IgA Nephropathy 2026

ICER SNAPSHOT

Reviewed by: IgA Nephropathy Foundation

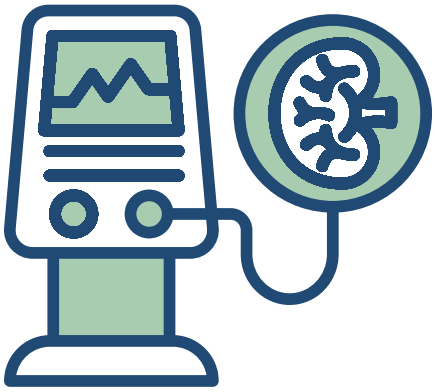
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This document's language was revised with assistance from Claude (Sonnet 4.5), an AI assistant created by Anthropic.

The ICER Snapshot is a summary designed to help the IgA nephropathy patient community learn about the key results and recommendations from ICER's 2026 Final Evidence Report on B-cell directed therapies for IgA nephropathy.

The information included is up to date as of March 31, 2026. New information about these treatments may become available, but is not captured here.

Let's Take a Look

What is IgA Nephropathy?
Impact on Patients and Families
Treatments & Clinical Trial Results
How Did ICER Calculate a Fair Price?
Policy Recommendations & Patient Engagement



What is IgA Nephropathy?



IgA Nephropathy (IgAN) is a kidney disease where **harmful antibody deposits build up in the kidneys**, causing inflammation and progressive damage. The kidneys clean toxins from the blood, and when they stop working properly, patients may need dialysis or a kidney transplant. IgAN mostly affects young adults, is more common in men, and is diagnosed more often in Asian Americans. About **200,000 Americans** have IgAN, costing the healthcare system around **$1.3 billion every year**. It is usually found through routine urine or blood tests, but a kidney biopsy is required to confirm the diagnosis.

Treatment for IgAN **aims to protect the kidneys from further damage**. Clinical guidelines recommend two main treatment goals: first, to reduce production of the harmful antibodies in the kidneys; and second, to shield the kidneys from additional damage resulting from these antibodies, and from protein leaking into the urine. In the past, systemic steroids have been commonly used to achieve these goals, but they have severe side effects.

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Glossary of Key Clinical Terms

B-cell therapies: Treatments that work by targeting the part of the immune system responsible for producing the harmful IgA antibodies that damage the kidneys.

Dialysis: A medical treatment that takes over the kidney's job of filtering waste and toxins from the blood when the kidneys can no longer do this on their own.

End Stage Kidney Disease (ESKD): ESKD is when the kidneys are so damaged they can no longer clean your blood well enough to keep you alive without dialysis or a kidney transplant.

Estimated glomerular filtration rate (eGFR): A numerical score that measures how well the kidneys are filtering waste out of the blood; a higher score reflects better kidney function, and a declining score signals deteriorating kidney health.

Glomerular disease: A group of kidney diseases in which there is damage to the glomeruli — the tiny filtering units inside the kidneys responsible for cleaning the blood.

Proteinuria: The presence of excess protein in the urine, which can be an early warning sign of kidney stress or damage.

Systemic glucocorticoids or "steroids": A class of anti-inflammatory steroid medications that work throughout the whole body to suppress immune activity and reduce inflammation.



Impact on Patients and Families

What ICER Learned from the Community

A 2019 patient advocacy report confirmed significant unmet needs in IgAN, with patients expressing **strong interest in treatments that reduce protein in the urine, slow kidney decline, or improve quality of life**.

Avoiding dialysis is a top priority for patients. As the disease progresses to end-stage kidney disease, **emotional and practical burdens increase significantly** for patients, families, and caregivers.

Access to specialized care is a major challenge, as **few nephrologists (kidney doctors) have specific expertise in glomerular diseases** — earlier access could improve outcomes and reduce patient anxiety.

Patients with IgAN often wait a long time before getting the right diagnosis, because the warning signs look a lot like other illnesses. **By the time IgAN is diagnosed, the kidneys may already be seriously damaged.**

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Treatments of Focus

1 SIBEPRENLIMAB

Voyxact®, Made by Otsuka Holdings Co., Ltd.

Sibeprenlimab is an injectable antibody treatment taken once every four weeks that blocks a specific protein (APRIL) responsible for triggering abnormal IgA antibody production in the immune system.

FDA Statuses

Sibeprenlimab Approved on: November 25, 2025

Indication: To reduce proteinuria in adults with primary IgA nephropathy at risk for disease progression

2 ATACICEPT

Made by Vera Therapeutics, Inc.

Atacicept is an injectable treatment that blocks two immune system proteins — APRIL and BAFF — both of which drive IgA antibody overproduction.

Atacicept PDUFA* Date: July 7, 2026

Indication: To be determined

*The PDUFA date is the deadline for the FDA to decide whether a new drug gets approved.

3 NEFECON

Tarpeyo®, Made by Calliditas Therapeutics AB; sometimes referred to as "delayed release" or "targeted release" of the steroid medication budesonide

Nefecon is an oral anti-inflammatory medication (budesonide) in a delayed-release form, designed to act in a specific section of the intestine where IgA production is regulated. It is taken once per day.

Nefecon Approved on: December 21, 2023

Indication: To reduce loss of kidney function in adults with primary IgAN who are at risk for disease progression

Comparators

A comparator is the treatment or standard of care that a new drug is tested against to see if it works better.

For this review, ICER compared how well all three B-cell therapies above (sibeprenlimab, atacicept, and Nefecon) worked compared to:

1. **no B-cell therapy**
2. **steroids** (specifically, reduced-dose methylprednisolone)
3. **each other**

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Clinical Trial Results & Overview

Who was studied?

Patients in the key clinical trials for the three treatments were generally:

- in their **late 30s to early 40s**
- **more men (~60%)** than women
- a significant percentage of **Asian participants**
- had **moderate kidney function** and **persistent proteinuria** (significant protein levels in their urine at the start of the trials)

Did the treatments reduce protein in the urine? Yes!

Sibeprenlimab, atacicept, and Nefecon **all reduced urine protein levels significantly more than placebo* at 9 months** (51%, 42%, and 30% reduction, respectively).

*Placebo: An inactive treatment intended to hide whether a patient received the studied drug.

Did the treatments protect kidney function? Yes (probably)!

Nefecon slowed the decline of kidney function compared to placebo. **Sibeprenlimab and atacicept** have early evidence that they **protect the kidneys**; further trials are underway.

Did the treatments improve quality of life? Not sure...

This was not consistently measured across trials. The one trial that did measure it (Nefecon) found little-to-no meaningful difference in quality of life between the treatment and placebo groups.

Safety

All three treatments were generally well tolerated.



Sibeprenlimab and atacicept were mostly tolerable, with low or no rates of serious infections or significant treatment-related side effects. **Nefecon was generally tolerable but carried some steroid-related side effects** — including swelling in the legs, feet, or hands, high blood pressure, and acne — and three patients experienced serious infections requiring hospitalization, though no deaths were linked to the treatment.

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What We Still Don't Know



- The **efficacy and safety of repeated or lengthy courses of Nefecon** or the **long-term efficacy and safety** of continued use of sibeprenlimab or atacicept
- How these therapies may work for people who have had a **kidney transplant**
- How these therapies may work for people who have **lower levels of proteinuria** that were not included in the clinical trials
- The **differences in side effects** between Nefecon and systemic steroids
- Given the short-term available evidence, whether there may be **rarer and longer-term side effects from sibeprenlimab and atacicept**

Clinical Conclusions

Sibeprenlimab, atacicept, and Nefecon each compared to no B-cell therapy

B+

We found that sibeprenlimab, atacicept, and Nefecon offer **at least some benefit** (B+) — and possibly significant improvement — compared to no B-cell therapy. However, questions remain about how much long-term benefit these treatments provide and whether they are safe.

Sibeprenlimab, atacicept, and Nefecon each compared to systemic glucocorticoids

P/I

In comparison to steroids, all three treatments showed some promise, but we don't have enough evidence to show they actually work better. We therefore rated this comparison **"promising but inconclusive"** (P/I).

Sibeprenlimab, atacicept, and Nefecon compared to each other

I

Given the lack of comparative data, we conclude that there is **insufficient** ("I") data to understand how the three B-cell treatments compare to each other.

ICER's report findings are not treatment advice. Patients and families should always talk with their doctors to make shared decisions about treatment for IgAN.

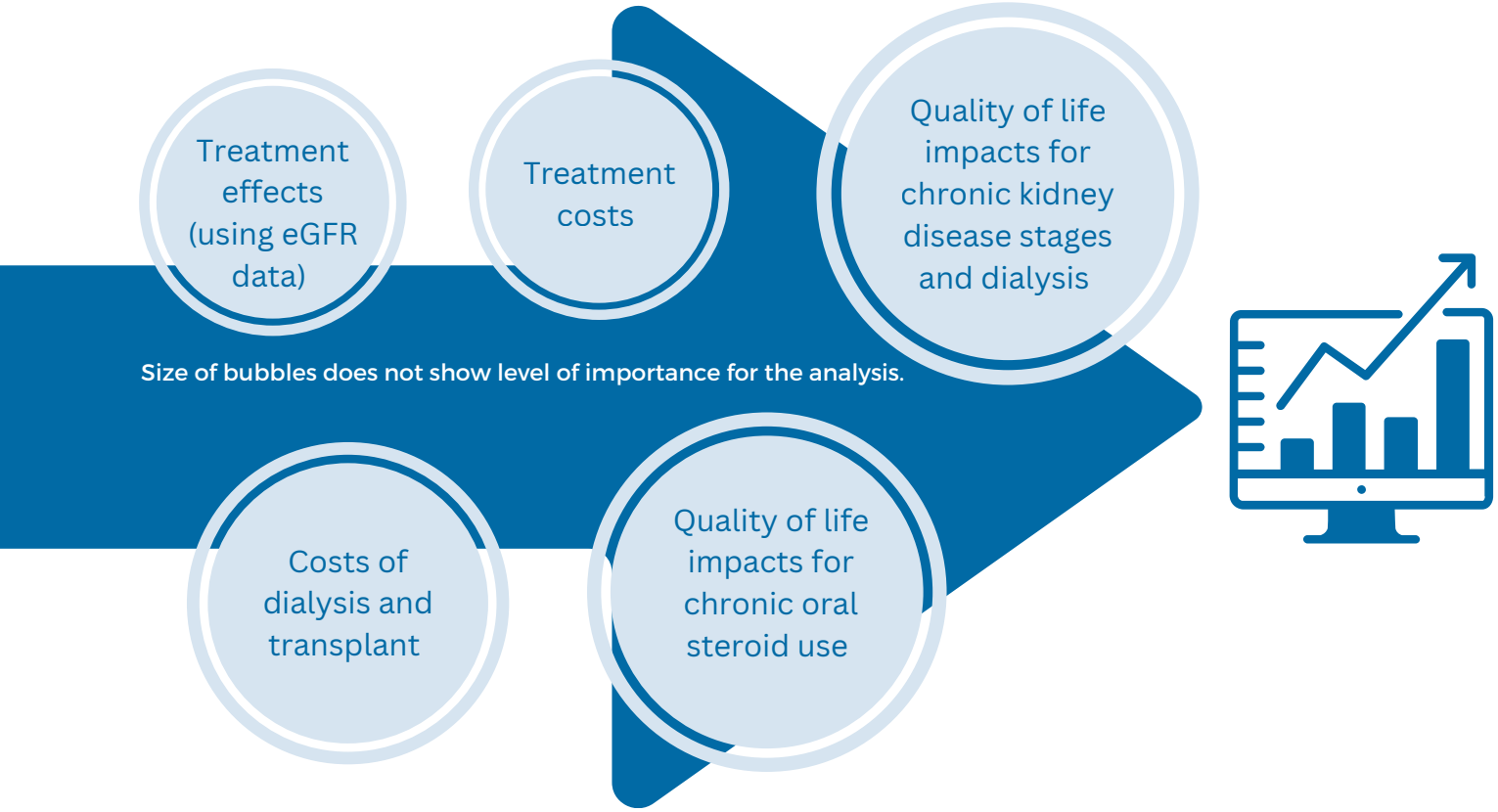
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How Did ICER Calculate Fair Prices?

Using economic modeling, we calculated the cost-effectiveness for how the B-cell treatments may delay ESKD by estimating the change in eGFR over time. See below for what types of information ICER considered to calculate a fair price range for these treatments.

Population:
Adults with IgAN

Factors Included in ICER's Economic Analysis



Fair Price Range for B-Cell Therapies

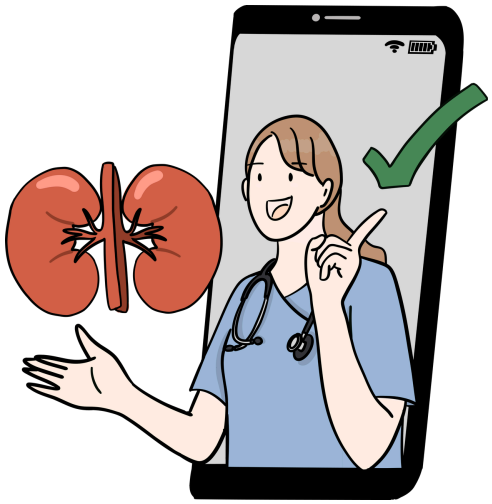
A fair price is how much a treatment should cost based on how well it works for patients. Our economic analysis concluded that the **B-cell therapies are cost-effective at the below prices:**

SIBEPRENLIMAB	ATACICEPT	NEFECON
$61,000 - $81,000 per year	**$60,000 - $80,000 per year**	**$110,900 - $143,000 for one 9-month treatment course**

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Key Policy Recommendations

The Policy Roundtable at the ICER public meeting included two patient experts living with IgAN whose contributions informed several policy recommendations for pricing, access, guidelines, and future research in IgAN. A few key recommendations are summarized below.



1. **Improving access to specialists**: Medical societies should actively support the training and mentorship of kidney specialists with expertise in glomerular diseases like IgAN, helping to close the gap between patient need and available expertise.

2. **Fair and value-based pricing**: Manufacturers should set drug prices that reflect the actual benefit these treatments provide to patients. Sibeprenlimab is currently priced beyond what its value justifies, and Nefecon is priced slightly above its value-based price. Atacicept has an opportunity to enter the market at a fairer, more competitive price.

3. **Patient advocacy**: Patient organizations play a critical role in helping patients make informed treatment decisions and should continue advocating for reduced insurance barriers and streamlined prior authorization processes, and should also advocate for fair pricing.



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Investment in early screening and research: Funding organizations should prioritize research into large-scale screening for IgAN and other kidney diseases, including in children. Many patients experience irreversible kidney damage before diagnosis, and understanding the broader costs and outcomes of early screening programs could meaningfully change how the disease is detected and managed.



Impact of Patient Engagement

Patient groups emphasized the **2019 Voice of the Patient Report** and the **substantial side effects of systemic glucocorticoids**. ICER therefore **compared the B-cell therapies to no B-cell therapies and to steroids** in the economic model.

We heard from patients about the **long journey of diagnosis and delays in care** which can lead to worse kidney function by the time IgAN is diagnosed. This insight informed ICER's **policy recommendation to improve access to kidney specialists**.

Patients shared with us outcomes that would have a meaningful impact on their lives including kidney function as well as **avoidance of dialysis and transplant which were all included** in the economic model.

The Institute for Clinical and Economic Review (ICER) is an independent nonprofit organization that does research on how well new treatments work and what a fair price should be. Patients and families should always talk with their doctor to make shared decisions about the best treatment option for them.

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