
FINALLY,
AN OPTION FOR C3G AND PRIMARY IC-MPGN PATIENTS AGED 12 AND ABOVE[1]
NOTE TO AFFILIATES:
TO PROVIDE LOCAL REPORTING INFORMATION
▽ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can help by reporting any side effects to Competent Authority or to Swedish Orphan Biovitrum AB by email:
ASPAVELI is indicated for the treatment of adult and adolescent patients aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated.
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ASPAVELI® ▽
(pegcetacoplan)
TARGET · CLEAR · PRESERVE

# Introducing Aspaveli — the first and only targeted treatment option for C3G and primary IC-MPGN patients aged 12 and above[1,2]

C3 glomerulopathy (C3G) and primary immune complex–mediated membranoproliferative glomerulonephritis (IC-MPGN) are complement-related diseases that are frequently diagnosed in childhood.[3–6] A diagnosis during childhood has lifelong consequences for affected patients and their families, and, until recently, there were no approved treatment options that directly targeted the underlying disease pathophysiology for patients aged 12–18 years with C3G or primary IC-MPGN.[2,7,8]

Dysregulation of the complement C3 protein is the central pathogenic driver of both C3G and primary IC-MPGN, and a growing body of evidence suggests that therapeutic targeting of the complement system may play a key role in disease management.[3–5,9]

Aspaveli is the first and only approved C3/C3b inhibitor and now offers a targeted treatment option for patients aged ⩾12 years with C3G and primary IC-MPGN.[1]

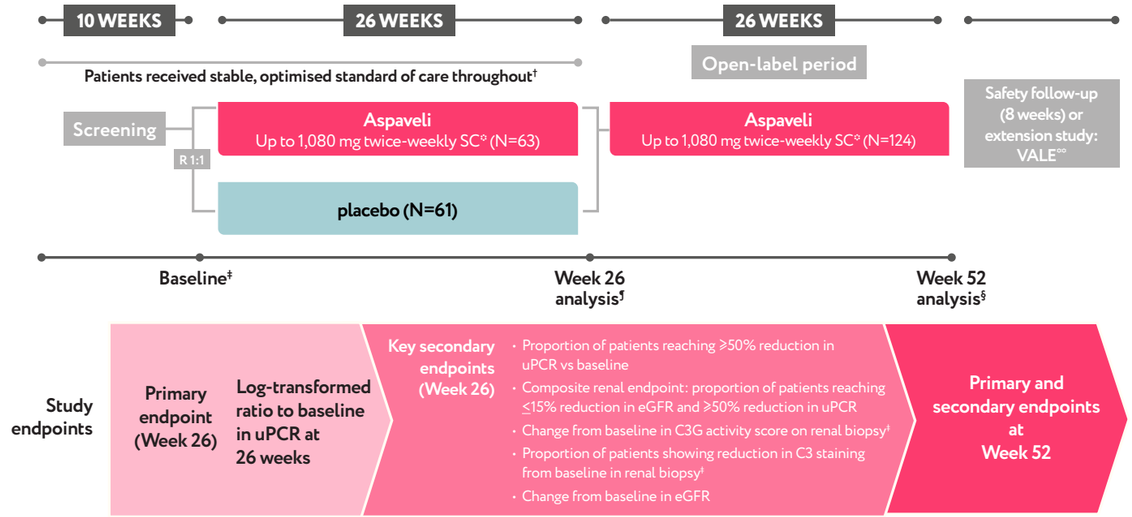
## Phase 3 VALIANT study: 44% of enrolled patients were 12–17 years of age[10]

The VALIANT study is the largest and broadest Phase 3 study in patients ⩾12 years with native or recurrent C3G or primary IC-MPGN.[9,10]

**VALIANT: Patient age at baseline[10]**

| | Aspaveli (N=63) | Placebo (N=61) | Overall (N=124) |
|---|---|---|---|
| **Age group – no. (%)** | | | |
| Adolescents (12–17 years) | 28 (44) | 27(44) | 55 (44) |
| Adults (⩾18 years) | 35 (56) | 34 (56) | 69 (56) |
| **Mean age – years (SD)** | | | |
| Among adolescents | 14.6 (1.7) | 14.8 (1.8) | 14.7 (1.7) |
| Among adults | 39.1 (15.9) | 30.6 (15.9) | 35.0 (16.4) |

# VALIANT study design




Aspaveli met the primary endpoint, demonstrating a statistically significant and clinically meaningful 68% relative reduction in proteinuria vs placebo at Week 26 ($p<0.0001$).[10]

° Stable, optimised antiproteinuric regimens: ACEis, ARBs, SGLT2is, MMF, and corticosteroids (prednisone <20 mg/d or equivalent) were permitted in both treatment arms.[10]

† All adults and adolescents weighing ⩾50 kg self administered 1,080 mg/20 mL. Adolescent patients weighing 30–34 kg received 540 mg/10 mL for the first 2 doses, then 648 mg/12 mL. Adolescent patients weighing 35–49 kg received 648 mg/12 mL for the first dose, then 810 mg/15 mL.[11]

‡ Adult baseline biopsies are those performed during screening to confirm diagnosis/eligibility, or historical biopsies conducted within 28 weeks of study randomisation. Baseline biopsies will not be required for adolescent patients if an adequate historical biopsy conducted at any time is available to confirm diagnosis.[11]

¶ The Week 26 biopsy is only required for adult patients to advance to the OLE period but is not required for adolescent patients who may advance to the OLE period without a biopsy.[10,11]

§ The Week 52 biopsy is optional for all patients.[12]

°° Participants entering the long-term extension study will not complete the follow-up period.[10]

# Aspaveli delivers on the 3 critical efficacy endpoints determined by the KHI consensus[10,13]

To address some of the challenges associated with developing novel treatments for these conditions, a panel of leading experts (nephrologists, pathologists, basic scientists, pharmaceutical leaders, patient advocacy groups and FDA representatives) from the Kidney Health Initiative (KHI) have reviewed evidence supporting the use of several endpoints as measures of clinical benefit in these conditions. Further, the KHI highlighted clinical markers that would be compelling in evaluating treatment outcomes with complement-targeted interventions.[13]

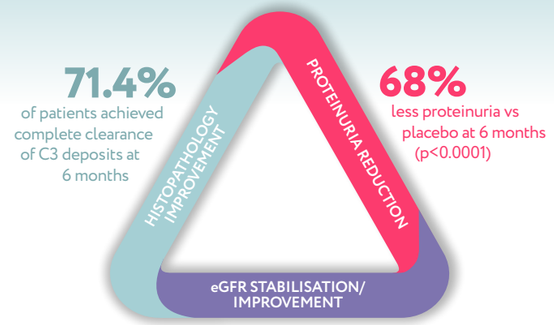
**KHI consensus: clinical efficacy benchmarks for effective therapeutic management of C3G and primary IC-MPGN:[13]**

1. >50% proteinuria reduction
2. eGFR stabilisation/improvement
3. Histopathology improvement (clearance of C3 deposits)

# Only Aspaveli delivers on the KHI efficacy triad[9,10,13]

Aspaveli is the first and only approved C3 inhibitor designed to target all three complement pathways: classical, alternative, and lectin.[1]

**Key outcomes from the Phase 3 VALIANT study (Full study population)*[10]**




**+6.3mL/min/1.73 m² at 6 months**
vs placebo (p=0.03)

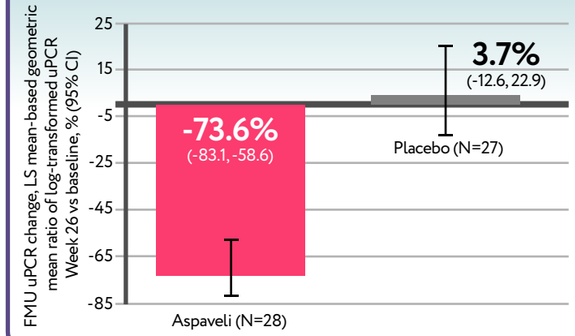
Only Aspaveli delivers on the KHI expert consensus of efficacy endpoints, with **beyond-target proteinuria reduction**[10,13,14]

**Aspaveli is the only disease-modifying treatment approved for:**[1,2]
- C3G and primary IC-MPGN
- Kidney-naïve and transplant
- Adults and adolescents

*The VALIANT Phase 3 trial was a randomised, double-blind, placebo-controlled study in 124 adolescents and adults (≥12 yrs) with C3G or primary IC-MPGN. The primary endpoint was the log-transformed change in urine protein-to-creatinine ratio (UPCR) at Week 26 compared with baseline. Aspaveli met the primary endpoint, demonstrating a statistically significant and clinically meaningful 68% relative reduction in proteinuria vs placebo at Week 26 (p<0.0001).[10]

# Aspaveli delivered consistently meaningful proteinuria reduction and stabilised eGFR vs placebo in adolescents[15]

**Change in proteinuria (Week 26 vs baseline) in the adolescent population*[15]**

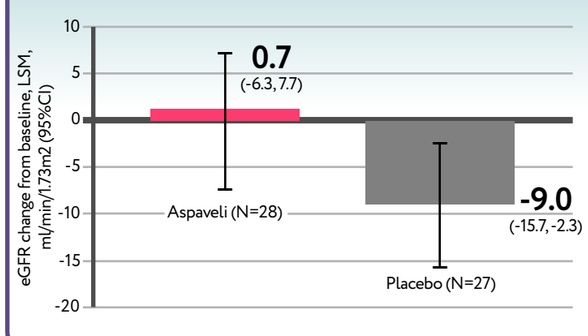



Relative reduction (95% CI), Aspaveli vs placebo

**74.5%**

(58.5, 84.3) **p<0.0001**

**Change in eGFR (Week 26 vs baseline) in the adolescent population*[15]**




Relative eGFR difference (95% CI), Aspaveli vs placebo

**+9.7**

(0.0, 19.4) **p<0.051**

*Primary endpoint for full VALIANT study population: Relative reduction (95% CI), Aspaveli vs placebo 68.1% (57.3, 76.2); p<0.0001 nominal.[10]

Secondary endpoint for full VALIANT study population: Relative eGFR difference, Aspaveli vs placebo +6.3 mL/min/1.73m², p=0.051 (nominal).[10]

# VALIANT study: Aspaveli was generally well tolerated, with few patients discontinuing treatment[10]

**Treatment-emergent adverse events at Week 26 by treatment group (Full study population)[10]**

| Patients, n (%) | Aspaveli (N=63) | placebo (N=61) |
|---|---|---|
| **Treatment-emergent adverse events (TEAEs)** | 53 (84) | 57 (93) |
| Treatment-related TEAEs | 25 (40) | 26 (43) |
| **Severe TEAEs** | 3 (5) | 4 (7) |
| **Serious TEAEs** | 6 (10) | 6 (10) |
| Serious infections | | |
| COVID-19 pneumonia | 1 (2) | 0 (0) |
| Influenza | 1 (2) | 0 (0) |
| Pneumonia | 1 (2) | 0 (0) |
| Viral infection | 0 (0) | 1 (2) |
| **TEAEs leading to treatment discontinuation** | 1 (2) | 1 (2) |
| **Deaths** (COVID-19 pneumonia, unrelated to Asapveli) | 1 (2) | 0 (0) |

Safety population (all patients that received a dose of Aspaveli or placebo). TEAEs defined as any new AE that began, or any preexisting condition that worsened in severity, after the first dose of study drug and up to 56 days beyond the last dose of Aspaveli or placebo.[10]

For more information contact Sobi Medical Information

[AFFILIATE TO INSERT CONTACT DETAILS]

**No encapsulated meningococcal infection**

cases among the four reported serious infections (Aspaveli, N=3; placebo, N=1)[10]

**Discontinuation due to TEAEs was 2%[10]**

Discontinuation rate is an important consideration in chronic conditions requiring continuous therapy[1]

# Getting started with Aspaveli[1]

As with other complement inhibitor therapies, Aspaveli may predispose individuals to serious infections caused by encapsulated bacteria.

**To reduce the risk of infection, all patients must be vaccinated against:**

- *Streptococcus pneumoniae*
- *Neisseria meningitidis types A, C, W, Y, and B*
- *Haemophilus influenzae Type B*

**Guidance on vaccination timing[1]**

| Patients with vaccination record | Patients with no prior vaccination record |
|---|---|
| *Ensure patients have been vaccinated against the above encapsulated bacteria within 2 years prior to Aspaveli initiation* | Ensure vaccines are administered at least 2 weeks prior to receiving the first dose of Aspaveli.<br><br>If immediate therapy is indicated, the required vaccines should be administered as soon as possible and the patient treated with appropriate antibiotics until 2 weeks after vaccination |

**Monitoring for serious infections[1]**

Vaccination may not be sufficient to prevent serious infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents. All patients should be monitored for early signs of infections caused by encapsulated bacteria including Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae, evaluated immediately if infection is suspected, and treated with appropriate antibiotics if necessary.

**NOTE TO AFFILIATES:**
USE THIS PAGE TO ADD LOCAL LEVEL VACCINATION GUIDANCE

# Dosing regimen for adolescent patients 12 years to <18 years of age[1]

- **For adolescent patients (12 years to <18 years),** dosing and volume are weight based, according to the following schedule:[1]

| Patient's body weight | First dose (volume) | Second dose (volume) | Maintenance dose (volume) |
|---|---|---|---|
| ⩾50 kg | 1080 mg (20 mL) | 1080 mg (20 mL) | 1080 mg (20 mL) twice weekly |
| 35 to <50 kg | 648 mg (12 mL) | 810 mg (15 mL) | 810 mg (15 mL) twice weekly |
| 30 to <35kg | 540 mg (10 mL) | 540 mg (10 mL) | 648 mg (12 mL) twice weekly |

Aspaveli can be self-administered using the Aspaveli injector

**OR**

A commercially available infusion pump with a reservoir of at least 20 mL[1]

## Missed dose[1]

- Administer Aspaveli as soon as possible after a missed dose. Resume the regular dosing schedule following administration of the missed dose even if this results in an interval of less than 3 days between the replacement dose and the subsequent one
- The median half-life of Aspaveli is 10.1 days in adult patients with C3G or primary IC-MPGN

## Post transplant C3G or primary IC-MPGN[1]

- Following confirmation of post-transplant recurrent C3G or primary IC-MPGN based on a renal allograft biopsy, Aspaveli can be started before the onset of clinical signs such as eGFR decrease or urine to protein-to-creatine ratio (uPCR) increase*

*There is limited experience with the use of Aspaveli in patients with recurrent C3G or primary IC-MPGN after transplantation in clinical studies.[1]

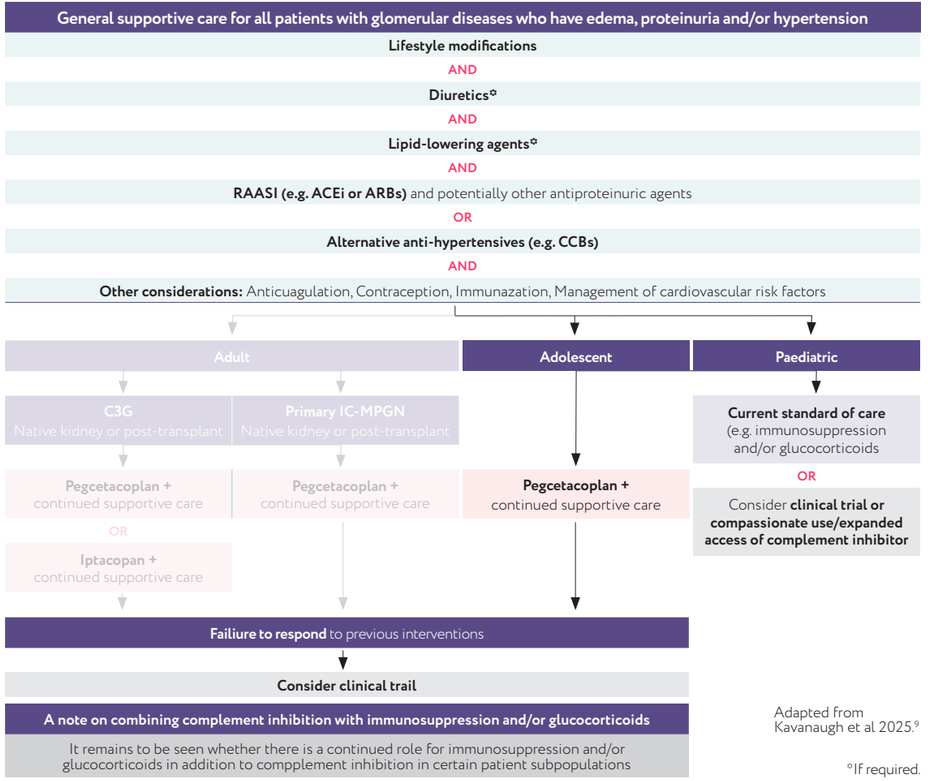
## Duration of use

- C3G and primary ICMPGN are chronic diseases. Discontinuation of this medicinal product is not recommended unless clinically indicated.[1] Physicians should consider close monitoring to prevent disease relapse[16]

# Exploring Aspaveli as a first-line option in C3G and primary IC-MPGN

In the absence of an optimal treatment strategy, the 2021 KDIGO guidelines recommend initial supportive care with ACE inhibitors or ARBs for all patients with C3G and primary IC-MPGN, with escalation to immunosuppressive therapy in those with significant proteinuria or progressive disease, and consideration of eculizumab or clinical trial enrolment if first-line treatment fails after 3–6 months.[17] Since then, complement dysregulation has been recognised as the central pathogenic driver of these diseases, and, alongside increasing clinical investigation and positive Phase 3 trial results for complement-targeted therapies, Kavanaugh et al. proposed a potential new treatment pathway in 2025[3–5,9]

It was proposed that based on current evidence, Aspaveli could be positioned as a first-line therapy—alongside background renin–angiotensin–aldosterone system (RAAS) inhibition—for patients presenting with significant proteinuria at diagnosis.[9]




Adapted from Kavanaugh et al 2025.[9]

*If required.

# Defuse C3 dysregulation with Aspaveli — preserving kidney health and making everyday memories possible[10]

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**NOTE TO AFFILIATES:**
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**Abbreviations**

ACEi, angiotensin-converting enzyme inhibitors; AE, adverse event; ARB, angiotensin-receptor blockers; C3G, complement 3 glomerulopathy; CCB, calcium channel blocker; IC-MPGN, immune complex-mediated membranoproliferative glomerulonephritis; eGFR, estimated glomerular filtration rate; KDIGO, Kidney Disease: Improving Global Outcomes; KHI, kidney health initiative; RAASi, renin–angiotensin–aldosterone system inhibitor; TEAE, treatment-emergent adverse event.

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