TAKHZYRO® (lanadelumab) Prescribing Information can be found here.
CINRYZE®▼ (human C1-esterase inhibitor) Prescribing Information can be found here.

Adverse events should be reported. Reporting forms and information can be found at: **https://yellowcard.mhra.gov.uk/**
Adverse events should also be reported to Takeda at: **AE.GBR-IRL@takeda.com**

A TAKEDA SUMMARY

Prophylaxis in hereditary angioedema
a United Kingdom Delphi consensus[1]

Since the last UK consensus statement in 2014, new effective licensed therapies for LTP in HAE have been approved for use by NICE in the UK, including TAKHZYRO and berotralstat. Additionally, NHS England published a policy for commissioning of plasma-derived C1 inhibitor for LTP in 2016, in which access criteria have been restricted primarily by HAE attack frequency.[1]

In view of the changes to the HAE landscape, a further Delphi consensus was conducted in 2021 with the aim of establishing current views on the management of LTP for HAE in the UK to highlight potential areas of improvement.[1]

The 2021 WAO/EAACI HAE guidelines currently recommend the use of LTP as the only way of achieving total disease control and to normalise patients' lives.[2]

The Delphi method[1]

Exploration phase
Telephone interviews with experts to identify broad issues

Responses edited and used to **construct questionnaires**

41 consensus statements were finalised

Evaluation phase
Conducted 25 June–25 July 2021
Specific questionnaires involving:

59	39	34
HCPs	patients	centres

The level of individual agreement with each statement was measured using a four-point Likert scale (strongly disagree, disagree, agree, or strongly agree)

Key areas for action identified by HCPs (% agreement with statement)[1]

Prophylaxis
Agreement was **100%** for all statements within this theme, related to:

1. **Desired outcomes for LTP** — To significantly reduce attack frequency and severity, and improve patient QoL
2. **Tolerability** — LTP should be well tolerated
3. **Ease of use** — LTP should be easy to self-administer, and not unduly burdensome
4. **Provision of information to patients** — Including efficacy, safety, and route of administration, to enable an informed choice
5. **The benefits of well-controlled disease** — Improves patient QoL and utilises fewer healthcare resources

Commissioning of prophylaxis for HAE

is based on too simplistic criteria – attack frequency alone is not appropriate…

83.9% agree

…potentially limiting the access of a cohort of patients who should be given prophylaxis

78.6% agree

Alternatives to the current CCP are preferable.

They could include a form of **validated PRO scoring** in conjunction with a **peer-review process**

96.4% agree

The prophylaxis policy should also take into account:

1. Attack severity
2. Duration of attack
3. Attack location
4. Impact of HAE on the patient

96.4% agree

80.4% agree

Compared with other countries,* the prophylaxis policy is far more **stringent** and **restrictive**, putting patients in the UK at a comparative **disadvantage**

Attenuated androgens
are effective for some patients, but unsuitable for specific groups (e.g. children and pregnant women)

100% agree

The WAO/EAACI HAE guidelines only recommend androgens as second line therapy.[2] Additionally, given the known side effects of danazol and the potential association of HAE with cardiovascular disease,[3] **this highlights a case for review of the current access policies in the UK**

Standardisation of patient reviews could improve:

Objective assessment and **access** to treatment — **91.2%** agree

Comparison of HAE management across the UK — **96.5%** agree

Data collection — **98.2%** agree

Patient management
should involve regular reviews and evaluations for LTP at **every visit** (at least once per year), in line with national and international guidelines

94.7% agree

The disease burden of HAE
is very individual; what may appear to not be a high disease burden can have a **huge impact** on a patient, and vice versa

98.2% agree

Psychological support is recognised as an area of potential benefit requiring further resources and research

Remote patient management
remains **popular** post-pandemic, particularly for stable patients…

94.7% agree

…and is something that has been identified as having benefits

Expert patient care

in specialist centres should be provided for patients with HAE

98.3% agree

These centres should maintain a sufficient cohort of patients to **ensure expertise, or work within a coordinated network of HAE specialists**

96.6% agree

PRO measures
are valuable tools that could **enable patient benchmarking and disease tracking** over time and **facilitate reviews**

Limitations of the survey included:

1. Not all HAE consultants may have been included
2. Potential bias in patient recruitment
3. The need to explore views on on-demand treatment for HAE in future research

Use this document with commissioners or service leads to advocate for improvements to standards of care in HAE.

TAKHZYRO is indicated for routine prevention of recurrent attacks of HAE in patients aged 2 years and older.[4,5]

CINRYZE is indicated for the treatment and pre-procedure prevention of angioedema attacks in adults, adolescents and children (2-years old and above) with HAE; routine prevention of angioedema attacks in adults, adolescents and children (6-years old and above) with severe and recurrent attacks of HAE, who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment.[6,7]

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*No attack metric connected to access of TAKHZYRO in Germany, France and Spain.

Abbreviations: CCP, clinical commissioning policy; HAE, hereditary angioedema; HCP, healthcare professional; LTP, long-term prophylaxis; NICE, National Institute for Health and Care Excellence; PRO, patient-reported outcome; QoL, quality of life; WAO/EAACI, World Allergy Organization/European Academy of Allergy and Clinical Immunology.

References: 1. Yong PFK, et al. *Clin Exp Immunol* 2024;217(1):100–116; **2.** Maurer M, et al. *Allergy.* 2022;77(7):1961–1990; **3.** Sundler Björkman L, et al. *Clin Transl Allergy.* 2022;12(3):e12135. **4.** TAKHZYRO GB Summary of Product Characteristics; **5.** TAKHZYRO NI Summary of Product Characteristics; **6.** CINRYZE GB Summary of Product Characteristics; **7.** CINRYZE NI Summary of Product Characteristics.

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