NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Targeted-release budesonide for treating primary IgA nephropathy

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of targeted-release budesonide within its marketing authorisation for treating primary immunoglobulin A (IgA) nephropathy.

Background

IgA nephropathy (also known as Berger's disease) is a chronic autoimmune kidney disease. It causes a build up of IgA containing immune complexes in the glomeruli of the kidneys. This causes inflammation and damage in the glomeruli and reduces their function, eventually leading to scarring of the whole kidney.[1-4] In IgA nephropathy, both kidneys are affected equally.[5] The condition is commonly classified as primary or secondary, with secondary disease associated with comorbidities such as IgA vasculitis and chronic liver disease.[6] The presentation of IgA nephropathy varies considerably and, in its early stages, may have no symptoms. The most common symptoms are blood or protein in the urine (haematuria or proteinuria).[5] IgA nephropathy is also associated with complications from reduced kidney function including high blood pressure, high cholesterol and cardiovascular problems. The rate of progression is variable, although ongoing decline in glomerular function may eventually lead to kidney failure, requiring transplant or life-long dialysis.[5] A particularly severe form of the disease known as rapidly progressive IgA nephropathy has been reported in a small proportion of people.[7]

It is estimated that around 4 in 10,000 people have primary IgA nephropathy in Europe.[8] Between 20% to 40% of people with IgA nephropathy develop kidney failure within 10 to 20 years of diagnosis, leading to end stage kidney disease in around 15% to 50% of people throughout their lifetime.[1, 9]

There is no cure for IgA nephropathy. The aim of current treatment is to prevent or delay kidney failure and associated complications. Initial treatment focuses on reducing protein levels in the urine and blood pressure. Antihypertensives such as angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) are given at the maximum tolerated licensed doses.[7] Supportive care also includes dietary modification and exercise with or without diuretics to remove extra fluid from the blood and reduce cholesterol levels. Some people remain at high risk of progression despite optimised supportive care with lifestyle modifications and the maximum tolerated licensed doses of ACE inhibitors or ARBs. Second-line treatments are offered to people with more than 1 gram of proteinurea per day. Second-line treatments may include glucocorticoids, sodium-glucose cotransporter-2 (SGLT2) inhibitors or entry into a clinical trial. Clinical experts explained that the use of glucocorticoids is rare or limited because of safety concerns associated with systemic use. SGLT2 inhibitors are being increasingly used since NICE recommendation TA775 was published. People with severely reduced kidney function may need dialysis or a kidney transplant.[1]

The technology

Targeted-release budesonide (Kinpeygo, Britannia Pharmaceuticals [STADA]) has a conditional marketing authorisation from the European Medicines Agency for the treatment of primary IgA nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio of 1.5 g/gram or more.

Intervention(s)	Targeted-release budesonide
Population(s)	Adults with primary IgA nephropathy at risk of rapid disease progression with a urine protein-to-creatinine ratio of 1.5 g/gram or more
Comparators	Established clinical management without targeted-release budesonide, such as ACE inhibitors and ARBs at the maximum tolerated licensed doses, diuretics and dietary and lifestyle modification, with or without: • Glucocorticoids • SGLT2 inhibitors
Outcomes	The outcome measures to be considered include: • proteinuria (for example, change from baseline in urine protein creatine ratio) • kidney function (eGFR) • disease progression (dialysis and/or transplant) • mortality • 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. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.
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	**Related Guidelines:** Dapagliflozin for treating chronic kidney disease (2022) NICE technology appraisal 775. Chronic kidney disease: assessment and management (2021) NICE guideline 203.
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 'Adult specialist renal services' page 65. Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2

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