for International Studies noted that the number of doctors per number of citizens in China is now comparable to that of upper middle income countries, and the number of hospital beds per number of citizens in China exceeds that of US, with the COVID-19 pandemic, in particular, triggering modernization, especially in the field of telemedicine
- Another speaker, Tara O'Toole, Senior Fellow and Executive Vice President, In-Q-Tel, said China wants to be a leader in the biotech industry, stressing that China aims to move up the financial value chain by developing and producing its own drugs
- Among the speakers' recommendations are evidence based health policy, defining and regulating the non profit sector, bundled payment, more robust ways of malpractice regulation, encouragement of transparent peer reviewed research, sharing of case studies of patient centered care, encouragement of randomized control trials for traditional Chinese medicine, and faster progress in the US in biotech and AI powered health services

THE DETAILS

WASHINGTON D.C., The United States — During a virtual hearing hosted by the U.S.-China Economic & Security Review Commission, several speakers presented testimonies on China's evolving healthcare system.

The speakers included Karen Eggleston, Senior Fellow, Freeman Spogli Institute for International Studies, Stanford University, Tara O'Toole, Senior Fellow and Executive Vice President, In-Q-Tel, and Jennifer Bouey, Senior Policy Researcher and Tang Chair in China Policy Studies, Rand Corporation.

Eggleston gave an overview of China's health system modernization since the spread of SARS, explaining that the country consolidated social health insurance giving citizens access to basic health services.

While she said China has made considerable progress, Eggleston listed areas in need of improvement such as high male smoking rates, and large urban and rural disparities. Rural areas are underserved and have access to fewer doctors.

Still, the number of doctors per number of citizens in China is now comparable to that of upper middle income countries, and the number of hospital beds per number of citizens in China exceeds that of US, according to Eggleston.

The COVID-19 pandemic, in particular, has given a boost to telemedicine, online consultations, and robots in healthcare. Also triggering a lot of ongoing reforms is the growing median age in China, which surpasses that of the US.

Eggleston ended her statement by giving a long list of recommendations including the promotion of healthy aging, stronger primary care, support for health education for the disadvantaged, and prioritization of mental health.

She also recommended evidence based health policy, defining community benefits in exchange for tax exemption, defining and regulating the non profit sector, bundled payment, and more robust ways of malpractice regulation.

In terms of research and development, she recommended encouragement of public-private collaborations, collaboration between Chinese and American scientists, encouragement of transparent peer reviewed research, sharing of case studies of patient centered care, and encouragement of randomized control trials for traditional Chinese medicine.

Meanwhile, O'Toole stressed that China has urgent and extensive healthcare needs and deficits and has already made plans to transform itself, with healthcare strategies closely tied with geopolitical ambitions. "The imperative to do better has been illuminated by COVID-19," she noted.

In particular, China plans on integrating digital technologies to create its own innovative pharmaceutical sector and dominating the biotechnology sector. China wants to be a leader in the biotech industry and policy shows this, O'Toole said, as regulations have become more aligned with FDA.

O'Toole pointed out that China has the highest incidence of cancer in world as well as a very high number of diabetics, not to mention the rising median age. The population "may very well get old before it gets rich," she said.

Among recent advancements, there has been a large effort to produce health apps and currently, 94% of physicians have already given them a try, according to O'Toole.

Hundreds of digital start ups are appearing, as well as international collaborations such as a partnership between Sanofi and a Chinese insurer aimed at creating algorithms to remotely manage diabetes and other conditions. Other Chinese companies like Alibaba are eager to get involved in digital health.

O'Toole stressed that China wants to move up the financial value chain by developing and producing its own drugs and "they are soon to be number one in the world's pharma industry."

She recommended that the US become more competitive in biotech and AI, and more rigorously collect and protect health data.

Then, Bouey explained how the Chinese CDC was restructured after SARS and implemented new systems for identifying and surveilling diseases. However, the CDC has been underfunded for years partially due to debt at the provincial government level, and front line physicians lack incentive to use the CDC system.

A lack of legal and administrative power inhibits the CDC from effectively distributing warnings and it must ultimately depend on local governments which have different priorities.

Her recommendations to US are to restore research and collaborations on public health between US and China CDC, restore dialogue with China to create global health strategy, and consider a US-China combined investment in innovation.

FDA Authorizes Emergency Use of Gilead's Remdesivir for Hospitalized COVID-19 Patients

Country: UNITED STATES | Region: NORTH AMERICA | Type: Drug Approval |
Keywords: #antiviral #covid-19 #emergencyuseauthorization #fda #gilead #hhs #hospitals #remdesivir |
Originally published: May 4, 2020

PRICENTRIC BRIEF:

- The Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for emergency use of Gilead's remdesivir – 5-day and 10-day treatment durations, depending on the severity of disease – for the treatment of hospitalized patients with COVID-19
- Under the emergency authorization, the FDA stipulated that remdesivir can only be administered in an in-patient setting via intravenous (IV) infusion by healthcare providers for adult and child patients with suspected or laboratory-confirmed COVID-19 and severe disease defined as SpO2 ≤ 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
- After the FDA reviewed topline data from NCT04280705, the randomized, double-blind, placebo-controlled trial conducted by NIAID, as well as data from NCT04292899, the Gilead-sponsored open-label trial that evaluated the different duration of remdesivir, the regulator concluded that the known and potential benefits of remdesivir outweigh the known and potential risks of the drug for patients hospitalized with coronavirus

THE DETAILS

WASHINGTON, D.C., The United States – The Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for emergency use of Gilead's remdesivir for the treatment of hospitalized patients with COVID-19, announced the FDA.

Under the emergency authorization, the FDA stipulated that remdesivir can only be administered in an in-patient setting via intravenous (IV) infusion by healthcare providers for adult and child patients with suspected or laboratory-confirmed COVID-19 and severe disease defined as SpO2 ≤ 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Gilead further added that both 5-day and 10-day treatment durations are suggested, depending on the severity of disease.

"The authorization is temporary and does not take the place of the formal new drug application submission, review and approval process. The EUA allows for the distribution and emergency use of remdesivir only for the treatment of COVID-19; remdesivir remains an investigational drug and has not been approved by FDA," said Gilead in a press release.

The Department of Health and Human Services (HHS) determined that there is a public health emergency due to the spread of the coronavirus, which allows the Secretary of HHS to justify the allowance EUA medicines and biologics to be used to mitigate the outbreak and treat infected patients.

Gilead's remdesivir is a direct acting antiviral that inhibits viral RNA synthesis, currently unapproved for any indication.

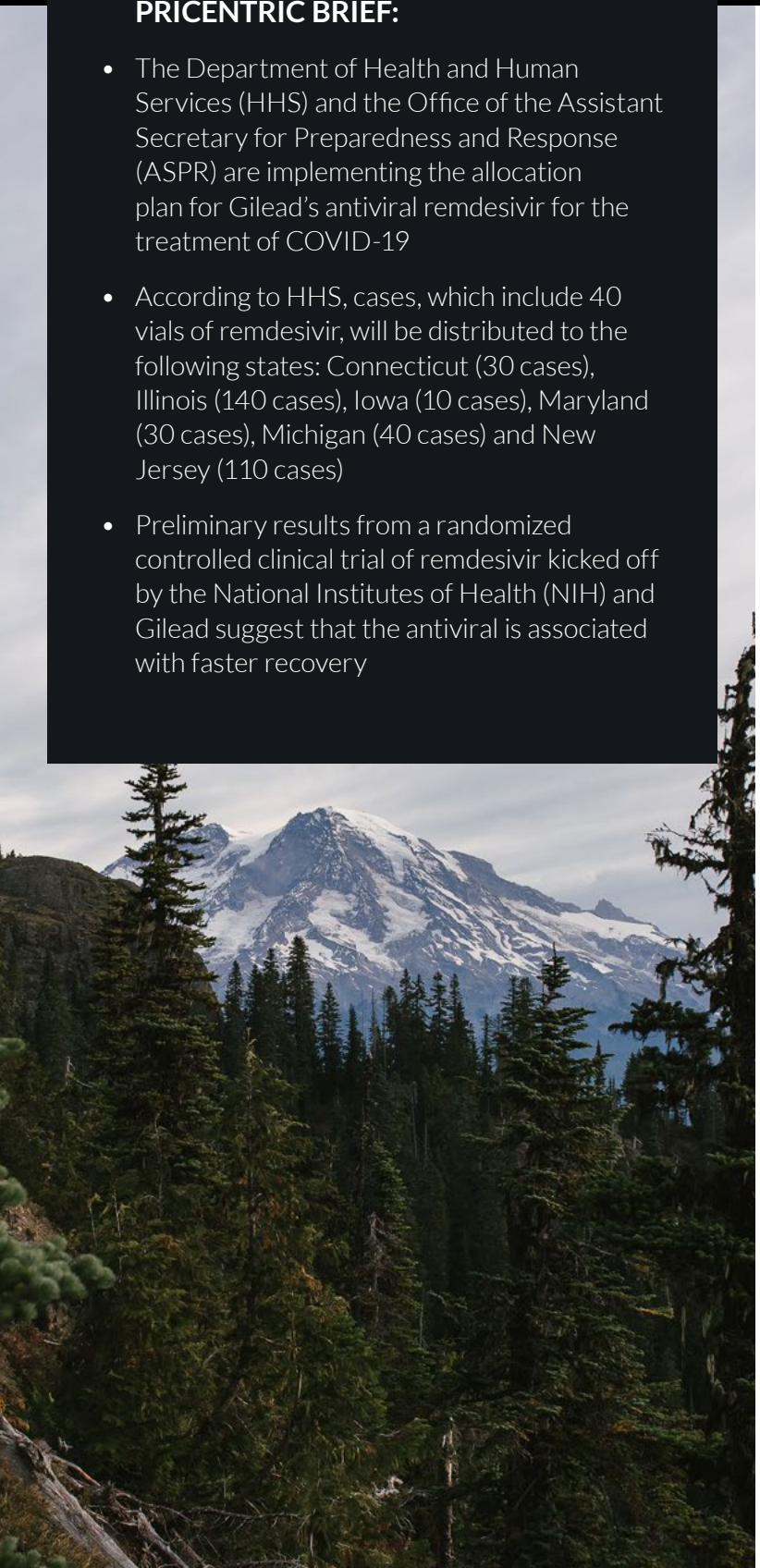
After the FDA reviewed topline data from NCT04280705, the randomized, double-blind, placebo-controlled trial conducted by NIAID, as well as data from NCT04292899, the Gilead-sponsored open-label trial that evaluated the different duration of remdesivir, the regulator concluded that the known and potential benefits of remdesivir outweigh the known and potential risks of the drug for patients hospitalized with coronavirus.

HHS Distributes Remdesivir Cases to States for COVID-19 Treatment

Region: NORTH AMERICA | Type: Regulation | Keywords: #aspr #covid-19 #donations #emergencyuseauthorization #gilead #hhs #remdesivir | Originally published: May 11, 2020

PRICENTRIC BRIEF:

- The Department of Health and Human Services (HHS) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) are implementing the allocation plan for Gilead's antiviral remdesivir for the treatment of COVID-19
- According to HHS, cases, which include 40 vials of remdesivir, will be distributed to the following states: Connecticut (30 cases), Illinois (140 cases), Iowa (10 cases), Maryland (30 cases), Michigan (40 cases) and New Jersey (110 cases)
- Preliminary results from a randomized controlled clinical trial of remdesivir kicked off by the National Institutes of Health (NIH) and Gilead suggest that the antiviral is associated with faster recovery



THE DETAILS

WASHINGTON, D.C., The United States – The Department of Health and Human Services (HHS) and with the Office of the Assistant Secretary for Preparedness and Response (ASPR) are implementing the allocation plan for Gilead's antiviral remdesivir for the treatment of COVID-19.

Granted Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) on May 1, 2020, remdesivir is being donated by Gilead to be divvied out for use by hospitalized patients with COVID-19.

According to HHS, cases, which include 40 vials of remdesivir, will be distributed to the following states: Connecticut (30 cases), Illinois (140 cases), Iowa (10 cases), Maryland (30 cases), Michigan (40 cases) and New Jersey (110 cases).

State health authorities are responsible for ensuring the doses reach the appropriate hospitals. Patients are eligible to receive remdesivir if they are on ventilators or on extracorporeal membrane oxygenation or if they require supplemental oxygen due to room-air blood oxygen levels at or below 94%.

Over the next six weeks, Gilead is committed to supplying 607,000 vials of remdesivir to treat 78,000 patients who are hospitalized with COVID-19.

Preliminary results from a randomized controlled clinical trial of remdesivir kicked off by the National Institutes of Health (NIH) and Gilead suggest that the antiviral is associated with faster recovery. However, data are not sufficient enough to determine if treatment with remdesivir led to lower mortality.

Project Orbis: April & May Drug Approvals

J&J Announces FDA Approval of Imbruvica in CLL, SLL

- The U.S. Food and Drug Administration (FDA) has approved Janssen's Imbruvica (ibrutinib) in combination with rituximab for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who are new to therapy
- The Phase 3 E1912 study study showed newly diagnosed patients ages 70 years or younger (median age of 58 years) treated with Imbruvica plus rituximab lived longer without disease progression, with a progression-free survival (PFS) rate of 88 percent at 37 months, compared to patients treated with fludarabine, cyclophosphamide and rituximab (FCR), with a PFS rate of 75 percent
- The application received approval through the U.S. FDA's Real-Time Oncology Review (RTOR) pilot program, received Priority Review designation, and was approved under a modified version of Project Orbis, which provides a framework for submission and review of oncology medicine applications among international regulatory agencies

FDA Approves Seattle's Tukysa, NDA Submitted Under Project Orbis

- The US Food and Drug Administration (FDA) approved Seattle Genetics' Tukysa (tucatinib) tablets in combination with chemotherapy (trastuzumab and capecitabine) for adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting
- Under Project Orbis, a collaborative effort among five countries that provides a framework for concurrent submission and review of oncology drug applications, the FDA worked with Australia's Therapeutic Goods Administration (TGA), Canada's Health Canada, Singapore's Health Sciences Authority (HSA), and Switzerland's Swissmedic to approve Tukysa, and while the FDA approved it, the drug is still under review by these other agencies
- The approval marks the first time the FDA, HSA, and Swissmedic partnered up under Project Orbis

Deciphera's Qinlock Approved for Fourth-Line GIST Treatment by FDA

- The Food and Drug Administration (FDA) approved Deciphera's Qinlock (ripretinib) for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib (branded as "Gleevec" by Novartis in the U.S.)
- The New Drug Application (NDA) for Qinlock is part of Project Orbis, an FDA initiative providing a framework for concurrent submission and review of oncology drugs among the U.S., Canada, Australia, Switzerland, and Singapore
- According to Richard Pazdur, M.D., Director of the FDA's Oncology Center of Excellence and acting Director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation and Research, "Despite the progress that has been made of the past 20 years in developing treatments for GIST, including four FDA-approved targeted therapies – imatinib in 2002, sunitinib in 2006, regorafenib in 2013, and avapritinib earlier this year – some patients don't respond to treatment and their tumors continue to progress"

ISPOR: Orlando

Pricentric Insights' news team attended the virtual conferences for ISPOR Orlando where we listened to presentations on current pharma trends. See below a brief for each presentation.

ISPOR Insights: Financing Treatment & Prevention of COVID-19

- In the event that a vaccine is ready to launch on the market, Tomas Philipson, PhD, MA from the White House Council of Economic Advisers, Washington, D.C. said the innovator should be paid to contract out production for fulfilling mass demand
- In response, Andrew Dillon from the National Institute for Health and Care Excellence, London, United Kingdom, said that the industry has to be careful about its reputation in terms of reward for innovation and there is a sensible balance between gifting it to the globe and being given a financial reward
- On preventative measures, Philipson critiqued universal healthcare systems and their regulatory constraints but Dillon countered that it is too soon to draw conclusions on the relative performance of different health care systems, especially in terms of morbidity

ISPOR Insights: Modeling the Value of Innovative Treatments for Alzheimer's Disease

- Charles Makin, BSPharm, MS, MBA, MM from Biogen, Cambridge, MA, explained the impact of Alzheimer's in the U.S., noting that direct medical cost of dementia is over three times that of cancer and 1 in 5 Medicare dollars is spent on patients with Alzheimer's and other dementias
- Fewer than 20% of published Alzheimer's cost benefit analyses include caregiver costs and caregiver QALYs – If these factors are considered, cost/QALY goes down, noted Peter Neumann, ScD from Tufts University, Boston, MA
- Sue Peschin, MHS from the Alliance for Aging Research, Washington, DC, said behavioral economics need to be considered to reflect real-world benefits for the individual and society and non QALY approaches should be developed, which emphasize patient centered outcomes

ISPOR Insights: Broadening the Impact of Value Assessment in the US

- According to William Vincent Padula, PhD, MS, MSc from the University of Southern California, Los Angeles, CA, the U.S. fails to present policy solutions to fix wasteful spending on healthcare, which he calls catastrophic, noting that $760 billion to $935 billion was spent on waste in U.S. healthcare while just $191 billion to $282 billion was spent on interventions to reduce waste
- Ensuring access in state Medicaid and private plans requires special consideration, Rena Conti, PhD from Boston University, Boston, MA, noted, because new drug prices or spending may be "too high", creating uneven access to cures within states and between payers
- Milestone based contracts are becoming more popular in the states, Conti said, and entails the pooling of funds, which will become more a part of our national conversation, "for good or for bad"

ISPOR Insights: Effects of Alternative Models on Access to Medications & Clinical Outcomes

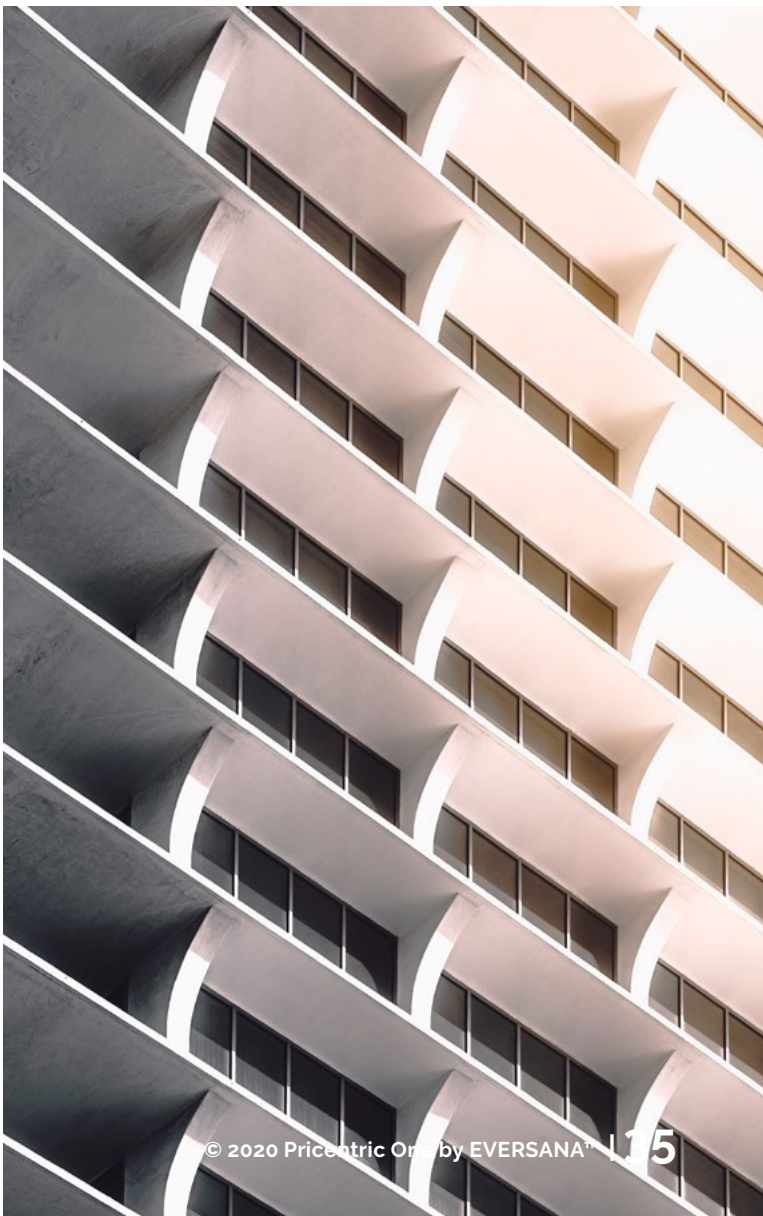
- Now that responsibilities are falling on providers, Michael S Barr, MD, MBA, MACP from the National Committee on Quality Assurance, Washington, DC., stressed the importance of digital quality measures (dQMs) which gather data from EHRs, registries, HIEs, claims, and patient experience surveys, thus creating better accountability at all levels of payment models
- Costs will be a new consideration among providers who previously had no financial incentive to avoid high cost therapies with either low or high value, such as HCV treatments, said Anupam B. Jena, MD, PhD from Harvard Medical School, Boston, MA
- In terms of the weaknesses of APMs, Jena explained that APMs will naturally focus on treatments whose value is easily quantified (ideally meeting quality metrics imposed by the APM) because of financial and measurement incentives but some types of value that are societally relevant may not be considered, such as a spill over effect to family members that act as caretakers and can now go back to work

ISPOR Insights: IRP in the US vs. Rest of World

- Andras Incze, PhD, MBA from Baden-Wuerttemberg Cooperative State University Germany, noted the large difference in new drug availability between lower income and higher income countries, with many new drugs unavailable to patients due to no launch or extended negotiations
- As an alternative to ERP, Louis P. Garrison, PhD from the University of Washington, The Comparative Health Outcomes, Policy, and Economics Institute, Seattle, suggests movement toward value-based pricing that better aligns with value delivered (effectiveness/ RWE), operating with a broader concept of value, and better management of global differential pricing
- Open the space to differential pricing, recommended Jaime Espin, PhD from the Andalusian School of Public Health, Armilla, GR, Spain, and try to remove the legal and technical barriers –ERP is not a panacea and results such as savings and launch delays depend on how it is implemented

ISPOR Insights: Valuation of Novel Therapies

- Omar Dabbous, MD, MPH from AveXis, argued that gene therapies need to be valued differently to other products since they involve elements of value that may not be captured in the usual payer value assessment and have as yet unknown long-term effects
- Sean Sullivan, PhD, MSc, RPh from University of Washington, stated that innovative financing models address uncertainty about the magnitude and durability of benefits, the desire to promote access to beneficial products to patients, rewards innovation in neglected therapeutic areas, and supports financial sustainability of health systems
- Broader contextual issues and considerations of innovative financing models, according to Sullivan, are pharmaceuticals that may demand a rationale for clinical use, sticky prices for high cost therapy, ongoing evidence development, government challenges, and innovative procurement mechanisms



ISPOR Insights: Reimbursement & Access Policy Studies

- According to a study referencing the SPEC database, developed by Tufts Medical Center, which includes 17 of the largest US health plans, the frequency in which health plans cite RWE varies greatly with one citing RWE 30% of the time while another cites RWE 5% of time, and citation of RWE varies by disease
- Another study presented by Farah Yehia, PhD from Johns Hopkins Bloomberg School of Public Health, estimated how much cost savings would result from requiring companies to return their tax credit once the orphan drug has generated over $1 billion in annual sales revenue—she said the funds could be used to foster further R&D for new orphan drugs
- Meanwhile, Dexter D. Waters from Thomas Jefferson University gave an overview of the Oncology Care Model (OCM), and, according to data from OCM reconciliation reports and Jefferson electronic medical records, the types of care that drove up costs were novel therapies, inpatient admissions, ED visits, skilled nursing facility placement, radiation therapy, Medicare Part D use, and Medicare Part B drug use

ISPOR Insights: Direct Treatment Comparison Strategy to Support HTA & Reimbursement Decisions

- Steven Peterson, MBA, from Janssen gave a rundown of preferences in North America and Asia, noting that the US prefers NMA with less acceptance of other ITC techniques, Canada also prefers NMA but accepts all forms of ITC methods if the rationale is clearly described, Australia prefers pairwise ITCs such as Bucher ITCs, MAICs and STCs, and Japan accepts NMAs which often include adaptations to Asian populations
- Agata Schubert, Msc, from Jannsen-Cilag gave a similar rundown in Europe, where the UK prefers NMA but accepts all forms of ITC methods if the rationale is clearly described, Germany has a strong preference for RCT while acceptance of ITCs have been limited, and France prefers NMA with less acceptance of other ITC techniques
- In general, Schubert emphasized an increasing acceptance of ITCs by major HTA bodies in Europe and around the world, according to several studies

ISPOR Insights: Will Canadian HTA and Drug Pricing Policy Developments Hinder Access?

- Brent Fraser, from CADTH, spoke of shifting from an HTA to an HTM (health technology management) approach, which entails early identification of disruptive technologies, strengthened engagement with stakeholders, life cycle HTA (in collaboration with regulators), and evidence informed implementation
- Meanwhile, in response to concerns about reference basket changes introduced by PMPRB, Tanya Potashnik, from PMPRB, pointed to evidence that many countries outperform Canada in terms of earlier drug launch times, despite having lower prices, noting that price is actually a weak determinate of time of launch, while market size, wealth of country, and expenditure are stronger determinants
- Potashnik added that studies showing a decline in the number of new clinical trials being started in Canada since the announcements of reforms in August 2019 are based on information in the Health Canada Clinical Trial Database that are incomplete and inappropriate to be considered in this context—in fact, she said, the number of new clinical trials being started in Canada has been markedly higher since the announcement of amendments, than the average of previous years

ISPOR Insights: How RWE May Become Leveraged in Re-Negotiations

- ICER will pilot a formal update process, explained Melanie D Whittington, PhD, from University of Colorado Anschutz Medical Campus, after a treatment has been on the market for 24 months, the purpose of which is to generate new RWE to inform updated assessments of therapies approved by the FDA under accelerated approval pathways
- Several RWE related frameworks are under development, said Judith Glennie, BScPhm, MSc, PharmD, such as a Draft Provincial / Territorial Supplemental Process (Oct 2018) for rare disease products only, a general framework by Health Canada / CADTH, and an oncology only framework by CanReValue
- Fabrizio Gianfrate, PhD, MSc, from University of Ferrara, said a joint task force has been initiated between the EMA and Heads of Medicines Agencies (HMA) representing agencies from across Europe, aiming to deliver a sustainable platform (DARWIN) to access and analyze healthcare data from across EU and create an EU big data "stakeholder implementation forum", among other goals

Zolgensma Proposed to Cost 167 Million Yen in Japan

Country: JAPAN | Region: ASIA & SOUTH PACIFIC | Type: Pricing & Reimbursement | Keywords: #chuikyo #genetherapy #listing #mhlw #nhi #novartis #pediatrics | Originally published: May 13, 2020

PRICENTRIC BRIEF:

- Japanese media have reported that the price of Novartis' spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec) is expected to be 167 million yen under the National Health Insurance (NHI) scheme
- In the case of Zolgensma, health official insiders from the MHLW suggested that the price of Zolgensma was established by the comparator method, its cost compared to that of Biogen's Spinraza (nusinersen), another groundbreaking treatment for SMA, and additionally, Zolgensma would receive the utility premium and a sakigake premium
- Once the price is made available and analysts have verified the amount in our source, the price will be reflected in Pricentric One

THE DETAILS

TOKYO, Japan – Japanese media have reported that the price of Novartis' spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec) is expected to be 167 million yen under the National Health Insurance (NHI) scheme.

Pending approval of its price by the Central Social Insurance Medical Council, or Chuikyo, Zolgensma would become the first drug with a price to exceed 100 million yen covered by the NHI.

In Japan, Zolgensma is approved for the treatment of SMA in patients aged 2 years and under who are pre-symptomatic at diagnosis and test negative for elevated anti-AAV9 antibodies.

The gene therapy was approved in March of this year by the Ministry of Health, Labor, and Welfare (MHLW) following sakigake fast-track designation in March 2018.

Japan currently has no pricing rules for cell and gene therapies, which thus far have been categorized as "regenerative medicine products," and instead used existing drug or medical device rules, depending on what each given innovative therapy does. For example, Novartis' CAR T-cell therapy Kymriah (tisagenlecleucel) was priced via Japan's cost-based method and initially, upon approval, was granted a 35% utility premium for its anti-tumor effect and 10% marketability premium for its orphan drug designation.

In the case of Zolgensma, health official insiders from the MHLW suggested that the price of Zolgensma was established by the comparator method, its cost compared to that of Biogen's Spinraza (nusinersen), another groundbreaking treatment for SMA. Additionally, Zolgensma would receive the utility premium, which awards its high efficacy, safety, and improvement over existing treatments, and a sakigake premium.

It is expected that Zolgensma will be administered to around 25 patients annually once it is covered by the NHI.

The price for Zolgensma is not yet confirmed. Once it is, and analysts have verified the amount in our source, the price will be reflected in Pricentric One.

HTA Decisions: Germany

- IQWIG has published a health benefits assessment report on **Abbvies' Rinvoq (upadacitinib)** for rheumatoid arthritis. The committee noted some considerable added benefit for a few patient groups because of available evidence. So, IQWIG gave Rinvoq a considerable added benefit in rheumatoid arthritis indication.
- IQWIG has published a health benefits assessment report on **Lilly's Trulicity (dulaglutide)** for type 2 diabetes mellitus. The committee noted some considerable added benefit for few patient groups because of available evidence. So, IQWIG gave Trulicity a considerable added benefit in type 2 diabetes mellitus indication.
- Germany's G-BA has published the benefit assessment report on **Sanofi's Dupixent (dupilumab)** for chronic rhinosinusitis with nasal polyps. The committee noted that dupilumab as an add-on to mometasone furoate is characterized by morbidity only positive effects that have no negative effects in other categories oppose. Consequently, adult CRS w NP patients with severe systemic corticosteroids and/or surgery not adequately controlled for Dupixent as an add-on to intranasal corticosteroids is an indication for one derived significant additional benefit compared to the appropriate comparator therapy.
- Germany's G-BA has published the benefit assessment report on **Merck's Keytruda (pembrolizumab)** for as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) -Chemotherapy for the first-line treatment of metastatic or non-resectable recurrent squamous cell carcinoma of the head and neck region in adults with tumors expressing PD-L1. The committee noted that given the open study design, the existing uncertainties at the endpoint overall survival in terms of the effect modifications that occurred and the crossing Kaplan-Meier curves and taking into account the missing usable one's data for patient-reported endpoints on morbidity and quality of life can be related only a hint of an added benefit can be derived from the reliability of the information.
- Germany's G-BA has published the benefit assessment report on **GSK's Benlysta (belimumab)** for as additional therapy for patients aged 5 years and older with active, auto antibody-positive systemic lupus erythematosus, which is high despite standard therapy disease activity. The committee noted that Benlysta is used as additional therapy in children and adolescents by5 to 17 years with active, autoantibody-positive systemic lupus erythematosus, who show high disease activity despite standard therapy, a clue for a non-quantifiable additional benefit compared to individual patient therapy derived.
- Germany's G-BA has published the benefit assessment report on **Merck's Keytruda (pembrolizumab)** for as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) -Chemotherapy for the first-line treatment of metastatic or non-resectable recurrent squamous cell carcinoma of the head and neck region (HNSCC) in adults with tumors expressing PD-L1. The committee found that In a trade-off between the positive effect on overall survival and the disadvantage for serious side effects, the G-BA provides for pembrolizumab in combination with cis or carboplatin and 5-FU versus cetuximab in combination with Cis or carboplatin and 5-FU an indication of a minor added benefit.
- Germany's G-BA has published the benefit assessment report on **Astellas' Xospata (gilteritinib)** for as monotherapy for the treatment of adult patients relapsed or refractory acute myeloid leukemia with an FLT3 mutation. The committee noted that the outcome "overall survival" shows a statistically significant and at the same time moderate advantage of Xospata over salvage chemotherapy. To patient-reported results of morbidity and quality of life are not valid data before.
- Germany's G-BA has published the benefit assessment report on **EMD Serono's Bavencio (avelumab)** for in combination with axitinib is used as first-line therapy in adult patients advanced renal cell carcinoma. Overall, there is no clear advantage in overall survival compared to sunitinib disadvantages in terms of morbidity and side effects. There is an indication of a significant added benefit of Avelumab in combination with axitinib compared to sunitinib.

HTA Decisions: Germany

- Germany's G-BA has published the benefit assessment report on **Merck's Keytruda (Pembrolizumab)** in combination with axitinib for the first-line treatment of the advanced renal cell carcinoma is indicated in adults. Overall, the benefits of overall survival and severe side effects are a significant improvement of the therapy-relevant benefit. Overall, an indication of a considerable added benefit of Pembrolizumab in combination with axitinib versus sunitinib found.
- Germany's G-BA has published the benefit assessment report on **Puma's Nerlynx (Neratinib)** for the advanced adjuvant treatment of adult patient hormone receptor-positive, HER2 overexpressed/amplified breast cancer in one early stage, less than a year ago, a trastuzumab-based adjuvant therapy completed. Uncertainties remain regarding the interpretation of the results regarding the relapses the low number of events. Overall, there is an indication of a minor added benefit of neratinib compared to the observing wait
- Germany's G-BA has published the benefit assessment report on **Bluebird's Zynteglo (Betibeglogene)** for the treatment of patients aged 12 years and over transfusion-dependent β-thalassemia (TDT) that do not have a β0 / β0 genotype and that fora hematopoietic stem cell transplantation (HSCT) is suitable, but for which none human leukocyte antigen (HLA) compatible, related HSZ donor available stands. Overall, there is a hint of a non-quantifiable additional benefit, because the scientific database does not allow quantification. The decision is limited to May 15, 2025.
- IQWIG has published a health benefits assessment report on **Janssen's Sirturo (Bedaquilin)** for multidrug-resistant pulmonary tuberculosis. In accordance with Section 35a (1) Sentence 11 SGB V, the additional benefit of an orphan drug by the admission as documented. The extent of the additional benefit is assessed by the G-BA.

HTA Decisions: United Kingdom

- NICE has published a technical assessment report on **Pfizer's Lorviqua (Lorlatinib)** for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer. NICE has recommended, within its marketing authorization, as an option for treating anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) in adults whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor or crizotinib and at least 1 other ALK tyrosine kinase inhibitor.
- NICE has published a technical assessment report on **Roche's Gazyvaro (Obinutuzumab)** for treating follicular lymphoma after rituximab. The committee gave a favorable decision on obinutuzumab within its marketing authorization, as an option for treating follicular lymphoma that did not respond or progressed up to 6 months after treatment with rituximab or a rituximab-containing regimen. It is recommended only if the company provides it according to the commercial arrangement.

HTA Decisions: France

- France's HTA body HAS published a technology assessment report on **Novartis' Tareg (valsartan)** for the treatment of arterial hypertension in children aged 1 to 5 years. The medical service provided by Tareg 3 mg/ml, the oral solution is important in the treatment of high blood pressure in children aged 1 to 5 years. the Commission considers that TAREG 3 mg/ml oral solution (valsartan) does not improve the medical service provided ASMR V in the current therapeutic strategy for the management of hypertension in children aged 1 to 5 years. The Commission underlines the practical interest of this formulation of valsartan in the oral solution for use in young children.

HTA Decisions: France

- France's HTA body HAS published a technology assessment report on **Amgen's Blincyto (blinatumomab)** for the treatment of adult patients with CD19 precursor ALL expressing CD19 with Philadelphia chromosome-negative in first or second complete remission with minimal residual disease (MRD) positive equal to or greater than 0.1%. The Commission takes note of the fact that the laboratory does not request the inclusion of the specialty BLINCYTO (blinatumomab) in this indication and recalls that therefore this specialty is not approved by local authorities in the indication: "as monotherapy in the treatment of adult patients with CD19 precursor ALL expressing CD19 with Philadelphia chromosome-negative in first or second complete remission with positive minimal residual disease (MRD) equal to or greater than 0.1% ".

- France's HTA body HAS published a technology assessment report on **Mylan's Fulvestrant (fulvestrant)** for the treatment of locally advanced or metastatic breast cancer, RH +, in postmenopausal women not previously treated with hormone therapy. The medical service provided by Fulvestrant Mylan 250 mg is important in as monotherapy in the treatment of locally advanced or metastatic breast cancer, positive for estrogen receptors, in postmenopausal women, not previously treated with hormone therapy. This specialty is a generic which does not improve the medical service provided ASMR V compared to the reference specialty

- France's HTA body HAS published a technology assessment report on **Mylan's Fulvestrant (fulvestrant)** in combination with palbociclib in the treatment of locally advanced or metastatic breast cancer, RH + / HER2-, in premenopausal women, previously treated with hormone therapy and/or in the event of symptomatic life-threatening visceral disease. short term. The medical service provided by Fulvestrant Mylan 250 mg is insufficient in combination with palbociclib to justify treatment by national solidarity in the treatment of locally advanced or metastatic breast cancer, positive for hormone receptors (RH), negative for the human epidermal growth factor (HER2) receptor 2 in premenopausal women and/or in the event of short-term life-threatening symptomatic visceral involvement.

- France's HTA body HAS published a technology assessment report on **Mylan's Fulvestrant (fulvestrant)** in combination with palbociclib in the treatment of locally advanced or metastatic breast cancer, RH + / HER2-, in postmenopausal women who have been previously treated with hormone therapy and without symptomatic visceral disease which is life-threatening in the short term. The medical service provided by Fulvestrant Mylan 250 mg is important in combination with palbociclib in the treatment of locally advanced or metastatic breast cancer, positive for hormone receptors (RH), negative for human epidermal growth factor 2 (HER2) receptor 2, in postmenopausal women who have previously been treated with hormone therapy, (at the advanced stage or during adjuvant treatment for early progressions), in the absence of symptomatic visceral damage threatening the short-term vital prognosis.

- France's HTA body HAS published a technology assessment report on **Mylan's Etoposide (etoposide)** for small cell lung cancer. The medical service provided by ETOPOSIDE MYLAN 20 mg / mL is important in the indications for marketing authorization. The specialty ETOPOSIDE MYLAN 20 mg / mL does not improve the medical service provided ASMR V compared to the other presentations of etoposide available by injection.

- France's HTA body HAS published a technology assessment report on **Mylan's Etoposide (etoposide)** for hodgkin lymphoma. The medical service provided by ETOPOSIDE MYLAN 20 mg / mL is important in the indications for marketing authorization. The specialty ETOPOSIDE MYLAN 20 mg / mL does not improve the medical service provided ASMR V compared to the other presentations of etoposide available by injection.

- France's HTA body HAS published a technology assessment report on **Mylan's Etoposide (etoposide)** for non-Hodgkin's lymphoma. The medical service provided by ETOPOSIDE MYLAN 20 mg / mL is important in the indications for marketing authorization. The specialty ETOPOSIDE MYLAN 20 mg / mL does not improve the medical service provided ASMR V compared to the other presentations of etoposide available by injection.

- France's HTA body HAS published a technology assessment report on **Mylan's Etoposide (etoposide)** for acute myeloid leukemia. The medical service provided by ETOPOSIDE MYLAN 20 mg / mL is important in the indications for marketing authorization. The specialty ETOPOSIDE MYLAN 20 mg / mL does not improve the medical service provided ASMR V compared to the other presentations of etoposide available by injection.

HTA Decisions: France

- France's HTA body HAS published a technology assessment report on **Mylan's Etoposide (etoposide)** for ovarian cancer. The medical service provided by ETOPOSIDE MYLAN 20 mg / mL is important in the indications for marketing authorization. The specialty ETOPOSIDE MYLAN 20 mg / mL does not improve the medical service provided ASMR V compared to the other presentations of etoposide available by injection.

- France's HTA body HAS published a technology assessment report on **Janssen's Darzalex (daratumumab)** for treatment of adult patients with newly diagnosed multiple myeloma and eligible for an autograft of stem cells, in combination with bortezomib, thalidomide, and dexamethasone. The medical service provided by Darzalex is important in the indication "in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma and eligible for an autologous stem cell transplant". The Commission considers that, pending the results on overall survival, Darzalex in combination with bortezomib, thalidomide, and dexamethasone (VTd protocol), brings an improvement in the rendered minor medical service ASMR IV compared to the VTd protocol in the treatment.

- France's HTA body HAS published a technology assessment report on **Merck's Keytruda (pembrolizumab)** in combination with axitinib in the first-line treatment, at an advanced stage, of renal cell carcinoma only with clear cells or with a contingent of clear cells. The medical service provided by KEYTRUDA (pembrolizumab) in combination with axitinib is important in the first-line treatment, in the advanced stage, of renal cell carcinoma only with clear cells or with a contingent of clear cells. The Commission considers that the combination of KEYTRUDA (pembrolizumab) with axitinib brings an improvement in the medical service rendered moderate ASMR III compared to sunitinib in the first-line treatment, in the advanced stage, of renal cell carcinoma with clear or with a contingent of clear cells.

- France's HTA body HAS published a technology assessment report on **EMD Serono's Bavencio (avelumab)** in combination with axitinib in the first-line treatment, at an advanced stage, of renal cell carcinoma, only with clear cells or with a contingent of clear cells. The medical service provided by BAVENCIO (avelumab) in combination with axitinib is moderate in the first-line treatment, in the advanced stage, of renal cell carcinoma only with clear cells or with a contingent of clear cells. The Commission considers, in the current state of the file, that the association BAVENCIO (avélumab) / axitinib does not bring any improvement in the medical service rendered (ASMR V) in the 1st line treatment, at the advanced stage, of carcinoma renal with clear cells or with a contingent of clear cells.

- France's HTA body HAS published a technology assessment report on **Genentech's Tecentriq (atezolizumab)** for the treatment of adult patients with lung cancer, small cell extended stage in 1st line, in combination with carboplatin and etoposide. The medical service rendered by Tecentriq is important in the indication of the Marketing Authorization. The Commission considers that Tecentriq, in combination with carboplatin and etoposide, brings an Improvement in Minor Rendering Medical Service ASMR IV compared to chemotherapy alone, as the first line of treatment for small cell lung cancer of extended stage.

- France's HTA body HAS published a technology assessment report on **Pfizer's Xalkori (crizotinib)** for the second line and more, in the treatment of advanced non-small cell lung cancer (NSCLC) with a rearrangement ROS1. The medical service rendered by Xalkori is weak and the Commission considers that Xalkori did not improve the medical service provided ASMR V in the therapeutic strategy.

- France's HTA body HAS published a technology assessment report on **Pfizer's Xalkori (crizotinib)** for the first line of treatment, in the treatment of advanced non-small cell lung cancer with a ROS1. The medical service rendered by Xalkori is insufficient to justify treatment by national solidarity. The medical service rendered by Xalkori is weak and the Commission considers that Xalkori did not improve the medical service provided ASMR V in the therapeutic strategy.

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Drug Approvals: United States

- **FENSOLVI (LEUPROLIDE ACETATE)** was approved by the FDA for the treatment of pediatric patients 2 years of age and older with central precocious puberty
COMPANY: TOLMAR

- **DARZALEX FASPRO (DARATUMUMAB & HYALURONIDASE-FIHJ)** was approved by the FDA for the treatment of adult patients with multiple myeloma
COMPANY: JANSSEN BIOTECH

- **ELYXYB (CELECOXIB)** was approved by the FDA for the acute treatment of migraine with or without aura in adults
COMPANY: DR REDDYS LABS LTD

- **TABRECTA (CAPMATINIB)** was approved by the FDA for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
COMPANY: NOVARTIS

- **FARXIGA (DAPAGLIFLOZIN)** was approved for heart failure by the FDA
COMPANY: ASTRAZENECA

- **RETEVMO (SELPEERCATINIB)** was approved by the FDA for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC); adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy; and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
COMPANY: LOXO ONCOLOGY INC

- **LYNPARZA (OLAPARIB)** was approved for OVARIAN CANCER (BRCA MUTATION) (BEVACIZUMAB) by the FDA
COMPANY: ASTRAZENECA

- **POMALYST (POMALIDOMIDE)** was approved for AIDS related Kaposi's Sarcoma by the FDA
COMPANY: CELGENE

- **QINLOCK (RIPRETINIB)** was approved by the FDA for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib
COMPANY: DECIPHERA PHARMACEUTICALS LLC

- **RUBRACA (RUCAPARIB)** was approved for metastatic castration-resistant prostrate cancer (BRCA mutation) by the FDA
COMPANY: CLOVIS

- **OPDIVO (NIVOLUMAB)** was approved for metastatic NSCLC by the FDA
COMPANY: BRISTOL MYERS SQUIBB

Drug Approvals: United States

- **TECENTRIQ (ATEZOLIZUMAB)** was approved by the FDA for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression, with no EGFR or ALK genomic tumor aberrations
  COMPANY: GENENTECH

- **LYNPARZA (OLAPARIB)** was approved for metazoic castration-resistant prostrate cancer by the FDA
  COMPANY: ASTRAZENECA

- **FERRIPROX (DEFERIPRONE)** was approved by the FDA for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate
  COMPANY: APOPHARMA INC

- **IMPEKLO (CLOBETASOL PROPIONATE)** was approved by the FDA for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, in patients 18 years of age or older
  COMPANY: MYLAN

- **KYNMOBI (APOMORPHINE)** was approved by the FDA for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease
  COMPANY: SUNOVION PHARMS INC

- **PHEXXI (LACTIC ACID, CITRIC ACID AND POTASSIUM BITARTRATE)** was approved by the FDA for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception
  COMPANY: EVOFEM INC

- **ALUNBRIG (BRIGATINIB)** was approved by the FDA for adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
  COMPANY: ARIAD

- **OPDIVO (NIVOLUMAB)** was approved for NSCLC (IPILIMUMAB & PLATINUM CHEMOTHERAPY) (RECURRENT) by the FDA
  COMPANY: BRISTOL MYERS SQUIBB

- **DUPIXENT (DUPILUMAB)** was approved by the FDA for children aged 6 to 11 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
  COMPANY: SANOFI

- **VESICARE LS (SOLIFENACIN SUCCINATE)** was approved by the FDA for the treatment of neurogenic detrusor overactivity (NDO), a form of bladder dysfunction related to neurological impairment, in children ages two years and older
  COMPANY: ASTELLAS

- **ARTESUNATE (ARTESUNATE)** was approved by the FDA or the initial treatment of severe malaria in adult and pediatric patients. Treatment of severe malaria with Artesunate for Injection should always be followed by a complete treatment course of an appropriate oral antimalarial regimen
  COMPANY: AMIVAS LLC

Drug Approvals: Europe

- **ZEPOSIA (OZANIMOD)** was approved by the EMA for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.
COMPANY: BRISTOL MYERS SQUIBB

- **ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC)** was approved by the EMA for the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1; or for patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene
COMPANY: NOVARTIS

Drug Approvals: China

- **NERLYNX (NERATINIB)** was approved by the NMPA for the extended adjuvant treatment of adult patients with early stage human epidermal growth factor receptor 2 (HER2) positive breast cancer, to follow adjuvant trastuzumab-based therapy
COMPANY: PUMA

- **BEVESPI AEROSPHERE (GLYCOPYRRONIUM & FORMOTEROL FUMARATE DIHYDRATE)** was approved by the NMPA in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema
COMPANY: ASTRAZENECA

Drug Launches: Europe & US

Country	Generic Name	Product Group	Company	Indication	Approval Date	Launch Date
GERMANY	HEPATITIS A, INACTIVATED, WHOLE VIRUS	AVAXIM	SANOFI	HEPATITIS A (PROPHYLAXIS)	28/04/2006	15/05/2020
GERMANY	DAROLUTAMIDE	NUBEQA	BAYER	NON-MET CAST-RESIST PROSTATE CANCER	27/03/2020	01/05/2020
GERMANY	PNEUMOCOCCUS, PUR POLYSACCHARIDES ANT	PNEUMOVAX NP	MERCK	PNEUMONIA	27/04/2015	01/05/2020
GERMANY	SOLRIAMFETOL	SUNOSI	JAZZ	OBSTRUCTIVE SLEEP APNEA, NARCOLEPSY	16/01/2020	15/05/2020
UNITED STATES	DARATUMUMAB & HYALURONIDASE	DARZALEX FASP	JANSSEN	MULTIPLE MYELOMA	01/05/2020	01/05/2020
UNITED STATES	LEMBOREXANT	DAYVIGO	EISAI	INSOMNIA	20/12/2019	20/05/2020
UNITED STATES	SELPERCATINIB	RETEVMO	ELI LILLY	NSCLC (RET FUSION+)	08/05/2020	11/05/2020
UNITED STATES	CAPMATINIB	TABRECTA	NOVARTIS	NSCLC (MET EXON 14 SKIPPING)	06/05/2020	07/05/2020

Price Changes: Europe & US

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing Date
GERMANY	TENOFOVIR ALAFENAMIDE	VEMLIDY	GILEAD SCIENCES	HEPATITIS B	-3.57%	01/04/2017
GERMANY	DACOMITINIB	VIZIMPRO	PFIZER	ONCOLOGY	-51.76%	01/05/2019
SPAIN	HYDROXYZINE	ATARAX	UCB	NEUROLOGY	+23.00%	01/01/2017
UNITED KINGDOM	IMMUNOGLOBULINS	HIZENTRA	CSL BEHRING	IMMUNOGLOBULINS	+27.78%	01/01/2014
UNITED STATES	IXABEPILONE	IXEMPRA	R-PHARM	ONCOLOGY	+1.82%	17/10/2007
GERMANY	POMALIDOMIDE	IMNOVID	CELGENE	IMMUNOSUPPRESSANTS	-6.08%	01/09/2013
GERMANY	PIRFENIDONE	ESBRIET	ROCHE	IMMUNOSUPPRESSANTS	-5.00%	15/09/2011

Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	MNF (EUR)	OLD MNF	Change	%Change
SHIRE	ELVANSE	LISDEXAMFETAMINE	ELVANSE CAPSULES 1 PACK 30 CAPS 20 MG	53.71	78.10	-24.39	-31.23%
SHIRE	ELVANSE	LISDEXAMFETAMINE	ELVANSE CAPSULES 1 PACK 30 CAPS 30 MG	53.71	78.10	-24.39	-31.23%
SHIRE	ELVANSE	LISDEXAMFETAMINE	ELVANSE CAPSULES 1 PACK 30 CAPS 40 MG	53.71	78.10	-24.39	-31.23%
SHIRE	ELVANSE	LISDEXAMFETAMINE	ELVANSE CAPSULES 1 PACK 30 CAPS 50 MG	53.71	84.90	-31.19	-36.74%
SHIRE	ELVANSE	LISDEXAMFETAMINE	ELVANSE CAPSULES 1 PACK 30 CAPS 60 MG	53.71	84.90	-31.19	-36.74%
SHIRE	ELVANSE	LISDEXAMFETAMINE	ELVANSE CAPSULES 1 PACK 30 CAPS 70 MG	53.71	86.45	-32.74	-37.87%
SHIRE	ELVANSE ADULT	LISDEXAMFETAMINE	ELVANSE ADULT CAPS 1 PACK 30 CAPS 30 MG	53.71	78.10	-24.39	-31.23%
SHIRE	ELVANSE ADULT	LISDEXAMFETAMINE	ELVANSE ADULT CAPS 1 PACK 30 CAPS 50 MG	53.71	84.90	-31.19	-36.74%
SHIRE	ELVANSE ADULT	LISDEXAMFETAMINE	ELVANSE ADULT CAPS 1 PACK 30 CAPS 70 MG	53.71	86.45	-32.74	-37.87%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 14 CAPS 1 MG	4323.67	4604.17	-280.50	-6.09%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 14 CAPS 2 MG	4523.42	4816.67	-293.25	-6.09%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 14 CAPS 3 MG	4789.75	5100.00	-310.25	-6.08%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 14 CAPS 4 MG	4922.92	5241.67	-318.75	-6.08%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 21 CAPS 1 MG	6485.50	6906.25	-420.75	-6.09%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 21 CAPS 2 MG	6785.13	7225.00	-439.87	-6.09%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 21 CAPS 3 MG	7184.63	7650.00	-465.37	-6.08%
CELGENE	IMNOVID	POMALIDOMIDE	IMNOVID CAPSULES 1 PACK 21 CAPS 4 MG	7384.37	7862.50	-478.13	-6.08%
GILEAD SCIENCES	VEMLIDY	TENOFOVIR ALAFENAMIDE	VEMLIDY TABLETS 1 PACK 30 TABS 25 MG	235.65	244.38	-8.73	-3.57%
GILEAD SCIENCES	VEMLIDY	TENOFOVIR ALAFENAMIDE	VEMLIDY TABLETS 1 PACK 90 TABS 25 MG	718.74	733.14	-14.40	-1.96%
PFIZER	VIZIMPRO	DACOMITINIB	VIZIMPRO TABLETS 1 PACK 30 TABS 15 MG	1873.97	3885.00	-2011.03	-51.76%
PFIZER	VIZIMPRO	DACOMITINIB	VIZIMPRO TABLETS 1 PACK 30 TABS 30 MG	1873.97	3885.00	-2011.03	-51.76%
PFIZER	VIZIMPRO	DACOMITINIB	VIZIMPRO TABLETS 1 PACK 30 TABS 45 MG	1873.97	3885.00	-2011.03	-51.76%

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