B-Cell Directed Therapies for IgA Nephropathy: Final Policy Recommendations

March 31, 2026

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the February 26, 2026 public meeting on the use of Nefecon (Tarpeyo®, Calliditas Therapeutics AB), sibeprenlimab (Voyxact®, Otsuka Holdings Co., Ltd.), and atacicept (Vera Therapeutics, Inc.) for the treatment of IgA Nephropathy (IgAN). At the meeting, ICER presented the findings of its revised report on these treatments, and the CTAF voting council deliberated on key questions related to their comparative clinical effectiveness, benefits beyond health and special ethical priorities, and long-term value for money at current prices. Following the votes, ICER convened a Policy Roundtable of two patients, two clinical experts, one payer, and two representatives from pharmaceutical manufacturers to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Sarah Emond, President and Chief Executive Officer at ICER. The main themes and recommendations from the discussion are organized by audience, and summarized below.

Health Equity

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that effective new treatment options for patients with IgAN are introduced in a way that will help reduce health inequities.

For many years, systemic glucocorticoids were the only treatment available for IgAN. Systemic glucocorticoids have significant toxicities. As such, the introduction of newer agents has substantial promise to improve clinical outcomes in IgAN. There is not a price yet available for atacicept, but sibeprenlimab has been given a high price. High prices are often correlated with more aggressive utilization management and patient-facing cost-sharing, and therefore can exacerbate inequity. In addition, there are inequities in diagnosis and access to specialty care. Even in settings with

universal access to health care, socioeconomic deprivation is associated with worse outcomes in IgAN.[1] At the Policy Roundtable, clinical and patient experts discussed the potential utility of routine screening with urinalysis in clinical practice as well as the need for equitable access to centers of excellence for glomerular diseases including IgAN. Finally, although IgAN is more common in men, women with IgAN have different treatment circumstances given that many are diagnosed at childbearing age. Better evidence is needed around the safety of IgAN treatments during pregnancy, and how clinical outcomes change when IgAN treatments are stopped, including during child-bearing years. Furthermore, since urinary tract infections are more common in women than men, women with IgAN are often misdiagnosed as having urinary tract infections. Awareness in clinical practice needs to be improved given that gross hematuria can be an initial manifestation of IgAN in both men and women.

To reduce inequity at a time of new awareness and new treatment options:

Manufacturers should take the following actions:

- Generate or collect safety and outcomes data about how new agents can be used in women of childbearing age including during pregnancy. Furthermore, there needs to be better understanding of how clinical outcomes change over the longer term when these medications are stopped, including for childbearing.
- As manufacturers promote public awareness as they introduce these new medications, they should be attentive to awareness in all communities.
- Manufacturers should align prices better with value, and payers should reduce friction in access for fairly-priced drugs, leading to improvements in equity.

Payers should take the following actions:

- Ensure that efforts at utilization management for medications for IgAN do not create requirements for large out-of-pocket spending that differentially affect vulnerable individuals.
- Ensure that efforts at utilization management for medications for IgAN are not overly complex or cumbersome.

Clinical specialty societies should take the following actions:

- Promote efforts to develop careers of nephrologists including through teaching and mentorship focused on the clinical care of glomerulonephritis, which will improve access to needed care.
- Promote laws that allow use of telemedicine across state lines when access to doctors with special expertise is limited.
- Promote efforts for early diagnosis of IgAN and other chronic kidney disorders in all communities at risk.

Payers

Recommendation 1

If the price of sibeprenlimab is reduced to a price aligned with value, and if the initial price of atacicept is aligned with value, payers should not require step therapy with systemic glucocorticoids or Nefecon before authorizing use of sibeprenlimab or atacicept for treatment of IgAN.

There is substantial unresolved uncertainty about the relative effectiveness of these treatment options. In terms of safety, there are no concerning safety signals for either sibeprenlimab or atacicept so far based on trial data alone. It is possible that with time, rarer side effects or longer-term side effects may become evident. Both types of steroids, however, show side effects from trial data. Many assume that these effects are not as severe for Nefecon than for systemic glucocorticoids although any difference has been difficult to demonstrate conclusively. In general, patients should not be required to take medicines with known serious side effects before gaining access to reasonably priced medications that do not have such side effects. As such, if prices of sibeprenlimab or atacicept are aligned with value in the future, step therapy should not require trials of systemic steroids or Nefecon before approval of sibeprenlimab or atacicept.

Recommendation 2

Payers should use the FDA labels and trial inclusion criteria as well as expert consensus to guide coverage policy for sibeprenlimab, Nefecon, and atacicept.

Although we know that individuals with IgAN and lower levels of proteinuria are likely to have some risk of deterioration of kidney function, individuals with less than 1 gram of proteinuria per day were not included in the key trials. As such, the efficacy and safety of these agents in individuals with low levels of proteinuria are unclear. However, clinical experts emphasized that treatment is also reasonable for individuals with low levels of proteinuria who still have deteriorating kidney function as measured by estimated GFR. Coverage policies should include patients represented in key trials (those with proteinuria of 1 gram per day or more) as well as patients with worsening kidney function despite lower levels of proteinuria.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy in the report: Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals. The relatively large number of patients with IgAN, combined with high annual prices for newer treatments, will lead payers to develop prior authorization criteria and to consider other limits on utilization.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right.[2] To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts, manufacturers, payers, and clinicians on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for Nefecon, sibeprenlimab, and atacicept.

Coverage Criteria

- **Age:** These treatments are likely to be covered for adult patients, in line with clinical trial eligibility criteria. If policies exclude children, there should be flexibility when evaluation by a glomerulonephritis expert recommends the use of these agents in a patient under 18.

- **Clinical Eligibility**: Although KDIGO guidelines are relatively new (2025), they do not yet describe the role of the newest therapies (sibeprenlimab and atacicept). Until new clinical guidelines are available, trial inclusion and exclusion criteria are reasonable to define eligibility criteria for therapy. Biopsy should be required to confirm diagnosis of IgAN, consistent with clinical guidelines.

- **Combination Therapy**: There are presently inadequate data on combination therapy of B-cell inhibitors with sparsentan, an endothelin receptor antagonist, which is an expensive medication. Until further clinical information is available, consistent with current clinical guidelines, eligibility for B-cell inhibitors should not depend on whether a patient is also receiving sparsentan.

- **Duration of Coverage and Renewal Criteria**: There are not currently adequate data to inform the duration of effective and safe treatment for sibeprenlimab and atacicept or the efficacy and safety of repeat courses of Nefecon. Given concerning signals in changes of key biomarkers after cessation of therapy, until further data are available, there should not be limitations on duration of approved therapy with sibeprenlimab or atacicept as long as these drugs are effective and reducing eGFR loss in individual patients. If prolonged courses of sibeprenlimab or atacicept are authorized by payers, prices should be introduced as/reduced to a value-based price. Similarly, if repeated/prolonged courses of Nefecon are

authorized by payers, potentially as new efficacy and safety data emerge, its price should be reduced to meet a value-based price for ongoing therapy.

Manufacturers

Recommendation 1

Manufacturers should set prices that will foster affordability and good access for all patients by aligning prices with the patient-centered therapeutic value of their treatments. In the case of IgAN, substantial new hope with the availability of these therapies is diminished by the extremely high price of sibeprenlimab. Nefecon is also priced slightly above a value-based price.

The manufacturer of sibeprenlimab should reduce the price by roughly 80% and the manufacturer of Nefecon should reduce the price of Nefecon by roughly 25% to align with value-based prices. The price for Nefecon has increased by more than one-third since initial pricing in 2022. Although there is not a price yet available for atacicept, the manufacturer of atacicept has an opportunity to enter the market at a more competitive price than sibeprenlimab, and one aligned with value. There is very little information about the comparative effectiveness of sibeprenlimab and atacicept, so a price difference may be very influential in coverage decisions between those two options.

Recommendation 2

Manufactures should create a cross-trial repository of blood and urine data and permit access by academic researchers to assist in better understanding how to identify patients with IgAN who are more or less likely to progress on and off various therapies.

Clinical experts noted that data from randomized trials potentially provide an extremely valuable source of information about risks in IgAN. The costs of generating these data were large, and the information generated from these data should be maximized.

Recommendation 3

Manufacturers should establish clinical registries to detect rarer side effects.

For sibeprenlimab and atacicept, there are no overtly concerning safety signals in relatively short-term trial data. Much of the current uncertainty about the balance between efficacy and safety with these newest medications is that rare or longer-term side effects might not yet be uncovered. Phase III clinical trials do not have duration or statistical power to detect some of these potential side effects. Assessing the potential of these types of side effects with larger and longer-term data sets may provide additional reassurance about the safety of long-term use.

Recommendation 4

Manufacturers should support studies to assess the efficacy of IgAN treatments in patients with IgAN and relatively lower levels of proteinuria (< 1 g/day), which is a key scientific unmet need.

Patients with relatively lower levels of proteinuria are thought to be at risk of disease progression, but were generally excluded from IgAN trials. As such, whether the treatments work to improve patient-meaningful outcomes is unclear. This evidence gap is important to resolve both for clinical practice as well as for coverage policy.

Clinicians and Clinical Societies

Recommendation 1

Clinicians and Clinical Societies should update treatment guidelines to provide specific guidance on the use of sibeprenlimab and atacicept.

Clinical societies should update their practice guidelines to include specific information about these newest options for IgAN. Nephrologists substantially disagree about the role of systemic steroids in treating IgAN, at least in comparison with Nefecon, and there are large practice variations across the world. Ideally, new guidelines should include the broadest possible range of international perspectives and minimize the influence of pharmaceutical manufacturers, to the extent possible, while including leading experts. In addition to the role of systemic steroids, key clinical guidance that would inform practice could include which patients to consider for which treatment options and how to monitor response to therapy and define treatment failure. Duration of therapy also remains an important uncertainty for all new treatments for IgAN. Payers and purchasers may be sources of information that could highlight evidence gaps that would inform coverage policy.

Patient Organizations

Recommendation 1

Patient organizations have a vital role to play to promote objective descriptions of the risks and benefits of new therapies to support shared decision-making for every patient. In addition, patient groups have a powerful voice and should apply that voice to create significant pressure for fair pricing and appropriate insurance coverage across all sectors of the health system.

Throughout this process, patients and patient organizations have emphasized the critical role of humanity, including access to care for novel IgAN therapies. Missed diagnoses and delayed diagnoses, as well as poor access to care even after diagnosis are often the source of anguish. When considering treatments, patients will have individualized priorities and concerns. As such, patient organizations have a powerful voice to advocate for fair access based on value-based prices. Initial

prices in line with value combined with reduced utilization management and prior authorization would improve patient access, patient experience, and affordability.

Research Funding Organizations

Recommendation 1

Research funding organizations should support pragmatic analyses assessing the feasibility and the effectiveness of large-scale screening for IgAN and other kidney diseases including among children, which would inform public health practices like school-based screening programs.

Presently, some countries outside the United States in which prevalence of IgAN is relatively high perform school-based screening for kidney disease. This is conceptually compelling, because many individuals with IgAN and other chronic kidney disorders have irreversible deterioration of kidney function before recognition of the disease. As with any screening program, false positives can occur. Ideally, before any adoption of widespread screening, better understanding is needed of whether these programs improve clinical outcomes and how much they cost.

References

1. Barratt J, Pitcher D, Wong K, Lightstone L, Gale DP. Levels of Socioeconomic Deprivation Are Associated with Worse Kidney Outcomes in Patients with IgA Nephropathy: Data from UK RaDaR: TH-PO618. *Journal of the American Society of Nephrology*. 2023;34(11S):263-264. doi:10.1681/ASN.20233411S1263d
2. Pearson SD, Towse A, Lowe M, Segel CS, Henshall C. Cornerstones of 'fair'drug coverage: appropriate cost sharing and utilization management policies for pharmaceuticals. *Journal of Comparative Effectiveness Research*. 2021;10(7):537-547.

Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the February 26, 2026 Public meeting of the CTAF.

Appendix Table 1. ICER Staff and External Collaborators Conflict of Interest Disclosures

ICER Staff and External Collaborators	Conflict of Interest
Michael J. DiStefano, PhD, Assistant Professor Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus	No conflicts to disclose.
Woojung Lee, PharmD, PhD, Associate Director of Health Economics and Decision Modeling, Institute for Clinical and Economic Review	No conflicts to disclose.
Avery McKenna, BS, Research Lead, Institute for Clinical and Economic Review	No conflicts to disclose.
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Deepika Paratane, MS, BPharm, PhD Student Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus	No conflicts to disclose.
Marie Phillips, BA, Health Economics Research Assistant Institute for Clinical and Economic Review Institute for Clinical and Economic Review	No conflicts to disclose.
David M. Rind, MD, MSc Chief Medical Officer Institute for Clinical and Economic Review	No conflicts to disclose.
Jason H. Wasfy, MD, MPhil, Associate Professor at Harvard Medical School, Director of Outcomes Research, Massachusetts General Hospital Cardiology Division Mass General Brigham	No conflicts to disclose.

Appendix Table 2. CTAF Panel Member Participants Conflict of Interest Disclosures

CTAF Member	Conflict of Interest
Ralph Brindis, MD, MPH Clinical Professor of Medicine, UCSF	No conflicts to disclose.
Bob Collyar Patient Advocate, Patient Advocates in Research, Co-Founder, Clinical Trials Information Project	No conflicts to disclose.
Felicia Cohn, PhD Bioethics Director, Kaiser Permanente Orange County	No conflicts to disclose.

CTAF Member	Conflict of Interest
Sanket Dhruva, MD, MHS, FACC Associate Professor of Medicine, UCSF School of Medicine	No conflicts to disclose.
Rena Fox, MD Professor of Medicine, UCSF	No conflicts to disclose.
Jeffrey Hoch, PhD Professor, University of California, Davis	No conflicts to disclose.
Jeffrey Klingman, MD Neurologist, Kaiser Permanente, Walnut Creek	No conflicts to disclose.
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Joy Melnikow, MD, MPH Professor emeritus, University of California, Davis	No conflicts to disclose.
Elizabeth Murphy, MD, DPhil Professor of Clinical Medicine, UCSF, Chief of Endocrinology and Metabolism Division	No conflicts to disclose.
Kavita V. Nair, PhD Professor of Neurology and Pharmacy, CU Skaggs School of Pharmacy & Pharmaceutical Sciences, Anschutz Medical Campus	No conflicts to disclose.
Ann Raldow, MD, MPH Associate Professor, UCLA	No conflicts to disclose.
Rita Redberg, MD, MSc, FACC, FAHA Professor of Medicine, Araxe Vilensky Endowed Chair in Cardiology, Core Faculty, Philip R Lee Institute for Health Policy Studies, Director, Inquiry Program, UCSF Division of Cardiology	No conflicts to disclose.
Anthony Sowry Patient Advocate, National Patient Advocacy Foundation	No conflicts to disclose.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Jonathan Barratt, PhD, FRCP Professor of Renal Medicine, University of Leicester	Dr. Jonathan Barratt has received funds from health care companies including: Calliditas, Vera Therapeutics, Otsuka, AstraZeneca, Argenx, Biogen, Novartis,Vertex, Takeda, Biohaven.
Leslie Fish, PharmD Executive Vice President, Clinical Pharmacy, IPD Analytics	Dr. Leslie Fish is a full-time employee at IPD Analytics.
Lobat Hashemi, PhD Global Head, Health Economics and Outcomes Research, Veloxis Pharmaceuticals	Dr. Lobat Hashemi is a full-time employee at Veloxis Pharmaceuticals and Calliditas Therapeutics.
Jay Jackson, PharmD, MPH Vice President, Health Economics & Outcomes Research	Dr. Jay Jackson is a full-time employee at Vera Therapeutics.

Policy Roundtable Participant	Conflict of Interest
Anthony "Tony" Pisa Individual Living with IgAN	Tony Pisa is a volunteer Patient Advocate with NephCure.
Samantha Schweisthal Individual Living with IgAN	Samantha Schweisthal is a volunteer Patient Ambassador for the state of Alabama with the IgAN Foundation.
Shikha Wadhwani, MD, MS, FASN Associate Professor of Medicine, Division of Nephrology & Hypertension, University of Texas Medical Branch	Dr. Shikha Wadhwani has received funds from health care companies including; Calliditas, Vera Therapeutics, Otsuka, Alexion, Biogen, Boehringer Ingelheim, Dimerix, Novartis, and Travere.