

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Difelikefalin for treating pruritus in people having haemodialysis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of difelikefalin within its marketing authorisation for treating pruritus associated with chronic kidney disease in adults having haemodialysis.

Background

Pruritus, or itch, commonly affects people with chronic kidney disease. It is a chronic, unpleasant symptom that can have a strong negative impact on people's quality of life, often leading to sleeplessness and mood disorders, including depression. The itching can be localised or generalised. When localised, it often occurs in the back, face, and arm. The urge to scratch can result in skin abrasions. It is also associated with a 17% increase in mortality in people having haemodialysis.¹ The prevalence of moderate to severe pruritus in people having haemodialysis in the UK has been estimated to be around 50%.² Applying this estimate to data from the most recent UK Renal Registry report suggests that there are about 10,000 people having haemodialysis and with moderate to severe pruritus in the UK.³

There are currently no approved treatments for pruritus associated with chronic kidney disease, although treatments for other conditions are sometimes used off label, such as the gamma aminobutyric acid (GABA) analogues gabapentin and pregabalin.

The technology

Difelikefalin (Kapruvia, Vifor Pharma UK) is a kappa opioid receptor agonist that suppresses itch and inflammation. Activation of kappa opioid receptors on immune cells results in reduced release of nerve-sensitising pro-inflammatory molecules. Difelikefalin does not cross the blood/brain barrier and does not activate central opioid receptors, thereby avoiding risks such as hallucination or opioid addiction.

Difelikefalin is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.

Intervention(s)	Difelikefalin
Population(s)	Adults having haemodialysis with moderate to severe pruritus
Comparators	Established clinical management without difelikefalin, including gabapentin and pregabalin
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> itching intensity adverse effects of treatment health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Chronic kidney disease in adults: assessment and management (2014) NICE guideline 182 Chronic kidney disease in adults (2017) NICE quality standard 5
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 15 Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1, 2 and 4. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

References

- 1) DermNet NZ. Uraemic Pruritus. 2010. Available from: <https://dermnetnz.org/topics/uraemic-pruritus/>. Accessed February 2021.
- 2) Rayner HC, Larkina M, Wang M, Graham-Brown M, van der Veer SN, Ecker T, Hasegawa T, Kleophas W, Bieber BA, Tentori F, Robinson BM. International comparisons of prevalence, awareness, and treatment of pruritus in people on hemodialysis. *Clinical journal of the American Society of Nephrology*. 2017 Dec 7;12(12):2000-7. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5718267/> Accessed February 2021.
- 3) UK Renal Registry. UK Renal Registry 21st Annual Report – data to 31/12/2017, Bristol, UK. . 2019. Available from: <https://www.renalreg.org/publications-reports/> Accessed February 2021.