National Institute for Health and Care Excellence

Health Technology Evaluation

Sparsentan for treating primary IgA nephropathy ID6308

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	CSL Vifor	Given the potential for sparsentan to address the unmet medical needs in IgA nephropathy (IgAN) around reducing proteinuria and preserving kidney function, it is entirely appropriate for NICE to evaluate this topic with a single technology appraisal.	Thank you for your comment. No action required.
Wording	CSL Vifor	Yes, the wording of the remit appropriately captures the objective of appraising sparsentan.	Thank you for your comment. No action required.
Timing Issues	CSL Vifor	CSL Vifor supports the current proposed timeline for the evaluation of sparsentan, which balances the need to provide guidance on this first in class, non-immunosuppressive treatment for IgA nephropathy (IgAN), with the need to include the 2-year confirmatory data from the pivotal PROTECT clinical trial.	Thank you for your comment. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	CSL Vifor	A recently published analysis of the IgAN cohort of the UK National Registry of Rare Kidney Diseases (RaDaR) identified that between 45% to 70% of people with IgA nephropathy develop kidney failure within 10 to 20 years of diagnosis and that, as the median age at diagnosis was 41 years and the median kidney survival was 11.4 years, few patients are expected to avoid kidney failure in their lifetime. CSL Vifor propose that this more recent information replace the existing figures in the scope, to appropriately capture the risk of kidney failure in UK IgAN patients. Pitcher, D; Braddon, F; Hendry, B; et al. Long-Term Outcomes in IgA Nephropathy. Clinical Journal of the American Society of Nephrology 18(6): 727-738, June 2023.	Thank you for your comment. The background information section has been updated to include figures from the analyses of the IgA nephropathy cohort of the UK National Registry of Rare Kidney Diseases
Population	CSL Vifor	The population has been defined appropriately.	Thank you for your comment. No action required.
Subgroups	CSL Vifor	No additional subgroups have been identified prospectively which should be considered separately. We propose that the subgroup suggested in the scope be amended to 'People **at risk of** rapidly progressive IgA nephropathy', as treating a subgroup of patients at higher risk of progression is more likely to be clinically and cost effective than those with rapidly progressive disease per se.	Thank you for your comment. The subgroups section has been updated to include people at risk of rapidly progressive IgA nephropathy.
Comparators	CSL Vifor	It is envisaged that sparsentan will be used as a foundational therapy in patients at risk of progression despite treatment with an angiotensin-converting enzyme inhibitor (ACEI) and/or angiotensin receptor blocker (ARB) alone.	Thank you for your comment. The appraisal committee will discuss the most appropriate

Section	Consultee/ Commentator	Comments [sic]	Action
		CSL Vifor concur with the views of the clinical experts at the previous IgAN scoping workshop [ID1434] that glucocorticoids are used sparingly due to safety concerns associated with systemic steroid use and that other immunosuppressive agents such as cyclophosphamide are restricted to patients with rapidly deteriorating renal function, which is not the population of patients studied in the pivotal PROTECT Trial. Even with a NICE evaluation we do not anticipate targeted-release budesonide will be established clinical practice at the time of this appraisal.	comparator during the development of this appraisal. This will depend on the final marketing authorisation, current clinical practice and the clinical and cost effectiveness evidence. The decision problem has been defined to allow committee to consider all comparators which are relevant to clinical practice. Targeted-release budesonide was recommended by NICE technology appraisal guidance 937. It is likely be part of established clinical practice at the time of first appraisal committee meeting for this appraisal. The scope has been updated by removing the wording '(subject to NICE evaluation)'.

Section	Consultee/ Commentator	Comments [sic]	Action
	Novartis Pharmaceuticals UK	Cyclophosphamide and mycophenolate mofetil (MMF) do not represent UK standard of care for the treatment of IgA nephropathy and should be removed as comparators. According to the KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases, cyclophosphamide is not recommended in IgA nephropathy, unless in the setting of rapidly progressive disease. MMF is not recommended by the KDIGO 2021 guideline except for in Chinese patients; in non-Chinese patients there is insufficient evidence to support its use (Practice Point 2.3.1.5). The final scope of the currently ongoing NICE appraisal of targeted-release budesonide for treating IgA nephropathy [ID1434] included neither of these treatments as comparators.	Thank you for your comment. The appraisal committee will discuss the most appropriate comparator during the development of this appraisal. This will depend on the final marketing authorisation, current clinical practice and the clinical and cost effectiveness evidence. No action required.
Outcomes	CSL Vifor	Yes, the outcome measures included in the scope will capture the most important health related benefits (and harms) of the technology.	Thank you for your comment. No action required.
Equality	CSL Vifor	CSL Vifor are not aware of any issues of inequality or discrimination arising from the proposed scope.	Thank you for your comment. No action required.
Questions for consultation	CSL Vifor	The existing care pathway for primary IgA nephropathy is as described the in the NICE response to comments on the draft remit and draft scope for ID1434] namely 'lifestyle modifications and ACE inhibitors / ARBs at the maximum tolerated licensed dose. If proteinuria >1g/d second-line treatments such as glucocorticoids (albeit rare or limited use due to safety concerns associated with systemic steroid use), SGLT2 inhibitors or entry into a clinical trial may be considered. Cyclophosphamide is only used in people with rapidly deteriorating renal function.	Thank you for your comments. Your comments will be considered by the committee during the appraisal process. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		As mentioned above, it is envisaged that sparsentan will be used as a foundational therapy in patients at risk of progression despite treatment with an angiotensin-converting enzyme inhibitor (ACEI) and/or angiotensin receptor blocker (ARB) alone. It is not envisaged that sparsentan would be a candidate for managed entry. Kidney failure requiring lifelong dialysis or transplantation can have substantial effect on carer's health-related quality of life. Beyond this is not considered that the use of sparsentan will result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation.	
Additional comments on the draft scope	CSL Vifor	The brand name for sparsentan is Filspari. Please include the brand name in 'The technology' section of the scope	Thank you for your comment. The scope has been updated to include the brand name for sparsentan.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

Kidney Care UK