PRICENTRIC ONE
BY EVERSANA™

INSIGHTS Newsletter

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COVID-19 Legislation Could Fuel Collaboration, Transparency

Our monthly insights article explores how exigent COVID-19 legislation could fuel greater interest in collaboration, transparency in Europe

Germany's "Success-Based" Contract for Zolgensma

German health insurance service company GWQ ServicePlus AG and Novartis subsidiary AveXis concluded a success-based reimbursement contract for Zolgensma

Vertex & Switzerland Agree on Orkambi, Symdeko, & Trikafta

Vertex Pharmaceuticals and Switzerland's Federal Office of Public Health (FOPH) and the Swiss Federal Social Insurance Office (FSIO) reached an agreement

NHS & Bayer's Deal for Tumor Agnostic Drug Vitrakvi

Bayer's Vitrakvi is recommended for use through the Cancer Drugs Fund (CDF) in neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumors

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Exigent COVID-19 Legislation Could Fuel Greater Interest in Collaboration, Transparency in Europe

While we all stay apart to tackle the greatest global health threat in modern history, pharmaceutical companies and regulatory agencies are coming together to address COVID-19 amidst the height of the pandemic.

In these times, regulatory adaptations that permit pharma and life science companies to swiftly source starting materials and push drugs to market at expedited times are a necessity. Regulatory bodies around the world are adapting their processes to accommodate these unprecedented circumstances, particularly to expedite the approval of promising treatments for the coronavirus. Likewise, public health authorities are prioritizing mitigating virus-initiated supply chain and manufacturing disruptions to ensure continuity of supplies of medicinal products.

Europe's system for regulating medicines updated its guidance on regulatory expectations on April 20 in the context of the outbreak. Releasing a Q&A document covering the concerns, the European Commission, EMA and national competent authorities agreed on a series of measures to mitigate the impact of disruptions caused by COVID-19 for medicinal products in the European Union.

Measures include extending the validity of GMP certificates and time-limited manufacturing and import authorizations, as well as the validity of GDP certificates and time-limited wholesale authorizations, until the end of 2021. The European Commission also said that if needed, inspections will be carried out remotely to support such extensions, with on-site inspections carried out as soon as feasible.

Outside global pandemic circumstances, vaccines, novel drugs and the likes are subject to strict regulatory requirements in Europe that aim to remove the risks of ineffective and unsafe products getting to market while ensuring that patients can ultimately benefit from innovative treatments as soon as possible. But in the case of the COVID-19 pandemic, standard protocol has been sidelined for potential treatments for the coronavirus. The phase 'necessity breeds innovation' comes to mind, looking at global adaptations like streamlined approvals and hastened government reactions potentially bringing more innovation to light and medicines to market more quickly.

Individual European countries are stepping up. France's National Agency for the Safety of Medicines and Health Products (ANSM) is assessing drug applications urgently, within an average deadline of 7 days as opposed to 60 days according to the regulatory deadlines, as well as clinical trial requests. In the UK, the MHRA is working closely with the Department of Health and Social Care (DHSC) and other healthcare partners to prioritize supporting and authorizing the development of vaccines and clinical trials of medicines by granting priority review and expedited assessment. In order to help streamline emergency access to medicines if needed, the Finnish Medicines Agency (Fimea) has decided some of the medicines used under special authorization can be released for consumption on the basis of a temporary special permit or no special permit, if applied for.

So much so that in Germany, eight of the country's associations of the medical device, laboratory, pharmaceutical and biotechnology industries are

demanding that, even in the current situation, the market economy principles may only be suspended moderately. The associations have urged that "underlying principles of the free and social market economy should not be lost sight of even in times of crisis to protect this industry." Their concerns echo previous ire towards prior legislation regarding compulsory discounts that remain even after the financial crisis in Europe was resolved.

Intellectual property (IP) rights are essential for the conventional running of the pharmaceutical industry, but recent developments – such as AbbVie foregoing its patent rights for HIV med Kaletra (lopinavir/ritonavir) after government intervention in Israel - have demonstrated that right now, nothing is status quo. The compulsory license (CL), the tool that enabled the Israeli government to override the patent holders' rights and promote generic competition, is relatively unprecedented, and sure to now be something pharma companies will consider after the pandemic passes.

In a similarly communal move, leaders from the World Health Organization (WHO) and Unitaid welcomed a proposal by Costa Rica which would involve companies voluntarily pooling their intellectual property for treatments, vaccines, and diagnostics for COVID-19. If enacted, governments or generic drugmakers would, on a voluntary basis, manufacture and sell products at much lower prices than currently available in the world market to all interested countries, a move that has previously been allowed for HIV/AIDS, tuberculosis, and hepatitis C treatments for only lower-income countries.

While voluntary, such a move requires pharmaceutical companies to be accountable and transparent, a topic that COVID-19 has brought to light, even more so than usual. Before the pandemic, Malta's Minister of Health Chris Fearne was spearheading efforts through the Valletta Group to increase medicine price transparency and improve access in Europe.

Before the COVID-19, joint-procurement of medicines was practiced by some regions, including the Nordics, but now, smaller European markets Montenegro, Iceland, Liechtenstein, Albania, Bosnia and Herzegovina, Serbia, Kosovo, and North Macedonia have teamed up with other EU Member States under legislation for the joint procurement of medicines and medical supplies in the fight against future pandemics, first enacted after the 2009 outbreak of H1N1. Thus far, Europe has planned to jointly-procure ventilators and personal protective equipment (PPE), announced European Commission President Ursula Von Der Leyen, but it's not been outright stated that the joint procurement of medicines for COVID-19 will follow. However, on the national level, the Germany's Federal Ministry of Health (BMG) took control of the procurement of Kaletra (lopinavir/ritonavir), Avigan (favipiravir), Foipan (camostat mesylate), and medicines with the active ingredients chloroquine and hydroxychloroquine to fight the coronavirus. On the European level, it's no doubt joint-procurement of medicines would help secure more equitable access to a vaccine and an improved security of supply, together with more balanced prices for the participating EU countries, as is the case with Germany. Recently-proposed legislation in Germany would allow the BMG to more strictly monitor and control the circulation of drugs, empowering the BMG. Mass joint-procurement is Europe would be a process that entails complete transparency from those participating. While the current crisis should encourage pharma and regulatory agencies to work together, the issue of drug price transparency extends beyond the duration of the pandemic.

The COVID-19 pandemic will most likely not spell the turning point for transparency or IP rights in pharma, but it could further fuel players to respond to calls for heightened transparency and affordable access to medicines and vaccines for all. Already, this has been an issue on the national-level in Europe, most recently observed in Belgium when it was approved that "secret" drug negotiations could be subject to auditing going forward. But currently, most major-scale attempts at increased transparency in Europe have not been solidified in legislation. WHO's Regional Director in Europe, Hans Kluge, has promised to explore ways to improve access to expensive medicines and align Europe with the World Health Assembly (WHA) resolution calling for increased transparency of markets for medicines, vaccines, and other health products. Whatever the outcome, such drastic, exigent regulatory interventions, albeit temporary, could have residual and long-lasting effects on the industry as a whole, and pharma must remain aware of these decisions and their impact going forward.

Pricentric Insights: China's Interim Measures for the NRDL and BMI Administration

PRICENTRIC BRIEF:

- The National Healthcare Security Administration (NHSA) has released a draft proposal on interim measures surrounding the administration of medicines under the Basic Medical Insurance (BMI) scheme, in which China addresses the management of the national reimbursed drug list, including the eligibility for the inclusion or exclusion of drugs, domestic, generics, and Western medicines, going forward
- In the proposal, China details which medicines are eligible for inclusion, how they will be included (negotiations) and paid for (with a co-pay or BMI pools), and which drugs won't be allowed entry, mainly due to low therapeutic value or price/cost
- The terms for agreement exclusivity have been outlined, as well as what clinical experts behind the formulation and adjustment are looking for when redetermining a drug's eligibility for inclusion

THE DETAILS

BEIJING, China – The National Healthcare Security Administration (NHSA) has released a draft proposal on interim measures surrounding the administration of medicines under the Basic Medical Insurance (BMI) scheme, in which China addresses the management of the national reimbursed drug list, including the eligibility for the inclusion or exclusion of drugs, domestic, generics, and Western medicines, going forward.

The following will be open for comment until mid-May.

In the first chapter, the NHSA underscores the importance of expanding the BMI scheme while keeping costs affordable for both China and patients. In this way, China seeks to improve the management behind the reimbursed drugs list (RDL).

The BMI RDL is to be formulated on the basis of generic drug name, or international non-proprietary name (INN), and all drugs of the same generic names as those listed in the RDL will be covered automatically. This is no surprise for China. Throughout the last year, Chinese health officials have sought to encourage greater use of generic drugs and pressured domestic drugmakers to increase the production of these cheaper drugs. For China, generics mean greater affordability not only for citizens, but the BMI scheme itself.

The level of drug reimbursement will be compatible with the flexibility of the BMI fund and insured to meet the reasonable demand for drugs. Both traditional Chinese medicines (TCM) and western medicines will be viewed with the same level of regard.

To uphold the importance of all medicines, the RDL is composed of five sections:

1. Common rules, which detail dosage form specifications, among other contents of the RDL
2. Western medicine, which contains chemical drugs and biological products
3. Formulated TCMs, which contains, as the name suggests, formulated TCMs
4. Negotiated medicines, which contains negotiated drugs within the validity of an agreement
5. TCM decoction pieces, which contains decoction pieces paid by the BMI which are not reimbursable

The NHSA is responsible for establishing the management policy system for the BMI, including clarifying the conditions and principles for use and payment of BMI reimbursable drugs across China and formulating, organizing, publishing, and adjusting the National RDL (NRDL), whereas the BMI management agency will specifically undertake the organization and implementation of the adjustment of the NRDL.

Provincial level healthcare security administrators are responsible for the administration of BMI reimbursable drugs within their respective territory. Likewise, local healthcare security administrators of pooling areas are responsible for implementing the RDL and related policies, such as reviewing, supervising, and managing BMI drug consumption by medical institutions, as well as the adherence of these institutions to settling and paying medical insurance costs.

In Chapter 2, the NHSA outlines the formulation of adjustment of the RDL, which will be comprised of chemical and biologic drugs, formulated TCMs, and TMS decoction pieces that were approved by China's national drug regulator. Support for essential and innovative drugs with indigenous IP rights will be included in the RDL.

A variety of medicines won't be included in the RDL, such as Class B OTC drugs, preventative vaccines and contraceptives, and medicines mainly used to enhance sexual function, treat hair loss, and reduce weight, among others.

China can also pull drugs from the RDL for a few reasons, but most notably if the national regulator revokes authorization or if the drug's risks outweigh its benefits. Additionally, drugs can be transferred out of the list if the drug's price is unreasonably high or unjustified compared to drugs in a similar therapeutic grouping, if its clinical value is unreliable or substitutable by another product, or if the drug doesn't meet safety, efficacy or economic measures.

The NHSA will be responsible for making adjustments to the RDL, which will occur once a year (in principle, China noted). To make adjustments, the NHSA will consider BMI fund income, expenditure, and affordability. Drugs submitted by manufacturers that meet the criteria for inclusion will be included in the following RDL.

The payment measures for RDL-exclusive medicines will be determined through access negotiation and the payment measures for non-exclusive RDL medicines will be determined through either centralized procurement or price competition to be granted access on the RDL.

When reviewing the eligibility for inclusion of a drug on the RDL, expert committees will consider: new products, drugs recommended for transfer onto the list, drugs recommended to be henceforth excluded, and medicines recommended for inclusion based on an adjustment to their scope of payment.

The national BMI agency will handle pharmaco-economics and medical insurance management, among other responsibilities, to tackle negotiations or access bidding for inclusion. Excluded medicines will enter into negotiations while non-exclusive products will be subject to manager access bidding. Products that succeed will be included in the RDL or have their scope of payment limitations adjusted accordingly.

Negotiated drug agreements are valid for 2 years. Upon expiration, if negotiated drugs are still exclusive for a variety of factors, contracts will be renewed via budget impact comparisons and analysis. During negotiations, medical institutions are able to negotiate prices, too. Agreements for all negotiated drugs should be renewed every two years.

Any expenses for RDL drugs incurred by those insured by the BMI scheme may be reimbursed by the fund, and the level of reimbursement is contingent on the scope of payment limitations or need. Western drugs are categorized by their therapeutic use, which stipulates how these drugs will be paid for. For example, "Category A Drugs" require a certain percentage payment (a co-pay) by the insured whereas "Class B Medicines" are paid for by pools.

In the final section of the proposal, China explains that the regulation of the RDL and its implementation will rely on the use of agreements, constant monitoring of consumption and use by medical institutions, and manufacturer adherence to China's policy and regulatory measures pertaining to this list.

On the following page is the NRDL as of December 2019.

http://www.nhsa.gov.cn/art/2020/4/29/art_48_3059.html

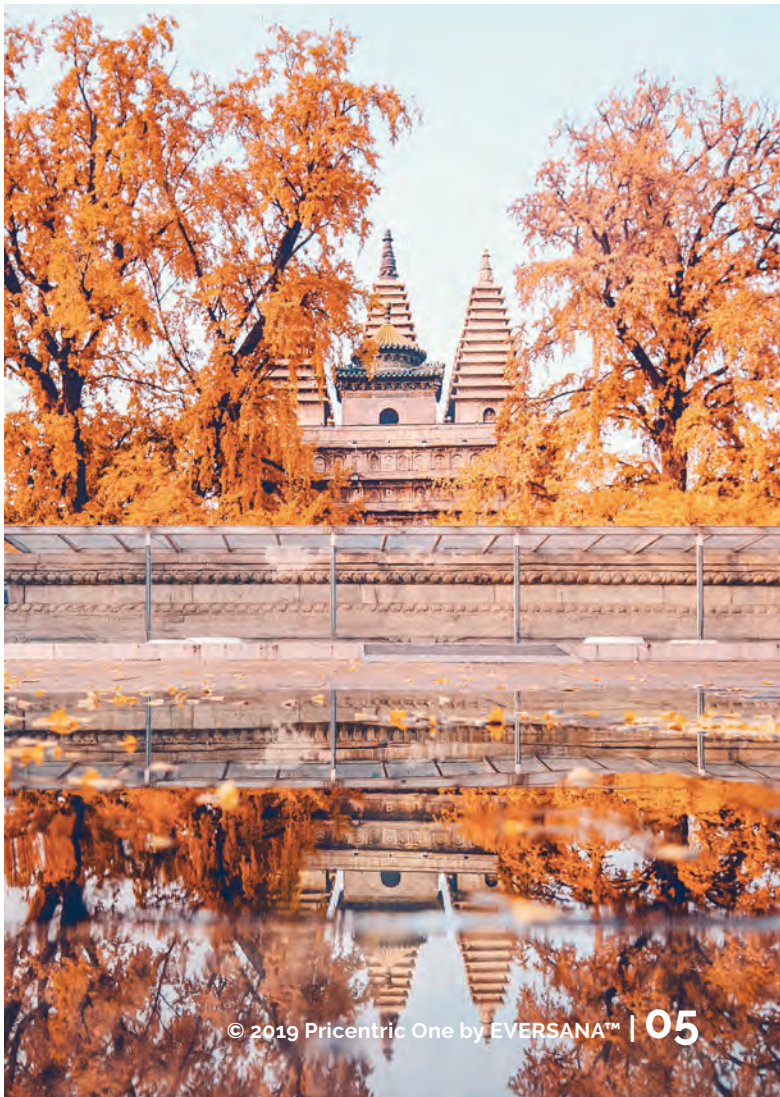
Drugs Added to China's NRDL

Newly Added Western Drugs:

ALCOAINE
ELBAWAY GRAVE
ELBASVIR & GRAZOPREVIR
SOFOSBUVIR & VELPATASVIR
PROPOFOL & TENOFOVIR
RECOMBINANT CYTOKINE PROTEIN
ALETINIB HYDROCHLORIDE
FRUQUINTINIB
RALTITREXED
OLAPARIB
PIRLOTINIB MALEATE
PERTUZUMAB
SINTILIZUMAB
LUCOTINIB
BOSENTAN
LEVOFLOXACIN
MACITENTAN
SELEXIPAG
MIGLUSTAT
TERIFLUNOMIDE
NANOFLOXACIN MALATE
BEDAQUILINE
DELAMANID
LIDOCAINE
VILANTEROL & UMECLIDINIUM BROMIDE
INDACATEROL & GLYCOPYRRONIUM BROMIDE
OMALIZUMAB
ADALIMUMAB
TOFACITINIB
INFLIXIMAB
EUREKLIN
RECOMBINANT HUMAN TISSUE-TYPE PLASMINOGEN KINASE DERIVATIVE
ROXADUSTAT
ACARBOSE
EXENATIDE
DAPAGLIFLOZIN
EMPAGLIFLOZIN
CANAGLIFLOZIN
RISENATIDE
MONOAMMONIUM GLYCYRRHIZINATE AND CYSTEINE AND SODIUM CHLORIDE
ARGININE GLUTAMATE
ILAPRAZOLE
VALSARTAN
DEFERASIROX
HYDROXYETHYL STARCH
PEGFILGRASTIM
AFLIBERCEPT
DEXAMETHASONE
TAFLUPROST
VARIOUS OIL FAT EMULSION (C6 ~ 24)
AMINO ACID
GADOTERIDOL

Successfully Renewed Western Drugs (Extension of 2 Years):

NIMOTUZUMAB
BEVACIZUMAB
ERLOTINIB
RECOMBINANT HUMAN ENDOSTATIN INJECTION
TRASTUZUMAB
EVEROLIMUS
SORAFENIB
APATINIB
CHIDAMIDE
LANTHANUM CARBONATE
SEVELAMER CARBONATE
AZILSARTAN
COAGULATION FACTOR VIIA
QUETIAPINE
PAROXETINE
MORINIDAZOLE AND SODIUM CHLORIDE
POSACONAZOLE
RECOMBINANT HUMAN UROKINASE
LIRAGLUTIDE
RECOMBINANT HUMAN BRAIN NATRIURETIC PEPTIDE
COMPAXIP OPHTHALMIC INJECTION
RANIBIZUMAB



NHS & Bayer Strike Deal for Tumor Agnostic Drug Vitrakvi

PRICENTRIC BRIEF:

- Bayer's Vitrakvi (larotrectinib) is recommended for use through the Cancer Drugs Fund (CDF) for the treatment of neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumors in adults and children if the disease is locally advanced or metastatic or surgery could cause severe health problems and there are no satisfactory treatment options
- According to the National Institute of Health and Care Excellence (NICE), which recommended use of the drug, the cost of larotrectinib is £5,000 per 100-ml vial of 20 mg per ml oral solution (excluding VAT; BNF online; £15,000 per 30-day supply)
- It is anticipated that Vitrakvi will be initially available for patients with confirmed NTRK gene fusion who will most likely benefit from treatment, and testing for these patients will likewise be rolled out once the NHS has the capacity for genetic testing, which is currently marred by the COVID-19 pandemic

Originally published: April 23, 2020

Country: UNITED KINGDOM | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #accessarrangement #bayer #cancerdrugsfund #cdf #nhs #nice

THE DETAILS

LONDON, United Kingdom – Bayer's Vitrakvi (larotrectinib) is recommended for use through the Cancer Drugs Fund (CDF) for the treatment of neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumors in adults and children if the disease is locally advanced or metastatic or surgery could cause severe health problems and there are no satisfactory treatment options, announced the National Health Service (NHS).

A tumor agnostic drug, Vitrakvi will now be included in the NHS' cancer services following an access deal endorsed by the National Institute of Health and Care Excellence (NICE), the UK's cost-effectiveness watchdog that recommended inclusion of the drug.

It is anticipated that Vitrakvi will be initially available for patients with confirmed NTRK gene fusion who will most likely benefit from treatment, such as children, teenagers, and young adults.

Testing for these patients will likewise be rolled out once the NHS has the capacity for genetic testing, which is currently marred by the COVID-19 pandemic.

Amanda Cunnington, Head of Patient Access at Bayer, said: "Today's positive announcement regarding access to Larotrectinib for NHS patients in England has been secured as a result of working closely with NICE and NHS England."

"We are now focused on working in collaboration with the NHS at national and local levels so that eligible patients across the country can be identified and treated with Larotrectinib."

According to NICE, the cost of larotrectinib is £5,000 per 100-ml vial of 20 mg per ml oral solution (excluding VAT; BNF online; £15,000 per 30-day supply).

Switzerland Strikes Deal with Vertex for CF Treatments Orkambi, Symdeko, & Trikafta Pending Approval

Country: SWITZERLAND | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #accessagreement #foph #fsio #indicationextensions #swissmedic #vertex

Originally published: April 21, 2020

PRICENTRIC BRIEF:

- Vertex Pharmaceuticals and Switzerland's Federal Office of Public Health (FOPH) and the Swiss Federal Social Insurance Office (FSIO) reached an agreement on the reimbursement of Orkambi (lumacaftor/ivacaftor) and Symdeko (tezacaftor/ivacaftor and ivacaftor) for patients in Switzerland living with cystic fibrosis (CF)
- Specifically, the agreement allows access to treatment with Orkambi for patients aged two years and older with CF who have two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, and access to treatment with Symdeko for patients aged 12 years and older with either two copies of the F508del mutation, or one copy of the F508del mutation, and another responsive residual function mutation in the CFTR gene
- The agreement includes any future indication extensions for patients of different ages for Symdeko and enables for the possibility for rapid patient access to Vertex's triple combination regimen, elexacaftor/tezacafotr/ivacaftor and ivacaftor (marketed as Trikafta), pending approval from Swissmedic

THE DETAILS

BERN, Switzerland – Vertex Pharmaceuticals and Switzerland's Federal Office of Public Health (FOPH) and the Swiss Federal Social Insurance Office (FSIO) reached an agreement on the reimbursement of Orkambi (lumacaftor/ivacaftor) and Symdeko (tezacaftor/ivacaftor and ivacaftor) for patients in Switzerland living with cystic fibrosis (CF).

Specifically, the agreement allows access to treatment with Orkambi for patients aged two years and older with CF who have two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, and access to treatment with Symdeko for patients aged 12 years and older with either two copies of the F508del mutation, or one copy of the F508del mutation, and another responsive residual function mutation in the CFTR gene.

The agreement includes any future indication extensions for patients of different ages for Symdeko and enables for the possibility for rapid patient access to Vertex's triple combination regimen, elexacaftor/tezacafotr/ivacaftor and ivacaftor (marketed as Trikafta), pending approval from Swissmedic.

An application for the triple combination regimen was submitted to Swissmedic on March 24, 2020.

Ludovic Fenaux, Senior Vice President, Vertex International, said, "This agreement is an important milestone for the cystic fibrosis community in Switzerland. Access to Orkambi and Symdeko is especially important at this time given the COVID-19 outbreak and that people with CF are vulnerable to infections. We are pleased that Vertex and the Swiss authorities have been able to work closely and flexibly to enable this agreement, so that almost 400 eligible Swiss patients will now have access to CFTR modulators to treat the underlying cause of their disease."

Between SEK 400 and 800 Million in Potential Savings for Medicines Under Swedish Drug Benefits Scheme

Country: SWEDEN | Region: EUROPE | Type: Pricing & Reimbursement |
Keywords: #drugcosts #medicalexaminations #referencepricing(irp) #savings #sideagreements #tlv #value-basedpricing | Originally published: April 7, 2020

PRICENTRIC BRIEF:

- In its review of the savings potential for medicines included within the drugs benefits scheme, the Dental and Pharmaceutical Benefits Agency (TLV) has come to the estimation that there is an opportunity to save between 400 and 800 million kronor within two to four years
- TLV has been developing value-based pricing to ensure reasonable costs for medicines while maintaining patient access, and recent work has found that the large savings potential is mainly achievable by combining TLV's reconsiderations with tripartite consultations between TLV, the regions, and pharmaceutical companies, and by side agreements between the regions and pharma, which lower drug costs
- The review was incited by the Medical Examination's estimate of a savings potential of 700 million kronor, which came to this conclusion by using external reference pricing (ERP); however, TLV believes this is not relevant to Swedish conditions that apply value-based pricing

THE DETAILS

STOCKHOLM, Sweden – In its review of the savings potential for medicines included within the drugs benefits scheme, the Dental and Pharmaceutical Benefits Agency (TLV) has come to the estimation that there is an opportunity to save between 400 and 800 million kronor within two to four years.

TLV has been developing value-based pricing to ensure reasonable costs for medicines while maintaining patient access. Recent work has found that the large savings potential is mainly achievable by combining TLV's reconsiderations with tripartite consultations between TLV, the regions, and pharmaceutical companies, and by side agreements between the regions and pharma, which lower drug costs. The size of the savings depends on the rebate from these side agreements.

Savings will be achieved through continued collaboration, as well as ongoing and long-term work.

Agenta Karlsson, Director General of TLV, said, "We must continue to find opportunities to lower costs for medicines, but in a way that ensures good access to new innovative medicines and a wide range of both new and older medicines within the benefits. The review shows that we, together with the regions and the pharmaceutical companies, can achieve this."

The review was incited by the Medical Examination's estimate of a savings potential of 700 million kronor, which came to this conclusion by using external reference pricing (ERP). However, TLV believes this is not relevant to Swedish conditions that apply value-based pricing.

Pre-Authorized Use of Zolgensma Allowed by Czech Republic

Originally published: April 23, 2020 | Country: CZECH REPUBLIC | Region: EUROPE | Type: Regulation | Keywords: #avexis #chmp #earlyaccess #ema #genetherapy #novartis #pediatrics

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"

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.

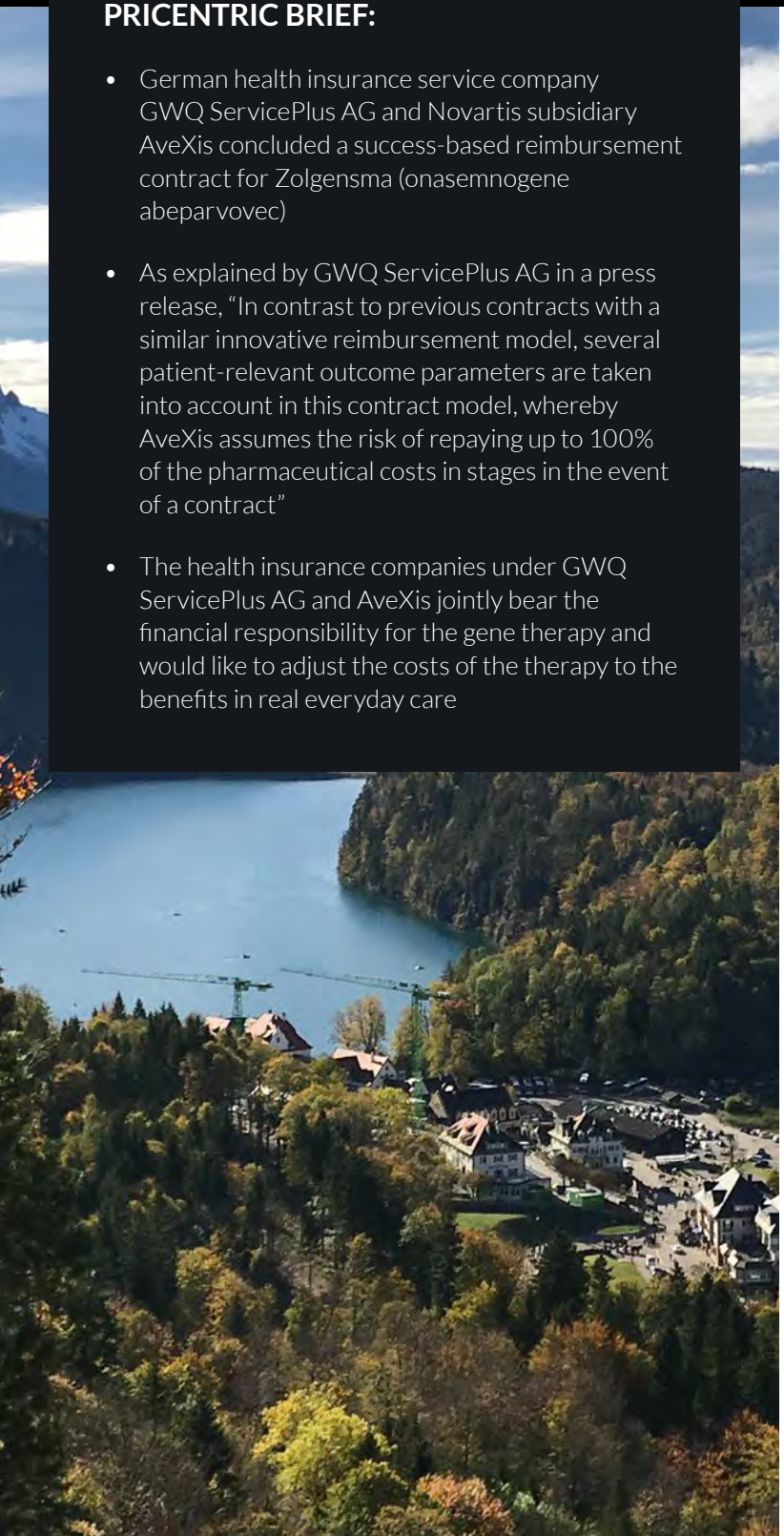
Adam Vojtech, Minister of Health, said, "We perceive the acute need for this experimental drug by patients, so we have allowed it to be used in the Czech Republic before the final decision of the European Medicines Agency is made."

Germany's GWQ ServicePlus AG, AveXis Conclude "Success-Based" Contract for Zolgensma

Country: GERMANY | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #avexis #chmp #ema #genetherapy #gwqserviceplusag #innovativepaymentmodel #novartis #payforperformance
Originally published: April 20, 2020

PRICENTRIC BRIEF:

- German health insurance service company GWQ ServicePlus AG and Novartis subsidiary AveXis concluded a success-based reimbursement contract for Zolgensma (onasemnogene abeparvovec)
- As explained by GWQ ServicePlus AG in a press release, "In contrast to previous contracts with a similar innovative reimbursement model, several patient-relevant outcome parameters are taken into account in this contract model, whereby AveXis assumes the risk of repaying up to 100% of the pharmaceutical costs in stages in the event of a contract"
- The health insurance companies under GWQ ServicePlus AG and AveXis jointly bear the financial responsibility for the gene therapy and would like to adjust the costs of the therapy to the benefits in real everyday care



THE DETAILS

DUSSEDORF, Germany – German health insurance service company GWQ ServicePlus AG and Novartis subsidiary AveXis concluded a success-based reimbursement contract for Zolgensma (onasemnogene abeparvovec).

As explained by GWQ ServicePlus AG in a press release, "In contrast to previous contracts with a similar innovative reimbursement model, several patient-relevant outcome parameters are taken into account in this contract model, whereby AveXis assumes the risk of repaying up to 100% of the pharmaceutical costs in stages in the event of a contract."

The health insurance companies under GWQ ServicePlus AG and AveXis jointly bear the financial responsibility for the gene therapy and would like to adjust the costs of the therapy to the benefits in real everyday care.

Upon approval of Zolgensma, GWQ ServicePlus AG aims to ensure immediate access for patients. In Germany, around 80 SMA patients are born each year.

At the end of March, The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending conditional marketing authorization for Zolgensma.

CHMP's opinion pertains to Zolgensma as treatment of patients with 5q muscular atrophy (SMA) with 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.

In March, the first infant in Germany with SMA was treated with Novartis' Zolgensma (onasemnogene abeparvovec) under the hardship program agreed to by the Paul Ehrlich Institute (PEI) in early February.

Under the scheme, Zolgensma is made available by AveXis, and the program for Germany will end as soon as Novartis' gene therapy receives approval in Europe.

Germany's Private Insurance Association Signs Deal with AveXis for Zolgensma

Country: GERMANY | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #avexis #genetherapy #innovativepaymentscheme #novartis #patientaccess #pediatrics #pkv #successbasedagreement
Originally published: April 24, 2020

PRICENTRIC BRIEF:

- The Association of Private Health Insurance (PKV) has become the second payer in Germany to sign a supply contract with AveXis, a Novartis company, for spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec)
- According to PKV, the contract between PKV and AveXis ensures those with private insurance are guaranteed immediate access to Zolgensma upon European approval, which is expected in June
- Babies diagnosed with SMA will be treated with Zolgensma in highly specialized centers with experience in the treatment of pediatric neuromuscular diseases, and the contract includes a success-oriented reimbursement agreement

THE DETAILS

BERLIN, Germany – The Association of Private Health Insurance (PKV) has become the second payer in Germany to sign a supply contract with AveXis, a Novartis company, for spinal muscular atrophy (SMA) gene therapy Zolgensma (onasemnogene abeparvovec), announced the association.

According to PKV, the contract between PKV and AveXis ensures those with private insurance are guaranteed immediate access to Zolgensma upon European approval, which is expected in June.

Babies diagnosed with SMA will be treated with Zolgensma in highly specialized centers with experience in the treatment of pediatric neuromuscular diseases, and the contract includes a success-oriented reimbursement agreement.

Florian Reuther, PKV Association Director, said, "With the contract we have legal certainty and can guarantee the high quality of care for our insured."

GWQ ServicePlus AG & AveXis Concluded First Reimbursement Agreement for Zolgensma

Earlier this week, German health insurance service company GWQ ServicePlus AG and Novartis subsidiary AveXis concluded a success-based reimbursement contract for Zolgensma (onasemnogene abeparvovec), the first reimbursement agreement set up for Zolgensma in Germany.

As explained by GWQ ServicePlus AG in a press release, "In contrast to previous contracts with a similar innovative reimbursement model, several patient-relevant outcome parameters are taken into account in this contract model, whereby AveXis assumes the risk of repaying up to 100% of the pharmaceutical costs in stages in the event of a contract."

The health insurance companies under GWQ ServicePlus AG and AveXis jointly bear the financial responsibility for the gene therapy and would like to adjust the costs of the therapy to the benefits in real everyday care.

Netherlands Includes Gilead's Yescarta in Basic Care Package

Originally published: April 21, 2020 | Country: NETHERLANDS | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #basiccare #gilead #lymphnode #yescarta #axicabtageneciloleucel

PRICENTRIC BRIEF:

- Yescarta (axicabtagene ciloleucel) is now included in the Dutch basic package for the treatment of certain types of lymph node cancer from May 1, 2020, after Minister Van Rijn (Medical Care) successfully negotiated its price
- Yescarta was originally placed in the 'lock', meaning that it was not directly included in the basic package in order to first assess its effectiveness and to negotiate a lower price with the manufacturer, as advised by the Netherlands Healthcare Institute
- The price agreement, which will not be made known to the public, applies until 2021

THE DETAILS

AMSTERDAM, The Netherlands — Gilead's Yescarta (axicabtagene ciloleucel) is now included in the Dutch basic package for the treatment of certain types of lymph node cancer from May 1, 2020, after Minister Van Rijn (Medical Care) successfully negotiated its price.

Yescarta was originally placed in the 'lock', meaning that it was not directly included in the basic package in order to first assess its effectiveness and to negotiate a lower price with the manufacturer, as advised by the Netherlands Healthcare Institute.

The price agreement, which will not be made known to the public, applies until 2021.

Later this year, the Ministry of Health, Welfare and Sport will publish an overview of price negotiations with drugmakers for 2018 and 2019, which should show the extent to which these negotiations have reduced the country's expenditure.

Russian Maximum Price Rules For Vital, Essential Drugs Amended

Originally Published: April 27, 2020 Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE
Type: Regulation | Keywords: #drugprices #fas #inn #maximumallowableprices #vitalandessentialdrugs

PRICENTRIC BRIEF:

- The Federal Antimonopoly Service (FAS) has prepared amendments to regulations on the prices of medicines on the Vital and Essential Drugs List following industry complaints of a lack of profitability when manufacturing these products due to extremely low maximum allowable sales prices
- The amendments stipulate that the maximum selling prices of wholesale and retail medicines included on the Vital and Essential Drugs List should not exceed the amount of the actual selling price established by the manufacturer of the medicinal product, the registered or re-registered maximum selling price of the manufacturer (as of the date of sale of the medicinal product by the manufacturer), and the size of the wholesale allowance and/or the size of the retail allowance
- The discussion regarding these amendments will last until May 11, 2020

THE DETAILS

MOSCOW, Russia – The Federal Antimonopoly Service (FAS) has prepared amendments to regulations on the prices of medicines on the Vital and Essential Drugs List following industry complaints of a lack of profitability when manufacturing these products due to extremely low maximum allowable sales prices.

Earlier last week, Russia's domestic pharmaceutical drugmakers warned of the possible cessation of production of more than 50 international non-proprietary names (INNs) of generic drugs listed on the Vital and Essential Drugs list.

Drugmakers explained there is no profitability for these drugs, a list that includes paracetamol, glucose solution, ibuprofen, and diphenhydramine antihistamine, among others, because the maximum allowable prices for these medicines set by Russia are extremely low. For example, drugmaker Biosynthesis reported that the maximum allowable price for a package of 20 paracetamol tablets 0.5 g is capped at 10.1 rubles, while the production cost for this pack is 16.46 rubles. Therefore, the allowable sales prices don't outweigh production costs.

The COVID-19 pandemic has only exacerbated this situation by increasing the demand for imported substances, and some drug companies are already beginning to suspend production.

The prices for Vital and Essential Drugs were registered in 2009, when the average values provided by the manufacturers themselves were taken as the basis, based on last year's sales. While domestic drugmakers enjoy an annual indexation of inflation of 6%, a sharp depreciation of the ruble in 2014 led to some drugs disappearing from circulation due to a lack of profitability.

Pharmaceutical representatives are cautioning that the same thing can happen now.

The Ministry of Health has proposed to amend the responsibilities of Roszdravnadzor to allow the authority to monitor the volume of drugs in circulation that are included in the Vital and Essential Drugs List.

The number of employees available and budget limitations will define the scope of Roszdravnadzor to carry out this task, explained the Ministry of Health.

The amendments stipulate that the maximum selling prices of wholesale and retail medicines included on the Vital and Essential Drugs List should not exceed the amount of the actual selling price established by the manufacturer of the medicinal product, the registered or re-registered maximum selling price of the manufacturer (as of the date of sale of the medicinal product by the manufacturer), and the size of the wholesale allowance and/or the size of the retail allowance, which should not exceed the size of the maximum wholesale allowance and/or the size of the maximum retail allowance established in the subject of the Russian Federation, and the decree.

What is not accounted for is the amount of value added tax (VAT) applied, that is, it depends on the taxation regimes applied by organizations participating in the drug distribution chain.

The amendments also establish a procedure for rounding up the maximum wholesale and retail allowances applied by organizations to actual selling prices established by drug manufacturers for medicines included in the List of Vital and Essential Drugs, eliminating legal uncertainty regarding the possibility of rounding up when setting selling prices, in order to eliminate the possibility of divergence from the rules regarding the setting of sales prices.

The discussion on this issue will go until May 11, 2020.

Latvia's Prescription by INN Guidelines Implemented

Country: LATVIA | Region: EUROPE | Type: Regulation | Keywords: #brandnamedrugs #competition #copayments #departmentofpharmacy #generics #inn #oecd #prescribingguidelines #pricereductions #who

Originally published: April 3, 2020

PRICENTRIC BRIEF:

- From now on in Latvia, doctors are prescribing by active ingredient, not the brand name of a medicine, and medicines with the same effect but lower cost will be dispensed to patients
- Inese Kaupere, Director of the Department of Pharmacy at the Ministry of Health, announced that due to the new state reimbursement procedure and the principle of the lowest price, drug manufacturers have already reduced the price of 250 reimbursed medicines
- As emphasized by the OECD, which supports Latvia's new prescribing guidelines, two thirds of the cost of medicines is paid for by Latvian patients themselves, so "policies to manage and promote the use of generic and biosimilar medicines can improve both patient access to medicines and the efficient use of public funds"

THE DETAILS

RIGA, Latvia – From now on in Latvia, doctors are prescribing by active ingredient, not the brand name of a medicine, and medicines with the same effect but lower cost will be dispensed to patients.

Latvians have been overpaying by EUR 25 million a year to purchase more expensive, brand name medicines despite the fact that medicines of equal quality and safety are available for less.

Inese Kaupere, Director of the Department of Pharmacy at the Ministry of Health, announced that due to the new state reimbursement procedure and the principle of the lowest price, drug manufacturers have already reduced the price of 250 reimbursed medicines.

"In addition, the range of reimbursable medicines at the same lowest price has increased, as manufacturers have also lowered the price of previously more expensive medicines, allowing patients to choose from a wider range of medicines. Namely, while in the past there was often only one of the cheapest reimbursable drugs for a diagnosis, manufacturers have now lowered the price of the drug and ensured that there are three or four drugs with the same effect at the same lowest price (or the cheapest drug)," explained Kaupere.

The World Health Organization (WHO) and the OECD both support Latvia's switch to prescribing by INN, which the agencies said not only promotes rational drug use and allows patients to save while improving healthcare in a letter to Latvia's Ministry of Health.

As emphasized by the OECD, two thirds of the cost of medicines is paid for by Latvian patients themselves, so "policies to manage and promote the use of generic and biosimilar medicines can improve both patient access to medicines and the efficient use of public funds."

Generic drug use accounted for 74% of total drug consumption in Latvia in 2017, 20% above the OECD average, but the OECD believes there is more room to exploit the potential of generic medicines to increase competition and reduce co-payments.

Biocon & Mylan Launch Pegfilgrastim Biosimilar Fulphila in Australia

Country: AUSTRALIA | Region: ASIA & SOUTH PACIFIC | Type: Biosimilar | Keywords: #biocon #druglaunch #mylan #pbs #pegfilgrastim | Originally published: April 14, 2020

PRICENTRIC BRIEF:

- Biocon and Mylan launched pegfilgrastim biosimilar Fulphila, based on Neulasta, in Australia, the duo's third co-developed biosimilar to launch in the country
- The biosimilar is approved for use to decrease the duration of severe neutropenia in cancer patients following chemotherapy to thereby reduce the incidence of infections manifested by febrile neutropenia
- Now launched, Fulphila is available on the Pharmaceutical Benefits Scheme (PBS), and Biocon CEO Dr. Christiane Hamacher commented, "[We] hope that continued penetration of our biosimilars will enable higher cost savings for the Australian healthcare system"

THE DETAILS

CANBERRA, Australia – Biocon and Mylan launched pegfilgrastim biosimilar Fulphila, based on Neulasta, in Australia.

The biosimilar is approved for use to decrease the duration of severe neutropenia in cancer patients following chemotherapy to thereby reduce the incidence of infections manifested by febrile neutropenia.

Now launched, Fulphila is available on the Pharmaceutical Benefits Scheme (PBS). A suite of patient services will be available at launch to further support patients and caregivers with treatment, explained both drugmakers.

Its approval was based on a comprehensive data package of analytical, nonclinical, and clinical data that confirmed Fulphila is highly similar to Neulasta and that no clinically meaningful differences in terms of safety and efficacy exist.

Dr. Christine Hamacher, CEO, Biocon Biologics, said, "We are extremely pleased to enable access to our high quality, affordable biosimilar pegfilgrastim for patients in Australia. Fulphila, co-developed by Biocon Biologics and Mylan, is the third biosimilar to be commercialized in Australia and we hope that continued penetration of our biosimilars will enable higher cost savings for the Australian healthcare system."

Similarly, Sylvain Vigneault, Mylan Australia Country Manager, commented, "Mylan is proud to launch Fulphila, the third biosimilar to be offered through the Mylan-Biocon Biologics partnership in Australia, as part of its commitment to expand access to more affordable medicines. Biosimilars ensure patients have timely and affordable access to quality, safe and effective treatments in a way that is sustainable for the Pharmaceutical Benefits Scheme.

"Globally, Mylan is a leader in biosimilars with one of the largest and most diverse biosimilars portfolios which includes 20 biosimilar and insulin analog products in development or on the market. We're pleased to continue to bring this experience and expertise to patients in Australia."

Janssen Proposes Spinraza Included in Russia's Vital, Essential Drugs List

Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Type: Pricing & Reimbursement | Keywords: #biogen | #federalfunding #janssen #orphandrug #rarediseases | Originally published: April 14, 2020

PRICENTRIC BRIEF:

- Janssen submitted a proposal to Russia to include spinal muscular atrophy (SMA) treatment Spinraza (nusinersen) by Biogen in the list Vital and Essential Drugs, offering the drug at almost 25% lower than the current average price for public procurement
- Katerina Pogodine, Managing Director of Janssen Russia, said, "We are open for further dialogue with interested parties on issues of price flexibility in order to ensure even wider access to the only currently available drug therapy for SMA in Russia"
- Recently, Russia's policymakers have been debating whether to add SMA treatments to the federal list of orphan drugs, which would direct federal funding for the procurement of medicines to treat the condition, alleviating regions from this responsibility

THE DETAILS

MOSCOW, Russia – Janssen has submitted a proposal to Russia to include spinal muscular atrophy (SMA) treatment Spinraza (nusinersen) by Biogen in the list Vital and Essential Drugs.

The company formed the submission using the minimum reference price for Spinraza, offering the drug at almost 25% lower than the current average price for public procurement.

The price will be effective from January 1 of the calendar year following the year in which the Commission of the Ministry of Health of Russia OK's Janssen's proposal to include Spinraza on the essential and vital drugs list.

Katerina Pogodine, Managing Director of Janssen Russia and CIS, General Director of Johnson & Johnson, said, "For several years now, our company has made significant efforts to support patients with SMA and to ensure access to treatment for this steadily progressive and potentially fatal disease.

"We are open for further dialogue with interested parties on issues of price flexibility in order to ensure even wider access to the only currently available drug therapy for SMA in Russia."

In August 2019, Russia's Ministry of Health designated Spinraza Orphan Drug status, and then in December 2019, Spinraza became available on the Russian market for patients.

Who Pays for Orphan Drugs in Russia?

Recently, Russia's policymakers have been debating whether to add SMA treatments to the federal list of orphan drugs, which would direct federal funding for the procurement of medicines to treat the condition, alleviating regions from this responsibility.

Orphan drugs tend to be more expensive, and patients and their families struggle to afford them. Listing SMA as a rare disease would financially help these patients.

It has also been suggested that Russia fund all orphan drugs, not just those listed as eligible for federal funding, proposed Elena Maksimkina, Director of the Department of Drug Support and Regulation of Medical Products at the Ministry of Health.

Federal funding supports the purchase of medicines for the treatment of 14 diseases, and the procurement of 17 more are allocated from regional budgets.

Minnesota House Says Yes to Emergency Insulin Assistance

Region: NORTH AMERICA | Type: Regulation | Keywords: #affordabilityact #copay #drugprices #insulin #patientassistanceprogram | Originally published: April 14, 2020

PRICENTRIC BRIEF:

- Having received 111 votes in favor from Minnesota's House, the Alec Smith Insulin Affordability Act (the Act), which would create a statewide insulin assistance program for Minnesotans, is about to enter the state's Senate and is expected to pass before being sent along to Governor Tim Walz to sign
- The Act provides Minnesotans who are unable to afford their insulin an emergency 30-day supply at their pharmacy for a co-payment of $35, and this offer would be extended to the uninsured, underinsured, Medicare beneficiaries, and those whose copays are too high
- As noted in the Act, if passed, "By July 1, 2020, each manufacturer must establish procedures to make insulin available in accordance with this section to eligible individuals who are in urgent need of insulin or who are in need of access to an affordable insulin supply"

THE DETAILS

SAINT PAUL, Minnesota, The United States – The Alec Smith Insulin Affordability Act (the Act), which would create a statewide insulin assistance program for Minnesotans, is about to enter the state's Senate and is expected to pass before being sent along to Governor Tim Walz to sign.

The emergency bill passed Minnesota's House on Tuesday, April 8, with 111 votes in favor and 22 against.

The Act provides Minnesotans who are unable to afford their insulin an emergency 30-day supply at their pharmacy for a co-payment of $35. The Act would extend this offer to the uninsured, underinsured, Medicare beneficiaries, and those whose copays are too high.

Moreover, patients with diabetes would be introduced to health care coverage options that offer better long-term, affordable insulin coverage.

As noted in the Act, "By July 1, 2020, each manufacturer must establish procedures to make insulin available in accordance with this section to eligible individuals who are in urgent need of insulin or who are in need of access to an affordable insulin supply."

Insulin manufacturers are responsible for making available patient assistance programs under the Act. In this way, the Act would be largely funded by a fee on insulin manufacturers.

If manufacturers refuse to comply with the Act, then Minnesota could issue fines, and the drugmaker would be liable to substantial fines.

Novartis' Kymriah Granted RMAT Designation by FDA

Originally published: April 22, 2020 | Region: NORTH AMERICA | Type: Drug Approval | Keywords:#21stcenturycuresact #carttherapy #cellandgenetherapy #fda #novartis #oncology #regenerativemedicine #rmat

PRICENTRIC BRIEF:

- The US Food and Drug Administration (FDA) has granted Regenerative Medicines Advanced Therapy (RMAT) designation to Novartis' Kymriah (tisagenlecleucel) for an investigational new indication to treat patients with relapsed or refractory (r/r) follicular lymphoma (FL)
- Enacted under the 21st Century Cures Act of December 2016, RMAT designation allows for expedited development and review of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious condition
- Kymriah received RMAT designation from the FDA due to preliminary clinical evidence from the ongoing, multi-center, phase 2 ELARA clinical trial, which is exploring the efficacy and safety of the CAR-T cell therapy in adult patients with r/r FL

THE DETAILS

WASHINGTON, D.C., The United States – The US Food and Drug Administration (FDA) has granted Regenerative Medicines Advanced Therapy (RMAT) designation to Novartis' Kymriah (tisagenlecleucel) for an investigational new indication to treat patients with relapsed or refractory (r/r) follicular lymphoma (FL).

RMAT was enacted under 21st Century Cures Act of December 2016 and allows for expedited development and review of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious condition.

Kymriah received RMAT designation from the FDA due to preliminary clinical evidence from the ongoing, multi-center, phase 2 ELARA clinical trial, which is exploring the efficacy and safety of the CAR-T cell therapy in adult patients with r/r FL.

Kymriah was the first CAR-T cell therapy to be granted approval from the FDA. It was authorized for the treatment of r/r pediatric and young adult acute lymphoblastic leukemia (ALL) and r/r adult diffuse large B-cell lymphoma (DLBCL).

In a press release, John Tsai, MD, Head of Global Drug Development and Chief Medical Officer, Novartis, said, "This designation supports the advancement of Kymriah, which could potentially address an unmet need in certain patients with follicular lymphoma, as we strive to reimagine medicine at Novartis. These patients are often faced with the burden of several years of various treatments as their disease continues to progress."

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

Originally published: April 20, 2020 | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #breastcancer #fda #healthcanada #hsa #oncology #projectorbis #realtimeoncologyreview #seattlegenetics #swissmedic #tga #tucatinib #tukysa

Pricentric Brief

- 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

The Details

WASHINGTON, D.C., The United States – 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.

Tukysa was previously granted Breakthrough Therapy designation and Priority Review by the FDA, and the application was reviewed under the Real-Time Oncology Review (RTOR) pilot program.

Clay Siegall, Ph.D., Chief Executive Officer at Seattle Genetics, said, "We're pleased to have collaborated with the FDA on our second expedited real-time oncology review, enabling us to rapidly bring this new targeted medicine to patients. Tukysa has shown impressive results in people with HER2-positive metastatic breast cancer, including in patients with active brain metastases, and offers patients an effective medicine following previous treatment with other anti-HER2 agents in the metastatic setting."

Under Project Orbis, a collaborative effort among five countriesthat 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.

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, said, "We are pleased to work with our Singapore and Switzerland colleagues for the first time, and to continue working alongside our Australian and Canadian colleagues as we facilitate new treatment options for patients – like today's first new molecular entity under Project Orbis."

Tukysa, in combination with trastuzumab and capecitabine, was evaluated in the trial HER2CLIMB, a randomized (2:1), double-blind, placebo-controlled trial that enrolled 612 patients with HER2-positive unresectable locally advanced or metastatic breast cancer who had previously received, either separately or in combination, trastuzumab, pertuzumab, and ado-trastuzumab emtansine (T-DM1), in which the primary efficacy outcome measure was progression-free survival (PFS) and additional efficacy outcome measures were evaluated in all randomized patients and included overall survival (OS), PFS in patients with a history or presence of brain metastases, and confirmed objective response rate (ORR).

Eli Lilly Launches Lower-Priced Humalog Mix75/25 KwikPens, Humalog Junior KwikPen

Region: NORTH AMERICA | Type: Drug Launch | Keywords: #drugprice #elililly #insulin

Originally published: April 17, 2020

PRICENTRIC BRIEF:

- Eli Lilly has made available lower-priced versions of its Humalog Mix75/25 KwikPen (insulin lispro protamine and insulin lispro injectable suspension, 100 units/mL) and Humalog Junior KwikPen (insulin lispro injection, 100 units/mL), which are eligible for the $35 co-pay program
- The non-branded version of Humalog Mix75/25 will be known as Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 KwikPen (100 units/mL), and the non-branded version of Humalog Junior KwikPen will be known as Insulin Lispro Injection Junior KwikPen (100 units/mL)
- According to the drugmaker, these non-branded insulin options, which are identical to their branded counterparts but with different packaging, will be available at a 50% lower list price of $265.20 for a package of 5 KwikPens

THE DETAILS

INDIANAPOLIS, Indiana, The United States – Eli Lilly has made available lower-priced versions of its Humalog Mix75/25 KwikPen (insulin lispro protamine and insulin lispro injectable suspension, 100 units/mL) and Humalog Junior KwikPen (insulin lispro injection, 100 units/mL).

The non-branded version of Humalog Mix75/25 will be known as Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 KwikPen (100 units/mL), and the non-branded version of Humalog Junior KwikPen will be known as Insulin Lispro Injection Junior KwikPen (100 units/mL).

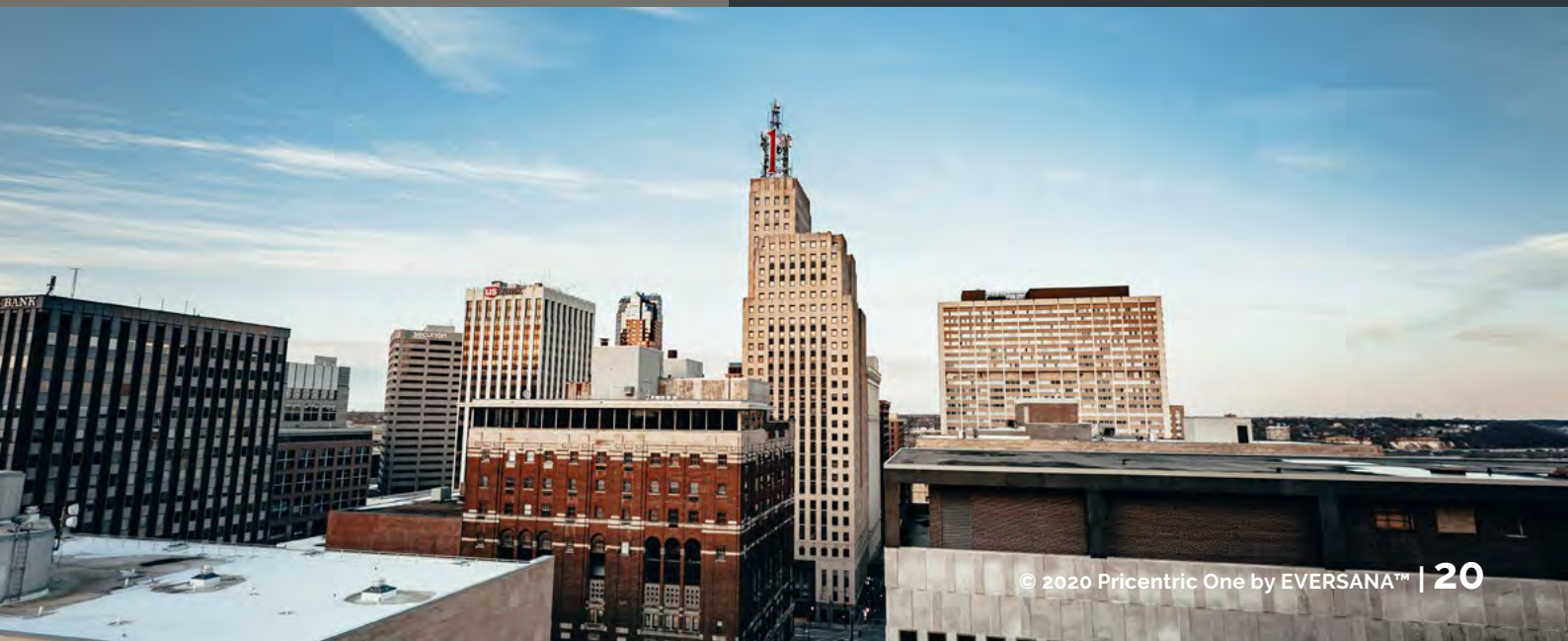
According to the drugmaker, these non-branded insulin options, which are identical to their branded counterparts but with different packaging, will be available at a 50% lower list price of $265.20 for a package of 5 KwikPens.

The Lilly Insulin Value Program preceded the launch, which cuts down out-of-pocket (OOP) costs for most Lilly-made insulins to $35 for people with either commercial insurance or none at all.

The non-branded insulins are eligible for the $35 co-pay program, explained Eli Lilly.

Lilly also reiterated that it continues to offer Insulin Lispro Injection (100 units/mL), the non-branded version of Humalog U-100, at a 50% lower list price of $137.35 per vial and $265.20 for a package of five KwikPens.

Insulin Lispro Injection was made available in May 2019 and now approximately 1 out of every 6 prescriptions filled for Humalog U-100 is for this non-branded option.



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Merck Launches Trastuzumab Biosimilar Ontruzant in US

Country: UNITED STATES | Region: EUROPE
Type: Biosimilar | Keywords: #druglaunch #merck #samsungbioepis #trastuzumab

Originally published: April 15, 2020

PRICENTRIC BRIEF:

- Merck launched trastuzumab biosimilar Ontruzant, which references Herceptin by Roche, in the US in both 150 mg single-dose vials and 420 mg multiple-dose vials
- According to Merck, Ontruzant is available at list prices (wholesale acquisition costs; WACs) that represent a 15% discount to the current list price of Herceptin
- Ontruzant is approved for use as adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; as part of a treatment regimen with docetaxel and carboplatin; and as a single agent following multi-modality anthracycline based therapy

THE DETAILS

WASHINGTON, D.C., The United States – Merck launched trastuzumab biosimilar Ontruzant, which references Herceptin by Roche, in the US in both 150 mg single-dose vials and 420 mg multiple-dose vials.

According to Merck, the rounded list price (wholesaler acquisition cost; WAC) for the 150 mg single-dose vial will be $1,325 and for the 420 mg multiple-dose vial it will be $3,709. These prices represent a 15% discount to the current list price of Herceptin, noted the drugmaker. Once prices are available in our source, they will be updated in Pricentric.

In the US, the current MNF (WAC) cost for Herceptin Infusion 1 Lyophilized Powder Vial 7.2 ML 150 MG is $1,422.63, according to data from Pricentric.

Ontruzant is approved for use:

- as adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel;
- as part of a treatment regimen with docetaxel and carboplatin; and
- as a single agent following multi-modality anthracycline based therapy.

Ontruzant is being launched in the US by Merck as part of a development and commercialization agreement with Samsung Bioepis.

The biosimilar was approved by the Food and Drug Administration (FDA) in January 2019 based on the review of a comprehensive data package by Samsung Bioepis that included, among other things, a comparative clinical study demonstrating that Ontruzant is highly similar to its reference product, Herceptin, in terms of the safety, purity and potency of the product.

EyeforPharma BCN & PHL: Conference Highlights

Pricentric Insights' news team attended the virtual conferences for EyeforPharma Barcelona and Philadelphia, where we listened to presentations on current pharma trends. See below a brief for each presentation.

EyeforPharma Barcelona

The Importance & Implications of DTx

- Jessica Shull, European Lead, Digital Therapeutics Alliance, emphasized that the pharma industry must align on the definition of DTx, which refers to evidence-based therapeutic interventions that are driven by software programs to directly improve the disease state of patients
- Jonas Duss, US CEO, Co-Founder, Kaia Health, explained the importance of prescribing DTx, rather than spreading the word through mass outreach as 40-70% patients who are clinically prescribed DTx maintain usage, compared to 15-40% of those targeted through mass outreach
- Duss said Europe is highly fragmented and the motivation of providers is polarized, while in the U.S., EMR integration has seen broader implementation as value-based arrangements are more experiment-friendly and access to DTx is quicker since the provider is the buyer of the solution and PCP's often belong to this overarching network

Pricing for Curative Medicines

- Alexander Natz from industry group EUCOPE predicted that if curative therapies work, they will be expanded, and price drops will happen "for bigger indications"
- Natz added that regulatory decision making bodies should issue mandatory requests for real-world evidence (RWE) and drugmakers must hedge the risk of payers through such evidence
- While Peter Bach, Director of Memorial Sloan Kettering Cancer Center, argued that drugs should be priced based on the short term benefit of what the drug provides, rather than extrapolating data, Natz countered that companies need to engage early with payers especially when there's an unmet need and assist them in their horizon scanning

Canada's Regulatory Approach to RWE

- Health Canada has recently put forth documents on overarching principles related to RWD, and CADTH recently sent out a notice to the industry encouraging RWE submissions, especially for populations often excluded from clinical trials such as children, seniors, and pregnant women
- At an RWE centered workshop hosted by CADTH, there was consensus around the fact that current evidentiary requirements are challenging and potentially not feasible for drugs used in the treatment of rare diseases and in oncology, and that RWE should be used as a supplement or complement to current evidence standards and not "in lieu of"
- The RWE Core Action Team (CAT), established as a result of the workshop, has already identified priority areas such as defining and addressing data gaps across the product life span, defining methodological capacity and standards, and optimizing data sharing in Canada

EyeforPharma Philadelphia

MIT's Financing Innovations for Curative Therapies

- Pharma Philadelphia virtual conference this week, Mark Trusheim, Strategic Director MIT NEWDIGS, spoke about a number of "precision financing innovations" for curative therapies developed by MIT FoCUS, a multi-stakeholder group engaging over 90 organizations
- Four precision financing solutions were developed: short-term milestone-based contracts, multi-period performance based annuities, Orphan Reinsurer and Benefit Manager (ORBM) and Risk Pools, and subscription models
- Regulatory challenges financing models include Medicaid drug price reporting and rebate process adapting to multi-year performance structures, anti-kickback statute needed to define an explicit safe harbor, FDA communication guidelines to enable appropriate performance metrics, and HIPAA patient privacy protection which can restrict access to developers and initial payers to outcomes data

Incentivizing Innovation

- As part of the virtual broadcast of EyeforPharma Philadelphia, a panel titled "Valuing Innovation" featured Sarah Emond, EVP and Chief Operating Officer, ICER, and Chris Leibman, SVP Value and Access, Biogen
- Edmond noted that while value assessment frameworks generally try to incentivize companies to invest in R&D, now, in the midst of the pandemic, companies are performing R&D for the social good, suggesting that the relationship between investment and the ultimate price for a product should be dissected because more value should perhaps be given to society in this circumstance
- When it comes to incentivizing innovation when it might not have an immediate use, Leibman spoke of Peter Kolchinsky's term "social contract," where some investments pay off, but there is an assumption that the reward period ends--in particular, with generics and biosimilars offering tremendous savings that the U.S. has yet to take hold of

Access and Affordability

- Daniel Staud, AVP Global Market Access, Merck, explained that Merck now addresses access strategy earlier than ever before, with senior commercial leaders aligning to "think about what is necessary around the burden of illness and standard of care, and what is necessary in terms of endpoints to demonstrate the value that's needed"
- On collaborating across stakeholders, Sheila Frame, VP Commercial: Marketing, Market Access and Patient Services, Sandoz, stressed the importance of cross-functionality, believing experience across pipelines is crucial to success
- Frame also expressed frustration around the idea of "niching" a product and said it's much better to think of it as a beachhead strategy, and when asked how to balance innovation when it comes to curative therapies, Frame pointed out that the opportunity is available to create space in the system very quickly

Tech Innovation in Healthcare

- Abbvie is looking to use wearables, apps, sensors, and IOT to find quantified measures for things that are more qualitative in nature while Pfizer is attempting to leverage drones, AR, VR, IOT, AI, blockchain and other technologies to maximize manufacturing capabilities, in addition to lower tech solutions for educating new hires about the company before they even walk in the door
- Natalija Jovanovic, Chief Digital Officer, Sanofi Pasteur, noted that individualization used to be considered too costly but now it's inevitable, and drugmakers are working with tech companies to co-create services, large and small, with Greg Silvesti, Head of Digital Health & Innovation, AbbVie, adding that siloed data needs to be put together and sifted for additional insights
- When asked whether regulatory openness and flexibility will change in tech innovation, Silvesti said, in addition to working on creating more decentralized and remote trials, changes will be accelerated on operational side, especially due to COVID-19

Unleashing Potential of RWE With Machine Learning

- Decisionmakers are being inundated with data requiring more sophisticated interpretation while being expected to be more efficient, and machine learning seems to be the answer, presenters at EyeforPharma Philadelphia explained
- Machine learning has been shown to assist in the early detection of Parkinson's Disease, Alzheimer's Disease, and Cytomegalovirus (CMV) infection, offering the potential of more efficient and effective patient care management
- Moreover, a collaboration between Merck and Optum called Learning Laboratory used RWE and machine learning to inform the development of outcome-based risk-sharing agreements (OBRSA) in the future US environment

HTA Decisions: Germany

- Germany's G-BA has published the benefit assessment report on Alexion pharma's Strensiq (Asfotase alfa) for long-term enzyme replacement therapy in patients in whom the hypophosphatasia has occurred in childhood and adolescence. The committee found that the register data could be changed due to significant differences in the patient characteristics, as well as the incomplete data collection not for the benefit assessment were taken into account.
- Germany's G-BA has published the benefit assessment report on Bayer's Vitrakvi (Larotrectinib) for as a monotherapy for the treatment of adults and pediatric patients with solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. The committee noted that the evidence presented did not allow any comparison with the appropriate comparator therapy, which is why an added benefit of larotrectinib is not proven.
- Germany's G-BA has published the benefit assessment report on Roche's Tecentriq (Atezolizumab) for use in combination with bevacizumab, paclitaxel and carboplatin adult patients for first-line treatment of the metastatic non-small cell lung gene carcinoma with non-squamous histology. The committee found that due to the different periods of study and related differences in the supply of NSCLC in the historical course and the insufficiently similar patient characteristics between the two studies as well as ambiguities regarding other factors, the adjusted indirect not immediately usable. An added benefit was therefore not proven.
- Germany's G-BA has published the benefit assessment report on Roche's Tecentriq (Atezolizumab) for in combination with carboplatin and etoposide is used for first-line treatment of adult patients with small cell lung cancer in the advanced stage (ES-SCLC). The G-BA decided that there were uncertainties due to the under-representation of patients with brain metastases, total completely missing data on patients with symptomatic metastases in the study, as well as due to a lack of subgroup analysis in the Endpoint category Side effects. Therefore, the data was limited overall. As a result, it can therefore only indicate an added value in terms of the certainty of the statement derived.

HTA Decisions: Germany

- Germany's G-BA has published the benefit assessment report on Roche's Tecentriq (Atezolizumab) for used in combination with nab-paclitaxel and carboplatin for the first-line treatment of metastatic NSCLC with non-squamous histology adult patients who have no EGFR mutations and no ALK-positive NSCLC. The committee noted that taking into account the rate of therapy discontinuations that were not statistically significant between treatment groups differs, the disadvantages of the side effects as a whole were not so serious to find a lower overall assessment to justify benefits. In summary, there was no added benefit of Tecentriq in combination with nab-paclitaxel and carboplatin versus nab-paclitaxel and carboplatin.

- Germany's G-BA has published the benefit assessment report on Roche's Tecentriq (Atezolizumab) for used in combination with nab-paclitaxel in adult patients treatment of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC - triple-negative breast cancer), the tumors of which were PD-L1 expression ≥ 1% and who have no prior chemotherapy for the treatment of have received metastatic disease. The G-BA noted that due to remaining relevant uncertainties related to that in the study the comparator nab-Paclitaxel used in IMpassion130 may have the identified additional benefit to its extent cannot be quantified. Overall, there was an indication of a non-quantifiable additional benefit.

- Germany's G-BA has published the benefit assessment report on Kyowa Kirin's orphan drug Crysvita (Burosumab) for used to treat children from 1 year old and adolescents in the skeletal growth phase with X-linked hypophosphatemia and-ray evidence of bone disease. The committee noted that in the overall view, there were no pre- or disadvantages for burosumab. Overall, there was a hint of a non- quantifiable one additional benefit because the scientific data basis did not allow quantification.

- Germany's G-BA has published the benefit assessment report on BMS/AbbVie's Empliciti (Elotuzumab) for used in combination with pomalidomide and dexamethasone to treat the relapsed and refractory multiple myeloma in adults who are at least two previous therapies, including lenalidomide and a proteasome inhibitor, received and showed progression under the last therapy. Overall, there was an indication of a significant additional benefit for E-Pd in comparison to Pd in the treatment of patients with relapsed and refractory multiple myeloma, which has at least two previous therapies, including lenalidomide and one proteasome inhibitor, and have shown progression under the last therapy have derived.

- Germany's G-BA has published the benefit assessment report on Tesaro and GSK's Zejula (Niraparib) for used as a monotherapy for maintenance therapy in adult patients relapse of a platinum-sensitive, poorly differentiated serous carcinoma of the ovaries tubes or with primary peritoneal carcinoma that was platinum-based chemotherapy is in remission. The disadvantage of side effects was achieved taking into account the clinical relevance because moderate disadvantages only arise at the endpoint of the have shown severe UE (CTCAE Grade 3), but have been shown in the present constellation does not amount to a lower level of benefit in the overall assessment of the would justify it. Overall, the G-BA concludes that an additional benefit of Zejula versus olaparib is not proven.

- Germany's G-BA has published the benefit assessment report on Servier's Lonsurf (Trifluridin & Tipiracil) for use as a monotherapy to treat an adult patient with metastatic gastric carcinoma including gastroesophageal adenocarcinoma transition that already has at least two systemic therapy regimens for the advanced disease have been treated. The committee noted that due to adverse events disadvantage for the occurrence of severe adverse events (CTCAE grade ≥ 3). The specific adverse events show both advantages and benefits for trifluridine / tipiracil with the best supportive care also disadvantages compared to placebo with the best supportive care.

- IQWIG has published a health benefits assessment report on Roche's Kadcyla (Trastuzumab emtansine) for breast cancer. The committee noted that in summary, these results for patients with HER2 positive breast cancer in the early stages following neoadjuvant taxane-based and HER2-directed therapy have the residual invasive disease in the breast and/or lymph nodes, an indication on a minor added benefit of trastuzumab emtansine compared to trastuzumab.

HTA Decisions: France

- France's HTA body HAS published a technology assessment report on Pfizer's Rapamune (Sirolimus) for the treatment of sporadic lymphangioleiomyomatosis with moderate pulmonary involvement or deterioration of pulmonary function. The transparency committee noted that the medical service rendered by Rapamune is important in the treatment and the Commission considers that Rapamune brings an improvement in the medical service rendered minor ASMR IV in the therapeutic strategy of sporadic lymphangioleiomyomatosis with moderate pulmonary involvement or deterioration of pulmonary function.

- HAS published a technology assessment report on Chiesi Pharmaceutical's Trydonis (Formoterol and Glycopyrronium bromide and Beclometasone) for treatment of severe chronic obstructive pulmonary disease in adults not treated satisfactorily by the combination of an inhaled corticosteroid and a long-acting beta-2 agonist. The medical service rendered by Trydonis is moderate in the continuous treatment of severe chronic obstructive pulmonary disease in adults.

- HAS published a technology assessment report on Chiesi Pharmaceutical's Trydonis (Formoterol and Glycopyrronium bromide and Beclometasone) for treatment of moderate COPD in adults not treated satisfactorily by the association of an inhaled corticosteroid. The medical service rendered by Trydonis remains insufficient to justify taking charge of national solidarity in the treatment of moderate COPD in adults not treated satisfactorily by the association of an inhaled corticosteroid.

- HAS published a technology assessment report on Gilead Science Inc.'s Viread (Tenofovir Disoproxil) for the treatment of pediatric patients aged 2 to less than 12 years suffering from chronic hepatitis B, with compensated liver disease. The medical service rendered by Viread is important in extending the indication for the treatment and the Commission considers that VIread brings, in the same way as BARACLUDE and PEGASYS, an improvement in the medical service rendered minor ASMR IV in the management of chronic hepatitis B in children aged 2 to less than 12 years old with compensated liver disease.

- HAS published a technology assessment report on Sanofi's Dupixent (Dupilumab) for the treatment of moderate to severe atopic dermatitis in adolescents aged 12 years and over who requires systemic treatment. The medical service provided by the Dupixent 200 mg and 300 mg specialties is important in the indication and in the dosages of the MMA and Dupixent 200 mg and 300 mg specialties provide an improvement in the rendering of moderate medical service ASMR III in the management of moderate to severe atopic dermatitis in adolescents aged 12 and over which requires systemic treatment.

- HAS published a technology assessment report on Chiesi Pharmaceutical's Trimbow (Formoterol and Glycopyrronium bromide and Beclometasone) for the treatment of severe chronic obstructive pulmonary disease in adults not treated satisfactorily by the combination of an inhaled corticosteroid and a long-acting beta-2 agonist. The medical service rendered by Trimbow is moderate in the continuous treatment of severe chronic obstructive pulmonary disease in adults.

- HAS published a technology assessment report on Chiesi Pharmaceutical's Trimbow (Formoterol and Glycopyrronium bromide and Beclometasone) for treatment of moderate COPD in adults not treated satisfactorily by the association of an inhaled corticosteroid. The medical service rendered by Trimbow remains insufficient to justify taking charge of national solidarity in the treatment of moderate COPD in adults not treated satisfactorily by the association of an inhaled corticosteroid.

- France's HTA body HAS published a technology assessment report on Merck's Bavencio (avelumab) for monotherapy treatment of adult patients with metastatic Merkel cell carcinoma previously treated with chemotherapy. The medical service rendered by Bavencio remains important in the monotherapy treatment of adult patients with metastatic Merkel cell carcinoma previously treated with chemotherapy and the Commission is not able to assess the therapeutic contribution of Bavencio compared to usual treatment. Consequently, it considers that Bavencio in monotherapy does not bring any improvement in the medical service rendered ASMR V in the management of patients with metastatic Merkel cell carcinoma previously treated with chemotherapy.

HTA Decisions: France

- HAS published a technology assessment report on AstraZeneca's Tagrisso (osimertinib) for first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with activating mutations in the epidermal growth factor receptor. The medical service rendered by Tagrisso is important in this extension of the marketing authorization indication and the Commission considers that Tagrisso brings an improvement in the medical service rendered moderate ASMR III compared to ITK anti-EGFR TARCEVA (erlotinib) and IRESSA (gefitinib), in the treatment of non-small cell lung cancer locally advanced or metastatic with activating mutations of EGFR in the first line.
- HAS published a technology assessment report on Cheisi's Beclospin (Beclometasone) for treatment of asthma in adults and children, when pressurized or dry powder inhalers cannot be used or are unsuitable and in treatment of children aged 5 years or less, with recurrent episodes of wheezing. The transparency committee noted that the medical service rendered by Beclospin is important in the indication of the Marketing Authorization and These specialties do not improve the medical service provided (ASMR V) in the therapeutic strategy.
- HAS published a technology assessment report on Eli Lilly's Cyramza (ramucirumab) for first-line treatment of adult patients with metastatic non-small cell lung cancer with activating mutations in the epidermal growth factor receptor in combination with erlotinib. The committee gave Cyramza is weak in this extension of the marketing authorization indication. The Commission considers that Cyramza does not improve the medical service provided ASMR V in combination with erlotinib in the first-line treatment of adult patients with metastatic non-small cell lung cancer with mutations activators of the epidermal growth factor receptor.
- HAS published a technology assessment report on Janssen's Imbruvica (Ibrutinib) for the treatment of adult patients with Waldenström macroglobulinemia in combination with rituximab. The medical service provided by Imbruvica (ibrutinib) in combination with rituximab is insufficient to justify treatment by national solidarity in the treatment of adult patients with Waldenstrom macroglobulinemia.
- HAS published a technology assessment report on Novartis' Lucentis (Ranibizumab) for the extension of indication to the treatment of retinopathy of prematurity. The medical service provided by Lucentis 10 mg / ml, solution for injection is insufficient in the extension of indication to the treatment of retinopathy of prematurity to justify treatment by national solidarity.
- HAS published a technology assessment report on Sandoz's Rixathon (rituximab) for the treatment of patients with pemphigus vulgaris and granulomatosis with polyangiitis and microscopic polyangiitis (for more details, see Marketing Authorization). The medical service provided by Rixathon is important "in combination with glucocorticoids, for the treatment of adult patients with severe and active polyangiitis with polyangiitis (Wegener's disease) and microscopic polyangiitis" and "in the treatment of patients with moderate to severe pemphigus vulgaris.

HTA Decisions: United Kingdom

- NICE has published a technical assessment report on Celgene's Revlimid (Lenalidomide) for previously treated follicular lymphoma (grade 1 to 3A) in adults. The committee noted that clinical-effectiveness evidence shows that, when people take lenalidomide with rituximab, their follicular lymphoma does not progress as quickly as when they take rituximab with chemotherapy. There is also evidence that lenalidomide with rituximab helps people live longer than rituximab with chemotherapy, although it is too early to tell for how much longer.

Drug Approvals: Europe

NILEMDO (BEMPEDOIC ACID) was approved by the EMA for use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin; or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
COMPANY: ESPERION

NUSTENDI (BEMPEDOIC ACID & EZETIMIBE) was approved by the EMA for use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe; alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are nable to reach LDL-C goals with ezetimibe alone; or in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.
COMPANY: ESPERION

VAXCHORA (VIBRIO CHOLERAE, STRAIN CVD 103-HGR, LIVE) was approved by the EMA to prevent cholera disease in adults and children aged from 6 years.
COMPANY: EMERGENT NETHERLANDS

RUXIENCE (RITUXIMAB) was approved by the EMA for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and pemphigus vulgaris (PV).
COMPANY: PFIZER

TREPULMIX (TREPROSTINIL) was approved by the EMA in the treatment of chronic thromboembolic pulmonary hypertension (CTEPH), a condition linked with high blood pressure in the lungs caused by blood clots.
COMPANY: SCIPHARM SARL

BUDESONIDE / FORMOTEROL TEVA PHARMA B.V. (FORMOTEROL & BUDESONIDE) was approved by the EMA for the treatment of asthma in adults for whom a combination product is considered appropriate. It can be used in patients: whose disease is not adequately controlled by treatment with other asthma medicines called corticosteroids and 'short-acting beta-2 agonists' taken by inhalation; whose disease is adequately controlled by treatment with corticosteroids and 'long-acting beta-2 agonists' taken by inhalation.
COMPANY: TEVA

CINACALCET ACCORDPHARMA (CINACALCET) was approved by the EMA to treat: secondary hyperparathyroidism (overactive parathyroid glands) in adults and children aged 3 years and older with serious kidney disease who need dialysis (to clear their blood of waste products); hypercalcaemia (high blood calcium levels) in adults with cancer of the parathyroid glands or with primary hyperparathyroidism when the parathyroid glands cannot be removed.
COMPANY: ACCORD

RYBELSUS (SEMAGLUTIDE) was approved by the EMA for the treatment of adults with insufficiently controlled type 2 diabetes to improve glycaemic control as an adjunct to diet and exercise.
COMPANY: NOVO NORDISK

TIGECYCLINE ACCORD (TIGECYCLINE) was approved by the EMA to treat adults and children older than eight years with complicated infections of the skin and soft tissue (the tissue below the skin), but not foot infections in people with diabetes.
COMPANY: ACCORD

SEVENFACT (COAGULATION FACTOR VIIA (RECOMBINANT)-JNCW) was approved by the U.S. FDA for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with hemophilia A or B with inhibitors (neutralizing antibodies).
COMPANY: LFB

Drug Approvals: United States

BRAFTOVI (ENCORAFENIB) was approved for METASTATIC COLORECTAL CANCER (BRAFV600E-CETUXIMAB) by the FDA for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy.
COMPANY: PFIZER

DOLUTEGRAVIR & LAMIVUDINE & TENOFOVIR DISOPROXIL FUMARATE (DOLUTEGRAVIR & LAMIVUDINE & TENOFOVIR DISOPROXIL) was approved by the FDA for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg.
COMPANY: CELLTRION

JELMYTO (MITOMYCIN) was approved by the FDA for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).
COMPANY: UROGEN PHARMA

REBLOZYL (LUSPATERCEPT-AAMT) was approved for ANEMIA (MYELODYSPLASTIC SYNDROME) by the FDA for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.
COMPANY: BRISTOL MYERS SQUIBB, ACCELERON

KOSELUGO (SELUMETINIB) was approved by the FDA for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).
COMPANY: ASTRAZENECA

TUKYSA (TUCATINIB) was approved by the FDA in combination with trastuzumab and capecitabine for treatment of 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.
COMPANY: SEATTLE GENETICS

PEMAZYRE (PEMIGATINIB) was approved by the FDA for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.
COMPANY: INCYTE

EMERPHED (EPHEDRINE) was approved by the FDA for the treatment of clinically important hypotension occurring in the setting of anesthesia.
COMPANY: NEXUS PHARMS

IMBRUVICA (IBRUTINIB) was approved for CLL (RITUXIMAB) by the FDA with rituximab for the initial treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
COMPANY: PHARMACYCLICS

TRODELVY (SACITUZUMAB GOVITECAN-HZIY) was approved by the FDA for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.
COMPANY: IMMUNOMEDICS

ONGENTYS (OPICAPONE) was approved by the FDA as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.
COMPANY: NEUROCRINE

MENQUADFI (MENINGOCOCCAL (GROUPS A, C, Y, W) CONJUGATE VACCINE) was approved by the FDA for the prevention of invasive meningococcal disease in persons 2 years of age and older.
COMPANY: SANOFI

Drug Launches: Europe & US

Country	Generic Name	Product Group	Company	Indication	Approval Date	Launch Date
SPAIN	RISANKIZUMAB	SKYRIZI	ABBVIE	PSORIASIS	26/04/2019	01/04/2020
GERMANY	GIVOSIRAN	GIVLAARI	ALNYLAM	ACUTE HEPATIC PORPHYRIA	02/03/2020	15/04/2020
FRANCE	DAPAGLIFLOZIN	FORXIGA	ASTRAZENECA	DIABETES MELLITUS (TYPE 2)	11/11/2012	01/04/2020
FRANCE	METFORMIN & DAPAGLIFLOZIN	XIGDUO	ASTRAZENECA	DIABETES MELLITUS (TYPE 2)	16/01/2014	01/04/2020
UNITED STATES	SELUMETINIB	KOSELUGO	ASTRAZENECA	NEUROFIBROMATOSIS	10/04/2020	10/04/2020
GERMANY	AUTOLOGOUS CD34+	ZYNTEGLO	BLUEBIRD	THALASSEMIA (PEDIATRIC)	29/05/2019	01/04/2020
UNITED STATES	PEMIGATINIB	PEMAZYRE	INCYTE	METASTATIC CHOLANGIOCARCINOMA	17/04/2020	20/04/2020
FRANCE	APALUTAMIDE	ERLEADA	JANSSEN	(FGFR2+)	14/01/2019	01/04/2020
UNITED KINGDOM	TREOSULFAN	TRECONDI	MEDAC	METASTATIC CASTRATION-SENSITIVE	20/06/2019	01/04/2020
UNITED STATES	OSILODROSTAT	ISTURISA	RECORDATI	PROSTATE CANCER	06/03/2020	10/04/2020
UNITED STATES	RABIES, INACTIVATED	IMOVAX	SANOFI	OVARIAN CANCER	N/A	03/04/2020
UNITED STATES	TUCATINIB	TUKYSA	SEATTLE GENETICS	CUSHING'S SYNDROME	17/04/2020	17/04/2020
UNITED STATES	CENOBAMATE	XCOPRI	SK LIFE SCIENCE	RABIES	21/11/2019	19/04/2020

Price Changes: Europe & US

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change	First Pricing Date
GERMANY	LEFLUNOMIDE	ARAVA	SANOFI	IMMUNOSUPPRESSANTS	-9.21%	15/07/2004
GERMANY	TERIFLUNOMIDE	AUBAGIO	SANOFI	IMMUNOSUPPRESSANTS	+10.11%	01/10/2013
GERMANY	RIVASTIGMINE	EXELON	NOVARTIS	NEUROLOGY	-12.33%	15/07/2004
GERMANY	CLOZAPINE	LEPONEX	MYLAN	NEUROLOGY	-12.04%	15/07/2004
GERMANY	BUPRENORPHINE	NORSPAN	GRUNENTHAL	NEUROLOGY	-18.50%	15/01/2007
GERMANY	OXYCODONE	OXYGESIC	MUNDIPHARMA	NEUROLOGY	-7.54%	15/07/2004
GERMANY	ROPINIROLE	REQUIP	GLAXOSMITHKLINE	NEUROLOGY	-12.89%	15/07/2004
GERMANY	METHYLPHENIDATE	RITALIN	NOVARTIS	NEUROLOGY	-5.63%	15/07/2004
GERMANY	PRAMIPEXOLE	SIFROL	BOEHRINGER INGELHEIM	NEUROLOGY	-16.38%	15/07/2004
UNITED KINGDOM	INSULIN GLARGINE & LIXISENATIDE	SULIQUA	SANOFI	DIABETOLOGY	-5.26%	19/02/2019
UNITED STATES	CLADRIBINE	MAVENCLAD	EMD SERONO	IMMUNOSUPPRESSANTS	+6.00%	02/04/2019

Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	MNF (EUR)	OLD MNF	Change	%Change
SANOFI	AUBAGIO	TERIFLUNOMIDE	AUBAGIO TABLETS 1 PACK 28 TABS 14 MG	805.84	731.86	+73.98	+10.11%
SANOFI	AUBAGIO	TERIFLUNOMIDE	AUBAGIO TABLETS 1 PACK 84 TABS 14 MG	2417.51	2195.59	+221.92	+10.11%
SANOFI	CABLIVI	CAPLACIZUMAB	CABLIVI INJ 1 LYO PWDR VIAL 1 ML 10 MG	3577.89	3635.44	-57.55	-1.58%
SANOFI	CABLIVI	CAPLACIZUMAB	CABLIVI INJ 7 LYO PWDR VIAL 1 ML 10 MG	25045.23	25448.08	-402.85	-1.58%
BRISTOL MYERS SQUIBB	OPDIVO	NIVOLUMAB	OPDIVO INFUSION 1 VIAL 10 ML 100 MG	1054.48	1037.87	+16.61	+1.60%
BRISTOL MYERS SQUIBB	OPDIVO	NIVOLUMAB	OPDIVO INFUSION 1 VIAL 4 ML 40 MG	421.79	415.15	+6.64	+1.60%
FRESENIUS	VELTASSA	PATIROMER CALCIUM	VELTASSA ORAL PWDR 1 PACK 30 SACHET 16.8 G	183.28	191.25	-7.97	-4.17%
FRESENIUS	VELTASSA	PATIROMER CALCIUM	VELTASSA ORAL PWDR 1 PACK 30 SACHET 8.4 G	183.28	191.25	-7.97	-4.17%
BRISTOL MYERS SQUIBB	YERVOY	IPILIMUMAB	YERVOY INFUSION 1 VIAL 10 ML 50 MG	3093.49	3062.86	+30.63	+1.00%
BRISTOL MYERS SQUIBB	YERVOY	IPILIMUMAB	YERVOY INFUSION 1 VIAL 40 ML 200 MG	12373.94	12251.44	+122.50	+1.00%
FRESENIUS	VELTASSA	PATIROMER CALCIUM	VELTASSA ORAL PWDR 1 PACK 30 SACHET 16.8 G	183.28	191.25	-7.97	-4.17%
FRESENIUS	VELTASSA	PATIROMER CALCIUM	VELTASSA ORAL PWDR 1 PACK 30 SACHET 8.4 G	183.28	191.25	-7.97	-4.17%
BRISTOL MYERS SQUIBB	YERVOY	IPILIMUMAB	YERVOY INFUSION 1 VIAL 10 ML 50 MG	3093.49	3062.86	+30.63	+1.00%
BRISTOL MYERS SQUIBB	YERVOY	IPILIMUMAB	YERVOY INFUSION 1 VIAL 40 ML 200 MG	12373.94	12251.44	+122.50	+1.00%

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