Regeneron and Sanofi
DUPIXENT® (dupilumab)
Prix Galien USA 2025 "Best Biotechnology Product"
Supplemental Information

Additional Background Information about Dupixent® and Its Impact

Type 2 inflammatory diseases are largely chronic, unpredictable, extremely burdensome and life-altering. The impact of these immunological conditions is often more than physical. Across atopic dermatitis (AD), asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), and prurigo nodularis (PN), patients are more likely to suffer from mental health conditions such as anxiety and depression that compound over time.[1,2,3,4,5]

Moderate-to-severe AD

In 2017, Dupixent became the first and only FDA-approved biologic indicated to treat moderate-to-severe atopic dermatitis. From the very first Dupixent AD trials, Regeneron heard from a number of patients and investigators who reached out to share their stories, often through tears. By addressing the key inflammatory cause of AD, Dupixent was able to significantly improve patients' eczema – and give many back their lives as the first biologic approved for AD. To this day, Dupixent remains the only biologic approved for patients 6 months of age and older.

In the U.S., moderate-to-severe AD affects approximately 1.6 million adults, an estimated 389,000 adolescents, an estimated 88,000 children aged 6 to 11 years, and an estimated 75,000 infants and young children less than 6 years of age.[6]

AD is misunderstood as a superficial skin disease, but it is often associated with a debilitating rash, intense itching and skin lesions covering much of a person's body, as well as problems with sleep and daily living.[7,8,9,10] To make others understand the horror of this disease, many patients explain that the moderate-to-severe form of this disease is like having poison ivy over half your body surface, but which never goes away. People with moderate-to-severe forms of the disease usually cannot control their symptoms with topical medications. Before Dupixent, these patients had to be prescribed systemic steroids or broad immune-suppressant medicines,[11,12] which are often ineffective, and also run the risk of serious side effects if used long-term.[13] Because of the constant pain and itch, which also disrupts sleep and working ability, AD imposes a significant economic impact (billions of dollars annually in the U.S. alone)[14] and, even more importantly, has one of the highest rates of associated mental health disorders and suicidal ideation.[15,16,17]

Dupixent has revolutionized the treatment of this disease. In AD clinical studies, heavily pre-treated patients saw a remarkable 70-80% average improvement from baseline, with significantly improved sleep, anxiety, depression and quality of life.[18,19] Dupixent was well tolerated, without the immunosuppressive side effects common to other classes of systemic medicines. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for moderate-to-severe atopic dermatitis.*

Moderate-to-severe asthma

When Dupixent was approved for moderate-to-severe asthma in 2018, it became the first biologic to demonstrate consistent benefit in terms of both reducing asthma exacerbations as well as increasing lung function. Additionally, Dupixent is the only biologic approved for oral corticosteroid-dependent asthma, regardless of phenotype, and is the first available in the U.S.

for at-home use – providing a critical new option for patients at serious risk for asthma attacks. Dupixent is also approved for use with other asthma medicines as a maintenance treatment of moderate-to-severe eosinophilic or oral steroid-dependent asthma in patients aged 6 years and older whose asthma is not controlled with their current asthma medicines.

Moderate-to-severe asthma affects approximately 900,000 people aged 12 years and older in the U.S. and an estimated 75,000 children aged 6 to 11.[6] These patients experience difficulty breathing and are at risk of severe asthma attacks (exacerbations) requiring emergency room visits or hospitalizations.[20]

Oral corticosteroids (OCS) can provide relief for severe, short-term symptoms. However, current asthma guidelines suggest limiting chronic use to the most severe patients due to the potential for serious side effects.[21,22,23]

After its initial approval in October 2018, Dupixent became the first biologic approved for both moderate and severe asthma patients with an eosinophilic phenotype (raised blood eosinophils), OCS-dependent asthma (regardless of biomarkers), and with the potential for self-administration at home.[18] In clinical studies, Dupixent significantly reduced asthma exacerbations, improved lung function and reduced or eliminated OCS use. In children aged 6 to 11 years, Dupixent is the only biologic medicine to improve lung function in a randomized Phase 3 trial. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for asthma.*

CRSwNP

Dupixent was the first FDA-approved medicine for adults with CRSwNP, changing the treatment paradigm and giving new hope to the many patients for whom systemic corticosteroids and surgery did not provide relief.

An estimated 90,000 people have CRSwNP in the U.S., and they suffer from a range of debilitating symptoms caused by obstruction of their sinuses and nasal passages.[6] These patients can have other type 2 inflammatory diseases as well – most notably asthma - which adds to their overall burden of disease.[24] Common care for these patients includes systemic steroids or nasal surgery, which often do not provide complete disease control.[24]

In clinical studies, Dupixent significantly reduced nasal polyp size, improved congestion and loss of smell while also reducing the need for surgery and systemic corticosteroids.[18] With its approval in CRSwNP, another condition with underlying type 2 inflammation, Dupixent's ability to target this important biological driver of disease was further cemented. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for CRSwNP.*

EoE

In 2022, Dupixent became the first and only FDA-approved medicine indicated to treat eosinophilic esophagitis. About 160,000 patients with EoE in the U.S. are currently being treated with therapies not specifically approved for the disease, of whom approximately 48,000 continue to experience symptoms despite multiple treatments.[6]

Common treatments for patients with EoE include disruptive and strict elimination diets to avoid food triggers, with some having to resort to invasive procedures or feeding tubes to ensure proper nutrition.[25,26]

In clinical trials, Dupixent reduced disease symptoms and esophageal inflammation compared to placebo.[18] With this first approval for Dupixent in a gastrointestinal disease, its role in addressing diseases with underlying type 2 inflammation across body systems was further established. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for EoE.*

PN

In late 2022, Dupixent became the first FDA-approved treatment specifically indicated for PN. There are about 75,000 adults in the U.S. living with PN in need of new treatment options.[6] High-potency topical steroids are commonly prescribed but are associated with safety risks if used long-term.[27]

In clinical trials, Dupixent reduced itch and skin lesions compared to placebo.[18] The approval of Dupixent for PN was its second in a dermatological disease, and established the effectiveness of targeting underlying type 2 inflammation to address both less common and prevalent chronic, inflammatory skin diseases. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for PN.*

Chronic Spontaneous Urticaria (CSU)

In 2024, CSU became the sixth indication for Dupixent approved globally.

CSU is a chronic inflammatory skin disease driven in part by type 2 inflammation, which causes sudden and debilitating hives and persistent itch. CSU is typically treated with histamine (H1) antihistamines, medicines that target H1 receptors on cells to control symptoms of urticaria. However, the disease remains uncontrolled despite antihistamine treatment in many patients, some of whom are left with limited alternative treatment options. These individuals continue to experience symptoms that can be debilitating and significantly impact their quality of life. Approximately 110,000 people aged 12 years and older suffer from uncontrolled moderate-to-severe CSU in Japan, for which there are currently limited treatments.

In Phase 3 clinical trials, Dupixent added to standard-of-care antihistamines experienced a significant reduction in itch severity compared to standard of care alone at 24 weeks. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for CSU.*

Chronic Obstructive Pulmonary Disease (COPD)

In 2024, COPD became the seventh indication for Dupixent globally, and the fifth for which it was the first-in-class for a disease. Dupixent also became the first biologic ever approved for COPD, demonstrating significant benefit in terms of reducing COPD exacerbations as well as improving lung function. Thus, Dupixent represented a novel treatment option for a population that had seen limited advancements beyond inhaled therapies for decades. *Because of its remarkable efficacy and safety profile, Dupixent is now the world's leading biologic treatment for COPD.*

Bullous Pemphigoid (BP)

In June 2025, Dupixent is on track to become the first biologic ever approved for BP, based on unprecedented efficacy and safety in its pivotal trial.

Summary of all FDA-approved Dupixent Indications

With the pending approval in BP, Dupixent will have been approved in 8 total indications – for 6 of these, Dupixent was the first approved biologic. Moreover, Dupixent will also be the world's

leading biologic for all eight of its approved indications. Across all approved indications globally, more than 1 million patients are being treated with Dupixent, with the potential for many more to benefit from this innovative medicine in the coming years.

Personal connections to atopic and allergic diseases
Many people who have been involved in the invention and development of Dupixent have a personal connection to atopic and allergic diseases, which bolsters their commitment to addressing the unmet needs of people with diseases exacerbated by type 2 inflammation.

In the early 1990s, the father of George D. Yancopoulos, M.D., Ph.D. (co-Founder, Board co-Chair, President and Chief Scientific Officer at Regeneron, who is a Principal Inventor and Developer of Dupixent) developed severe AD while undergoing lung cancer treatment, and Dr. Yancopoulos witnessed the severity of this disease first-hand. It was, in part, this experience that motivated Dr. Yancopoulos to initiate and relentlessly lead the Dupixent program for more than 30 years.

Remarkably, his own daughter subsequently developed serious AD and asthma, and she is currently a successful responder to Dupixent treatment. The person who confirmed Dupixent's action in living cells was Jamie Orengo, Vice President of Allergy and Immunity at Regeneron, who is a caregiver to her three children with AD and other allergic diseases, and who are also currently successfully being treated with Dupixent.

Regeneron and Sanofi are committed to bring Dupixent to younger patients with severe AD because of stories like the following from a physician who reached out in a letter.

> "*I met this family when she was first admitted to my children's hospital (transferred by ambulance from a community hospital ~3 hours away). Prior treatment had been cycles of prednisone, oral anti-Staph antibiotics, pound jars of triamcinolone and chronic daily sedating antihistamines.*
>
> *The family was in crisis. During hospitalizations from November through February, this girl was miserable, and unable to interact with hospital staff….THIS IS A TRULY HORRIBLE DISEASE...we had to restrain her so she wouldn't scratch herself constantly and bleed and get infections.*"
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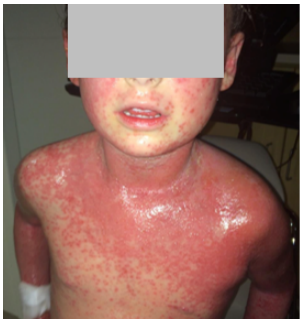
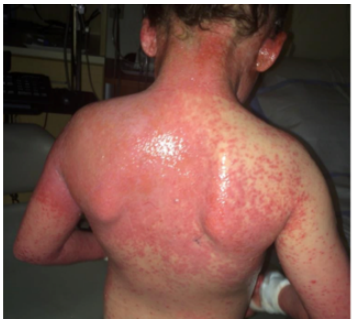
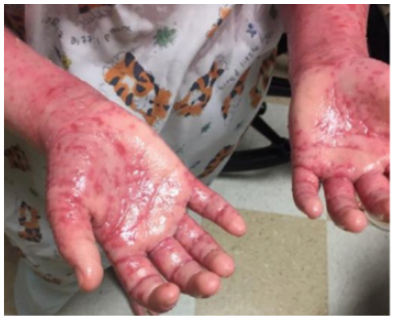
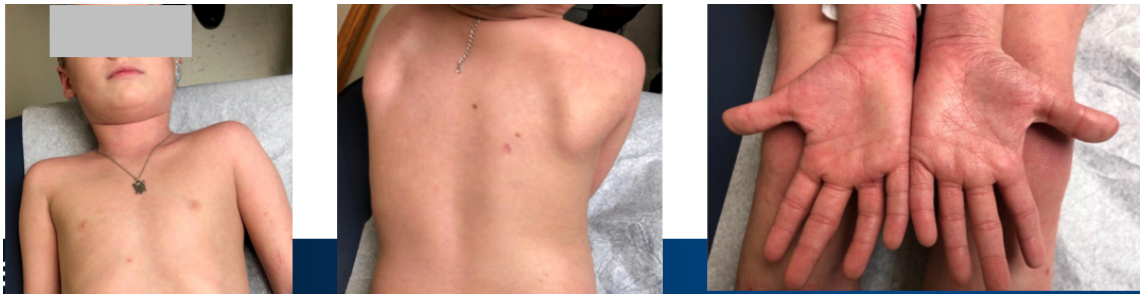
> This is how she looked when she was admitted:

"*After three doses of dupilumab, she is a pistol…THIS IS WHAT DUPILUMAB CAN DO*:"



"We all want you to know how grateful we are for dupilumab...[My patient's] quality of life has vastly improved, and so has mine… As a scientist, I don't think there is anything more rewarding than seeing that you can use the power of science to do this, to change a little girl's life…and I think that's why many of us do what we do…"

Another family with two young children living with severe AD shared their story with Regeneron. The older brother lived with severe AD and multiple food allergies, began receiving Dupixent at 17 months; the younger brother lived with severe AD and began Dupixent at 8 months. Both saw 100% skin clearance within 16 weeks of treatment.

"Having seen the effect of dupilumab started at eight months in Ralph compared with 17 months in Robin, no child with severe AD at six months unresponsive to TCS should wait any longer for dupilumab" -- mother of both children

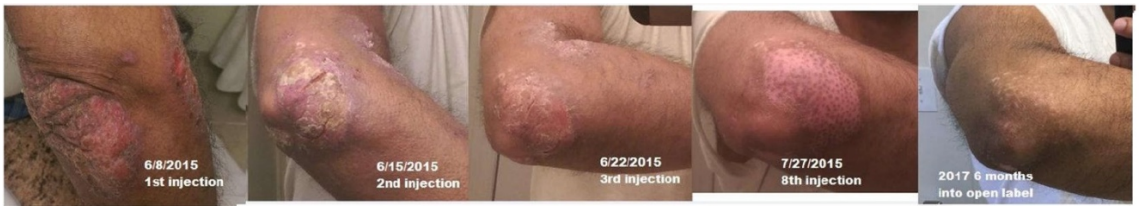
Older sibling

Younger sibling

Many patients with AD have proactively contacted Regeneron and Sanofi to tell us how Dupixent has changed their lives or shared their experiences publicly:

"Getting access to Dupixent remains the single most significant thing that has ever happened to me. It has changed the course of my life in ways that were unimaginable only a few years ago." – Sirish (adult with AD), via email[Error! Bookmark not defined.]

Images provided by Sirish during the clinical trial:



"…I am so passionate about Dupixent. This drug has been life changing for me…" – Sue (adult with AD), via email[Error! Bookmark not defined.]

"After two weeks my old skin started to shed, and I had new, normal skin for the first time in my life…I don't think I slept a full night in my entire adolescence…This medicine [Dupixent] has totally changed my way of life." – Anne (adult with AD), via email[Error! Bookmark not defined.]

"Dupixent has been life-changing for me. I was diagnosed at age 6, and I am currently 32 years of age. I have severe eczema and typically dress completely covered to prevent the stares, questions and comments. I have not been able to wear my wedding ring for 7 years because of the dyshidrotic eczema on my hands. I have never been bowling with my children, the oldest being 12. I have a hard time allowing anyone to touch me because my skin is so hypersensitive; it drives me insane. I have never slept all the way through the night. My self-esteem is highly affected, and exercise is nearly impossible with the sweat pouring and irritating the wounds. Sometimes, just getting out of bed, walking, or taking a shower is enough to send me to tears. Dupixent has given me a new life. It has given me life back. I now know what all eczema took from me, and I am forever grateful for the opportunity to be on this medication." – Nicole[28]

"I have had AD for at least 67 years of my 70 years on this earth. My life as a child was hell because of weeping medicated baths and teasing by other children. My adult life has also been equally affected by the use of corticosteroids on my skin, which is now permanently affected due to chronic steroids. When my new dermatologist brought up Dupixent about six months ago, I was skeptical and scared. I started March 22. I STOPPED itching in 24 hours. It has been a MIRACLE." – Pinkas[Error! Bookmark not defined.]

"I love Dupixent! Before I started injections I was beyond miserable. If there's a worse word for it... I've been using Dupixent since January 17, 2018, and within the first day of taking it, I noticed a drastic change. The itch started to cease quickly, and all of my eczema patches started to dry up and peel off. After about a month, many of my active spots healed. The hyperpigmentation on my face, hands and legs have lightened up. My derm said hyperpig can take a year to go away. I'm fine with that because I never thought I'd be able to look myself in the mirror and not cry. I rejoice quite often because I

have a normal life again. I can cook, clean and go to work consistently without having to book an appointment." – Sam[29]

"I've been suffering from eczema my entire life. In the past few years, I've had major break outs, really major. You know, the ones when you can't sleep, stop scratching, and you're covered in sores. Nothing works, not even rounds and rounds of prednisone where the only thing you get are horrible side effects. Ugh! No fun. I've taken Dupixent 5 times so far, one being the initial dose of 2 units and the other 3 self-administered, and it's been a miracle for me. I also suffer from hideous asthma (of course), and my side effect from Dupixent has been NO asthma episodes! I feel like I'd imagine [how] a normal person feels. I CAN BREATHE AND DO THINGS! And I'm not dying of asthma attacks all the time…There aren't enough stars to rate Dupixent as high as I want to. It really is magical unicorn fairy dust!!" – Zia[29]

"We were following the success of dupilumab in teen and adult AD sufferers for a while and eagerly awaiting for it to be approved in Ella's age group… at 5 and a half years old, she was approved. Within 4 weeks, we began to see a noticeable decrease in her AD symptoms, particularly her itching. A child that had been spending 5 and a half years itching relentlessly was sitting quietly, reading a book, something she never was able to sit through prior to this, and engaging in normal childhood activities. This was a huge change for us. 2 months in and we weren't using any topicals to control her AD, and she wasn't needing bleach baths, and we weren't using any wet wraps. On February 6, 2021, just shy of her 6th birthday, Ella slept through the night for the first time in her entire life. I cannot overstate the miracle that this was for us. Ella's skin was healing, her body was healing, our family was healing. We had finally found a therapy that worked for Ella, and it truly changed the course of her life. It gave us our child back." – Amy (mother of child with AD)[29]

U.S. physicians have also spoken of how impressed they are that Dupixent has lived up to its promise as the first biologic medicine to target the underlying type 2 inflammation in AD:

"We heard many times that patients even considered suicide because their disease was so bad. Some said they were about to destroy their marriage; and one patient was about to close his law office. But this drug basically enabled them to have a life." – Dr. Emma Guttman-Yassky, Mount Sinai[30]

"…patients mostly are bothered a lot of times by the itching, and improvement can be seen as quickly as two weeks…Patients just say 'this has changed my life. For the first time, I don't itch at night. For the first time, I can leave my house. I can wear shorts. – Dr. Anabelle Garcia, Sonterra Dermatology[31]

Dupixent has also been shown to improve lung function in moderate-to-severe asthma patients. The reaction from patients and U.S. physicians to Dupixent has been overwhelmingly positive.

"*My son has poorly controlled asthma despite adhering to his medication regime and being extremely well cared for by his consultant. [Dupixent] offers him the chance to live with improved breath – breathing is overlooked by those of us fortunate enough to enjoy good health!" – Natalie*[32]

"This medication appears to have efficacy in a much broader range of patients than the currently available biologics. It has the potential to be a game changer for some patients, but we won't really know until it is out in the real world." – Dr. Sally Wenzel, University of Pittsburgh[33]

Dupixent is the first and only FDA-approved medicine indicated for EoE. Although it is a rare disease, EoE has a large impact on patients' lives. People with EoE are more likely to have depression and anxiety, especially as they get older, which can be related to fears about disease progression and difficulties with managing their disease, such as adapting eating habits to adhere to strict diets.[5,25,34]

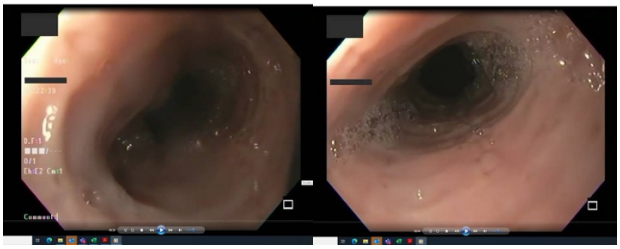
Patients with EoE saw a remarkable 69% reduction in disease symptoms with Dupixent, compared to 32% for placebo.[18] **Dupixent is the first and only biologic to show positive and clinically-meaningful results in this population as part of a Phase 3 trial. Dupixent may improve underlying biological processes related to tissue damage in EoE, as shown by the normalization in the expression of genes associated with scarring and barrier function in these patients.**[35]

"*The hardest part, I would say, of this disease on my life probably was in high school. I was extremely small for my age. I was 15 and was about 60 pounds, and I was around 4'5" or 4'6", so I clearly looked very different than the rest of my friends. And as a freshman in high school, it's hard in general. Everyone has a tough time, but having a disease that makes you look and feel so isolated and different – that was a really big challenge." – Jori, person with EoE*[28]

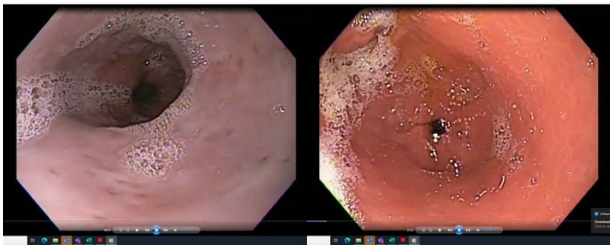
"My husband has EoE – and then three of our four kids. Charlie is eleven; and Gage is nine; and Tinley is six. The kids definitely have different takes on the disease. With Charlie not having a feeding tube, he has a lot more in his diet; it's easier for him. Gage hates all of it. He hates the disease, and he hates that he has a feeding tube, and he wants it to all go away." –Kara, caregiver to family with EoE[28]

Visuals of esophageal impact before and after Dupixent:

Before



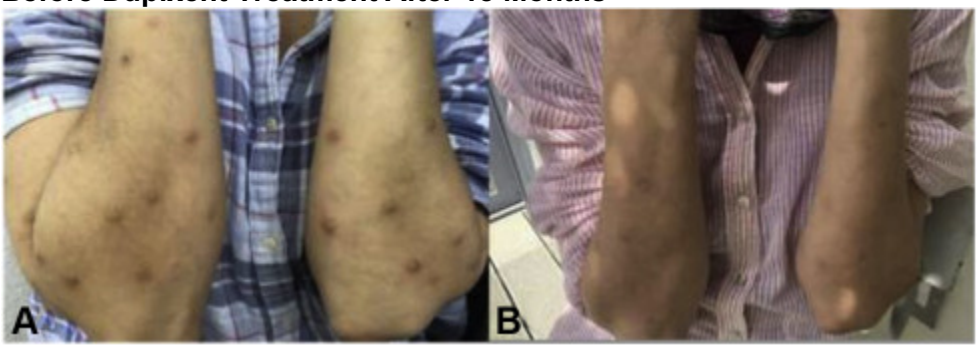
After



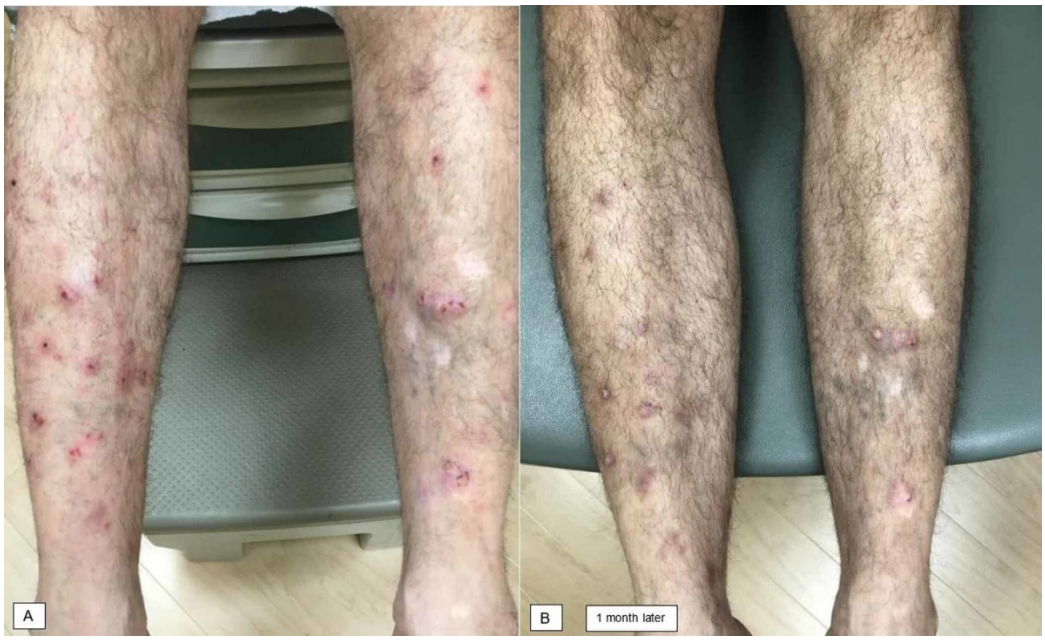
Dupixent is the first and only treatment indicated for PN.[Error! Bookmark not defined.] **Although it is a rare disease, it has one of the highest impacts on quality of life amongst inflammatory skin diseases due to the extreme itch it causes.**[36,37] **Patients with PN saw significant reductions in itch and skin lesions, two of the key signs and symptoms of disease.**[18]

A 51-year-old woman with prurigo nodularis was experiencing intense itch, had multiple skin lesions and reported negative impact on daily life activities and sleep impairment in the last 20 years, during which multiple topical and immunosuppressive treatments had been unsuccessful. After three months of treatment with Dupixent, she had a substantial reduction in itch with only two active skin lesions. The clinical benefit continued up to 18 months, at which point she was asymptomatic and had no side effects from treatment.[38]

Before Dupixent Treatment After 18 Months



A 65-year-old man with prurigo nodularis presented with lesions on his lower extremities, groin and trunk had been previously and unsuccessfully treated with phototherapy, thalidomide, and topical corticosteroids. After one month of treatment with Dupixent, he had significant improvement in itch and skin lesions, and did not report any adverse events.[39]



The approval of Dupixent in adults with COPD, a chronic respiratory disease that damages the lungs and causes progressive lung function decline, has been heralded by the patient and HCP community alike.

> *"We finally have a weapon to add to our armamentarium. I'm tired of small changes. I think this is the biggest step forward we've made in a long time."* – Dr. Kevin Fussell, Encinitas, Calif.
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> *"The days of hopelessness for patients with COPD are over."* – Ayeshia Wright, Nurse Practitioner, Charlotte, N.C.
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> *"This is the door of hope for so many patients, families and providers."* – Jean Wright, MD, CEO, COPD Foundation
>
> *"This is an absolute game changer and a huge win for COPD patients. This drug will be a significant improvement to the symptoms and quality of life of the 25-30% of my COPD patients who have type 2 inflammation. A meaningful add-on drug that significantly reduces exacerbation rates above any triple therapy — that is huge."* – Dr. Bryan Krajicek, Omaha, Neb.
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> *"I never thought I would see this [kind of innovation for COPD] in my lifetime."* – Dr. Nicola Hanania, Baylor College of Medicine, Houston, Texas
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> *"My father noted that of all the medicines he tried over his 13-year journey with COPD, Dupixent was the only one where he felt a marked difference. After years of being unable to leave his home on his own, he is now able to take himself to get a haircut!"* Jamie, caregiver of a participant in a Dupixent COPD trial
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> *"I had a severe COPD patient, on oxygen, with labored breathing and each time he came in for a scheduled visit – he was so bad – I worried I would have to call for an ambulance to have him taken to the ED. After his third dose of Dupixent, he had a follow up appointment, and he was 'hop scotching' through the office and smiling like I had never seen before. He remarked just how much it has changed his life, to the point where he no longer relies on oxygen constantly."* – Jennifer Rozak, NP

Most recently, Dupixent has been approved in the U.S. for patients with CSU who have failed standard-of-care antihistamines, characterized by the sudden onset of hives on the skin and/or swelling deep under the skin.

We believe that future generations will look back and regard Dupixent as a significant landmark in the management of chronic type 2 inflammatory conditions. This biological treatment is a tangible demonstration of how addressing the root cause of a problem can lead to the invention of exciting, multi-tasking and innovative therapies for diseases with high unmet medical needs.

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