



2020 Anylam Patient Access Philosophy Report

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Chen, living with hATTR amyloidosis, and his wife Kaline (Brazil)

When we first published our Patient Access Philosophy in 2017,

we had no way of anticipating the extraordinary developments of 2020. This year, in developing our second progress report in the midst of a global health crisis, the way we think about and approach patient access seems more urgent than ever. We firmly believe that it's not enough for companies to innovate new medicines. Our job is to listen, respond, and help as many people as possible who need access to these treatments and associated care. People deserve an opportunity to lead fuller, healthier lives...today. Not someday.

Our commitment is guided by quantifiable and transparent metrics that encourage us to hold ourselves accountable where we can help patients overcome barriers in obtaining our medicines. What are the results?

In the United States, public and commercial insurance plans cover 98 percent of patients who are prescribed our first marketed treatment, ONPATTRO® (patisiran), as well as over 90 percent of patients on our second treatment, GIVLAARI® (givosiran). We have not raised the price of either product since launch. For those receiving ONPATTRO and GIVLAARI through a commercial plan, and enrolled in Alnylam Assist®, our patient services and education program, more than three quarters of patients face no copays at all.

But access isn't just about insurance coverage. Patients and families suffering rare disorders often seek help in understanding their condition and what the future may

hold. To date, nearly 30,000 people have received free third-party genetic testing through a program called Alnylam Act®, which is available to people in the U.S., Canada and Brazil to help them reach a diagnosis and make more informed healthcare decisions.

Rare conditions don't recognize national borders. That's why patient access to treatment is a global priority. At present, patients have access to our three approved therapies in 24 countries via direct reimbursement contracts and 34 distributor agreements worldwide. In Europe, we are also broadening the reach of educational efforts through an advocacy support program called Patient Empowerment Group for Access and Sustainability (PEGASUS), which is now available in 14 countries.

With patient access in mind, we've negotiated nearly 30 value-based agreements with U.S. payers, two-thirds of them for ONPATTRO and the rest for GIVLAARI. These aren't one-size-fits-all guarantees that promise real-world outcomes will match clinical trial endpoints. Rather, we listen to payers' concerns, in the same way we listen to patients and physicians, and tailor our approach to respond to those concerns. Payer feedback has been core to our efforts. In Europe and other markets where value-based agreements are less common, our approach is proving to be a positive one: our therapies are being reimbursed faster than the average for other orphan drugs.

Especially in times like these, access is about flexibility in points of care as much as it is about addressing financial burdens and coverage. Months before the novel coronavirus appeared, we began analyzing

barriers facing patients who wished to be infused with ONPATTRO in their own homes. Over the course of 2020, we've seen health authorities relaxing some existing constraints in ways we believe set the stage for innovation in the delivery of care, a matter of great importance to our patients even after the world emerges from the pandemic.

Alnylam's Patient Access Philosophy came into existence at a troubling moment for the biopharmaceutical industry. A series of "bad actors" participated in blatant price gouging, in one case increasing the list price of the product, meant for HIV and cancer patients, by 5,000 percent. In 2020, Alnylam leaders joined more than 200 organizations across the U.S. and Europe to make a public commitment against this and other unethical acts of profiteering with a pledge to collaborate with key parties in the healthcare system to assure patient access, including in the U.S. a pledge to banish unreasonable price increases on our respective medicines.

Our pledge in 2017 was our first stance in accountability for our delivery of value and access. At our best, biotechnology companies reinvent the way science and medicine treat disease. Alnylam remains relentless in ensuring that patients who need our innovation have access to it. The reason is simple. Patients should never have to wait for hope.



John Maraganore, PhD, Chief Executive Officer,
Alnylam Pharmaceuticals

Section 1: Helping patients navigate today's healthcare system

Prior to the COVID-19 outbreak, Anylam had been working for several years in the U.S. to break down barriers that prevented patients with rare diseases from being administered treatment in their homes. Patients had made it clear that they sought alternatives more aligned with their preferred way of accessing treatment, but COVID-19 dramatically raised the stakes. Worldwide, some people were being forced to choose between discontinuing treatment and risking infection, and such a stark choice motivated Anylam to increase its advocacy efforts to improve point of care options and make home infusion more accessible.

The COVID-19 pandemic caused our Patient Services team to expand its efforts to address point of care challenges. The team was determined to help patients who wished to continue treatment, remain adherent to their dosing regimens: eight months into the pandemic, time-to-therapy has returned to pre-pandemic levels. In Germany, we undertook similar efforts and while 90 percent of rare disease patients

overall experienced interruptions in care at the height of the pandemic, according to a EURORDIS-Rare Diseases Europe study (May 2020), none of the patients on Anylam therapy postponed treatment.

To complement our work with regulators during the early months of the pandemic, we reached out to patients and healthcare providers to understand and help address their needs, where possible.

Support for unprecedented times

In late March of 2020, an Anylam Assist® Case Manager was conducting a patient check-in call, with a patient who was prescribed and treated with ONPATTRO® (patisiran). The Case Manager learned that they had missed their most recent scheduled dose of ONPATTRO because there was great concern about the risk of getting sick if they entered an infusion center. The patient had received both a liver and heart transplant, and his physician feared that if he contracted COVID-19 that he could die. Although the patient was anxious to return to treatment, he had been under quarantine for three weeks and did not plan on leaving his home for the foreseeable future.

Anylam Assist was able to facilitate site of care transitions for many patients, the majority of whom did not miss a dose, in the midst of a global pandemic. Within a few weeks, the patient was able to resume treatment at home.

Although many people continue to feel vulnerable and isolate during the pandemic, both patients and their physicians have expressed gratitude for the changes that have enabled uninterrupted treatment.



For patients living with rare diseases, barriers to access, affordability, testing and diagnosis can seem overwhelming. Our response has been the creation and evolution of patient-facing programs that provide resources, support, and services to people in need.

Our support for patients on their journey began with the introduction of the Alnylam Act program in 2014, which sponsors no-charge third-party genetic testing and counseling. To date, out of patients genotyped through Alnylam Act in the U.S., Canada and Brazil, there have been nearly 1,800 positive test results for mutations for three rare and ultra-rare diseases, helping them to speed their time to diagnosis.

Through Alnylam Assist, we offer personalized support to patients on Alnylam therapies by helping them understand their insurance coverage and providing education. Over the past year, we've seen a significant rise in the number of patients taking advantage of our Alnylam Assist Patient Education Liaisons, and a related increase in patient satisfaction scores. The rapid work to address patients in need during the pandemic has been thanks to the Patient Services team. Our Case Managers are agile problem solvers, helping patients to navigate the sudden obstacles of day-to-day life, and those presented by the pandemic.

As a company, we're also on a journey of building strong relationships with our patient communities. As we help educate patients seeking proper diagnosis and care, we are learning from them. Patient insights have also been instrumental in helping us develop more effective clinical and real-world endpoints to streamline access to new RNAi therapeutics.

This was the case with our most recently approved therapy, OXLUMO™ (lumasiran). By seeking input from the patient community, along with our payer partners, we were able to announce agreements-in-principle for a new, value-based framework. This framework is designed to address payer concerns specific to these patients, overcoming potential access barriers and improving speed of access.

At Alnylam, we believe that these efforts create a virtuous cycle within the innovation ecosystem. Proactive actions for better access today lead to further innovation that will enable us to help even more people in the future.

“For me, as a working person, it's great to no longer have to take vacation time for the infusions, thanks to flexible appointments.”

Home care patient on Alnylam therapy, Germany

Lauren, an Alnylam Assist Case Manager (USA)



Key Anylam Programs



The Anylam Assist[®] support program offers personalized services throughout treatment with ONPATTRO[®] (patisiran), GIVLAARI[®] (givosiran), and OXLUMO[™] (lumasiran). Services help patients understand insurance coverage for therapy and options and eligibility for financial support, materials to help start conversations with physicians and family members, and information on patient advocacy organizations and other resources.



Anylam Act[®] is a sponsored, no-charge, third-party genetic testing and counseling program for patients with a family history or suspected diagnosis of hATTR amyloidosis, acute hepatic porphyria, or primary hyperoxaluria Type 1. The Anylam Act program was developed to reduce barriers to genetic testing and counseling as a way of helping people make more informed decisions about their health. Healthcare professionals who use this program have no obligation to recommend, purchase, order, prescribe, promote, administer, use or support any Anylam product.

In Europe, Anylam has expanded its educational and support efforts through digital resources, new initiatives and trainings, and genetic testing.



- **Patient Empowerment Group for Access and Sustainability (PEGASUS):** supports advocacy understanding of the access environment by ensuring they are informed, empowered partners through the exchange of best practices and involvement in Health Technology Assessment processes.
- **Regional disease education websites:** two European patient advocacy sites for hATTR amyloidosis and acute hepatic porphyria designed to help provide useful resources for patients or those at risk, and to help drive earlier, more accurate diagnosis.
- **GENILAM:** a genetic testing and disease awareness program in Italy that aims to spread knowledge about hATTR amyloidosis where there are limited resources. The program supports physician education on the importance of early and correct diagnosis, and has been shown to improve diagnosis rates and timing.

Helping patients from clinical development through commercialization



U.S. patients enrolled in Alnylam Assist:

- >540 for ONPATTRO or GIVLAARI
- Connected with a Patient Education Liaison
 - 93.47% ONPATTRO
 - 100% GIVLAARI
- Satisfaction score
 - 4.9/5 ONPATTRO
 - 4.7/5 GIVLAARI



Longest duration of treatment:

- 7 years ONPATTRO
- 4 years GIVLAARI



11 programs providing access to investigational medicines currently in clinical development



Home administration:

- 20% average U.S. patients on ONPATTRO and GIVLAARI
- 7 EU countries offer homecare for ONPATTRO



>450 patients worldwide to date who received ONPATTRO, GIVLAARI or OXLUMO under compassionate access



Infusion-ready sites:

- >280 U.S.

Clearing financial barriers



U.S. patients enrolled in commercial copay program:

- >130 on ONPATTRO



U.S. patients with zero cost-share:

- 70% ONPATTRO
- 88% GIVLAARI

“Many patients with devastating rare diseases encounter tremendous challenges for years, and cannot wait for a commercial drug to become available in their country. Expanded access programs and compassionate use can fundamentally change lives for patients, caregivers and advocates. We have established programs to help qualifying patients whose treating physicians seek early access to our innovative medicines when no other options are available.”

Karen Frascello, Director of Global Medical Affairs and Early Access at Alnylam Pharmaceuticals and author of The Global Guide to Compassionate Use Programs



Education and improving diagnosis



- 55 global patient education events hosted by Alnylam since ONPATTRO approval



European PEGASUS advocacy education program in 2020

- 14 countries
- 28 advocates
- 21 patient organizations



- 24 grants provided to patient organizations globally since ONPATTRO launch



- ~30,000 people genotyped through Alnylam Act across three programs (TTR, AHP, PH1)
- 1,800 positive test results for mutations related to TTR, AHP, PH1
- >775 people who participated in GENILAM local genetic program in Italy since June 2019

“Particularly for patients with rare and ultra-rare diseases, financial and administrative barriers too often get in the way of crucial diagnoses. Alnylam Act is important because it allows patients to make a choice about genetic testing that isn’t influenced by out-of-pocket cost concerns.”

Elizabeth Fieg, MS, CGC, Senior Genetic Counselor, Brigham and Women’s Hospital

“

Acute hepatic porphyria (AHP) is an unpredictable and unforgiving group of diseases, which can significantly interfere with activities of daily life, including the disruption of sleep and work. AHP often leads to lack of socialization and ultimately, a life of isolation. Thus, the development of new treatments was essential. Long before their therapy became available, Alnylam sought feedback from our organization each step of the way. Our synergetic working relationship has translated into resources that matter: Alnylam Assist is critical for AHP patients and their caregivers seeking time-sensitive guidance to secure access to potentially life-altering AHP treatments.”



Desiree Lyon, Global Director of the American Porphyria Foundation (APF)

The symptoms of AHP often resemble those of other diseases. Misdiagnosis is common and patients can wait years for an accurate and confirmed diagnosis. Early and accurate diagnosis can make a meaningful difference in a person’s ability to maintain their quality of life by:

- Avoiding complications from misdiagnoses, including unnecessary hospitalizations and surgeries
- Managing factors that may trigger attacks
- Understanding what is happening in their bodies and why

Alnylam partnered with the APF to provide support, resources and programs that assist with access to care. We also partner to educate healthcare professionals on identifying and managing AHP.

“For many conditions, early diagnosis can inform management and can help mitigate the risk of disease progression and complications. For patients with rare diseases, in particular, delayed diagnosis often leads to significant anxiety and increased pain and suffering. Access to genetic testing is a critical step in not only establishing the diagnosis and empowering the patient to become knowledgeable about their disease, but also has a downstream impact on family members. Genetic testing of at-risk family members can help allay anxiety by patient education and avoidance of risk factors, as well as improve outcomes with targeted disease management.”

Manisha Balwani, MD, MS, FACMG, Professor, Division of Medical Genetics and Genomics, Department of Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai



Nathan, living with acute hepatic porphyria (USA)

Section 2: Breaking down barriers to expedite access to treatment

When launching new products, biotech companies often focus on the U.S. market, the largest in the world. At Anylam, we find this path too narrow. Rare diseases strike patients and families everywhere, and we endeavor to gain regulatory approval and pricing and reimbursement across a broad group of countries, which is steadily increasing.

We view patient access as a responsibility requiring innovation in developing mechanisms and models that remove barriers to access, by responding to the concerns of payers and physicians.

Anylam devoted 18 years and nearly \$6 billion to developing our first three treatments for rare diseases, so it is imperative now that we reach as many patients as possible throughout the world with these new medicines. Our first therapy, ONPATTRO, is now reimbursed in more than 23 countries worldwide.

More than 98 percent of patients in the U.S. covered by commercial or government plans have confirmed coverage for ONPATTRO and nearly 94 percent of such patients now have confirmed coverage for GIVLAARI.

Beyond U.S. borders, ONPATTRO has been approved in Canada, and European, Asian and Latin American countries, and has had significant success in receiving reimbursement. In Japan, ONPATTRO achieved commercial access three months following approval. In many European countries, ONPATTRO achieved reimbursement faster than any other drug granted orphan status by the European Medicines Agency (EMA).

In Italy, for example, the average time from EMA approval to reimbursement is 37 months for orphan drugs. Anylam cut that time frame in half – and achieved Pricing & Reimbursement (P&R) in 17 months. In Belgium, where the average time to P&R is 50 months, we achieved it in 14 months.

GIVLAARI access milestones in Canada, Europe, Middle East and Africa (CEMEA)

- Received an Improvement of Medical Benefit (ASMR) score of II in France, concluding that GIVLAARI offers significant additional therapeutic value. In 2019, only two new commercial medicines received a similar ASMR score.
- Obtained a Considerable Benefit rating in Germany and secured a strong health technology assessment (HTA) rating in Italy.
- Expanded the global reach of commercialization activities via a new partnership agreement with Taiba Middle East, a leading distributor of specialty pharmaceutical products in the Gulf Cooperation Council region.

This speed would not be possible without careful planning and a flexible, collaborative approach. As a company, we are committed to keeping this dialogue open by leading industry conversations about cost drivers for orphan medicinal products, and incorporating alternative economic frameworks that assess the value of therapies for rare diseases. Prior to approval, we approached European governments early to listen and engage. We anticipated their concerns and provided the qualitative data to arrive at consensus on value that supported the reimbursement process.

As a result, the value of our medicines has been acknowledged by payers with positive HTA ratings in key markets: in France and Germany, the ONPATTRO assessment was superior to competitor offerings and other orphan drugs; in addition, GIVLAARI has received strong ratings in Germany, France, Italy, and Portugal. In short, we spoke their language earlier in the process, which helped to expedite access to treatment for patients who need it.

Planning took a slightly different shape in the U.S. Prior to launch, we designed and proactively offered value-based arrangements (VBAs) to private and public payers. Under these agreement frameworks, Alnylam minimizes payer risk in a variety of ways that assure patient access. So far in the U.S., we've signed nearly 20 such VBA arrangements for ONPATTRO and 10 for GIVLAARI with commercial payers. Our success is beginning to inspire similar dialogue in other countries.

VBA agreements with payers are just one example of how we are implementing our Patient Access Philosophy. In the years to come, these innovative reimbursement frameworks may speed access to treatments for patients suffering other conditions, including more prevalent chronic diseases.

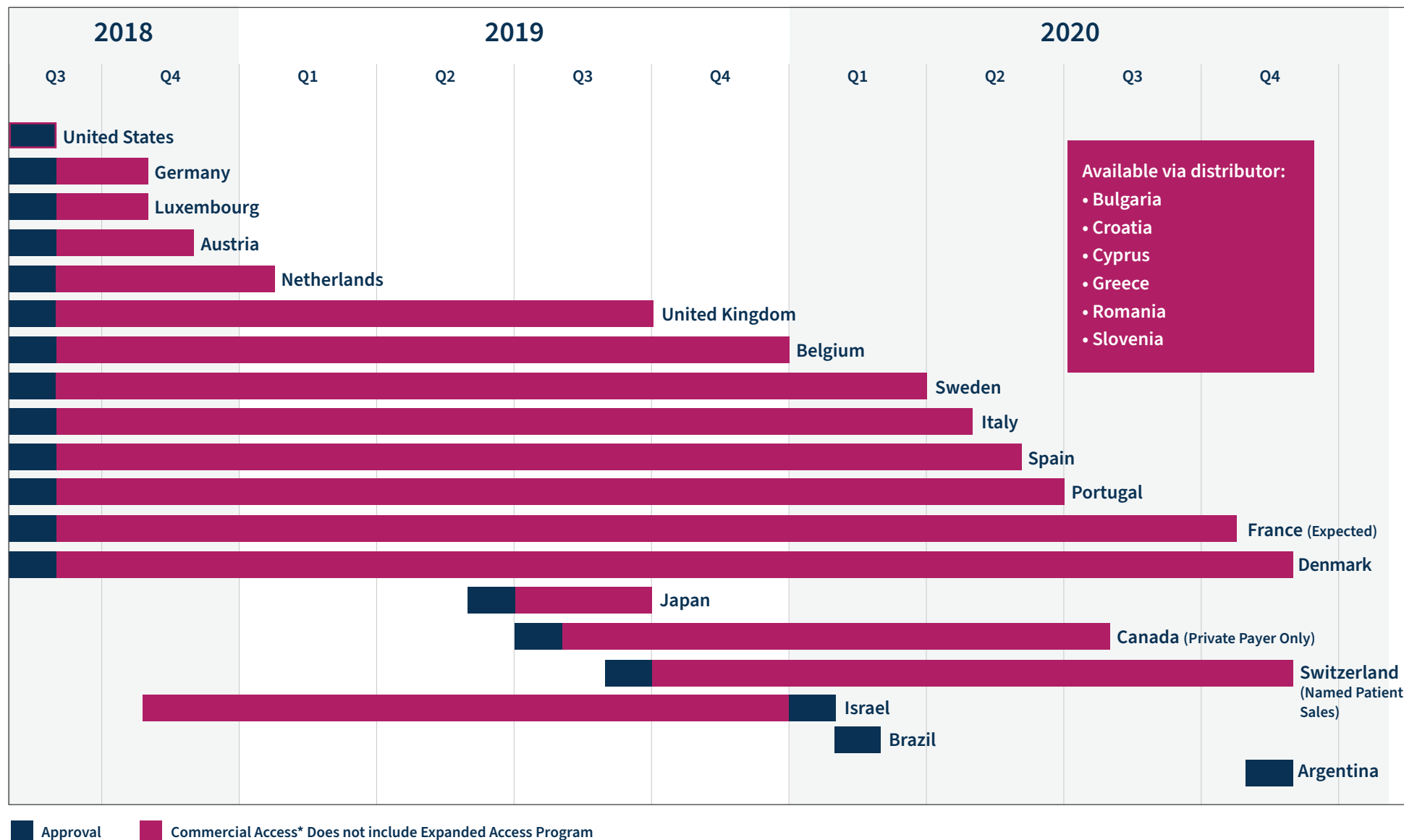
Whether evolving approaches to reimbursement or trailblazing global markets, Alnylam is breaking down barriers to access by delivering value to those who need it, making the concept of value-based care a reality.

“I know my patients who are with you are in the best of hands.”

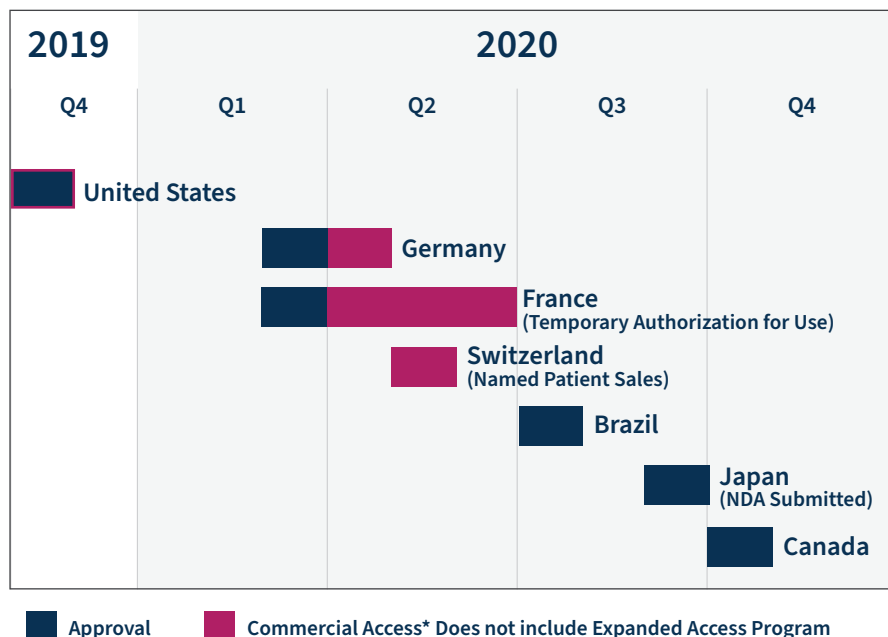
Dr. Maike Dohrn, University of Aachen, Germany



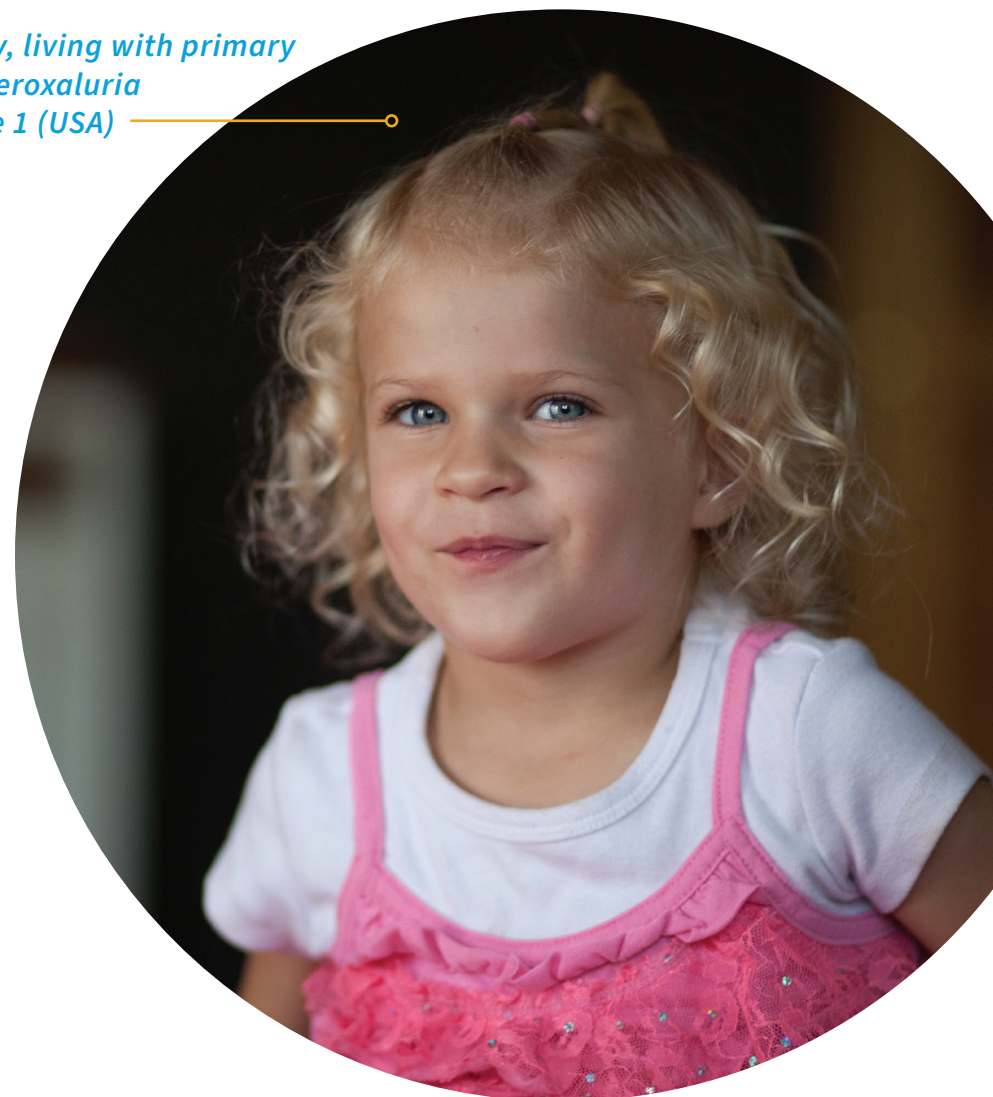
ONPATTRO Approval and Reimbursement Milestones



GIVLAARI Approval and Reimbursement Milestones



Lucy, living with primary hyperoxaluria type 1 (USA)



**NOW APPROVED FOR PATIENTS
IN THE US & EU**

 **OXLUMO™**
(lumasiran) for injection
94.5 mg/0.5 mL

Delivering value to patients and payers



Patients worldwide receiving commercial therapy:

- >1,150 ONPATTRO
- >150 GIVLAARI



CEMEA countries where patients have broad access, if prescribed:

- >50 markets have access to ONPATTRO via direct contracts or distributor agreements



U.S. lives with confirmed access to ONPATTRO or GIVLAARI across commercial, Medicare, Medicaid and other government payer categories: >98% and >90%



U.S. signed Value-based Agreements:

- 19 ONPATTRO
- 10 GIVLAARI
- 3 in principle OXLUMO



Zero price increases beyond Consumer Price Index for All Urban Consumers (CPI-U) on two launched products



11 months faster reimbursement time for ONPATTRO in Europe, than the average orphan drug

Alistair, living with hATTR amyloidosis (Canada)



Section 3: Looking forward: our commitment to patients today, for a better tomorrow

Three years ago — even before we launched our first medicine — Alnylam committed to making our therapies available to those who need them. We promised to work with all stakeholders to achieve this goal. This report tracks our progress, holds us accountable to our promise, and helps guide us to areas for future growth.

For all three of our products approved in the U.S. as of December 1, 2020, we have proactively partnered with payers, prior to launch, to forge innovative reimbursement contracts that meet their unique needs while also ensuring patient access. We recognize that no single solution can meet all payer challenges. Each drug and each patient population presents unique challenges, colored by a myriad of factors.

We've developed innovative reimbursement contracts – not 'one size fits all,' but tailored frameworks based on the needs and practical constraints of individual payers. VBAs are a core component to our approach to ensuring price is connected to the value a treatment delivers.

In the spirit of understanding and responding, Alnylam continues to evolve new frameworks that address three critical payer risks:

- 1) Is the drug the right drug for the patient with an outcome-based measure?
- 2) How many patients have the disease?
- 3) How can we ensure budget predictability for use across a wide range of ages?

Our close collaboration with payers over the years has been instructive, so much so that we determined the insights we gleaned could have value for others. The result is our new Rare Disease Trend Report that presents payers' perspectives each year on current and future rare disease management considerations and perceived challenges. Our hope is that the insights from the report will lead to more innovative approaches and opportunities for rare disease and orphan drug management – as well as applications in the realm of chronic disease.

As we continue developing new drugs and overcoming barriers to access in this golden age of medicine, our core principles guide us. This year, we've recommitted to the philosophy we outlined three years ago by signing on to two new pledges in the U.S. and Europe, helping lead the industry closer to a model that prioritizes access:



U.S. New Commitment to Patient: In early 2020, we co-signed, along with 215 biotech CEOs and leaders, a new biotechnology and pharmaceutical industry commitment to patients and the public to ensure that we act with the highest integrity and corporate responsibility — always putting the interests of patients first.

European Biotech Social Pact: Similarly, our CEO John Maraganore recently joined with more than 60 life sciences leaders of European and U.S. biotechs to sign the European Biotech Social Pact. The pact encourages biotech companies to be a force for good in partnering with European authorities, citizens and patients to create a system where scientific investment ultimately yields effective, affordable, and accessible therapeutics for future generations.



In fulfilling these commitments, and our original mission, we believe we will be serving the interests of patients, their caregivers, and healthcare providers, as well as society at large. We believe this is just the beginning.

Case Studies

Changing the way patients access medicines in the U.S.

The topic of pricing and value in rare disease can be contentious. If there's one point of agreement, it's the need for greater collaboration among manufacturers and payers. Alnylam has been a trailblazer in this regard, having forged more than 30 value-based arrangements (VBAs) with public and private insurers since 2018. In parallel, we're committed to enhancing policy environments so VBAs can support patient access in diverse therapeutic settings.

Our initiatives include advocacy for expanding and refining how VBAs are implemented between payers and innovators, as well as increasing the availability of home infusion, and more.

Need for change

The objective behind VBAs is easy to explain. Manufacturers and payers are determined to accelerate coverage decisions on behalf of patients. Manufacturers seek compensation for the outcomes that medicines deliver in the real world, though this value may yet be uncertain. This is where VBAs come in – they are designed to help assure that the value obtained by payers for a prescribed medicine will be measured over time and that the cost is more predictable.

Over the last several years, Alnylam has publicly urged the Department of Health & Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to expand or reinterpret rules to facilitate innovation around VBAs. We have also worked with states, which have explored VBA options for their Medicaid programs. In addition, Alnylam has undertaken proactive negotiations with each Medicaid agency that has received permission from CMS to execute VBAs. While focusing on rare diseases, we hope and expect that the results will extend to innovators, payers and patients in diverse therapeutic areas for years to come.

Receiving care in setting best for each patient

Many medicines require infusing patients with specialized technology in safe settings, which may include their own homes. This often entails complex operations, especially during a pandemic. But when the clinical setting changes there's a ripple effect that can impact physician compensation and cause other unintended consequences.

There are complex rules that govern the home infusion of Medicare patients in the U.S. These rules are based on decades-old precedent. Alnylam led an industry coalition that urged CMS to grant temporary allowance of home infusion in Medicare during the COVID-19 Public Health Emergency (PHE) period.

Beyond that, Alnylam believes it is critical for patients with debilitating diseases such as hATTR amyloidosis to have access to home infusion. As a result, we have advocated for CMS to adjust its long-standing rules such that ONPATTRO patients covered by Medicare may receive infusions in their homes. CMS has recently announced an intent to do this on a permanent basis in a preliminary rule-making action.

Expanding the use of VBAs

Alnylam believes a fundamental part of being an innovative company is working in novel ways with payers. However, U.S. public policies often impede manufacturer-payer discussions from achieving success. Alnylam has found innovative ways to work within the existing regulatory framework to execute VBAs. Moreover, we have also collaborated with our trade associations, industry colleagues and patient advocacy groups to advocate for additional flexibilities to enable these agreements. Earlier this year, CMS issued a new set of government pricing guidelines that, when implemented, will be more adaptable and foster new ways for industry and payers to collaborate to accelerate access to new treatment approaches and options.

Healthcare policies and regulations are often entrenched and resistant to change. Upgrading the policy environment to facilitate value-based healthcare takes long-term commitment of talent, brainpower and resources. To all of this, Alnylam says, challenge accepted!

“Being able to help problem solve with patients, by breaking it down, figuring out what next steps need to happen, who needs to be involved, and getting that end result is what inspires me to do what I do every day. I’m developing relationships with the patients and their caregivers. I get to know their families and hear about their lives and what they’ve really gone through since the time that they were diagnosed and even before.”

Calleen, Alnylam Assist Case Manager

Veronica, living with acute hepatic porphyria (Spain)



About Alnylam Pharmaceuticals

Our Science Is Changing the Way Medicine Treats Disease™

Alnylam has led the translation of RNAi (RNA interference) from Nobel Prize-winning discovery into an innovative, entirely new class of medicines. Founded in 2002 by a team of distinguished scientific leaders, Alnylam's vision is to harness the potential of RNAi therapeutics to transform the lives of people living with diseases for which there are limited or inadequate treatment options. Our pioneering work has delivered the world's first and only approved RNAi therapeutics – ONPATTRO® (patisiran) in 2018, GIVLAARI® (givosiran) in 2019 and OXLUMO™ (lumasiran) in 2020. We are advancing a deep pipeline of innovative RNAi-based medicines in four therapeutic areas: genetic medicines, cardio-metabolic diseases, infectious diseases, and central nervous system (CNS) and ocular diseases.



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*Cece, living with hATTR
amyloidosis (USA)*