



The Burden of Chronic Spontaneous Urticaria in Belgium: A National Action Plan to Improve Diagnosis, Treatment and Patient Outcomes

White paper

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Disclaimer

External experts have contributed to this report via a multi-stakeholder round table and through in-depth interviews. Input from the round table and these interviews was analysed and resulted in this summarising report. External experts did not co-author this report and therefore do not necessarily agree with every element and/or recommendation contained herein.



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1 Executive Summary

Chronic spontaneous urticaria (CSU) is an autoimmune-mediated condition affecting 0.4% of people worldwide. Despite its prevalence, CSU **remains underrecognized and is often misperceived** as a minor skin disorder. In reality, CSU imposes a **substantial physical, psychological, and socio-economic burden**. Symptoms such as wheals, angioedema, persistent itch, pain, and sleep disruption significantly impair daily functioning, mental well-being, social participation, and work productivity. At the same time, gaps in disease awareness and misaligned perceptions between patients and healthcare professionals (HCPs) hinder optimal care.

To address these challenges, the Belgian Health Care Knowledge Centre (KCE) **NEED framework** was applied to CSU for the first time to assess its impact. This structured methodology enables a comprehensive assessment of unmet needs across patients, HCPs, payers, and society. Insights were gathered through medical boards, clinician and patient interviews, extensive literature reviews, patient surveys and validated during stakeholder interviews and a multi-stakeholder roundtable. Together, these findings form the basis of this practical, implementation-ready action plan to improve CSU care in Belgium.

Underestimated disease burden

Patients identify the unpredictability of CSU as one of its most debilitating aspects. Itch severely affects sleep, daily activities, relationships, and mental health, while stigma adds emotional strain. CSU also generates significant healthcare utilisation and productivity losses. **Compared with psoriasis or atopic dermatitis, CSU patients report worse quality of life, fewer effective treatment options and higher healthcare utilisation.**

Unmet patient needs

Key unmet needs identified include:

- **Long delays before diagnosis and fragmented care pathways**, often diagnosis takes years and involving multiple HCPs ("medical shopping" among patients)
- **Limited awareness among HCPs of the true burden of CSU**, leading to misaligned treatment goals (inconsistent treatment and limited patient education, misalignment between patient expectations such as full symptom control and physician treatment goals, HCPs provide limited information about CSU to patients)
- **CSU patients receive suboptimal care in Belgium** due to restricted access to guideline-recommended add-on treatments
- **Absence of systematic patient-reported outcome (PRO) monitoring**, including quality-of-life assessments, hindering personalised and effective care.

Addressing these gaps is essential to ensure timely, evidence-based, and patient-centred care.

Guideline translation gaps

International guidelines recommend **a stepwise approach, including earlier use of effective add-on treatments** such as omalizumab (and the up dosing thereof). In Belgium, however, access is limited to severe CSU patients ($UAS7 \geq 28$) after prolonged antihistamine failure. This leaves **moderate CSU patients ($16 \leq UAS7 < 28$) with suboptimal or off-label alternatives**. Neighbouring countries reimburse earlier effective add-on treatments, highlighting the need to create Belgian guidelines and update reimbursement criteria to align with international standards and real-world evidence.

The need for systematic PRO monitoring

Routine and systematic PRO collection, telemonitoring, and centralised data interpretation can improve disease control, align patient and physician perspectives, and reduce unnecessary healthcare utilisation. Belgium-specific real-world evidence is also needed to support reimbursement decisions and demonstrate the long-term cost-effectiveness of optimal CSU care. A NIHDI-initiated Evidence Platform meeting could pave the way for a national virtual CSU registry to generate such evidence.

Priority actions

This white paper outlines a coordinated action plan supported by all involved stakeholders. It calls on the medical community, healthcare authorities, and policymakers to:

- **Reduce delays in treatment**
- **Improve integrated care aligned with international standards**
- **Establish systematic PRO monitoring**
- **Create a national virtual CSU registry to measure and address the disease burden**

Recognising CSU as a high unmet medical need and implementing these measures will enable Belgium to deliver optimal, cost-effective care and significantly improve the lives of people living with CSU.



Report intent: This report brings together evidence-based insights and implementation-ready recommendations that can support coordinated, tangible improvements in CSU care. By consolidating clinical expertise, patient perspectives, real-world evidence, and international best practices, the report provides a solid foundation for policy refinement, guideline alignment, and improved access to effective treatments.



Call for implementation: Through this report, we call on the medical community, healthcare authorities, and policymakers to formally recognise CSU as a high unmet medical need and to commit to implementing this co-created CSU action plan. This includes timely diagnosis, guideline-aligned treatment, systematic PRO monitoring, and the development of a national virtual CSU registry. Implementing these measures will enable Belgium to deliver optimal, cost-effective care and measurably improve the lives of people living with CSU.



2 Introduction

2.1 CSU prevalence and symptoms

The global prevalence of chronic spontaneous urticaria (CSU) is estimated to be 0.4% and predominantly impacts individuals of working age. Women are affected twice as often as men. CSU is a mast cell-mediated skin disorder characterised by recurrent episodes of hives and angioedema, accompanied by persistent itch, pain, fatigue, and sleep disturbances lasting six weeks or longer. (Weller et al., 2022; Balp, 2015; Balp, 2017; Kolkhir, 2025).

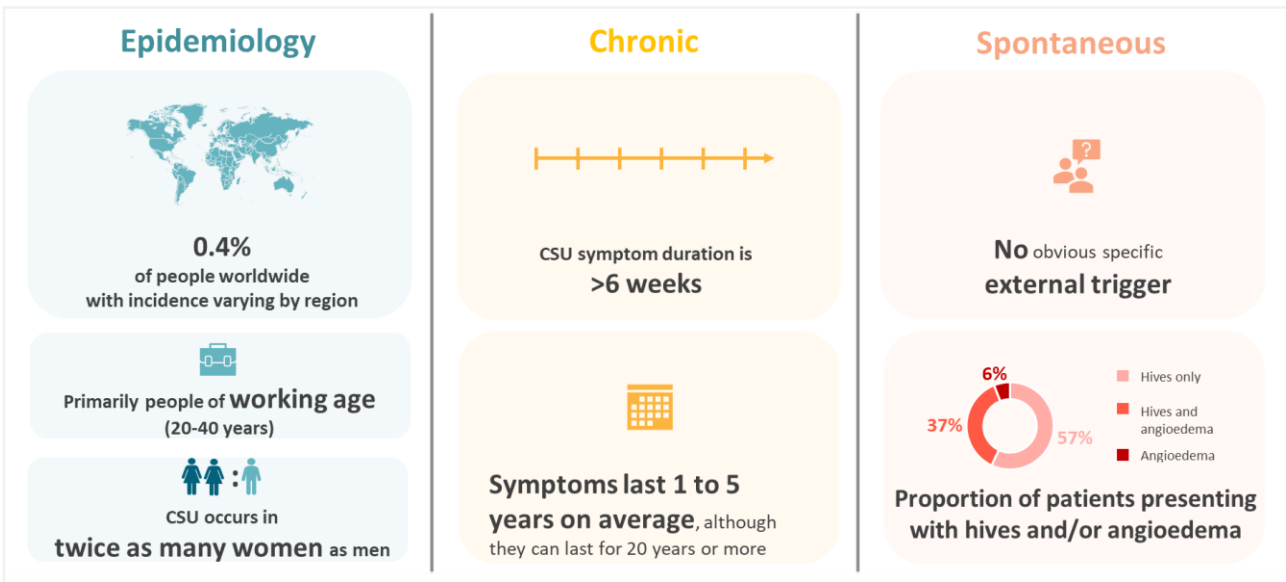


Figure 1. Overview of key facts on chronic spontaneous urticaria and its epidemiology (Weller et al., 2022)

Clinically, CSU presents as pruritic pink-to-red papules and plaques, often with central pallor or raised welts. In individuals with darker skin tones, lesions may appear lighter, darker, or similar in colour to surrounding skin. Lesions can be widespread and frequently occur in pressure-prone areas. Scratching may lead to excoriations or dermatographism.

Despite these recognisable clinical features, the overall severity and impact of CSU are often underestimated in routine practice. Limited awareness about the disease burden among healthcare professionals (HCPs) contributes to misalignment between patient expectations and physician treatment goals. Insufficient communication and patient education further fuel frustration and “medical shopping”, as patients seek alternative opinions to achieve better disease control. The average disease duration is 4.8 years, underscoring the chronic and burdensome nature of CSU (Mostmans et al., 2023).



Figure 2. Typical clinical appearance of chronic urticaria: pruritic pink-to-red papules and plaques, including central pallor
Image Credit: Cuoregentile - stock.adobe.com raised welts

2.2 Suboptimal diagnosis in current practice

Patients experience an average delay of two years between symptom onset and diagnosis. During this period, they typically consult multiple HCPs, often starting with a general practitioner and subsequently cycling through dermatologists, allergists, and emergency departments. Many patients report seeing more than six physicians before receiving a confirmed diagnosis.



Disease activity is commonly assessed using the Urticaria Activity Score over 7 days (UAS7), which aggregates daily itch intensity and wheal severity into a score ranging from 0 to 42 (Zuberbier et al., 2014). Based on UAS7 values, chronic spontaneous urticaria is typically classified into mild, moderate, or severe disease. Although widely used, this tool and the categorisation have limitations:

- It captures only itch and wheals, not angioedema.
- It does not reflect psychological burden or broader quality-of-life impairments.
- It often fails to align with patient-reported disease severity, resulting in a misalignment between patient-reported disease burden and physician-assessed disease activity, complicating severity assessment.

Combined with inconsistent PRO monitoring and the fluctuating multifaceted nature of CSU, these limitations hinder accurate assessment and timely treatment escalation.

2.3 Current CSU guidelines & treatment pathway

International guidelines provide a clear, evidence-based framework for optimal CSU management. To ensure alignment with these standards, we consulted one of the leading global experts, Prof. Dr. Ana Maria Giménez-Arnau (Hospital del Mar, Spain). She is a world-renowned dermatologist and researcher who played a pivotal role in developing the 2021 EAACI/GA²LEN/EuroGuiDerm/APAAACI international guidelines for the diagnosis and management of CSU. As a key figure within the GA²LEN network—originally established with support from the European Commission—she has contributed extensively to the clinical validation of next-generation therapies and to ensuring that European clinical practice remains aligned with the latest evidence-based safety and efficacy protocols. These international guidelines, developed by leading experts, recommend a stepwise treatment approach beginning with antihistamines and progressing to add-on therapies such as omalizumab, dupilumab and remibrutinib when symptoms persist. They integrate clinical trial data, real-world evidence, and patient-reported outcomes to support consistent, effective CSU management.

However, Belgian practice diverges significantly from these international standards. Access to omalizumab is restricted to patients with severe CSU (UAS7 $\geq$ 28) and only after six months of failed approved-dose antihistamine therapy. As a result:

- Moderate CSU patients lack access to guideline-recommended treatments
- Off-label alternatives are frequently used, often with limited efficacy and tolerability
- Delay in effective treatment prolongs disease burden and reduces quality of life.

Neighbouring countries, including France, the Netherlands, Germany, and the Scandinavian nations, allow earlier and broader access to effective add-on treatments as recommended by the international guidelines, underscoring the need for Belgium to develop national guidelines and re-evaluate its reimbursement criteria.

Throughout the CSU treatment pathway, the burden of disease is frequently underestimated, as perceptions of CSU differ markedly between healthcare professionals and patients. This misalignment often leads to delays in both treatment initiation and escalation. Ultimately, achieving sustained disease control, or preventing recurrence, relies on effective patient education, treatment adherence, and timely access to evidence-based and innovative therapies.



The current Belgian treatment pathway is illustrated below:

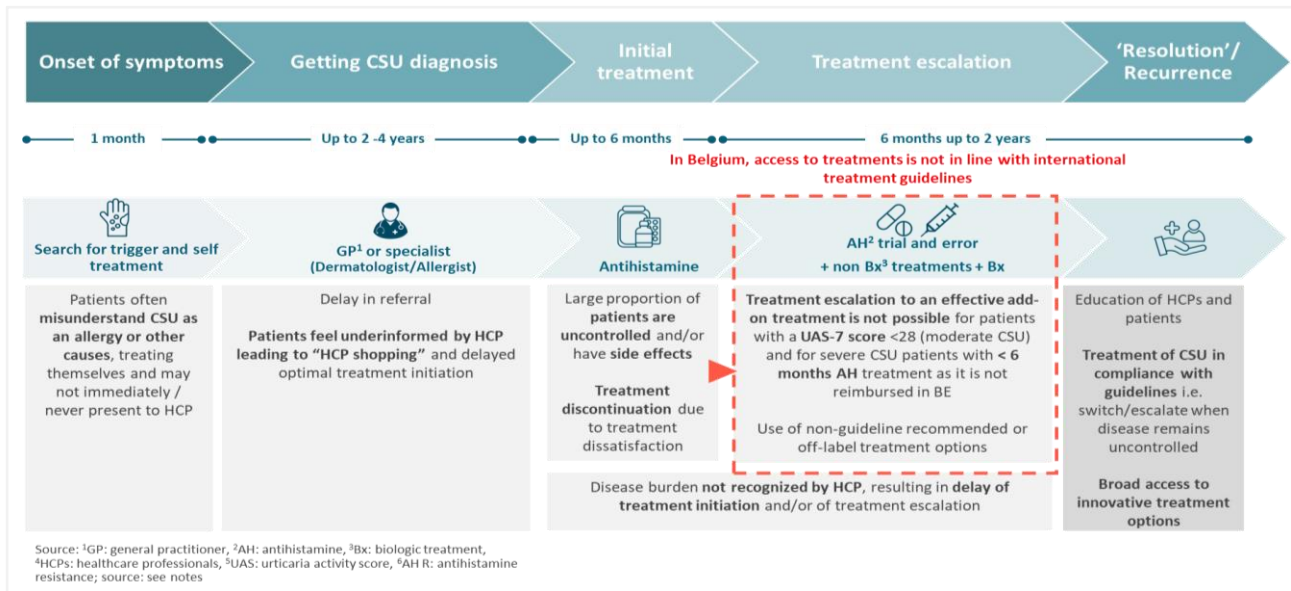


Figure 3. The Belgian CSU treatment pathway

2.4 The need for action: addressing diagnostic delays, treatment gaps, and unmet needs

The burden of CSU extends far beyond visible symptoms. The unpredictable nature of flare-ups leads to anxiety, frustration, sleep disruption, and social withdrawal. Evidence shows that the psychosocial burden of CSU may exceed that of other chronic inflammatory skin diseases such as atopic dermatitis and psoriasis (Balp et al., 2024).

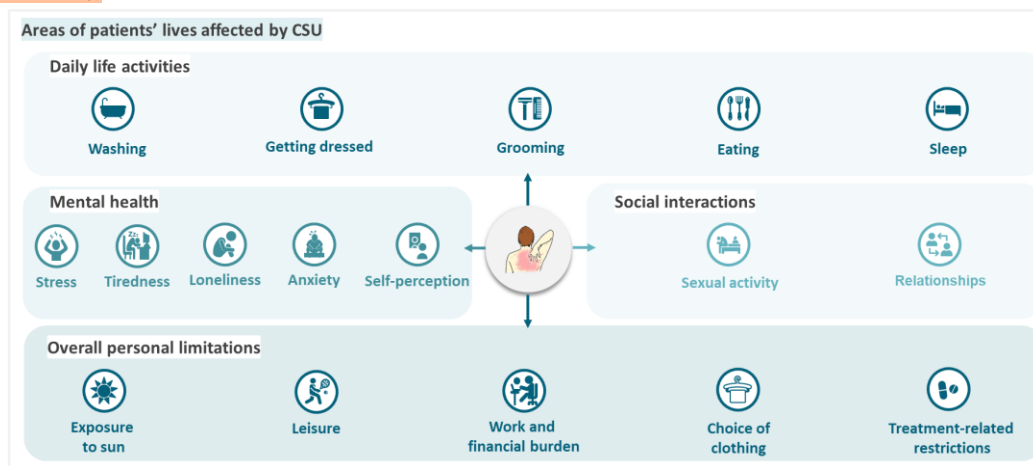


Figure 4. The impact of CSU on different areas of the patient, affecting daily life activities, mental health, social interactions and overall limitations in their personal life

CSU also imposes significant economic and societal costs. Recurring symptoms and inadequate disease control contribute to:

- Increased healthcare utilisation, including emergency visits
- Reduced productivity and work impairment
- Absenteeism and long-term career impact

These cumulative effects underscore the urgent need for earlier diagnosis, improved disease awareness, guideline-aligned treatment, and equitable access to effective therapies in Belgium.



3 The applied approach to build the CSU action plan

3.1 A multi-stakeholder approach

To robustly validate the burden of disease and develop a practical action plan to improve CSU care in Belgium, a structured, evidence-driven, and collaborative approach was applied. For the first time, the **Belgian Health Care Knowledge Centre (KCE) NEED framework** (Needs Examination, Evaluation and Dissemination framework)—a methodology designed to assess unmet medical needs across multiple dimensions—was applied to CSU.

The NEED assessment and patient journey analysis were subsequently validated and enriched, reflecting real-world Belgian practice and evidence, gathered through:

- Medical boards with dermatologists and internal medicine
- In-depth interviews with clinicians, payers, and public health experts
- Literature reviews and analysis of international best practices
- Patient boards and surveys capturing lived experience
- A multi-stakeholder roundtable hosted at NIHDI

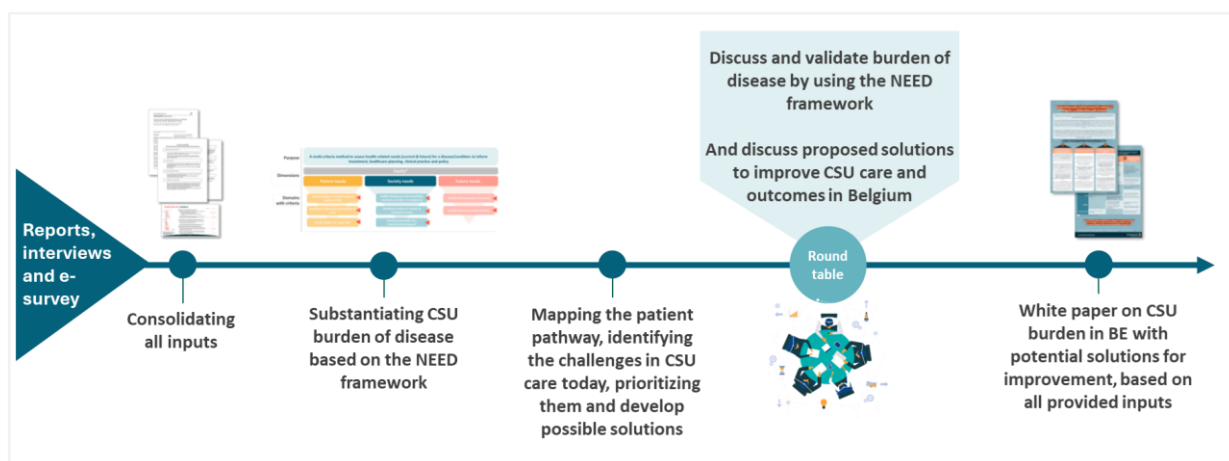


Figure 5. The project approach to validate disease burden and detail the action plan to improve CSU care

This comprehensive evidence-base framework enabled a detailed mapping of the CSU patient journey and the identification of critical unmet needs contributing to the overall disease burden. The NEED assessment and patient journey analysis were subsequently validated and enriched through broad **multi-stakeholder dialogue and interviews**. Representatives from government bodies, health authorities, dermatology centres, patient organisations, health insurance funds, public health researchers, and academia contributed their expertise. This consolidated Belgian perspective was complemented by international insights from Prof. Dr. Ana Maria Giménez-Arnau, whose extensive expertise provided valuable real-world validation of guideline-aligned CSU management. Together, these inputs formed the foundation for an **implementation-ready national action plan**.

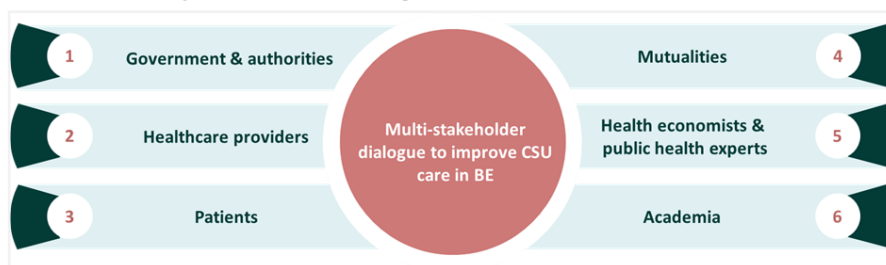


Figure 6. Overview of the involved stakeholders to validate the CSU burden through the NEED framework and to draw the CSU action plan for Belgium



3.2 The NEED framework: assessing the burden of disease from multiple perspectives

The NEED framework, developed by Sciensano in collaboration with the KCE, offers a structured methodology to evaluate unmet medical needs across four key dimensions:

- Patient needs
- Social needs
- Future needs
- Equity considerations

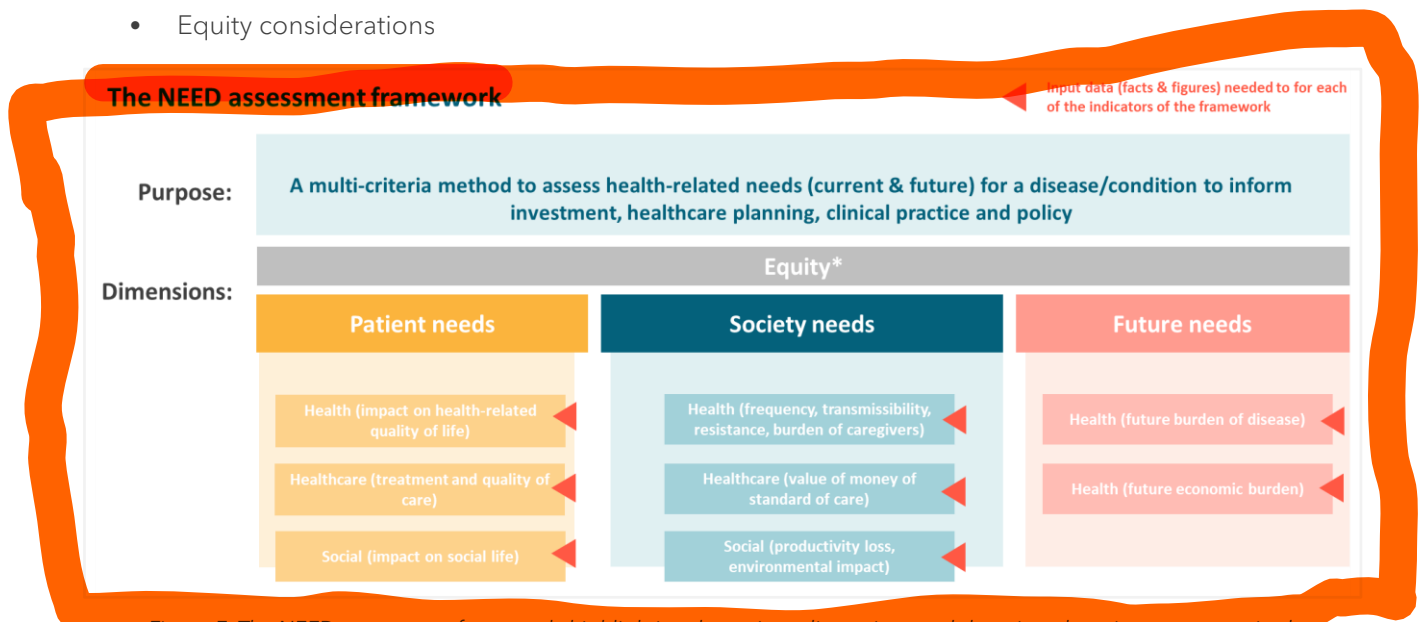


Figure 7. The NEED assessment framework, highlighting the various dimensions and domains where input was required to complete the model (indicated by red triangles)

Its purpose is to support evidence-based policy decisions by identifying where unmet needs are most pressing and where interventions should be prioritised. The framework is designed to enable comparison across diseases and to guide resource allocation in a transparent and systematic manner.



4 Addressing unmet needs to understand the disease burden of CSU

The assessment of the CSU burden was guided by the KCE NEED framework, which provides a structured methodology to evaluate unmet needs across multiple dimensions.

For CSU, the NEED framework was applied using a **mixed-methods approach**, combining:

- Primary data (interviews, boards, surveys)
- Secondary data (literature, epidemiology, economic analyses)
- Qualitative and quantitative evidence

All data were generated and analysed using scientifically sound methodologies, in line with KCE's recommendations.

This chapter summarises the key findings across four domains: **patient needs, social needs, future needs, and equity** and provides a comprehensive overview of the CSU disease burden. It highlights the areas where unmet needs are most significant and where targeted policy action is required.

A detailed version of the completed framework for CSU with all underlying sources and data is included in the annex. Below, a summary is provided for each of the dimensions.

Dimension	Domain	Criterion	Indicator	Input
Patient needs	Health	Impact on general health-related quality of life The extent to which a health condition affects a patient's quality of life	Years of life lived with disability (per case)	Most patients suffer from CSU for more than one year; a considerable number of patients even seem to be affected for longer than 5 years. Approximately 14% of patients with CSU still needed medical care after 5 years, but this percentage decreased to 12.4% and 11.3% by the 3rd and 5th years. After 5 years, 6.4% of patients were still in need of medical CSU care. Patient-reported outcome measures (EQ-5D, QoL, EQ-5D, SF-36, PCS) consistently show that CSU patients have worse QoL scores (10-65 of 0-100) compared to both the general population and patients with other chronic skin conditions such as atopic dermatitis.
	Healthcare	Burden of treatment The extent to which the current treatment burden affects patients' quality of life	Experienced burden of treatment	Patients receiving treatment for chronic urticaria experience approximately twice the rates of depression, anxiety, and sleep difficulties compared with controls and have higher healthcare utilization, including physician visits (9.1 vs. 4.8), emergency room visits (0.8 vs. 0.3), and hospitalizations (0.3 vs. 0.2). Second-generation antihistamines are the first-line treatment for CSU. Standard dosing is used initially. If symptoms do not resolve, treatment is escalated and/or a second-generation antihistamine is added. In some cases, a third-generation antihistamine is added. In some cases, a third-generation antihistamine is added.
	Social	Impact on social life The impact of the health condition on patients' social life, including on their social support needs and their capacity to establish meaningful relationships with the community, family and/or friends	Social support needs	Living with CSU carries stigma and discrimination for 63% of patients, with 13% being stared at or asked if they are contagious, 13% experiencing refusal of physical contact, and 13% being made the subject of jokes or insults. Despite this, 82% of patients feel their condition is recognised by healthcare providers, 72% by family and friends, and 60% by colleagues, bosses, or teachers.
	Healthcare	Costs The financial burden of the health condition on patients and the healthcare system	Value for money of standard of care	Healthcare costs per unit of health gain (disaggregated presentation of total healthcare expenditures and total health effects of standard of care)
Social needs	Health	Burden on informal caregivers The extent to which the quality of life of informal caregivers is affected by their caregiving activities	Loss in informal caregivers' quality of life	It was observed that patients' poorer quality of life due to CSU was associated with higher rates of anxiety in the cohabitants, a poorer quality of life of the family and lower sexual satisfaction among the cohabitants. Intimacy/sexual relationships may be impaired in CSU patients due to both physical and emotional distress, often leading to loneliness.
	Healthcare	Prevalence The extent to which a health condition is present in the population	Implementation of effective primary prevention	Annual direct medical costs in Europe are estimated at €915-€1,295 per patient (2025 values) with average costs around €1,000. The largest cost drivers are therapies (>70%), inpatient care (>20%), and emergency visits (>15%), with even higher shares of inpatient costs in some countries (up to 47% in Germany). ER visits and number of hospitalizations were significantly higher among patients with CSU compared to those with AD or PSD.
	Health	Future burden of disease The impact of a health condition on the health of future generations	Future prevalence/incidence	Future projections suggest that the global burden of urticaria will continue to rise through 2086. Analysis of data shows an increasing trend in incidence, with environmental and lifestyle factors such as air pollution and dietary intake significantly correlated with future prevalence.
	Healthcare & social	Future economic burden The impact of a health condition on future healthcare expenditures and productivity, in monetary terms	Future direct costs Future indirect costs	In future years, years lived with disability (YLD) from CSU could be reduced if patients receive guideline-based treatment and specialized care, as shown in Scandinavian centers where disease severity, quality of life, and healthcare use improved over two years. Future direct costs of CSU could be reduced through guideline-based treatment and close monitoring, as shown in Scandinavian centers where adherence led to fewer hospital visits, less medication use, and overall lower medical resource utilization. Personalized treatment adjustments may further prevent unnecessary emergency care and optimize cost efficiency. Future indirect costs of CSU could be reduced through guideline-based management, lower future indirect costs, such as fewer missed workdays and increased productivity.

Figure 8. The completed NEED framework across the different dimensions. A detailed version can be found in the annex

4.1 Patient needs

The NEED framework highlights CSU as a multifaceted condition with a profound impact on physical health, psychological well-being, daily functioning, and financial stability.

Impact on physical health

- Pain is a frequent and distressing symptom, reported by 55% of patients during exacerbations.



- Pain typically occurs at the site of hives, angioedema, or joints and is described as burning, stinging, aching, or soreness after scratching.
- Comorbidities are common: 68% of patients report at least one comorbidity, and 54% report two or more, increasing disease complexity and treatment needs (Bernstein, 2025).

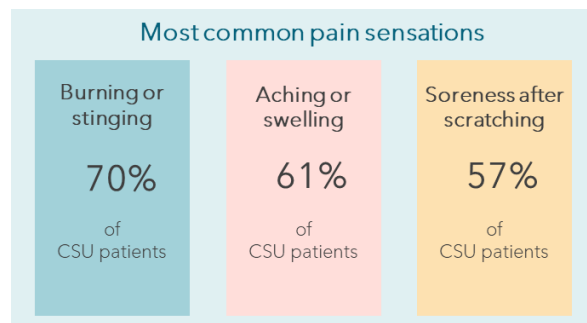


Figure 9. The most common pain sensations (AWARE Study Belgium)

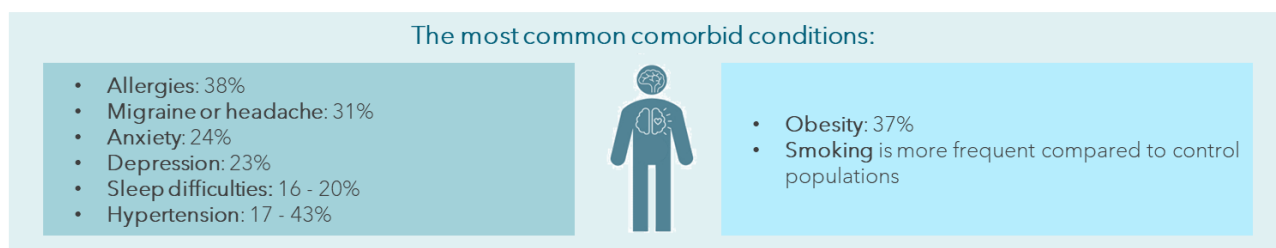


Figure 10. The most common comorbidities in CSU (Balp MM et al_2025, Balp_2015)

Impact on psychological health

CSU is not merely a physical condition; its unpredictability profoundly affects emotional well-being.

- Itch disrupts sleep, strain relationships, and contribute to anxiety and frustration.
- The visible nature of CSU can lead to stigma, social withdrawal, and feelings of vulnerability.
- Patients have a sixfold increased risk of anxiety and depression compared with the general population, largely due to chronic itching, uncertainty, and social distress associated with the disease (Balp MM et al_2025).
- Research shows elevated risks of suicidal ideation, suicide attempts, and certain malignancies compared with controls.
- Anxiety is highly prevalent: 66.5% of CSU patients experience mild to severe symptoms, significantly higher than in atopic dermatitis or psoriasis (Balp MM et al., 2024).

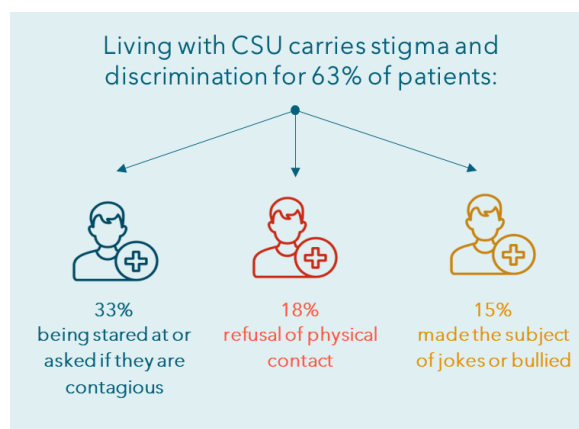


Figure 11. Living with CSU carries stigma & discrimination (Weller_2025)

Impact on daily activities

CSU affects nearly every aspect of daily life:

- Patients avoid social interactions, sports, certain clothing, and intimate relationships.
- Routine activities such as cycling, sitting on specific surfaces, or travelling to warmer climates may trigger symptoms.
- Educational and professional performance is often impaired (Weller, 2025): in a Belgian survey, 33% of school-attending patients reported a severe impact of CSU on their educational activities (IPSOS survey).



- Economic burden for patients
- For patients, the economic burden of CSU extends far beyond direct medical care:
- Out-of-pocket costs for non-reimbursed treatments, travel, and alternative care are substantial.
- Many patients report monthly expenses of €50 or more, higher than in atopic dermatitis or psoriasis (Balp MM et al., 2024; Patient focus group).
- Absenteeism and reduced work participation contribute to long-term financial strain.



Figure 12. CSU out-of-pocket costs (Patient focus group)

4.2 Social needs

CSU affects not only patients but also their families, partners, and broader social environment.

Impact on close relationships

- Poorer patient quality of life is associated with higher anxiety levels in cohabitants and reduced family well-being.
- Sexual dysfunction is reported by 58% of patients, affecting intimacy and relationship satisfaction (Sanchez-Diaz_2022).
- Emotional strain and unpredictability of symptoms can lead to loneliness and reduced social connectedness (Sanchez-Diaz_2022; CSU Adboard BOD).

Economic burden for society

- CSU generates significant direct and indirect costs:
- Higher healthcare utilisation than psoriasis or atopic dermatitis, including more hospitalisations and emergency visits.
- Increased absenteeism, presenteeism, and overall work impairment compared with both healthy controls and those with atopic dermatitis or psoriasis (Balp MM et al., 2024).
- Over 20% of patients miss at least one hour of work per week; overall work impairment reaches 27% and rises with disease severity (Bernstein, 2023; patient focus group).

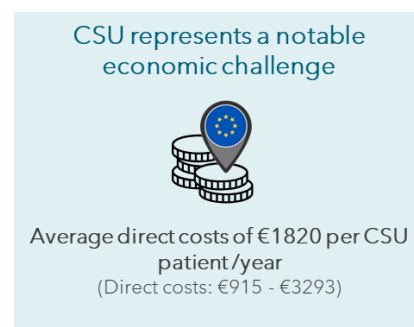


Figure 13. Average economic burden per CSU patient per year (Balp_2015)



Figure 14. The absenteeism/presenteeism/work impairment rate for CSU patients (compared to healthy controls), the overall work productivity loss and the indirect costs per patient/per year



4.3 Future needs

Global projections indicate that the burden of CSU will continue to rise over the next 20 years (Tan, 2025).

- Environmental factors such as air pollution and dietary patterns are increasingly associated with CSU prevalence.
- Modern lifestyle and environmental factors may further worsen disease expression and symptom severity, as rising urticaria rates are linked to air pollution (ozone, PM, NO₂) and dietary patterns high in dairy, processed foods, sugar-sweetened beverages, trans fats, alongside low intake of vegetables, nuts, omega-3s, and whole grains.
- Anticipating these trends is essential for long-term planning of healthcare resources and prevention strategies.

4.4 Equity in CSU care

Inequities in CSU care arise from clinical, systemic, and social factors that affect patients unevenly.

Clinical and systemic inequities

- Limited disease awareness among primary care physicians contributes to delayed diagnosis and referral.
- Limited access to guideline-recommended treatments in Belgium disproportionately affects moderate CSU patients, who lack access to effective add-on treatments.
- Compared with neighbouring countries, Belgian patients face more barriers to guideline-aligned care.

Social inequities

- Patients without strong support networks experience higher psychological burden.
- Workplace, cultural, and linguistic barriers can delay care and reduce treatment adherence.
- The broader economic and psychological impact of CSU is often underestimated by payers, resulting in insufficient investment in patient education and equitable access to treatment.



5 The CSU patient journey analysis & prioritised unmet needs

The findings from the NEED framework, scientific literature with perspectives from multidisciplinary experts, clearly demonstrate that patients with CSU face substantial unmet needs throughout their care pathway. Mapping these needs along the patient journey provides a structured overview of where delays, inefficiencies, and misalignments occur, and where targeted actions can have the greatest impact.

The patient journey reveals four critical areas where unmet needs accumulate:

- **Delayed diagnosis, involving multiple HCPs**
- **Limited disease awareness and on the true burden of CSU among HCPs**
- **Inability to apply international guidelines**, resulting in CSU patients receiving suboptimal care in Belgium
- **Lack of systematic PRO monitoring**, including quality-of-life assessments.

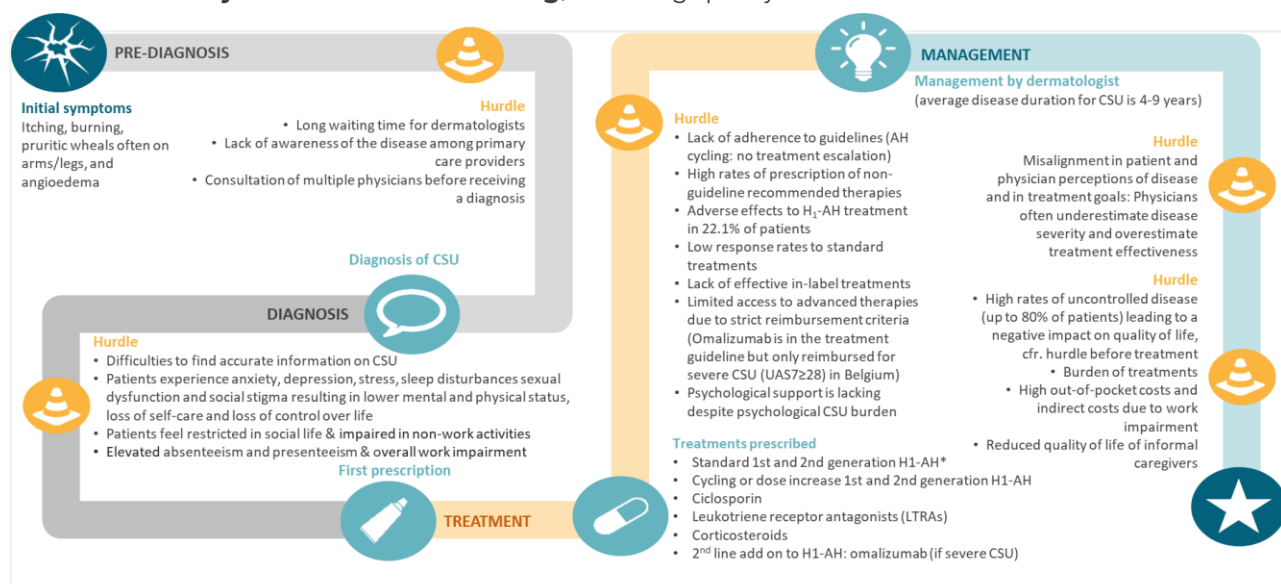


Figure 15. The CSU patient journey illustrating key unmet needs and hurdles in CSU care

5.1 Long delays before diagnosis, involving multiple HCPs

Patients typically experience a diagnostic delay of **two years** from symptom onset. During this period, they often consult multiple healthcare professionals, starting with general practitioners and subsequently visiting dermatologists, allergists, emergency departments, and other specialists. Many patients report seeing more than **six physicians** before receiving a confirmed diagnosis (Weller-2025_RWE). These delays are driven by:

- Limited awareness of CSU among primary care providers
- Misinterpretation of symptoms as allergic reactions or acute urticaria
- Lack of clear referral pathways
- Absence of structured diagnostic tools in routine practice

Early recognition and referral are essential to reduce disease burden and prevent unnecessary healthcare utilisation.

The pre-diagnostic phase of CSU is often characterised by uncertainty, which patients find particularly challenging and burdensome, with significant implications for mental well-being. Timely and accurate diagnosis is therefore essential, as confirmation of the condition provides psychological relief, reduces uncertainty, and enables earlier treatment intervention. This not only improves symptom control and quality of life but also mitigates emotional distress while reducing unnecessary healthcare utilisation and associated costs.



5.2 Limited awareness among HCPs of the true burden of CSU

A significant gap exists between how patients and healthcare professionals perceive CSU. While patients experience CSU as a debilitating, unpredictable condition, many HCPs underestimate its physical, psychological, and social impact. This misalignment can undermine treatment adherence and patient trust. Even among specialists, understanding of CSU severity and its impact on daily life is not always consistent, leaving patients uncertain about diagnosis, management, and long-term care. In addition, pharmacists may also provide inconsistent advice, particularly regarding antihistamine dosing, which can further confuse patients and affect therapy adherence. This misalignment leads to:

- Underestimation of disease severity
- Delayed treatment escalation
- Insufficient patient education
- Frustration and “medical shopping” as patients seek alternative opinions

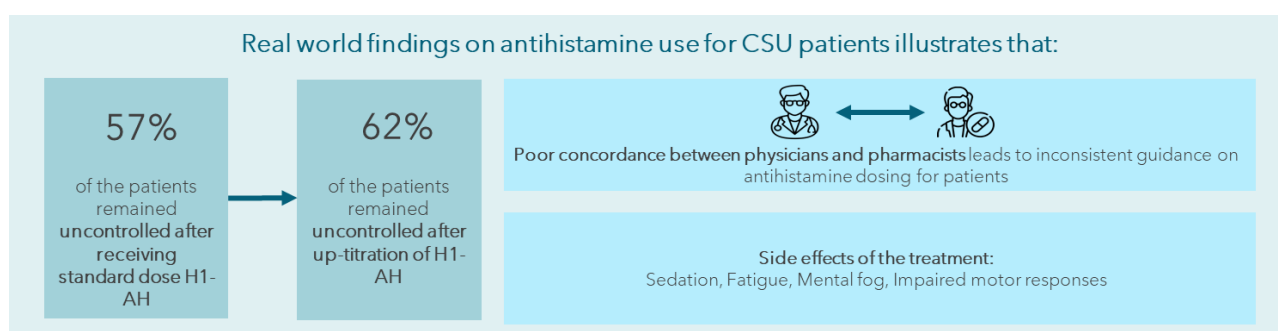
Improving disease awareness, strengthening alignment and coherence across HCPs and with patients’ perceptions, is essential for timely, patient-centred care.

5.3 CSU patients receive suboptimal care in Belgium, as the guidelines cannot be applied

Although international guidelines recommend a stepwise treatment approach, including early escalation to effective add-on treatments (or the up dosing thereof), such as omalizumab, Belgian reimbursement criteria restrict access to patients with severe CSU ($\text{UAS7} \geq 28$), who fail to respond to approved-dose antihistamines. As a result:

- Moderate CSU patients lack access to guideline-recommended therapies
- Off-label treatments are frequently used, often with limited efficacy and tolerability
- Treatment delays prolong disease burden and reduce quality of life
- Belgian practice diverges from neighbouring countries (The Netherlands, Germany, France, and the Scandinavian nations), where earlier and broader access to effective add-on treatment is standard, in line with international guidelines

This gap between guidelines and real-world practice represents one of the most significant unmet needs in Belgian CSU care. Folia and international guidelines recommend second-generation antihistamines as first-line therapy, with dose escalation up to fourfold for persistent symptoms; however, these treatments often fail to achieve adequate disease control. To rectify this, Belgian guidelines should translate the international evidence to the local context and ensure timely access to effective add-on treatment as recommended. This update should integrate the cost-effectiveness of these therapies into considerations



and should include mental-health support for patients who need it.

This approach promotes personalised care pathways, resulting in better symptom control.

5.4 Lack of systemic PRO monitoring, including quality-of-life assessments

Patient-reported outcomes (PROs) are essential for understanding individual disease activity, treatment response, and quality of life. However, PRO monitoring in Belgium is inconsistent and mostly absent. Current challenges include:



- Limited use of validated tools such as UAS7, AAS, DLQI, and angioedema-specific measures
- Lack of digital tools for routine monitoring
- Minimal integration of PROs into clinical decision-making
- No centralised system for interpreting or aggregating PRO data

This lack of monitoring is particularly problematic given the fluctuating nature of CSU. Long-term follow-up is essential for improving outcomes and providing integrated care encompassing psychological health support, education, and continuous monitoring. Systematic PRO monitoring would enable:

- More accurate assessment of disease severity
- Better alignment between patient and physician perspectives
- Timely treatment adjustments.



6 Solutions to improve care

The unmet needs identified across the CSU patient journey highlight the necessity for coordinated evidence-based interventions. Improving CSU care in Belgium requires actions across four key domains: **accelerating diagnosis, aligning care with international guidelines, implementing systematic PRO monitoring, and establishing a national virtual CSU registry**. Together, these measures form the foundation for a more efficient, equitable, and patient-centred care pathway.



Figure 17. The prioritised challenges, along with proposed solutions, based on multi-stakeholder expert opinions

6.1 Reduce delays in treatment

Accelerating the diagnosis of CSU and reducing delays are critical priorities within the CSU care action plan, as prolonged diagnostic pathways contribute to ongoing symptoms, psychological distress, and diminished quality of life. A confirmed diagnosis can provide significant relief for patients; recognition and validation of their condition substantially reduce the emotional and mental burden associated with uncertainty. The pre-diagnosis phase is often marked by confusion and anxiety, which many patients experience as particularly challenging, underscoring the importance of timely and accurate diagnosis to support patients' mental well-being. Early diagnosis also enables prompt initiation of appropriate treatment, which is crucial to prevent disease escalation and psychological trauma related to the disease symptoms. From a future perspective, early treatment is crucial, as patients having suffered from severe disease may become hesitant to discontinue therapy due to fear of symptom recurrence. This underscores the importance of achieving early disease control and providing clear, evidence-based guidance on treatment discontinuation.

Timely diagnosis is essential to reduce disease burden and prevent unnecessary healthcare utilisation. Current delays, often spanning two years and involving multiple healthcare professionals, can be addressed through:

- **Increased awareness among primary care providers**, enabling earlier recognition of CSU symptoms and supporting accurate differentiation between acute urticaria, allergic reactions, and CSU
- **Educational initiatives** for GPs, dermatologists and pharmacists
- **Clear referral pathways** to dermatologists and internal medicine



- **Improved patient information** on the disease and the treatment options, empowering individuals to seek appropriate care sooner

Earlier diagnosis will reduce patient frustration, limit “medical shopping”, and enable faster initiation of effective treatment.

6.2 Improve integrated care aligned with international guidelines

CSU patients may receive suboptimal treatment because international guidelines cannot always be fully applied. These guidelines are evidence-based, validated across multiple healthcare systems, and reflect the latest scientific and clinical consensus. Multi-stakeholder perspectives confirm that they provide a robust foundation for high-quality CSU care and should therefore be translated and adapted to the local context. Localising international guidelines into practical, country-specific guidance is essential to strengthen referral pathways, standardise clinical decision-making, and ultimately improve overall CSU management.

To achieve high-quality Belgian treatment guidelines, the latest scientific evidence must be combined with country-specific health technology assessment (HTA) and cost-effectiveness considerations. Reimbursement frameworks should be aligned with these adapted guidelines to ensure timely and equitable access to innovative treatments, supported by clear guidance on their appropriate and value-based use. This alignment is critical to support equality in care and to support future sustainable healthcare decision-making.

Improving CSU care also requires an integrated, patient-centred approach that extends beyond symptom control alone. Treatment guidelines should explicitly incorporate mental health screening and access to psychological support where appropriate, as psychosocial factors (including social interactions and relational dynamics) have a substantial impact on patients’ disease burden. Systematically integrating mental health considerations into routine CSU care supports more holistic management and leads to improved patient outcomes. To ensure equitable, guideline-aligned care, the following actions are needed:

- Ensure access to guideline-recommended effective add-on treatments
- Creating national guidelines in alignment with the recommendations from the International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria
- Promoting multidisciplinary collaboration between dermatologists, internal medicine, primary care physicians, and mental health professionals
- Strengthening patient education to improve adherence and shared decision-making

Aligning Belgian practice with international standards will reduce reliance on off-label treatments, improve disease control, and enhance patient quality of life.

6.3 Establish systematic PRO monitoring

Systematic collection of patient-reported outcomes (PROs) is essential for personalised, effective CSU management. Current monitoring is inconsistent and often absent.

Establishing systematic PRO is a key enabler of high-quality, personalised CSU care, as it captures the full patient experience and integrates it into routine disease management. CSU symptoms such as wheals and angio-oedema are episodic and fluctuate over time, meaning they are not always visible during clinical visits. Without systematic PRO monitoring, patient data remain incomplete, limiting healthcare professionals’ ability to fully assess disease burden and the effectiveness of treatment.

Systematic collection of PROs, supported by telemonitoring tools and centralised data interpretation, provides HCPs with actionable, real-time insights into symptom severity, flare-ups, and treatment response.



Centralised interpretation and physician dashboards that visualise symptom trends enable timely clinical decisions and targeted interventions through efficient triage of urgent cases, drawing on successful telemonitoring models used in other chronic diseases. This approach helps avoid unnecessary healthcare utilisation while ensuring that patients who need prompt attention are identified early.

PRO monitoring is also essential for aligning patient and physician perspectives on disease burden. Self-reported patient data improves the quality of clinical assessments and actively engages patients in their care, fostering shared decision-making. Patients who are systematically monitored through PROs often report fewer symptoms and improved well-being, as they feel seen, supported, and taken seriously, even when follow-up is largely automated. In addition, prolonged imbalances between psychological, social, and physiological factors in CSU can increase the risk of mental health problems. Regular assessment of PROs allows for early identification of distress and enables timely preventive or supportive interventions, reinforcing an integrated and holistic care approach.

Consistent use of PRO data in clinical decision-making further enhances patient motivation and adherence. To address this gap, Belgium should implement:

- **Routine use of validated PRO tools**, including UAS7, AAS, DLQI, and angioedema-specific measures
- **PRO use should be evaluated** to improve its uptake, interpretation, and integration into clinical workflows
- **Embedding PRO monitoring via digital platforms** (enabling continuous monitoring and remote follow-up) **into personalized disease management** is therefore essential to improving CSU outcomes, enhancing patient experience, and supporting more efficient, responsive, and integrated care delivery

Structured PRO monitoring will improve alignment between patient and physician perspectives, support treatment optimisation, and generate valuable real-world evidence.

6.4 Create a national virtual CSU registry

To better measure and address the full disease burden of CSU and to support optimal and cost-effective care in Belgium, systematic and sustainable data collection is essential. Without structured real-world data collection, the true burden of CSU remains underestimated, limiting evidence-based decision-making in both clinical practice and reimbursement policy.

A national virtual CSU registry can address this gap by embedding data collection directly into routine care. Clinical information should be recorded by dermatologists within their electronic patient records (EPDs) and automatically transferred to a central registry hosted at Sciensano. This linkage ensures minimising administrative workload and integrating data capture seamlessly into existing workflows. Standardising the clinical data elements across EPD systems would allow their use within federated data networks, enabling robust analysis and supporting CSU as a potential pilot for broader disease-related data initiatives in Belgium. Comparable “only once” automated registration models already exist, such as the integration of CAR-T therapy data into the Belgian Cancer Registry and gene therapy data for Duchenne muscular dystrophy, collected in collaboration with Sciensano. Because data would be automatically captured from routine care processes, the additional administrative workload would remain limited.

To better measure and address the full disease burden of CSU, there is a need to:

- Set up a **national virtual CSU registry** with data collected by dermatologists in the EPD and automatically registered at Sciensano.
- Funding is needed to set up this standardised data collection and automated extraction from EPD systems to ensure reliable real-world evidence.



- The upcoming **NIHDI-initiated Evidence Platform meeting could serve as the starting point** for developing this registry, with **CSU as a potential pilot**, ensuring alignment with national priorities and stakeholder expectations.

A national virtual CSU registry would provide a robust foundation for evidence-based policy and reimbursement decisions. Such a registry should collect real-world data on disease severity, treatment patterns, outcomes, and PROs.

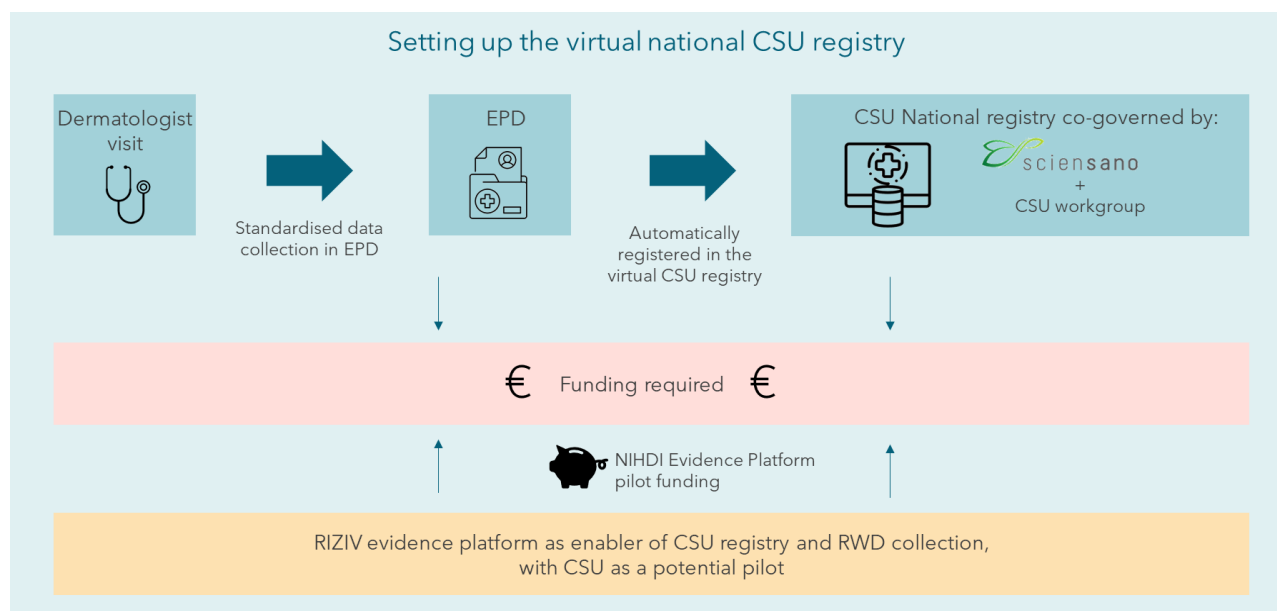


Figure 18. Funding requirements and options for the virtual national CSU registry



7 Roles and responsibilities

Improving CSU care in Belgium requires coordinated action across the entire healthcare ecosystem. Each stakeholder group plays a distinct and essential role in reducing diagnostic delays, ensuring guideline-aligned treatment, implementing systematic PRO monitoring, and supporting the development of a national virtual CSU registry.

The Belgian CSU working group plays a central role in the national improvement strategy. Composed of leading clinicians with extensive expertise in CSU, the group is well positioned to guide awareness initiatives, create national/local guidelines, support PRO optimisation, and contribute to the development of a national virtual CSU registry. Their authority and credibility ensure that proposed changes are clinically sound and broadly supported across the healthcare landscape. The CSU working group assumes responsibility for the prioritization of its assigned tasks, in consultation with the other stakeholders.

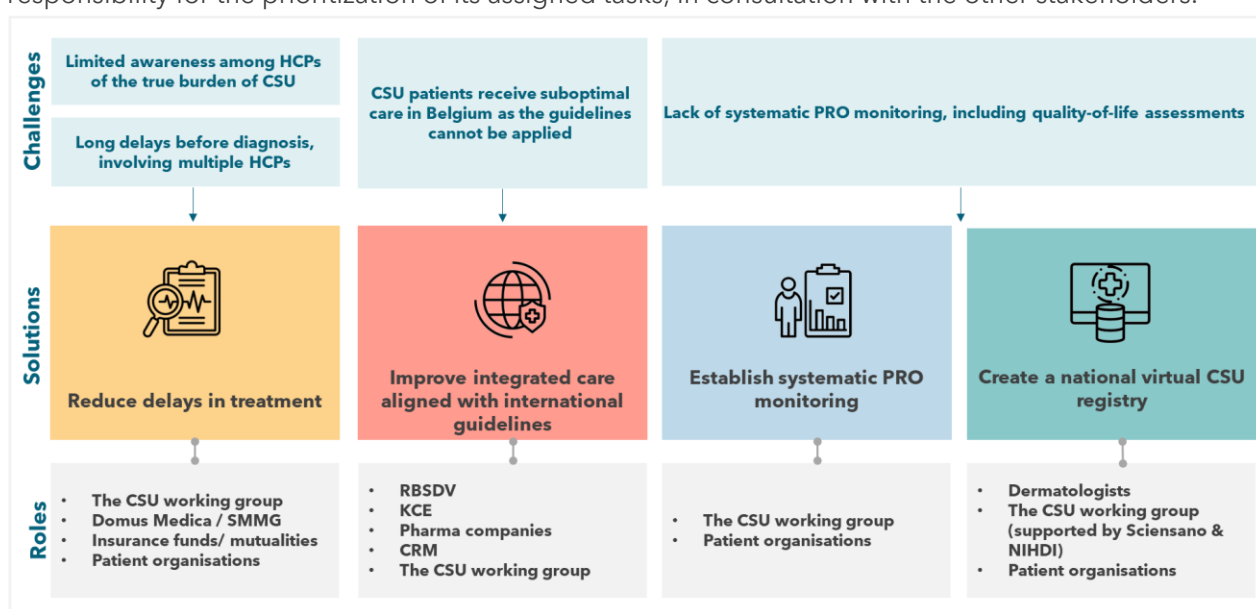


Figure 19. Prioritised challenges with the proposed solutions and assigned roles & responsibilities

7.1 Stakeholder responsibilities to reduce delays in treatment

Accelerating diagnosis and reducing delays requires coordinated efforts across the care pathway, with a strong focus on education, awareness, and alignment.

- The **CSU working group** should leverage its clinical expertise and national network to coordinate awareness initiatives, promote guideline implementation, and launch programmes aimed at minimising diagnostic delays.
- **Domus Medica/SMMG** should use their educational platforms and networks to raise CSU awareness among GPs, support early diagnosis and referral, and promote guideline dissemination through targeted training and continuing medical education.
- **Health insurance funds** can actively contribute to awareness campaigns and ensure alignment with broader rare-disease strategies, helping to reach both patients and frontline healthcare providers.
- **Heel de huid**, as a patient organisation supporting individuals, should use its network to highlight the impact of CSU and advocate for greater awareness by educating patients, HCPs, and pharmacists.

These combined efforts will help ensure earlier recognition of CSU, reduce unnecessary healthcare utilisation, and improve patient experience.



7.2 Stakeholder responsibilities to improve integrated care aligned with international standards

Ensuring integrated, guideline-aligned care requires collaboration between scientific bodies, professional associations, and policymakers.

- **The Royal Belgian Society of Dermatology (RBSDV)** should lead the clinical development process, ensuring that Belgian CSU treatment guidelines are collaborative, inclusive, and clinically relevant. The **CSU working group** should coordinate multidisciplinary expertise to ensure alignment of CSU care in Belgium with internationally validated guidelines. It should identify inconsistencies with these standards and promote consistent implementation across all care settings.
- **KCE** can play a supportive role by translating international, highly validated guidelines into Belgium-specific recommendations and aligning the reimbursement framework accordingly. Creating and integrating CSU guidelines within the guideline development program is a key step.
- **Pharma companies** should support guideline development with robust evidence and real-world data and collaborate with clinical bodies and policymakers to ensure innovations align with guideline-based care and remain accessible within the Belgian reimbursement framework.
- **Commission Reimbursement of Medicines (CRM)** should ensure that reimbursement decisions consistently support evidence-based access to medicines, in alignment with internationally validated clinical guidelines

This alignment will enable consistent, evidence-based care and ensure equitable access to effective treatments.

7.3 Stakeholder responsibilities to establish systematic PRO monitoring

Systematic PRO monitoring is essential for personalised, effective CSU management and requires coordinated leadership.

- **The CSU working group** should take the lead in selecting relevant PRO measurements, standardising processes, and integrating PROs into the care pathway through centralised interpretation, telemonitoring, dashboards, and patient support.
- **Patient organisations**, including Heel de huid, play a crucial role in developing and promoting solutions that enable systematic PRO implementation and ensure that PROs are meaningfully integrated into personalised disease management. Heel de huid is strongly committed to supporting this initiative.

Together, these efforts will ensure that PROs become a routine and impactful component of CSU care.

7.4 Stakeholder responsibilities to create a national virtual CSU registry

While PRO monitoring captures the patient experience, complementary clinical data is essential to fully understand the disease burden and support optimal, cost-effective care. A national virtual CSU registry is therefore a critical next step.

- **Dermatologists and the CSU working group**, supported by **Sciensano** and in collaboration with **NIHDI**, should take responsibility for enabling the collection of standardised data within electronic patient records (EPDs), ensuring automated integration into the registry, and securing funding through the upcoming Evidence Platform.
- The registry should operate under the joint governance, with active involvement from patient representatives to ensure patient-centred data collection and interpretation.
- **Patient organisations** should contribute to developing and promoting solutions that facilitate the collection of PROs into EPDs. Heel de huid is highly committed to driving the development of these solutions.



A national virtual CSU registry will provide the real-world evidence needed to refine policy, improve clinical practice, and ensure alignment between patient needs and reimbursement frameworks.

7.5 Responsibilities per stakeholder group

Clear responsibilities are critical to achieving sustainable, patient-centred improvements.

Dermatologists & internal medicine

Dermatologists and internal medicine are central to the diagnosis and management of CSU. Their responsibilities include:

- Ensuring timely and accurate diagnosis, supported by appropriate use of validated tools
- Applying international guidelines and escalating treatment when indicated
- Educating patients about disease mechanisms and treatment expectations
- Implementing systematic PRO monitoring, including UAS7, AAS, DLQI, and angioedema-specific tools
- Contributing data to a national virtual CSU registry to support real-world evidence generation
- Collaborating with primary care to streamline referral pathways and improve continuity of care

Primary care physicians

Primary care physicians are often the first point of contact for patients with CSU symptoms. Their responsibilities include:

- Diagnosing CSU early and differentiating it from acute urticaria or allergic reactions
- Initiating first-line treatment in line with international guidelines
- Referring patients promptly to dermatologists or internal medicine when symptoms persist
- Providing ongoing support for treatment adherence and patient education

Strengthening the role of primary care is essential to reduce diagnostic delays and improve patient experience.

Patients and patient organisations

Patients are active partners in their own care. Their responsibilities include:

- Engaging in shared decision-making with their healthcare providers
- Using PRO tools to monitor symptoms and communicate changes
- Adhering to treatment plans and reporting barriers to adherence
- Participating in registry initiatives, where appropriate, to support evidence generation

Empowered patients contribute to better outcomes and more efficient care pathways.

Patient organisations play a vital role in amplifying the patient voice and supporting shared decision-making. Heel de huid, a patient organisation supporting individuals, should utilise its network and connections to highlight the impact of CSU and advocate for greater awareness by educating patients, HCPs and pharmacists. Their responsibilities include:

- Providing accessible education on CSU, treatment options, and self-management
- Supporting PRO adoption by helping patients understand and use monitoring tools
- Collecting patient insights to inform policy and guideline updates
- Raising awareness of the psychosocial burden of CSU among the public and policymakers
- Contributing to the design of the national virtual CSU registry to ensure patient-centred data collection

Their involvement ensures that care improvements reflect real patient needs.



Health authorities and policymakers

Health authorities and policymakers are essential to enabling structural improvements in CSU care. Their responsibilities include:

- Ensuring access to guideline-recommended add-on treatments, aligned with international guidelines and real-world evidence
- Evaluating reimbursement policies based on real-world evidence and health economic analyses
- Supporting the development of a national virtual CSU registry, ensuring data can inform reimbursement decisions
- Facilitating multi-stakeholder collaboration, including Evidence Platform meetings
- Ensuring equitable access to effective treatments across regions and populations
- Supporting PRO-based care models that improve outcomes and reduce unnecessary healthcare utilisation
- Integrating PROs into national quality-of-care frameworks

Their leadership is crucial to achieving sustainable, system-level change and balancing clinical needs with long-term sustainability.

Health insurance funds

Health insurance funds have the potential to actively contribute to awareness campaigns, similar strategies than those used for rare diseases. Their responsibilities include:

- Promoting patient education to improve adherence and avoid costs
- Collaborating on the development of a national virtual CSU registry

Their engagement is essential to support patients and policy.

Academic and research institutions

Academic centres and research groups contribute to the evidence base needed for continuous improvement. Their responsibilities include:

- Conducting clinical and epidemiological research on CSU and its comorbidities
- Analysing registry data to generate insights on treatment effectiveness and disease burden
- Supporting validation of PRO tools and digital monitoring solutions
- Contributing to guideline creation based on emerging evidence

Their expertise strengthens the scientific foundation of CSU care in Belgium.

Industry partners

Industry partners contribute through research, innovation, and collaboration. Their responsibilities include:

- Supporting evidence generation, including real-world studies and health economic analyses
- Providing educational resources for HCPs and patients
- Collaborating transparently with stakeholders to align on guideline-based care
- Contributing to registry development, ensuring data quality and interoperability

Their role is to support multi-stakeholder decision-making.



8 The CSU action plan

The CSU Action Plan **provides a coordinated, implementation-ready roadmap** to improve the diagnosis, management, and long-term outcomes of patients with chronic spontaneous urticaria in Belgium. It builds on the unmet needs identified in the NEED framework and patient journey analysis and reflects the consensus of clinicians, patients, policymakers, payers, and international experts.

8.1 Strategic priorities

The plan focuses on four strategic priorities:

- Accelerating diagnosis,
- Aligning care with international guidelines,
- Implementing systematic PRO monitoring, and
- Establishing a national virtual CSU registry.

Each priority includes concrete actions, responsible stakeholders, and expected impact. Together these key actions form a coherent roadmap to improve CSU care across the patient journey and within the Belgian healthcare context.

Strategic priority Reduce delays in treatment

Objective

Ensure timely recognition and diagnosis of CSU to reduce disease burden and prevent unnecessary healthcare utilisation.

Key actions

- **Develop clear referral pathways** for primary care physicians
- Provide **targeted education** for GPs, dermatologists, allergists, and emergency physicians on CSU recognition and differentiation from acute urticaria via academic institutions to embed CSU-related content into undergraduate and postgraduate medical education, fostering long-term awareness, competence, and early recognition among future HCPs.
- Targeted educational materials need to be designed for general practitioners (GPs) and pharmacists to align with dermatology best practices.
- Regular **educational sessions and workshops** for HCPs on evidence-based CSU treatment approaches.
- Create and distribute **patient-friendly information materials** to support disease understanding and early help-seeking, based on systematic identification of information needs.
- Promote **interdisciplinary collaboration** between primary and specialist care.

Expected impact

- Shorter diagnostic delays
- Reduced “medical shopping”
- Earlier initiation of effective treatment
- Improved patient satisfaction and trust in the care pathway



Strategic priority

Improve integrated care aligned with international guidelines

Objective

Ensure that Belgian CSU care is consistent with international guidelines and that patients have equitable access to effective treatments.

Key actions

- **Create national guidelines** to align with the International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria recommendations, via the CSU expert working group, including tailored guidance for dermatologists and GPs, with a strong focus on early recognition, accurate diagnosis, stepwise treatment, and clear referral criteria to CSU specialists.
- The CSU guidelines need to be submitted to relevant Belgian medical societies for review and endorsement to strengthen legitimacy and uptake.
- A national dissemination plan needs to be developed to integrate the Belgian CSU guidelines into routine clinical practice and raise awareness among HCPs across healthcare settings, competence, and early recognition among future HCPs.
- Engagement with health authorities, insurance funds, and policymakers to support reimbursement of effective add-on treatments in alignment with the international guidelines to allow earlier access and access to the moderate and severe CSU population.
- **Promote multidisciplinary care models**, including dermatology, internal medicine, mental health, and primary care.
- **Strengthen patient education** to support adherence and shared decision-making.

Expected impact

- Improved disease control and quality of life
- Reduced reliance on off-label treatments
- More efficient use of healthcare resources and less impact on society
- Alignment with neighbouring countries and European best practices

Strategic priority

Establish systematic PRO monitoring

Objective

Integrate patient-reported outcomes into routine care to support personalised treatment and timely escalation.

Key actions

- Existing PRO practices across healthcare settings need to be evaluated to identify challenges and gaps, informing improvement priorities and the development of a standardised PRO framework.
- **Implement routine use of validated PRO tools** (UAS7, AAS, DLQI, angioedema-specific measures).
- Introduce **digital platforms** for remote monitoring and follow-up.
- Ensure **interoperability** with existing hospital systems and digital tools.
- Provide **training for HCPs** on interpreting PRO data and integrating it into clinical decisions.
- Ensure **consistent documentation** of PROs across care settings.



- **A dedicated expert group needs to be established to evaluate the follow-up and practical use of PROs in CSU care**, ensuring they are meaningfully integrated into clinical decision-making and continuous quality improvement.

Expected impact

- More accurate assessment of disease severity
- Better alignment between patient and physician perspectives
- Earlier treatment optimisation
- Stronger real-world evidence base for policy decisions

Strategic priority

Create a national virtual CSU registry

Objective

Generate high-quality real-world evidence to inform policy, reimbursement, and clinical practice.

Key actions

- Launch an **NIHDI-initiated Evidence Platform meeting** to define scope, governance, and data standards for the CSU pilot
- Develop a **national virtual registry** capturing disease severity, patient and treatment information, outcomes, and PROs (within Sciensano), enabling monitoring of disease management, supporting reimbursement discussions, and contributing to data-driven policy decisions.
- Enable **use** of a national CSU registry **for better decisions** (supported by health economic analyses to evaluate long-term value and cost-effectiveness) **and research across centres**.

Expected impact

- Improved understanding of disease burden and treatment outcomes
- Enhanced quality of care across regions
- Support for future guideline creation and innovation

8.2 A coordinated, multi-stakeholder implementation approach

Successful implementation of the CSU Action Plan requires sustained collaboration between clinicians, patient organisations, policymakers, payers, researchers, and industry partners. A structured governance model, supported by regular evaluation and transparent communication, will ensure that progress is monitored and that actions remain aligned with patient needs and emerging evidence.



9 Conclusion

Chronic spontaneous urticaria (CSU) remains a significantly underestimated condition in Belgium, despite its profound physical, psychological, social, and economic burden on patients. The findings of this report clearly demonstrate that the current care pathway does not fully meet patient needs, nor does it reflect the standards set by international guidelines. Diagnostic delays, limited disease awareness, restricted access to effective treatments, inconsistent PRO monitoring, and the absence of structured real-world data collection all contribute to a fragmented and suboptimal care experience.

The multi-stakeholder assessment conducted through the KCE NEED framework, combined with extensive patient journey analysis, provides a comprehensive and evidence-based understanding of where improvements are most urgently required. The **four strategic priorities identified—accelerating diagnosis, aligning care with international standards, implementing systematic PRO monitoring, and establishing a national virtual CSU registry—form a coherent and actionable roadmap** for meaningful change.

Achieving these improvements will require coordinated leadership across the healthcare ecosystem. The **Belgian CSU working group will play a key role**, together with dermatologists, internal medicine, primary care physicians, patient organisations, the royal Belgian society of dermatology, Domus Medica/SMMG, insurance funds/mutualities, KCE, Sciensano, CRM, NIHDI, pharma companies and academic partners, each having a distinct and essential role to play. Their combined efforts can ensure that Belgian CSU care becomes more timely, equitable, data-driven, and patient-centred.

By implementing the actions outlined in this report, Belgium can **significantly reduce the burden of CSU, improve quality of life for thousands of patients, and align national practice with the highest international standards.** The path forward is clear, the evidence is strong, and the collective will of stakeholders provides a solid foundation for sustainable, long-term improvement.

Annex – Detailed overview of NEED framework for CSU and used sources

Dimension	Domain	Criterion	Indicator	Input
Patient needs	Health	Impact on general health-related quality of life The extent to which a health condition impacts the general health-related quality of life of patients.	Years of life lived with disability (per case)	Most patients suffer from CSU for more than one year, a considerable number of patients even seem to be affected for longer than 5 years. Approximately 64% of patients with CSU still needed medical care after 1 year, but this percentage decreased to 32.4% and 17.3% by the 3rd and 5th years. After 5 years, 8.4% of patients were still in need of medical CSU care. Patient-reported outcome measures (DLQI, CU-Q20L, SF-6D, EQ-5D, MCS, PCS) consistently show that CSU patients have worse QoL scores (SF-6D of 0.625) compared to both the general population and patients with other chronic skin conditions such as atopic dermatitis (AD) and psoriasis (PsO) (SF-6D of 0.686 and 0.770). Comorbidities are highly prevalent: 68% of CSU patients report at least one comorbidity, and 54% report more than two. Common comorbidities include allergies (38%), migraine/headache (31%), anxiety (24%), depression (23%), sleep difficulties (16–20%), and hypertension (17–43%). Obesity is present in ~37% and smoking is more frequent compared to controls. CSU patients experience frequent hives (up to 85%), recurrent angioedema (40–60%), and related symptoms such as itch, pain, fatigue, and sleep disturbances. In CSU, intense itch and recurrent hives and/or angioedema are the most distressing symptoms, often accompanied by pain. Over half of patients (55%) report pain during flares, most commonly at hive sites (59%), angioedema (34%), or joints (34%), with burning or stinging, swelling, and soreness after scratching frequently described. 37% of patients reported stress due to the unpredictable nature of CSU. Other common emotional effects among inadequately controlled CSU patients are feeling moody (29%), feeling unattractive (28%), 66.3% of CSU patients experienced mild to severe anxiety (GAD-7 score ≥5), which is higher than in patients with Atopic Dermatitis (51.7%) and Psoriasis (48.8%). CSU is associated with a 6-fold increased risk of anxiety or depression due to chronic itching, unpredictability, and disease burden. Anxiety occurs in 72.4% and depression in 75.7% of CSU patients. Patients commonly experience tight skin (47%), joint dysfunction (24%), and frequent or severe joint pain (12–19%), which can limit mobility. 82% report symptom triggers, most commonly friction and sweating which discourages physical activity such as sports or cycling. Patients with CSU often adopt self-care practices alongside prescribed treatments, including using soothing or moisturising creams (51%), avoiding certain clothing (47%) and foods (39%), and taking vitamins or antioxidant supplements (45%). CSU affects social activities, work, sports, clothing choices, relationships (with sexual dysfunction in 58% of patients), and self-image. Everyday activities, such as cycling or sitting on certain surfaces, are restricted, and even their choice of vacation destination is different due to CSU symptoms (because of sweat being a trigger for symptoms).
		Impact on physical health The extent to which a health condition impacts the physical health of patients	Experienced burden of physical symptoms related to the health condition	
		Impact on psychological health The extent to which a health condition impacts psychological health of patients.	Experienced burden of psychological symptoms related to the health condition	
		Impact on autonomy The extent to which a health condition impacts the autonomy of patients.	Anxiety/depression before vs today	
			Mobility before vs today	
			Self-care before vs today	
			Usual activities before vs today	
		Impact on life expectancy The impact of a health condition on life expectancy of patients.	Years of life lost (per death)	Patients with CSU have a higher risk and higher rates of leading causes of death in the US compared with controls, including suicidal ideation or suicide attempts and malignant neoplasms.
		Treatment effectiveness The extent to which the current overall treatment is effective.	Effectiveness of current overall treatment (standard of care)	Real-world evidence showed that in CSU patients: 57% of patients receiving H1-AH (with standard dose) remained uncontrolled 62% of patients remained uncontrolled after up-titration of H1-AH 27.1% of patients remained uncontrolled after treatment with omalizumab Patient-reported data indicated that: 84% of patients report inadequate disease control after treatment with H1-AH 89% of patients report inadequate disease control after treatment with glucocorticoids 80% of patients report inadequate disease control after treatment with omalizumab and 94% for dupilumab - Other add-on therapies (montelukast, doxepin, cyclosporin) also show high inadequate-control rates at 89%, 94%, and 93%
	Healthcare			



Dimension	Domain	Criterion	Indicator	Input
Patient needs	Healthcare	Burden of treatment The extent to which the current overall treatment is burdensome for patients.	Experienced burden of treatment	Patients receiving treatment for chronic urticaria experience approximately twice the rates of depression, anxiety, and sleep difficulties compared with controls and have higher healthcare utilisation, including physician visits (9.1 vs. 4.9), emergency room visits (0.8 vs. 0.3), and hospitalisations (0.3 vs. 0.2). Second-generation antihistamines are the first-line treatment for CSU. Standard dosing is used initially; if symptoms do not resolve, the dose may be doubled and increased up to four times the standard dose (off-label). Higher doses increase the risk of side effects, particularly sedation. Omalizumab is considered safe for long-term use, with about 4% of patients experiencing side effects such as headache, fatigue, or injection-site reactions. Systemic corticosteroids used short-term during exacerbations, but long-term use can lead to serious adverse effects, including fractures, muscle atrophy, metabolic disturbances, cardiovascular risks, ocular complications, psychiatric symptoms, and increased infection risk.
			Experienced burden of side-effects of treatment	
		Quality of care The extent to which the care provided, including its organisation, provision of information, involvement in decisions, and diagnostic processes, meets quality standards.	Experience with the organisation of care	Patients with CSU experience significant unmet needs, including misalignment between patient and physician perceptions of disease burden and treatment satisfaction. Key unmet needs include better knowledge of CSU among primary care physicians (46%), understanding of underlying causes (45%), information about available treatments (44%), and improved access to specialists (43%) and treatments (42%). Guideline adherence is poor, leading to high rates of non-recommended therapies and delayed, difficult diagnoses, with a mean of 2.7 diagnostic tests per patient and 13.6% receiving no tests at all. Unnecessary emergency visits occur due to disease unpredictability, angioedema, long waiting lists, and limited specialist access.
			Quantity of information received	Patients address a key unmet need being lack of knowledge on CSU among primary care physicians (46%), understanding of its underlying causes (45%), information about available treatments (44%), and improved access to specialists (43%) and treatments (42%), with 86% stating they must actively seek additional information to supplement their doctors' advice.
			Clarity of information received	70% of CSU patients need to consult multiple sources to understand their condition, 48% find available information difficult to understand, and while social media and support groups provide some advice, accessing reliable, structured information remains challenging.
			Involvement in treatment choice	Patients with CSU experience significant unmet needs, including misalignment between patient and physician perceptions of disease burden and treatment satisfaction.
			Diagnostic timing	45% of patients with CSU experienced symptoms for more than one year before receiving a diagnosis. The mean diagnostic delay ranged from 2 to 4.3 years, during which patients consulted an average of 6.1 physicians. This prolonged and variable diagnostic process not only contributed to significant frustration but also had a considerable negative impact on patients' emotional well-being.
			Treatment availability	International guidelines and Folia recommend second-generation antihistamines as first-line therapy, with dose escalation up to four-fold in case of persistent symptoms. In case symptoms persist after up-titration, no treatment option exists for patients with moderate CSU in Belgium (since Omalizumab is only accessible for severe CSU). This is in contrast with EU treatment guidelines and applied in countries like: The Netherlands, Germany, and France.
			Forgone care (medical care that a person needs but does not receive)	Physicians often overestimate the benefit that patients gain from their treatment, and this is likely to contribute to the undertreatment of CSU and the failure to achieve complete control of CSU. Furthermore, the fluctuating nature of CSU may influence a physician's assessment depending on the patient's disease state at the time of the assessment. On average, CSU patients had 0.3 emergency room visits per patient over the past 6 months (n=50).



Dimension	Domain	Criterion	Indicator	Input
Patient needs	Social	Impact on social life The impact of the health condition on patients' social life, including on their social support needs and their capacity to establish meaningful relationships with the community, family and/or friends	Social support needs	Living with CSU carries stigma and discrimination for 63% of patients , with 33% being stared at or asked if they are contagious, 18% experiencing refusal of physical contact, and 15% being made the subject of jokes or bullied. Despite this, 82% of patients feel their condition is recognised by healthcare providers, 72% by family and friends, and 60% by colleagues, bosses, or teachers.
		Impact on education The impact of the health condition on patients' education.	Years of education lost	CSU has a notable negative impact on professional and academic pursuits . Among the few CSU patients attending school (n=3), 67% reported significant effects, including reduced social contact due to increased homeschooling, decreased productivity or academic performance, and, in one-third of cases, reconsideration of educational choices.
		Impact on work The impact of the health condition on patients' working conditions, including capacity to work, working hours and working environment	Changes in working conditions	Over 20% of patients have reported at least 1 h of missed work per week , with an overall work impairment of 27%, and this likelihood of working part-time.
		Financial consequences Costs borne by patients to be able to access reimbursed or non-reimbursed healthcare	Average out-of-pocket healthcare costs per patient	68.4% patients reported out-of-pocket expenses data . A monthly average of \$1786.94 (US), 569.13 CAD (CA), £2070.67 (UK), V789.80 (DE), V289.02 (FR), V549.94 (IT), and U17,071.30 (JP) was reported. In Europe, out-of-pocket expenses (including transportation, alternative medicine, and other costs) account for an average of 30% of total direct medical costs (ranging from 9–64%). A higher proportion of patients with CSU reported average monthly out-of-pocket costs of ≥€50/€50 compared to AD or PSO.
		Frequency How common a health condition is with reference to the size of the population (the population at risk) and a measure of time.	Average non-healthcare costs per patient	In Europe, out-of-pocket expenses (including transportation, alternative medicine, and other costs) accounting for an average of 30% of total direct medical costs (ranging from 9–64%). A higher proportion of patients with CSU reported monthly average out-of-pocket costs of ≥€50/€50 compared to AD or PSO.
		Prevalence or incidence	Prevalence or incidence	The prevalence of CSU is reported to be between 0.1% and 0.8% in European countries . The lifetime prevalence for acute urticaria is approximately 20%.
Society needs	Health	Transmissibility The extent to which a health condition can be transmitted from one organism to another.		Not applicable for CSU
		Antimicrobial resistance The extent to which, due to drug resistance, antibiotics or other antimicrobial medicines used to treat or manage a health condition are ineffective, or infections related to a health condition become increasingly difficult or impossible to treat. (Existing antimicrobial resistance to treatments used & Volume of antibiotics delivered to treat the disease (proxy))		Not applicable for CSU



Dimension	Domain	Criterion	Indicator	Input
Society needs	Health	Burden on informal caregivers The extent to which the quality of life of informal caregivers is affected by their caregiving activities.	Loss in informal caregivers' quality of life	It was observed that patients' poorer quality of life due to CSU was associated with higher rates of anxiety in the cohabitants, a poorer quality of life of the family and lower sexual satisfaction among the cohabitants. Intimacy/sexual relationships may be impaired in CSU patients due to both physical and emotional distress, often leading to loneliness.
	Healthcare	Value for money of standard of care The health gain achieved for the level of healthcare spending associated with the standard of care for a health condition. It allows for the identification of inefficiencies in the healthcare system	Healthcare costs per unit of health gain (disaggregated presentation of total healthcare expenditures and total health effects of standard of care)	Annual direct medical costs in Europe are estimated at €915–€3,293 per patient (2025 values) with average costs around €1,820. The largest cost drivers are therapies (≈57%), inpatient care (≈20%), and emergency visits (≈15%), with even higher shares of inpatient costs in some countries (up to 47% in Germany). ER visits and number of hospitalisations were significantly higher among patients with CSU compared to those with AD or PSO.
		Preventability The extent to which a health condition can be avoided or mitigated through primary prevention strategies	Implementation of effective primary prevention strategies	Not applicable for CSU
	Social	Productivity losses The costs related to work absenteeism, presenteeism, early labor force exits of patients with the health condition and their caregivers.	Costs related to work absenteeism, presenteeism, or/and early labor force exits of patients	Patients experience higher absenteeism, presenteeism, and overall work impairment compared with healthy controls and with patients who have psoriasis or atopic dermatitis. On average, CSU patients report about double the rates of absenteeism (≈13% vs. 6%) and presenteeism (≈34% vs. 17%), with overall work productivity losses around 27–40%, depending on disease severity. This burden translates into substantial indirect costs, estimated at €600–€1,345 per patient annually in Belgium (2025 values). One German study reported a total monetary loss due to impairment in total work productivity and activity loss of €2.2 billion in 2018. This translates to an estimated loss of €395 million in 2025 in Belgium.
		Environmental impact of standard of care The impact of the management of a health condition on the natural environment.	Costs related to work absenteeism, presenteeism or/and early labor force exits of caregivers	Not applicable for CSU
			Greenhouse gas emissions related to the standard of care	Not applicable for CSU
			Hazardous waste related to standard of care	Not applicable for CSU
			Use of natural resources and raw materials related to standard of care	Not applicable for CSU



Dimension	Domain	Criterion	Indicator	Input
Future needs	Health	Future burden of disease The impact of a health condition on the health of future generations.	Future prevalence/incidence	Future projections suggest that the global burden of urticaria will continue to rise through 2046. Analysis of data shows an increasing trend in incidence, with environmental and lifestyle factors such as air pollution and dietary intake significantly correlated with future prevalence.
			Future years of life lost	Not applicable for CSU
			Future years lived with disability	In future years, years lived with disability (YLD) from CSU could be reduced if patients receive guideline-based treatment and specialized care, as shown in Scandinavian centers where disease severity, quality of life, and healthcare use improved over two years.
	Healthcare & social	Future economic burden The impact of a health condition on future healthcare expenditures and productivity, in monetary terms.	Future direct costs	Future direct costs of CSU could be reduced through guideline-based treatment and close monitoring, as shown in Scandinavian centers where adherence led to fewer hospital visits, less medication use, and overall lower medical resource utilization. Personalized treatment adjustments may further prevent unnecessary emergency care and optimize cost efficiency.
			Future indirect costs	Future indirect costs of CSU could be reduced through guideline-based management can lower future indirect costs, such as fewer missed workdays and increased productivity

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